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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206 AI63

Federal Employees Health Benefits (FEHB) Program and Department of Defense (DoD) Demonstration Project

AGENCY: Office of Personnel Management.

ACTION: Interim regulation.

SUMMARY: OPM is issuing an interim regulation to implement the portion of the Defense Authorization Act for 1999 that establishes authority for a demonstration project under which certain Medicare and other eligible DoD beneficiaries can enroll in health benefit plans in certain geographic areas under the Federal Employees Health Benefits (FEHB) Program. The demonstration project will run for a period of three years from January 1, 2000, through December 31, 2002. This regulation specifies only the requirements that differ from existing FEHB Program regulations because of unique aspects of the demonstration project.

DATES: The effective date of this regulation is July 6, 1999. Comments must be received on or before September 7, 1999.

ADDRESSES: Comments must be sent to Abby L. Block, Chief, Insurance Policy and Information Division, OPM, Room 3425, 1900 E Street, NW., Washington, DC 20415–0001.

FOR FURTHER INFORMATION CONTACT: Michael W. Kaszynski, (202) 606–0004. You may submit comments and data by sending electronic mail (E-mail) to: *mwkaszyn@opm.gov*.

SUPPLEMENTARY INFORMATION: The purpose of this regulation is to implement the portion of the Defense Authorization Act for 1999, Public Law 105–261, that amended chapter 55 of title 10, United States Code, and chapter 89 of title 5, United States Code, to establish a demonstration project under which certain Medicare and other eligible DoD beneficiaries can enroll in health benefit plans under the FEHB Program. The legislation was signed into law on October 17, 1998. The demonstration project will run for a period of three years from January 1, 2000, through December 31, 2002. DoD, with OPM concurrence, has selected eight geographic areas to serve as demonstration areas. The legislation requires that between 6 and 10 geographic areas be selected. No more than 66,000 individuals can participate in the demonstration project at any one time. Beneficiaries who are provided coverage under the demonstration project will not be eligible to receive care at a military medical treatment facility or to enroll in a health care plan under DoD's TRICARE program. Individuals who disenroll or cancel enrollment from the demonstration project are not eligible to reenroll in the demonstration project. OPM will establish separate risk pools for developing demonstration project enrollee premium rates. The Government contribution for demonstration enrollees will be paid by DoD and cannot exceed the amount that the Government would have contributed had the enrollee been enrolled as a regular FEHB enrollee in the same health benefits plan and level of benefits.

The legislation requires OPM and DoD to jointly produce and submit two reports to Congress designed to assess the viability of expanding access to the FEHB Program to certain Medicare and other eligible DoD beneficiaries permanently. The first report is due by April 1, 2001; the second is due by December 31, 2002. The reports will focus on enrollee participation levels, impact on Medicare Part B enrollment, impact on premium rates and costs as compared to regular FEHB enrollees, impact on accessibility of care in military treatment facilities, impact on medical readiness and training in military treatment facilities, impact on the cost, accessibility, and availability of prescription drugs for DoD beneficiaries, and recommendations on eligibility and enrollment.

OPM has determined it necessary to specify certain differences from existing FEHB Program regulations because of the unique features of the demonstration project. This regulation amends Part 890 of title 5, Code of Federal Regulations (CFR) to authorize these differences. Should the program be extended beyond the three year demonstration project period, we will regulate to address any necessary changes to these provisions.

Waiver of Notice of Proposed Rule Making

Pursuant to section 553(b)(3)(B) of title 5 of the United States Code, I find that good cause exists for waiving the general notice of proposed rulemaking. The notice is being waived because FEHB Program carriers need the information contained in these regulations now to define policy parameters and operational requirements for the demonstration project in order to prepare and submit benefit and rate proposals. Carriers need sufficient time to implement changes necessary for enrollments to be effective January 1, 2000, as required by Public Law 105–261.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation will only affect health insurance carriers under the Federal Employees Health Benefits Program.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professionals, Hostages, Iraq, Kuwait, Lebanon, Reporting and record keeping requirements, Retirement.

Office of Personnel Management.

Janice R. Lachance,

Director.

For the reasons set forth in the preamble, OPM is amending 5 CFR Part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for Part 890 is revised to read as follows:

Authority: 5 U.S.C. 8913; § 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; § 890.102 also issued under sections 11202(f), 11232(e), 11246 (b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section 721 of Pub. L. 105–261, 112 Stat. 2061.

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

2. A new Subpart M is added to read as follows:

Subpart M—Department of Defense Federal Employees Health Benefits Program Demonstration Project

Sec.

Subpart M—Department of Defense Federal Employees Health Benefits Program Demonstration Project

§ 890.1301 Purpose.

The purpose of this subpart is to implement the portion of the Defense Authorization Act for 1999, Public Law 105–261, that amended chapter 55 of title 10, United States Code, and chapter 89 of title 5, United States Code, to establish a demonstration project under which certain Medicare and other eligible Department of Defense (DoD) beneficiaries can enroll in health benefit plans in certain geographic areas under the Federal Employees Health Benefits (FEHB) Program. The legislation was signed into law on October 17, 1998. The demonstration project will run for a period of three years. The legislation requires the Office of Personnel Management (OPM) and DoD to jointly produce and submit two reports to Congress designed to assess the viability of expanding access to the FEHB Program to certain Medicare and other eligible DoD beneficiaries permanently. OPM is authorizing certain differences from regular FEHB Program practices in order to ensure the successful implementation of the demonstration project. This subpart authorizes those differences.

§ 890.1302 Duration.

The demonstration project will run from January 1, 2000, through December 31, 2002.

§ 890.1303 Eligibility.

(a) Eligible enrollees must live within one of the demonstration areas and meet the definition of an eligible beneficiary in 10 U.S.C. 1108 (b). An eligible beneficiary under this subpart is—

(1) A member or former member of the uniformed services described in section 1074(b) of title 10, United States Code, who is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c *et seq.*);

(2) An individual who is an unremarried former spouse of a member or former member described in section 1072(2)(F) or section 1072(2)(G) of title 10, United States Code;

(3) An individual who is—

(i) A dependent of a deceased member or former member described in section 1076(b) or 1076(a)(2)(B) of title 10, United States Code, or of a member who died while on active duty for a period of more than 30 days; and

(ii) A "member of family" as defined in section 8901(5) of title 5, United States Code; or

(4) An individual who is—

(i) A dependent of a living member or former member described in section 1076(b)(1) of title 10, United States Code, who is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act, regardless of the member's or former member's eligibility for such hospital insurance benefits; and

(ii) A "member of family" as defined in section 8901(5) of title 5, United States Code.

(b) An eligible beneficiary may enroll in an FEHB plan under chapter 89 of title 5, United States Code, for self-only coverage or for self and family coverage. A self and family enrollment will include coverage of a dependent of the military member or former member who meets the definition of a "member of family" in section 8901(5) of title 5, United States Code. A self and family enrollment will not cover a person related to the beneficiary that does not qualify as a "member of family" (as defined in section 8901(5) of title 5, United States Code) of the military member or former member.

(c) A person eligible for coverage under this subpart shall not be required to satisfy any eligibility criteria specified in chapter 89 of title 5, United States Code, or in other subparts of this part (except as provided in paragraphs (a)(3), (a)(4), and (b) of this section) as a condition for enrollment in health benefit plans offered through the FEHB Program under the demonstration project.

(d) For purposes of determining whether an individual is a "member of family" under section 8901(5) of title 5, United States Code, for purposes of paragraph (a)(3) and (a)(4) of this section, a DoD member or former member described in section 1076(b) or 1076(a)(2)(B) of title 10, United States Code, shall only be deemed to be an employee under 8901(5) of title 5, United States Code, for the purpose of determining enrollment eligibility of a demonstration project dependent beneficiary.

(e) A person who is eligible to enroll in the FEHB Program as an employee as defined in section 8901(1) of title 5, United States Code, is not eligible to enroll in an FEHB plan under the demonstration project.

§ 890.1304 Enrollment.

(a) The 1999 health benefits open season for demonstration enrollees will be held concurrent with the open season for regular FEHB enrollees. Open seasons also will be held during the same period in the years 2000 and 2001. Eligible beneficiaries will be able to enroll for coverage, change enrollment tiers (e.g., self-only or self and family), or change health benefit plans or plan options during these periods.

(b) Demonstration project enrollees are required to pay associate membership dues if they enroll in open employee organization sponsored plans that are participating in the demonstration project.

(c) DoD will deny enrollment of eligible beneficiaries when the total number of beneficiaries and family members enrolled in the demonstration project reaches 66,000.

(d) Eligible beneficiaries can enroll only in health plans offered by health benefit carriers who are participating in the demonstration project.

(e) Beneficiaries and family members enrolled in the demonstration project are not eligible to obtain services from military treatment facilities or to enroll in a health care plan under the TRICARE Program.

(f) An eligible beneficiary enrolled in an FEHB plan under the demonstration project may change health benefits plans and coverage in the same manner as any other FEHB Program enrollee, except as provided for in this subpart.

§ 890.1305 Termination and cancellation.

(a) If a DoD enrolled beneficiary moves out of a demonstration area, the enrollment of the beneficiary and all family members will be terminated. If a beneficiary moves to an area located within a demonstration area, he or she will continue to be eligible to participate in the demonstration project. If the beneficiary was enrolled prior to the move in an HMO that does not serve the new demonstration area, the beneficiary will have an opportunity to

select a new health plan offered by a carrier participating in the demonstration project in the new area. If the beneficiary was enrolled in a fee-for-service plan prior to the move and moves to another area that is within an existing demonstration area, the beneficiary can maintain his or her current coverage.

(b) If a DoD beneficiary disenrolls, cancels, or terminates enrollment for any reason, he or she will not be eligible to reenroll in the demonstration project. Once coverage ends, members have the right to revert back to all of the benefits to which they were entitled to under title 10 of the United States Code. Medicare covered members who had a Medigap policy prior to their enrollment in the demonstration project are entitled to reinstate that coverage under the conditions stated in section 1108(l) of title 10 United States Code.

(c) Demonstration project beneficiaries and members of family are eligible for Temporary Continuation of Coverage (TCC) under the conditions and for the durations described in subpart K or until the end of the demonstration project, whichever occurs first. The effective date of TCC for demonstration project beneficiaries or members of family will be the day after other coverage under this subpart ends. Beneficiaries or members of family selecting TCC must enroll in a health plan offered by a carrier participating in the demonstration project. If an individual enrolled in DoD TCC moves from a demonstration project area, coverage ends. Beneficiaries will be responsible for paying the entire DoD premium rate (OPM's approved net-to-carrier DoD rate plus 4 percent for contingency and administration reserves) plus 2 percent of this premium rate for administration of the program. DoD will make arrangements to collect premiums plus the 2 percent administrative charge from beneficiaries and forward them to OPM's Health Benefits Fund. OPM will establish procedures for receiving the 2 percent administrative payment into the Health Benefits Fund and making this amount available to DoD for administration of the program.

(d) Enrolled demonstration project beneficiaries are not eligible for the temporary extension of coverage and conversion opportunities described in subpart D of this part.

§ 890.1306 Government premium contributions.

The Secretary of Defense is responsible for the Government contribution for demonstration project enrolled beneficiaries. The Government contribution toward demonstration project premium rates will be determined in accordance with subpart E of this part.

§ 890.1307 Data collection.

Carriers will compile, maintain, and when requested by OPM or DoD report data on their plan's experience necessary to produce reports containing the following information and analysis:

(a) The number of eligible beneficiaries who elect to participate in the demonstration project.

(b) The number of eligible beneficiaries who elected to participate in the demonstration project and did not have Medicare Part B coverage before electing to participate.

(c) The costs of health benefits charges and the costs (direct and indirect) of administering the benefits and services provided to eligible beneficiaries who elect to participate in the demonstration project as compared to similarly situated enrollees in the FEHB Program.

(d) Prescription drug costs for demonstration project beneficiaries.

§ 890.1308 Carrier participation.

(a) All carriers who participate in the FEHB Program and provide benefits to enrollees in the geographic areas selected as demonstration project areas must participate in the demonstration project, except as provided for in paragraphs (b), (c), and (d) of this section.

(b) Carriers who have less than 300 FEHB enrollees may, but are not required to, participate in the demonstration project.

(c) Carriers may, but are not required to, participate in the demonstration project if their service area overlaps a small portion (as determined by OPM) of a demonstration project geographic area.

(d) Carriers offering fee-for-service plans with enrollment limited to specific groups will not participate in the demonstration project.

[FR Doc. 99–16912 Filed 7–2–99; 8:45 am]
BILLING CODE 6325–01–U

RAILROAD RETIREMENT BOARD

20 CFR Part 220

Determining Disability

CFR Correction

In Title 20 of the Code of Federal Regulations, parts 1 to 399, revised as of Apr. 1, 1999, page 337, part 220, Apendix 3 is corrected by revising the second entry, in the second column under "JOB TITLE: MACHINIST" to read "<40 degrees abduction".

[FR Doc. 99–55521 Filed 7–2–99; 8:45 am]
BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–99–093]

Drawbridge Operation Regulations: Harlem River, NY

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations governing the operation of the Triborough (125th Street) Bridge, mile 1.3, across the Harlem River in New York City, New York. This deviation from the regulations authorizes the bridge owner to keep the bridge in the closed position from August 2, 1999, through August 31, 1999, and from September 7, 1999, through October 6, 1999. This action is necessary to facilitate the removal and replacement of the bridge counterweight lift cables.

DATES: This deviation is effective from August 2, 1999, through August 31, 1999, and from September 7, 1999, through October 6, 1999.

FOR FURTHER INFORMATION CONTACT: Joe Arca, Project Officer, First Coast Guard District, at (212) 668–7165.

SUPPLEMENTARY INFORMATION: The Triborough (125th Street) Bridge, mile 1.3, across the Harlem River has vertical clearances of 54 feet at mean high water, and 59 feet at mean low water in the closed position. The current operating regulations listed at 33 CFR § 117.789(d) require the bridge to open on signal from 10 a.m. to 5 p.m., if at least four hours notice is given.

The bridge owner, the Triborough Bridge and Tunnel Authority (TBTA), requested a temporary deviation from the operating regulations for the Triborough (125th Street) Bridge in order to remove and replace the counterweight lift cables. During the process of this work the bridge can not be opened. Vessels that can pass under the bridge without an opening may do so at all times during the closed periods. This work is essential for public safety and the continued operation of the bridge. In accordance with 33 CFR § 117.35(c), this work will be performed

with all due speed in order to return the bridge to normal operation as soon as possible.

This deviation to the operating regulations authorizes the TBTA to keep the Triborough (125th Street) Bridge, mile 1.3, across the Harlem River in New York City, New York, in the closed position for repairs from August 2, 1999, through August 31, 1999, and from September 7, 1999, through October 6, 1999.

This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: June 21, 1999.

Robert F. Duncan,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 99–17054 Filed 7–2–99; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 173

[USCG 1998–3386]

RIN 2115–AF62

Adjustment of Fees for Issuing Numbers to Undocumented Vessels in Alaska

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard increases the fees it charges for issuing numbers to undocumented vessels in Alaska. It is doing this because the current fees do not cover its costs for issuing numbers to those vessels. This final rule brings the fees into full compliance with the general Federal statute on user fees, allowing the Coast Guard to fully recover its costs, and makes it more convenient for the public by offering additional methods to pay for this service.

DATES: This final rule is effective on September 1, 1999.

ADDRESSES: The comment received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–1998–3386. They are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov*. You may obtain a copy of this rule by calling the U. S. Coast Guard Infoline at 1–800–368–5647, or read it on the Internet, at the Web Site for the Office of Boating Safety, at *http://www.uscgboating.org* or at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: For questions on this final rule, call or write Janice B. Giles, Program Development and Implementation Division, Office of Boating Safety, Coast Guard, telephone 202–267–0911, (email: jgiles@comdt.uscg.mil), or Sue Hargis, Seventeenth Coast Guard District (Alaska) Boating Safety Specialist, (907) 463–2297 (email: shargis@cgalaska.uscg.mil). For questions on viewing the docket, call Dorothy Walker, Chief, Dockets, Department of Transportation. telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Regulatory History

On February 1, 1999, we published a notice of proposed rulemaking (NPRM) entitled "Adjustment of Fees for Issuing Numbers to Undocumented Vessels in Alaska" in the **Federal Register** (64 FR 4816). We sent press releases concerning the proposed increase to all major newspapers in Alaska. We received one letter commenting on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

Title 33 of the Code of Federal Regulations (CFR), part 173, sets forth the requirements for issuing certificates of number to owners of vessels that are not documented, typically recreational boats. The Coast Guard's issuing numbers to undocumented vessels is unique to Alaska and the Seventeenth Coast Guard District; in all other parts of the nation, State or Territorial authorities act as the issuing authorities. We retain the responsibility for Alaska under Title 46 of the United States Code (U.S.C.), sub-section 12301(a), because the government of Alaska has not sought the approval of the Coast Guard for a State system of numbering vessels.

This final rule amends 33 CFR 173.85 so the charged fees cover the costs we incur for the number-issuing service we provide in Alaska. The increased fees affect those people who own undocumented vessels subject to 33 CFR 173.11 and who operate them principally in Alaska. This final rule also offers more methods for paying the fees.

The current $6 fee, set in 1972 (33 CFR 173.85), does not accrue to the Coast Guard. The money collected goes into the general fund of the U.S. Treasury as miscellaneous receipts of the Department of Transportation. Even if the money did accrue to us, it would cover barely 25 percent of the costs we incur for providing the service. The new fees will cover most, if not all, of these costs.

Under 46 U.S.C. 2110, the new fees will also be available to reimburse the Coast Guard for the full cost of accomplishing fee collection.

The development and application of a cost methodology came in for detailed discussion in the NPRM. That discussion rested on a contracted-for study of all user fees collected by the Coast Guard. A copy of the analysis is in the docket for this rulemaking. We adapted a system that employs Activity-Based Costing (ABC), which assigns costs to the activities required to produce a product, rather than to categories of expenses. All the fees we developed were rounded down to the nearest whole dollar, to simplify collection and accounting, and to conform to 46 U.S.C. 2110(a)(3). We must now set these fees in accordance with the criteria specified in 31 U.S.C. 9701 and Revised Circular A–25 of the Office of Management and Budget (OMB), which establishes guidelines for Federal agencies to assess fees for their services.

Discussion of Comment and Changes

In addition to publishing an NPRM, during February 1999 we published notices in local Alaskan newspapers: the Juneau Empire, Anchorage Daily News, Ketchikan Daily News, and Fairbanks News-Miner. We received only one comment on this rulemaking, which supported the fee increase.

Changes to 33 CFR 173.85. The three-year fee for an original or transferred certificate of number will increase from $6 to $24. The fee to renew a certificate of number will increase from $6 to $16. The fee for a duplicate certificate of number will increase from $1 to $9. The fee for replacing a lost or destroyed Validation Sticker will increase from $0.25 to $9. We may now accept payment of fees by check, money order, or major credit card (MasterCard or Visa), or in cash.

Regulatory Evaluation

This final rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget (OMB) has not reviewed this rule under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44

FR 11040, February 26, 1979). We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Cost of Rule

For the owner of an undocumented vessel who needs to obtain an original or a transferred certificate of number, the increase in fees resulting from this final rule is a one-time increase of $18, or $6 a vessel a year. For the same owner who needs to obtain a renewal certificate, the increase is a one-time increase of $10, or $3.33 a vessel a year (See Table 1). The fees for duplicate certificates and replacement stickers arise "as needed" and are not subject to further analysis.

BILLING CODE 4910–15–U

Table 1: Transactions and associated fees

A/ Service provided	B/ Current fee (1972)	C/ New fee (1999)	D/ Increase	E/ Annual cost of increase (D/3 years)
Original certificate	$6	$24	$18	$6 yr.
Renewal certificate	$6	$16	$10	$3.33 yr.
Duplicate certificate	$1	$9	$8	$2.67 yr.
Replacement sticker	$0.25	$9	$8.75	$2.92 yr.

BILLING CODE 4910–15–C

To determine the fees set forth in this rulemaking, the Coast Guard adopted Activity-Based Costing (ABC), a methodology that assigns costs according to the activities required to produce an output. An alternative would have been to use the Consumer Price Index (CPI), an inflation index showing how prices change for goods such as food, housing, and medical care for a typical consumer. Although ABC and CPI are not directly related, it is useful to compare the two to make sure our fee increase is within the range most people would expect.

In 1972, we set the fee for an original certificate of number at $6.00. If we had accomplished routine adjustments based on the CPI between 1972 and 1998, the fee for an original certificate of number would have increased to $20.31 [1972 price × (1998 CPI/1972 CPI): $6.00 × (146.9/43.4) = $20.31]. As presented in Table 1, adjustments based on ABC yield a new fee for an original certificate of number of $24.00.

This comparison shows that the increase set forth by the Coast Guard to recover costs based on ABC is close to the increase that would have occurred had it been linked with the inflation rate for Alaska.

Under the general Federal statute on user fees, the Coast Guard must recover its costs for services provided to the public. Further, under 31 U.S.C. 9701 and Circular A–25, the Coast Guard must review these fees every two years to ensure full-cost recovery. Fees for issuing numbers to undocumented vessels in Alaska have gone unreviewed since 1972. The annual cost of the increases as outlined in this final rule and Table 1 is justified because of (1) the 17-year period between establishment and review of the fees and (2) the outcome of Coast Guard analysis using ABC.

Benefits of Rule

The fee increases will allow the Coast Guard both to recover its costs for issuing numbers to undocumented vessels and to maintain the service required by the general public. Full-cost recovery benefits the involved parties by (1) delivering service to owners of undocumented vessels in Alaska and (2) letting the Coast Guard meet Federal mandates on cost recovery.

This final rule will also increase convenience to the public by allowing more ways for them to make their payments.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this final rule would have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

Because the effects of this final rule will be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

Records of the Coast Guard indicate that as of December 31, 1997, there were 32,414 undocumented vessels numbered by the Coast Guard in Alaska. Of those 32,414 undocumented vessels, about 23 percent—7,107 vessels (4,945 commercial fishing vessels, 1,656 commercial passenger-carrying vessels, and 506 rental or livery vessels)—belong to commercial entities, some of which may qualify as small entities. The economic impact of this rule on these small entities, however, is minimal (see Table 2).

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Table 2: Annual cost of fee increase

Service provided	Proposed fee increase	Annual cost of increase
Original certificate	$18.00	$6.00/year
Renewal certificate	$10.00	$3.33/year
Duplicate certificate	$ 8.00	$2.67/year
Replacement sticker	$ 8.75	$2.92/year

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For the five years 1994 through 1998 inclusive, we analyzed the number of transactions recorded by the Seventeenth District for issuing original, renewal, and transfer certificates. We assessed the aggregate economic effects of the then-proposed rule across the fleet of undocumented vessels in Alaska (See Table 3). We consider five years long enough to accurately represent the number of transactions that will occur in the future. The data reflect the cost of the fee increase across the fleet of undocumented vessels. We estimate that 23% of these transactions may involve small entities. Therefore, the aggregate cost of the fee increase on small entities is $31,760.70 ($138,090 × 23%).

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Table 3: Aggregate cost of fee increase across the fleet

Service provided	Average transactions per year*	Cost per current fee	Cost per proposed fee	Difference
Original certificate	2,785	$16,710 ($6 x 2,785)	$66,840 ($24 x 2,785)	$50,130
Renewal certificate	8,796	$52,776 ($6 x 8,796)	$140,736 ($16 x 8,796)	$87,960
Total	**11,581**	**$69,486**	**$207,576**	**$138,090**

*Avg. transactions per year calculated from the five-year period, 1994-1998, inclusive.

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Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding this final rule so that they could better evaluate its effects on them and participate in the rulemaking. For clarification of the new fees, they can ask the Seventeenth Coast Guard District, Boat Registration Office, in person, by telephone or by e-mail as listed in **FOR FURTHER INFORMATION CONTACT.**

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal enforcement. The Ombudsman will annually evaluate the enforcement and rate each agency's responsiveness to small business. If you wish to comment on enforcement by the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This final rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this final rule under E.O. 12612 and have determined that this rule does not have sufficient implications for federalism to warrant the preparation of a Federalism Assessment. The Coast Guard is complying with the general Federal statute on user fees, and with the specific Federal statute for services provided under Title 46 of the United States Code, subtitle II.

Unfunded Mandates Reform Act and Enhancing the Intergovernmental Partnership

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) and E.O. 12875, Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), govern the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This final rule will not impose an unfunded mandate.

Taking of Private Property

This final rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this final rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

Environment

We considered the environmental impact of this final rule and concluded that under figure 2–1, paragraph (34)(a), of Commandant Instruction M16475.lC, the rule is categorically excluded from further environmental documentation. The rule merely adjusts the fees charged to owners of undocumented vessels for issuing vessel's numbers and validation stickers. A "Categorical Exclusion Determination" is available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 173

Marine safety, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 173 as follows:

PART 173–VESSEL NUMBERING AND CASUALTY AND ACCIDENT REPORTING

1. Revise the citation of authority for Part 173 to read as follows:

Authority: 31 U.S.C. 9701; 46 U.S.C. 2110, 6101, 12301, 12302; OMB Circular A–25; 49 CFR 1.46.

2. Revise § 173.85 to read as follows:

§ 173.85 Fees levied by the Coast Guard.

a. In a State where the Coast Guard is the issuing authority, the fees for issuing certificates of number are:

(1) Original or transferred certificate of number and two validation stickers—$24.

(2) Renewed certificate of number and two validation stickers—$16.

(3) Duplicate certificate of number—$9.

(4) Replacement of lost or destroyed validation stickers—$9.

(b) Fees are payable by check or money-order made payable to the "U.S. Coast Guard"; by major credit card (MasterCard or Visa); or, when the owner applies in person, in cash.

Dated: June 24, 1999.

Ernest R. Riutta,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Operations.

[FR Doc. 99–17053 Filed 7–2–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ–005–ROP; FRL–6371–2]

Approval and Promulgation of Implementation Plans; Phoenix, Arizona Ozone Nonattainment Area, Revision to the 15 Percent Rate of Progress Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is making minor changes to its 1998 15 percent rate of progress federal implementation plan (1998 FIP) for the metropolitan Phoenix (Arizona) ozone nonattainment area. The 1998 FIP contains a demonstration that the Phoenix metropolitan area has in place sufficient measures to meet the 15 percent rate of progress (ROP) requirement in the Clean Air Act. This action does not alter the basic conclusion in the 1998 FIP that the Phoenix metropolitan area has met the 15 percent ROP requirement as soon as practicable.

EFFECTIVE DATE: August 5, 1999.

FOR FURTHER INFORMATION CONTACT: Frances Wicher, Office of Air Planning (AIR–2), U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California 94105. (415) 744–1248, wicher.frances@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background Information

EPA is making minor changes to its 1998 15 percent rate of progress federal implementation plan (1998 15 percent ROP FIP or 1998 FIP) for the metropolitan Phoenix (Arizona) ozone nonattainment area. We proposed this action on March 26, 1999 at 64 FR 14659 (Reference 1).

Specifically, we are changing the control strategy (that is, the list of control measures) that makes up the basis for the 15 percent ROP demonstration for the Phoenix area by deleting the National Architectural Coatings Rule and adding phase II of Arizona's Clean Burning Gasoline (CBG) program to the control strategy in the 1998 FIP. Neither of these changes affects our basic conclusion in the 1998 15 percent ROP FIP that the Phoenix metropolitan area has in place sufficient measures to meet the 15 percent rate of progress requirement in CAA section 182(b)(1) as soon as practicable. Therefore, we are not making any changes to the language in the Code of Federal Regulations noting that we have determined that the Phoenix area has demonstrated the 15 percent ROP. See 40 CFR 52.123(g). We are making these changes under our federal planning authority in CAA section 110(c).

We are also clarifying that the transportation conformity budget for the Phoenix ozone nonattainment area is 87.1 metric tons of VOC per ozone season average day.

We describe in detail the Clean Air Act's 15 percent ROP requirement, the 1998 FIP, and our proposed revisions to the 15 percent plan and the transportation conformity budget in the proposal and in the Technical Support Document (TSD) for this action (Reference 2). We also discuss in the proposal and the TSD our interpretation of the CAA section 172(c)(9) requirement for contingency measures and our policies for implementing this requirement. We will not repeat this information here. Readers interested in this information should consult the proposal and the TSD. We devote the majority of this preamble to summarizing our responses to the most significant comments received on the proposal.

II. Summary of EPA's Response to Comments Received on the Proposal

We received three comment letters on the proposal. The Arizona Department of Environmental Quality (ADEQ) supported the revisions to the 15 percent ROP FIP as well as our interpretation of the Clean Air Act's contingency measure requirement. No response to ADEQ's letter is necessary.

The Maricopa Association of Governments (MAG) requested that we clarify certain issues regarding the revised transportation conformity budget. We have made the requested clarifications in the section on the conformity budget later in this preamble and discuss them more fully in section VI.B. of the TSD.

Finally, the Arizona Center for Law in the Public Interest (ACLPI) commented on the proposed revisions to the 15 percent ROP demonstration and our interpretation of the contingency measure requirement. A summary of our responses to ACLPI's most significant comments follows. We provide our complete responses to all of ACLPI's comments in section VI.A. of the TSD.

A. Comments on the Revisions to the 15 Percent ROP Demonstration

Comment: ACLPI contends that we have failed to propose additional control measures to make up the shortfall in the 15 percent ROP demonstration as we said we would do in our motion for voluntary remand in *Aspegren* v. *Browner,* No. 98–70824, a petition to review certain aspects of the 1998 FIP. ACLPI filed the petition on behalf of several Phoenix area residents in the U.S. Court of Appeals for the Ninth Circuit.

Response: The control strategy in the 1998 FIP included three proposed national rules for various categories of consumer and commercial products. When issued in September, 1998, the final rules resulted in slightly fewer emission reductions than we had estimated in the 1998 FIP.

In our motion for voluntary remand we stated that we would consider the effect of the final national rules on the 15 percent ROP demonstration for Phoenix, determine if additional control measures are needed to assure expeditious attainment of the 15 percent ROP goal in the area, and promulgate additional measures only if we determined that additional measures were needed. See *Aspegren,* paragraph 10, Motion for Voluntary Remand, October 29, 1998. As discussed below, we have done exactly that. Furthermore, the statement in our motion merely restates our Clean Air Act obligation under section 110(c) of the Act to demonstrate that the Phoenix area continues to meet, as expeditiously as practicable, the requirements of section 182(b)(1)(a) for a 15 percent ROP. That obligation, and moreover our authority, for this action are limited to making this demonstration and are not affected by statements of intent in our motion for voluntary remand.

We have evaluated the effect of the final national rules on the 15 percent ROP demonstration for the Phoenix area and determined that these rules result in a loss of 1 metric ton per day from the 15 percent ROP plan as of April 1, 1999. We have replaced these lost emission reductions in the ROP analysis by revising the control strategy in the 15 percent ROP plan to include emission reductions from the second phase of Arizona's Cleaner Burning Gasoline (CBG) program. The second phase of the CBG program did not go into effect until May 1, 1999, one month after the demonstration date in the 1998 FIP. Thus, with this revision, the demonstration date for the 15 percent ROP goal moves from April 1 to the CBG-phase II start date of May 1, 1999.

Even though there is now a shortfall as of the old April 1 demonstration date, the Clean Air Act does not require us to promulgate additional measures if we can still show that the 15 percent ROP goal is being met as expeditiously as practicable. We have, in fact, shown that May 1, 1999 is the most expeditious date by which the 15 percent ROP goal can now be met in the Phoenix area and that all the control measures necessary to meet this goal are already in place. See the proposal at page 14661. We, therefore, have met our Clean Air Act obligation.

Comment: ACLPI notes that in our revised FIP proposal we are giving additional credit to Arizona's CBG rule and claims that we stated in our 1998 FIP proposal that if we approved the CBG program in lieu of the federal reformulated gasoline program (RFG) we would give it the same amount of credit. ACLPI quotes language from the proposal (at page 3690) in which we stated that emission reductions from an approved CBG program that exceeded those from federal RFG "may be used by the State in any future rate-of-progress demonstrations." ACLPI claims that we do not explain this policy reversal to credit the CBG program with more emission reductions and that failure to provide an explanation is arbitrary, capricious and an abuse of discretion.

Response: We fully explain in the proposal for this rule the source of the additional reductions from the State's CBG program. See the proposal at page 14661. To summarize, in the 1998 FIP, we only credited phase I of the two-phased federal reformulated gasoline (RFG) program in the 15 percent ROP demonstration. See table 5 on page 3690 of the proposed 1998 FIP (Reference 3). Arizona's CBG program is also a two-phased program. Phase I of the State program was implemented last year, and for the purposes of the 1998 FIP, we considered it equivalent to phase I of the federal RFG program.

The second phase of the CBG program is similar to the more stringent phase II federal RFG program—a program we did not credit in the 1998 FIP. When phase II CBG went into effect on May 1, 1999, it generated an additional 2 metric tons per day (mtpd) in reductions over the reductions from phase I of the State program. Since we did not credit phase II of either the federal or State program in the 1998 FIP, this 2 mtpd reduction is new to the 15 percent ROP plan and does not duplicate reductions already accounted for in the plan. More simply, these are new reductions from a new program which first went into place in May, 1999.

The statement from the 1998 FIP proposal that ACLPI quotes was not a policy statement; rather it was simply intended to indicate to the State and others that any excess emission reduction credits could be used in future ROP demonstrations. As such, it is not a policy declaration from which we need to explain a deviation as required by the Court in the case cited by ACLPI (*Western States Petroleum Ass'n.* v. *EPA,* 87 F.3d 280 (9th Cir. 1996)). Further, it is still true that any excess reductions can be applied to future ROP demonstration.

Comment: ACLPI claims that we still fail to make the "as soon as possible" showing by refusing to consider other control measures that could be implemented to achieve the 15 percent milestone before May 1, 1999. ACLPI also notes that the issue will be moot by the time we finalize the proposed revisions to the FIP because May 1, 1999 will have passed.

Response: Contrary to ACLPI's claim, we did make the "as soon as practicable" demonstration in the proposed revision to the FIP. Our demonstration was simple because less than two months separated the proposal in mid-March, 1999 and the revised demonstration date of May 1, 1999. As we stated in the proposal at page 14661, "[t]his time period is so short that we cannot complete this rulemaking prior to May 1, 1999 and still provide an adequate period for the public to comment and then for sources to comply with any new rules." Based on

this reasoning, we concluded that there are no other measures available for the Phoenix area that could meaningfully advance the date by which the 15 percent ROP is demonstrated. See the proposal at page 14662.

ACLPI fails to identify the "other control measures that could be implemented to achieve the 15 percent milestone before May 1, 1999" that it claims we are refusing to consider. Without this specific information, we are unable to determine the validity of their claim and cannot further respond to their comment. We believe, however, that we have considered all practicable and available controls and found none that could have advanced the May 1 demonstration date.

We agree with ACLPI that the issue is now moot because the May 1 date has passed.

B. ACLPI's Comments on the Section 172(c)(9) Contingency Measures

Comment: ACLPI disputes our position that the contingency measure requirement only pertains to nonattainment area plans as a whole and not specifically to the 15 percent ROP provision of the nonattainment plan. ACLPI states that our position ignores the plain language of the Act that section 172(c) applies to all nonattainment plan provisions.

Response: In the proposal and TSD, we respond to similar assertions made by ACLPI in its brief for the *Aspegren* petitioners. Please see page 14662 of the proposal and pages 20–22 of the TSD. We add the following to our previous response.

We do not agree that the contingency measure requirement in section 172(c)(9) pertains specifically to the 15 percent ROP requirement. We believe a better reading of the Act is that contingency measures are required as part of the overall nonattainment plan and not as a feature of each component part of that plan, such as the 15 percent ROP plan.

Under the CAA, a nonattainment plan is a compendium of elements that together provide for progress toward and expeditious attainment of the air quality standards in an area. Within an area's nonattainment plan, the section 172(c)(9) contingency measures serve as the first remedial step in addressing a failure of the area actually to make the required progress or to attain by the required date. Thus, we believe that a failure in any plan element that results in an area not making the required progress or not attaining triggers the contingency measures. In contrast, tying the contingency measures to a failure in a specific provision of the nonattainment plan—e.g., the 15 percent ROP provision—would too narrowly limit the conditions for their implementation, thereby weakening their remedial role in assuring an area's overall progress toward and expeditious attainment of the air quality standards.

A requirement for inclusion of contingency measures in the 15 percent ROP plan would make sense if a disapproval of the plan under section 182(b)(1)(A) for failure to provide for a 15 percent ROP triggered the contingency measures. It does not. The consequences of a 15 percent ROP plan disapproval are sanctions under section 179(a) and FIPs under section 110(c) unless the state revises the plan to make it approvable.

A requirement to include contingency measures in ROP plans would also make sense if the only way to ensure that states developed and submitted adequate contingency measures were to incorporate the requirement into another nonattainment area provision. Contingency measures, however, are a required submittal directly under the Act, and a state's failure to submit approvable contingency measures is by itself subject to the Act's sanctions and FIP provisions.

Contrary to ACLPI's contention, our position is supported by the plain language of section 172(c)(9). While the other subsections in section 172(c) begin with "such *plan provisions* shall * * *", section 172(c)(9) begins with "such *plan* shall. * * *" (emphasis added). "Such plan" refers to the overall nonattainment plan rather than an individual element or provision of it. This difference in language between the contingency measures requirement and the other requirements in section 172(c) emphasizes that the contingency measures serve to backstop the entire nonattainment plan and not just particular elements of it.

Moreover, our position is supported by the trigger for implementing contingency measures in section 172(c)(9) itself. The section 172(c)(9) contingency measures are not triggered by failures of the ROP or attainment plan to actually provide RFP or attainment; they are triggered by the failure of an area to actually make reasonable further progress or to attain by its required deadline.

This distinction between a plan's failure and an area's failure is not trivial. To determine if a plan succeeded or failed, one only reviews the current status of the measures and assumptions in that plan. In other words, the plan is evaluated in isolation without regard to other factors that may influence emissions and air quality in an area, such as economic and population growth and sources violating air quality rules.

In contrast, to determine if an area succeeded or failed to meet its ROP milestone, one determines if current emissions in the area are at or below the ROP target level. See *General Preamble* at page 13509. To do this, one looks at the current status of all in-place, real, permanent and enforceable controls—even those not relied on in or anticipated by the 15 percent ROP plan—and current socio-economic data to calculate a whole new inventory of actual emissions. In other words, all factors that influence emissions in an area are taken into account. The original ROP plan is referenced only to obtain the target emissions level. See the *General Preamble* at pages 13504 and 13518 (Reference 5).

The determination of whether an area attained or failed to attain is even more simple; only ambient air quality data is examined. The status of the attainment demonstration plan is not reviewed at all. See *General Preamble* at page 13506.

Because the trigger for implementing contingency measures in section 172(c)(9) is thus independent of the success or failure of any particular plan provision, it follows that the contingency measures are also independent of any particular plan provision. They are elements of the overall nonattainment plan, serving its purpose of "eliminating or reducing the severity and number of violations of the national ambient air quality standards and achieving expeditious attainment of these standards." Section 176(c)(1)(A) of the Clean Air Act.

We emphasize that the above discussion addresses only the circumstances for triggering contingency measures. Under the Act, states are required to implement the non-contingent provisions of their SIPs regardless of whether they meet a milestone or attain. If a state determines that a SIP measure is no longer needed to meet the Act's requirements, it must request and EPA must approve a SIP revision, consistent with section 110(l), to remove the measure before the state is relieved of its statutory obligation to implement it.

Comment: ACLPI continues to claim that EPA's guidance documents clearly recognize that contingency measures must be included in a 15 percent ROP plan submittal and asserts that our "attempt to reinterpret our guidance is unpersuasive." ACLPI provides, as an example, our explanation in the proposal that the term "rate-of-progress plan" in the EPA document *Guidance for Growth Factors* (Reference 4) is a

compact reference to all the submittals due on November 15, 1993 and not just the 15 percent ROP plans. ACLPI also claims that we have ignored that this guidance document specifically defines the term "rate-of-progress plan" as that part of the SIP revision due November 15, 1993 "which describes * * * how the areas will achieve an actual [VOC] emissions reduction of at least 15 percent."

Response: The first paragraph of the Executive Summary in the *Guidance for Growth Factors* contains a short definition of "rate-of-progress plan." The full definition of the term is in Appendix A to the document. In Appendix A, the rate-of-progress plan is defined as "the *portion of the SIP revision due by November 15, 1993,* that describes how moderate and above ozone nonattainment areas plan to achieve the 15 percent VOC emissions reduction." (Emphasis added). This definition goes on to note that "[a]ll moderate intrastate areas that choose to utilize the EKMA [air quality model], are also required to include their attainment demonstration in this SIP revision."

This definition makes clear that the ROP plan is only a portion of a larger SIP revision due by November 15, 1993. It is also clear that another part of that SIP revision, separate from the ROP plan, is the attainment demonstration for certain moderate nonattainment areas.

With this definition in mind, we return to the Executive Summary. As noted by ACLPI in its comments, the attainment demonstration is also distinguished here from the rate-of-progress plan. However, right after this distinction is made, the following statement is made:

> States must submit their fully adopted rate-of-progress plans to EPA by November, 1993. Moderate ozone nonattainment areas not using [the Urban Airshed Model] must include an attainment demonstration *in their fully adopted rate-of-progress plans.*

(Emphasis added).

As a distinct requirement, these attainment demonstrations, cannot logically be in the ROP plans. Therefore, the term "rate-of-progress plan" as used in this statement cannot have the meaning given to it just a few paragraphs before in the Executive Summary and in Appendix A. The only meaning that does make sense here is the one we have suggested: it is a compact reference to all the submittals due on November 15, 1993.

Knowing that the exact meaning of the term "rate-of-progress plan" in the *Guidance for Growth Factors* is dependent on the context, we now evaluate the statement that ACLPI claims proves we consider contingency measures as a required element of 15 percent ROP plans. This statement is from the last paragraph of the Executive Summary of the *Guidance for Growth Factors:*

> In addition, this document describes the requirements for contingency measures that must be included in the rate-of-progress plans for moderate and above ozone nonattainment areas, and provides examples of possible contingency measures.

Read together with the very similar statement on attainment demonstrations discussed above, the clause "included in the rate-of-progress plans" is clearly intended to mean "a part of the overall set of plans submitted at the same time as the rate-of-progress plans" that is, submitted by November 15, 1993. Given this reading, this statement becomes consistent with every other piece of EPA guidance on the section 172(c)(9) contingency measures for ozone nonattainment areas: they were a separate and distinct part of the overall SIP submittal due in November, 1993.

EPA's basic guidance on ozone contingency measures is found in the *General Preamble* at page 13510 and in Chapter 9 of *Guidance for Growth Factors.* A close reading of this guidance discloses that the primary connection made between the requirement in section 182(b)(1)(A) for 15 percent ROP plans and the requirement in section 172(c)(9) for contingency measures is the identical submittal date. This guidance is clear that we consider the contingency measures to be a separate statutory requirement that we can act on independently from the 15 percent ROP plan.

EPA's purpose in issuing guidance is to provide the states and the general public with advance notice of how it will generally interpret the Act's requirements. See General Preamble at 13498. We actually apply these interpretations at the time we act on SIP revisions (or promulgate FIPs). Therefore, if there is any question about the meaning of EPA's guidance on 15 percent ROP plans and contingency measures, it can best be answered by reviewing just how we have applied the guidance in actual rulemakings on 15 percent ROP plans.

Nationally, we have taken final action on 32 separate 15 percent ROP plans (including the Phoenix FIP) in 24 different rulemakings. See Appendix B to the TSD for a complete listing. In 16 of these rulemakings (two-thirds of the total), we acted on the 15 percent ROP plans without concurrently acting on the contingency measures. If we considered the 15 percent ROP plan and the contingency measures elements of the same requirement, then we could not have acted on either without acting on both.

In the other 8 rulemakings, we did act on the contingency measures concurrently with the 15 percent plan. In many of these instances, the State voluntarily chose to use the excess emission reductions in its 15 percent ROP plan to satisfy its contingency measure requirement. For these rulemakings, we did look at the merits of the ROP plan, most specifically, at the claim of excess emission reductions, to determine the approvability of the contingency measures. Conversely, we did not look at the approvability of the contingency measures to determine the approvability of the 15 percent ROP plan. In all the other cases, we treated the contingency measures and the 15 percent ROP plans as strictly separate requirements and did not link the approvability of one to the presence or approvability of the other.

ACLPI dismisses this rulemaking record as "utterly irrelevant" and not negating our previous actions with respect to Arizona or the clear import of our guidance. We have already discussed our guidance and the fact that it does not require contingency measures in complete and approvable 15 percent plans. Since the guidance at issue is guidance applicable to every 15 percent plan in the country, the fact that we have consistently applied it to the same effect is clearly relevant to determining the appropriate interpretation of our guidance. Equally, neither of our two final actions on Arizona's 15 percent ROP plans—the 1998 FIP and today's action—have included contingency measures.

III. The New Transportation Conformity Budget For VOCS

Under EPA's conformity rule, we identify a transportation conformity budget whenever we approve any control strategy plan, such as the 15 percent ROP plan, into the SIP. See 40 CFR 93.118(e)(4)(iii). This requirement also applies when we promulgate a control strategy in a FIP as we are doing today.

We are identifying a transportation conformity budget for the Phoenix ozone nonattainment area of 87.1 metric tons of VOC per ozone season average day. The analysis supporting identification of this budget can be found in section V.B. of the TSD. This budget is for 1996 and reflects all on-road mobile source control measures that are included in the 15 percent ROP control strategy.

After the effective date of this action, all transportation actions taken in the Phoenix ozone nonattainment area that are required to show conformity to a budget under Clean Air Act section 176(c) and EPA's conformity rule in 40 CFR part 93 must conform to the budget established by this rule. This transportation conformity budget is based in part on a number of SIP-approved transportation control measures (TCMs)(including the Arizona's vehicle emission inspection program and the Cleaner Burning Gasoline program). Any future ozone conformity determinations must also demonstrate the expeditious implementation of these TCMs as well as any other SIP-approved TCMs for ozone.

Once effective, the transportation conformity budget established by this rule will be the only approved and applicable transportation conformity budget for ozone in the Phoenix nonattainment area. Previous ozone budgets, whether submitted by Arizona or promulgated by EPA in the 1998 FIP, will no longer be valid for transportation conformity determinations because we have not found any State-submitted budgets to be adequate for use under our conformity rule and because we are replacing the budget in the 1998 FIP.

IV. Statement of Final Action

Under our authority in CAA section 110(c) and for the reasons discussed in the March 26, 1999 proposal, EPA determines that the Phoenix metropolitan area has in place sufficient control measures to meet the 15 percent rate of progress requirement in CAA section 182(b)(1)(A) as soon as practicable. This determination is based on our analysis of the effect of the control measures listed in Table 2 of the proposal on emissions in the Phoenix area.

Consistent with CAA section 176(c) and 40 CFR part 93 and under our authority in section 110(c), we are also identifying a transportation conformity budget for the Phoenix ozone nonattainment area of 87.1 metric tons of VOC per ozone season average day.

V. Administrative Requirements

A. Executive Order 12866

Under Executive Order 12866, (58 FR 51735; October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires EPA to prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure of $100 million or more in any one year by state, local, and tribal governments, in aggregate, or by the private sector. Section 203 requires EPA to establish a plan for obtaining input from and informing any small governments that may be significantly or uniquely affected by the rule. Section 205 requires that regulatory alternatives be considered before promulgating a rule for which a budgetary impact statement is prepared. EPA must select the least costly, most cost-effective, or least burdensome alternative that achieves the rule's objectives, unless there is an explanation why this alternative is not selected or this alternative is inconsistent with law.

This rule does not include a Federal mandate and will not result in any expenditures by State, local, and tribal governments or the private sector. Therefore, EPA has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. Because small governments will not be significantly or uniquely affected by this rule, EPA is not required to develop a plan with regard to small governments.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This rule will not have a significant impact on a substantial number of small entities because it simply revises a demonstration based on previously established requirements and contains no additional requirements applicable to small entities. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

This rule contains no information requirements subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

E. Applicability of Executive Order 13045: Children's Health Protection

This rule is not subject to E.O. 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), because it is not economically significant under E.O. 12866 and it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

F. Executive Order 12875: Enhancing Intergovernmental Partnerships

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates." This rule does not create a mandate on State, local or tribal governments nor impose any enforceable duties on these entities. Accordingly, the requirements of

section 1(a) of Executive Order 12875 do not apply to this rule.

G. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

This action neither creates a mandate nor imposes any enforceable duties on tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

H. The National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (NTTAA), section 12(d), Public Law 104–113, requires federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments. If use of such technical standards is inconsistent with applicable law or otherwise impractical, a federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of the agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards.

This rule does not include any technical standards; therefore, EPA is not considering the use of any voluntary consensus standards.

I. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major" rule as defined by 5 U.S.C. 804(2).

J. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 7, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Ozone.

Dated: June 28, 1999.

Carol M. Browner,

Administrator.

References

1. 64 FR 14659–14665 (March 26, 1999); *Approval and Promulgation of Implementation Plans; Phoenix, Arizona Ozone Nonattainment Area, Revisions to the 15 Percent Rate of Progress Plan;* Proposed rule.

2. Air Division, U.S. EPA, Region 9, "Final Addendum to the Technical Support Document for the Notice of Final Rulemaking on the Clean Air Act Section 182(b)(1) 15 Percent Rate of Progress Requirement for the Phoenix Metropolitan Ozone Nonattainment Area," June 14, 1999.

3. 63 FR 3687–3693 (January 26, 1998); *Approval and Promulgation of Implementation Plans; Phoenix Arizona Ozone Nonattainment Area, 15 Percent Rate of Progress Plan and 1990 Base Year Emission Inventory;* Proposed rule.

4. *Guidance for Growth Factors, Projections, and Control Strategies for the 15 Percent Rate of Progress Plans,* Office of Air Quality Planning and Standards, U.S. EPA. EPA–452/R–93–002, March 1993.

5. 57 FR 13498 (April 16, 1992). *State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990.* General Preamble for future proposed rulemakings.

[FR Doc. 99–16932 Filed 7–2–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[UT–001–0018; UT–001–0019; UT–001–0020; FRL–6368–8]

Approval and Promulgation of Air Quality Implementation Plans; Utah; Foreword and Definitions, Revision to Definition for Sole Source of Heat and Emissions Standards, Nonsubstantive Changes; General Requirements, Open Burning and Nonsubstantive Changes; and Foreword and Definitions, Addition of Definition for PM_{10} Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On March 26, 1999, EPA published a direct final and proposed rulemaking approving State Implementation Plan (SIP) revisions submitted by the Governor of the State of Utah. On July 11, 1994, the Governor submitted a SIP revision for the purpose of establishing a modification to the definition for "Sole Source of Heat" in UACR R307–1–1; this revision also made a change to UACR R307–1–4, "Emissions Standards." On February 6, 1996, a SIP revision to UACR R307–1–2 was submitted by the Governor of Utah which contains changes to Utah's open burning rules, requiring that the local county fire marshal has to establish a 30-day open burning window in order for open burning to be allowed in areas outside of nonattainment areas. Other minor changes are made in this revision to UACR R307–1–2.4, "General Burning" and R307–1–2.5, "Confidentiality of Information." In addition, on July 9, 1998, SIP revisions were submitted that would add a definition for "PM_{10} Nonattainment Area" to UACR R307–1–1. This action is being taken under section 110 of the Clean Air Act.

EFFECTIVE DATE: This final rule is effective August 5, 1999.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air and Radiation Program, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado, 80202 and the Air and Radiation Docket and Information Center, Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Copies of the state documents relevant to this action are available for public inspection at the Utah Department of Environmental Quality, Division of Air Quality, 150 North 1950 West, Salt Lake City, Utah.

FOR FURTHER INFORMATION CONTACT: Cindy Rosenberg, EPA, Region VIII, (303) 312–6436.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever "we", "us", or "our" are used, we mean the Environmental Protection Agency (EPA).

Table of Contents

I. EPA's Final Action

We are approving the Governor's submittal of July 11, 1994, to revise the definition for "Sole Source of Heat" to define which households may continue burning during woodburning bans so that those households with small portable heaters still qualify under the definition of households for which wood or coal burning is the only source of heat. We are also approving a change made under "Emissions Standards," which moves section 4.13.3 D to section 4.13.3.E. We are approving the submittal of February 6, 1996, which made changes to Utah's open burning regulations (in "General Burning") to require that the local county fire marshal establish a 30-day window during which open burning activities may occur in areas outside of nonattainment areas during the spring and fall closed burning seasons. This applies to all areas in the State outside of Salt Lake, Davis, Weber, and Utah Counties where the state forester has permitted the local county fire marshal to establish the open burning window. Minor changes were also made to R307–1–2.4, "General Burning" as well as R307–1–2.5, "Confidentiality of Information." Lastly, we are approving the Governor's submittal of July 9, 1998, adding a definition for "PM_{10} Nonattainment Area" in R307–1–1.

II. Summary of SIP Revision

A. Review of Revisions

1. Review of the Changes to "Foreword and Definitions" Concerning the Definition for "Sole Source of Heat"

The residential woodburning regulation revision was developed by the Utah Division of Air Quality with input from local governments and the public. The Air Quality Board approved two changes to the woodburning rule at the December 9, 1993, hearing which were later submitted by the Governor on July 11, 1994. The revision to R307–1–1 changes the definition for "Sole Source of Heat." This change defines which households may continue burning during woodburning bans so that those households with small portable heaters still qualify under the definition of households for which wood or coal burning is the only source of heat. The second revision, which was made to the residential woodburning regulations under R307–1–4.13, specifies the actions which must be taken if contingency measures are implemented in the Salt Lake, Davis or Utah County nonattainment areas. These plans were requested to be withdrawn by the Governor in a November 9, 1998, letter to the Regional Administrator. We returned the portions of these plans with a letter to the Governor on January 29, 1999. However, a nonsubstantive change was made in this section as a result of the revision. This change moves section 4.13.3 D to section 4.13.3.E. For the purposes of ease and efficiency for the State, the revised sub-section number is being approved, and thus, there will be no section 4.13.3.D.

2. Review of the Changes to "General Requirements" Concerning Open Burning Regulations and Minor Changes to Rules

On February 6, 1996, the State of Utah submitted its revised open burning regulations in order to make them more consistent with Utah Code 65A–8–9. Utah made revisions to its open burning regulations for areas outside of nonattainment areas because they were found to be in conflict with Utah Code 65A–8–9. The Code prohibits open burning between June 1 and October 31, unless a permit has been issued, whereas the open burning regulations allowed burning between March 30 and May 30 and between September 15 and October 30 in areas outside of nonattainment areas. These changes were made under UACR R307–1–2.4.4.

The following are requirements for open burning under Utah Code 65A–8–9 which pertain to the rule change addressed by the SIP:

1. June 1 through October 31 of each year is to be a closed fire season throughout the State.

2. The state forester has jurisdiction over the types of open burning allowed with a permit during the closed fire season.

The open burning requirement that was previously in the Utah SIP pertaining to this rule change is as follows:

For areas outside of Salt Lake, Davis, Weber, and Utah Counties (nonattainment areas), open burning is allowed during the periods of March 30 through May 30 and September 15 through October 30 with a permit issued by the authorized local authority.

The open burning requirement that was adopted by the Utah Air Quality Board on September 6, 1995 is as follows:

For areas outside of the designated nonattainment areas, open burning is allowed during the March 30 through May 30 period and the September 15 through October 30 period if the local county fire marshal has established a 30-day window for such open burning to occur with a permit issued by the authorized local authority and the state forester has allowed for such permit to be issued.

Other minor changes were made to the open burning regulations as well. Section R307–1–2.4, "General Burning" has had numbers added to it to make it more consistent with Utah Code 19–2–114. Section R307–1–2.4.3.C is corrected to refer to Subsection R307–17–3 in place of section 4.13.3 of the regulations. More minor changes were also made throughout the open burning regulations to change capitalization and to correct references.

Minor changes were also made under R307–1–2.5, "Confidentiality of Information" including a changed statutory reference in R307–1–2.5.1.B. Additional changes were made to correct references and capitalization of section headings.

3. Review of the Changes to "Foreword and Definitions" Concerning the Addition of a Definition for PM_{10} nonattainment Areas

On January 7, 1998, the Air Quality Board approved the addition of the definition for "PM_{10} Nonattainment Area." This revision was made to ensure that the currently designated nonattainment areas within the State for PM_{10} would be held to the same requirements after the pre-existing PM_{10} NAAQS were revoked as they were prior to the revocation of the NAAQS. Since this revision was made, the United States Court of Appeals for the District of Columbia Circuit ruled on May 14, 1999, in *American Trucking Associations, Inc.* v. *U.S. Environmental Protection Agency* (Nos. 97–1440 and 97–1441), to vacate our new standards for PM_{10}. We are now unable to approve any revocations of the old PM_{10} standard. Nonetheless, this definition can still be approved without a revocation of the PM_{10} standard because it reaffirms the designation status for the nonattainment areas, set forth in 40 CFR 81.345.

B. Procedural Background

The CAA requires States to observe certain procedural requirements in developing SIP revisions for submittal to EPA. Section 110(a)(2) of the CAA provides that each SIP revision be adopted after going through a reasonable notice and public hearing process prior to being submitted by a State. We have evaluated each of the above Governor's submittals and discuss them below.

1. July 11, 1994 Submittal

Copies of the proposed changes were made available to the public and the State held public hearings for the changes to "Foreword and Definitions" and "Emissions Standards" on October 5, 1993, October 6, 1993, October 7, 1993, and October 13, 1993. The changes to the State's rules were adopted by the Air Quality Board on December 9, 1993 and became effective on January 31, 1994; the revision was formally submitted by the Governor on July 11, 1994. We determined the submittal was complete on September 22, 1994. A portion of this revision included PM_{10} contingency plans which were requested to be withdrawn by the Governor in a November 9, 1998, letter to the Regional Administrator. We returned this portion of the submittal with a letter to the Governor on January 29, 1999.

2. February 6, 1996 Submittal

Copies of the proposed changes were made available to the public and the State held public hearings for the changes to "General Requirements" on July 14 (two separate hearings), 17, 18, and 19, 1995. The changes to the State's rule were adopted by the Air Quality Board on September 6, 1995 and became effective on October 31, 1995; the new open burning regulations, along with the other nonsubstantive changes to "General Requirements," were formally submitted by the Governor on February 6, 1996. We determined the submittal was complete on August 14, 1996.

3. July 9, 1998 Submittal

Copies of the proposed changes were made available to the public and the State held public hearings for the changes to "Foreword and Definitions" on December 16, 1997 and January 5, 1998. The changes to the State's rule were adopted by the Air Quality Board on January 7, 1998 and became effective on January 8, 1998; the new definition was formally submitted by the Governor on July 9, 1998. We determined the submittal was complete on October 16, 1998.

III. EPA's Response to Public Comments

The following discussion responds to the adverse comments that we received concerning the **Federal Register** direct final rule approving Utah's definition of "PM_{10} Nonattainment Area."

Comment: We received an adverse comment from the Utah Petroleum Association regarding the definition of "PM_{10} Nonattainment Area." They believe that we had no reason to approve the new definition for "PM_{10} Nonattainment Area" unless we intended to revoke the pre-existing PM_{10} standard for the nonattainment areas in Utah (Salt Lake County, Utah County, and Ogden City). The Utah Petroleum Association believes that we should either revoke the standard for these nonattainment areas at the same time as we approve this new definition or provide Utah with a commitment for a date in the future when the revocation will occur. They believe that we have no legal basis for approving this definition if we do not follow the above. If we cannot take one of these two actions, they believe that we should wait to approve this definition until we are able to do so. They also believe that if we cannot revoke the PM_{10} standard at the same time as we approve this definition or if we cannot commit to a date when the standard will be revoked, that the approval of the definition brings a result that is contrary to the intent of Utah in submitting the definition to us for approval into the SIP. The commentors cite Utah's explanation of this new definition to show that the State intended for the revocation to take place shortly after the approval of the definition. The State certified that adding the definition would enable them to guarantee that all rules that currently apply in the PM_{10} nonattainment areas would remain in place after the PM_{10} standard is revoked.

EPA's Response: The State adopted this definition so that all requirements applying in the PM_{10} nonattainment areas would remain in place once we revoked the PM_{10} standard in those areas. But, this definition can also be approved without a revocation of the PM_{10} standard because it simply reaffirms the designation status for the nonattainment areas contained in 40 CFR 81.345. With regard to the Utah Petroleum Association's assertion that we should only approve this definition at the same time as we revoke the standard, that action is not necessary for this definition to be effective. Furthermore, we were unable to revoke the PM_{10} standard at the time that the previous direct final rule for this action was published because we had not yet approved State revisions to nonattainment SIPs for Salt Lake County and Utah County.

Nor did the State intend for these two actions to occur at the same time. Contrary to the comment, the State did not request a simultaneous revocation and approval of this definition. The State has since requested a revocation for the nonattainment areas. However, after this action was published and the comment received, the United States Court of Appeals for the District of Columbia's Circuit ruled on May 14, 1999 to vacate our new standards for PM_{10}. We are now unable to approve any revocations of the old PM_{10} standard. Despite this, we have no reason not to act on the revision and believe we should not further delay the State's request for the "PM_{10} Nonattainment Area" definition to be federally approved.

The Utah Petroleum Association has asserted that we have no legal basis for approving the definition for "PM_{10} Nonattainment Area" absent a revocation for these areas. In truth, there are no legal requirements surrounding this definition because it does not impose any new requirements on the nonattainment areas. As already noted, this definition reaffirms the areas' designation status contained in 40 CFR 81.345.

IV. Background for the Action

On March 26, 1999, we published notices of direct final (64 FR 14620) and proposed rulemakings (64 FR 14665) for the State of Utah. The proposed

rulemaking specified that we would withdraw the direct final rule if adverse comments were filed on the rulemaking. The 30-day comment period concluded on April 26, 1999. During this comment period, we received a comment letter in response to rulemaking and the direct final rule was withdrawn in the **Federal Register** on May 11, 1999 (64 FR 25214).

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled "Regulatory Planning and Review."

B. Executive Order 12875

Executive Order 12875: Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates." Today's rule does not create a mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13045

Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Executive Order 13084: Consultation and Coordination with Indian Tribal Governments

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of Congress and to the Comptroller General

of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 7, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: June 16, 1999.

Patricia D. Hull,

Acting Regional Administrator, Region VIII.

40 CFR part 52, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart TT—Utah

2. Section 52.2320 is amended by adding paragraph (c)(41) to read as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

(41) On July 11, 1994 the Governor of Utah submitted revisions to the Utah State Implementation Plan (SIP) to revise the definition for "Sole Source of Heat" under UACR R307–1–1, "Foreword and Definitions," to allow the exemption of those households with small portable heating devices from mandatory no-burn periods. This revision also made changes to the residential woodburning regulations under UACR R307–1–4.13.3 "No-Burn Periods," which specifies the actions which must be taken if contingency measures are implemented in the Salt Lake, Davis or Utah County nonattainment areas. These plans were requested to be withdrawn by the Governor in a November 9, 1998, letter to the Regional Administrator. EPA returned the portions of these plans with a letter to the Governor on January 29, 1999. A nonsubstantive change was made in this section as a result of the revision which moves section 4.13.3 D to section 4.13.3.E; this change was also approved by EPA. On February 6, 1996 the Governor of Utah submitted revisions to the Utah State Implementation Plan to revise Utah's open burning regulations, under UACR R307–1–2.4, to require that the local county fire marshal establish 30-day open burning windows during the spring and fall closed burning seasons in areas outside of Salt Lake, Davis, Weber, and Utah Counties as granted by the state forester. There were also minor changes made to the open burning regulations under UACR R307–1–2.4, "General Burning" and minor changes made to UACR R307–1–2.5 "Confidentiality of Information." On July 9, 1998 the Governor of Utah submitted revisions to the Utah SIP to add a definition for "PM_{10} Nonattainment Area," under UACR R307–1–1, "Foreword and Definitions."

(i) Incorporation by reference.

(A) UACR R307–1–1, a portion of "Foreword and Definitions," revision of definition for "Sole Source of Heat," as adopted by Utah Air Quality Board on December 9, 1993, effective on January 31, 1994.

(B) UACR R307–1–4, a portion of "Emissions Standards," as adopted by Utah Air Quality Board on December 9, 1993, effective on January 31, 1994.

(C) UACR R307–1–2, a portion of "General Requirements," open burning changes and nonsubstantive wording changes, as adopted by Utah Air Quality Board on September 6, 1995, effective on October 31, 1995.

(D) UACR R307–1–1, a portion of "Foreword and Definitions," addition of definition for "PM_{10} Nonattainment Area," as adopted by Utah Air Quality Board on January 7, 1998, effective on January 8, 1998.

(ii) Additional Material.

(A) July 20, 1998, fax from Jan Miller, Utah Department of Air Quality, to Cindy Rosenberg, EPA Region VIII, transmitting Utah Code 65A–8–9, regarding closed fire seasons.

(B) October 21, 1998, letter from Richard R. Long, Director, EPA Air and Radiation Program, to Ursula Trueman, Director, Utah Division of Air Quality, requesting that Utah withdraw the submitted Salt Lake and Davis County PM_{10} Contingency Measure SIP revisions, the Utah County PM_{10} Contingency Measure SIP revisions, and the Residential Woodburning in Salt Lake, Davis and Utah Counties PM_{10} Contingency Measure SIP revision.

(C) November 9, 1998, letter from the Governor of Utah, to William Yellowtail, EPA Region VIII Administrator, requesting that the submitted Salt Lake and Davis County and Utah County PM_{10} Contingency Measure SIP revisions and the Residential Woodburning in Salt Lake, Davis and Utah Counties PM_{10} Contingency Measure SIP revision be withdrawn.

(D) December 16, 1998, letter from Larry Svoboda, EPA Region VIII, to Ursula Trueman, Utah Department of Air Quality, clarifying revisions that were made to UACR R307–1–4.

(E) January 5, 1999, letter from Ursula Trueman, Utah Department of Air Quality, to William Yellowtail, EPA Region VIII Administrator, concurring on EPA's clarification of revisions that were made to UACR R307–1–4.

(F) January 29, 1999, letter from William Yellowtail, EPA Region VIII Administrator, to the Governor of Utah returning the Salt Lake and Davis County and Utah County PM_{10} Contingency Measure SIP revisions and the Residential Woodburning in Salt Lake, Davis and Utah Counties PM_{10} Contingency Measure SIP revision.

[FR Doc. 99–16931 Filed 7–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300863A; FRL–6089–3]

RIN 2070–AB78

Difenoconazole; Pesticide Tolerance; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Technical amendment.

SUMMARY: EPA is issuing a technical amendment to the regulation which established tolerances for the fungicide Difenoconazole, that published in the **Federal Register** on June 2, 1999. This amendment correctly revises 40 CFR 180.475.

DATES: This regulation is effective July 6, 1999.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703–305–7740; e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be affected by this action if you import commodities containing residues of Difenoconazole. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the "FOR FURTHER INFORMATION CONTACT" section.

II. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document and various support documents from the EPA Internet Home Page at *http://www.epa.gov/. On the Home Page select "Laws and Regulations" and then look up the entry for this document under the* "**Federal Register** - Environmental Documents." You can also go directly to the "**Federal Register**" listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number [OPP–300863A]. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703–305–5805.

III. What Does this Technical Correction Do?

This technical correction revises 40 CFR 180.475 which published in the **Federal Register** of June 2, 1999 (64 FR 29581) (FRL–6081–5), and inadvertently omitted certain commodities and should have reserved paragraph (c).

This correction to the pesticide tolerance is subject to the objection procedures in FFDCA section 408(g) and 40 CFR part 178.

IV. Why Is this Technical Correction Issued as a Final Rule?

EPA is publishing this action as a final rule without prior notice and opportunity to comment because the Agency believes that providing notice and an opportunity to comment is unnecessary and would be contrary to the public interest. As explained above, the correction contained in this action will simply correct by revising 180.475 to include the commodities that were inadvertently omitted. EPA therefore finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) to make this amendment without prior notice and comment. For the same reasons, EPA also finds that there is "good cause" under FFDCA section 408(b)(2) to make this minor modification to the establishment of tolerances without notice and comment.

V. Do Any of the Regulatory Assessment Requirements Apply to this Action?

No. This final rule does not impose any new requirements. It only implements a technical correction to the Code of Federal Regulations (CFR). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). In addition, since this action is not subject to notice-and-comment requirements under the Administrative Procedure Act (APA) or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

EPA's compliance with these statutes and Executive Orders for the June 2, 1999 final rule, which established tolerances for residues of the fungicide Difenoconazole in or on bananas, as discussed in the preamble for the final rule (64 FR 29581, at 29588).

VI. Will EPA Submit this Final Rule to Congress and the Comptroller General?

Yes. The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental Protection, Administrative Practice and Procedure, Agricultural Commodities, Pesticides and Pests, Reporting and Recordkeeping Requirements.

Dated: June 23, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.475 [Amended]

2. Section 180.475 is revised to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide difenoconazole (((2*S*,4*R*)/(2*R*,4*S*)/(2*R*,4*R*)/(2*S*,4*S*)) (1–((2–(2-chloro-4–(4-chlorophenoxy)phenyl)-4-methyl-1,3-dioxolan-2-yl)methyl)-1*H*–1,2,4-triazole) in or on the following raw agricultural commodities:

Commodity	Parts per million
Bananas[2]	0.2
Barley grain[1]	0.1
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat by-products	0.05
Eggs	0.05
Goats, fat	0.05
Goats, meat	0.05
Goats, meat by-products	0.05
Hogs, fat	0.05
Hogs, meat	0.05
Hogs, meat by-products	0.05
Horses, fat	0.05
Horses, meat	0.05
Horses, meat by-products	0.05
Milk	0.01
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat by-products	0.05
Rye, grain[1]	0.1
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat by-products	0.05
Wheat, forage	0.1
Wheat, grain	0.1
Wheat, straw	0.1

[1]There are no U.S. registrations on Barley, grain and Rye, grain as of April 12, 1995.
[2]There are no U.S. registrations on Bananas as of June 2, 1999.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) Indirect or inadvertent residues. [Reserved]

[FR Doc. 99–16961 Filed 7–2–99; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–105; RM–9295]

Radio Broadcasting Services; Madison, IN

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 266A to Madison, Indiana, as that community's second local FM transmission service in response to a petition for rule making filed on behalf of Madison Broadcasting Company. *See* 63 FR 37090, July 9, 1998. Coordinates used for Channel 266A at Madison are 38–49–15 NL and 85–18–46 WL. With this action, the proceeding is terminated.

DATES: Effective August 9, 1999. A filing window for Channel 266A at Madison, Indiana, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent Order.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the application filing process should be addressed to the Audio Services Division, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–105, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information

Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 reads as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Indiana, is amended by adding Channel 266A at Madison.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17065 Filed 7–2–99; 8:45 am]
BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–69; RM–9468]

Radio Broadcasting Services; Buda and Giddings, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document reallots Channel 268C1 from Giddings, Texas, to Buda, Texas, and modifies the license for Station KROX to specify operation on Channel 268C1 at Buda in response to a petition filed by LBJS Broadcasting Company, L.P. *See* 64 FR 12924, March 16, 1999. The coordinates for Channel 268C1 at Buda are 29–57–00 and 97–22–13. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 9, 1999.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 99–69, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800, facsimile (202) 857–3805.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Giddings and Channel 268C1 and adding Buda and Channel 268C1.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17066 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–63; RM–9398]

Radio Broadcasting Services; Shelby and Dutton, MT

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document reallots Channel 250C from Shelby, Montana, to Dutton, Montana, and modifies the construction permit for Station KLHK to specify operation on Channel 250C at Dutton in response to a petition filed by Shelby Media Association. *See* 64 FR 8786, February 23, 1999. The coordinates for Channel 250C at Dutton are 47–57–46 and 111–39–14. Canadian concurrence has been obtained for this allotment. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 9, 1999.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 99–63, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Montana, is amended by removing Channel 250C at Shelby and adding Dutton, Channel 250C.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17068 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–222; RM–9407]

Radio Broadcasting Services; Lordsburg and Hurley, NM

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of BBC Radio, substitutes Channel 288C1 for Channel 289C3 at Lordsburg, NM, reallots Channel 288C1 from Lordsburg to Hurley, NM, as the community's first local aural service, and modifies petitioner's construction permit (BPH–970725MO) to specify the alternate channel and new community of license. *See* 63 FR 69608, December 17, 1998. Channel 288C1 can be allotted to Hurley in compliance with the Commission's minimum distance separation requirements with a site restriction of 9.6 kilometers (5.9 miles) north, at coordinates 32–47–00 NL; 108–08–30 WL, to avoid a short-spacing to Channel 288B, El Porven, Chihuahua, Mexico, and to accommodate petitioner's desired transmitter site. Mexican concurrence in the allotment has been obtained since Hurley is located within 320 kilometers (199 miles) of the U.S.-Mexican border. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 9, 1999.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–222, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

Part 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334. 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under New Mexico, is amended by adding Hurley, Channel 288C1, and removing Channel 289C3 at Lordsburg.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17069 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–224; RM–9416]

Radio Broadcasting Services; Belfield, ND

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of High Plains Broadcasting, Inc., allots Channel 230C1 to Belfield, ND, as the community's first local aural service. *See* 63 FR 69608, December 17, 1998. Channel 230C1 can be allotted to Belfield in compliance with the Commission's minimum distance separation requirements without a site restriction, at coordinates 46–53–06 NL; 103–11–48 WL. Canadian concurrence in the allotment has been obtained since Belfield is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective August 9, 1999. A filing window for Channel 230C1 at Belfield will not be opened at this time. Instead, the issue of opening a filing window for

this channel will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–224, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303. 334. 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under North Dakota, is amended by adding Belfield, Channel 230C1.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17076 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–226; RM–9415]

Radio Broadcasting Services; Burlington, ND

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of High Plains Broadcasting, Inc., allots Channel 276C1 to Burlington, ND, as the community's first local aural service. *See* 63 FR 69608, December 17, 1998. Channel 276C1 can be allotted to Burlington in compliance with the Commission's minimum distance separation requirements without a site restriction, at coordinates 48–16–42 NL; 101–25–36 WL. Canadian concurrence in the allotment has been obtained since Burlington is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective August 9, 1999. A filing window for Channel 276C1 at Burlington will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–226, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334. 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under North Dakota, is amended by adding Burlington, Channel 276C1.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17078 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–225; RM–9417]

Radio Broadcasting Services; Medina, ND

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of High Plains Broadcasting, Inc., allots Channel 222C to Medina, ND, as the community's first local aural service. *See* 63 FR 69608, December 17, 1998. Channel 222C can be allotted to Medina in compliance with the Commission's minimum distance separation requirements without a site restriction, at coordinates 46–53–36 NL; 99–17–54 WL. Canadian concurrence in the allotment has been obtained since Medina is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective August 9, 1999. A filing window for Channel 222C at Medina will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–225, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under North Dakota, is amended by adding Medina, Channel 222C.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17077 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–230; RM–9422]

Radio Broadcasting Services; Hazelton, ND

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of High Plains Broadcasting, Inc., allots Channel 280C to Hazelton, ND, as the community's first local aural service. *See* 63 FR 71415, December 28, 1998. Channel 280C can be allotted to Hazelton in compliance with the Commission's minimum distance separation requirements with a site restriction of 20.4 kilometers (12.7 miles) north, at coordinates 46–38–05 NL; 100–25–40 WL, to avoid a short-spacing to Station KGIM-FM, Channel 279C1, Redfield, SD. Canadian concurrence in the allotment has been obtained since Hazelton is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective August 9, 1999. A filing window for Channel 280C at Hazelton will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–230, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334. 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under North Dakota, is amended by adding Hazelton, Channel 280C.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17079 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–231; RM–9421]

Radio Broadcasting Services; Gackle, ND

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of High Plains Broadcasting, Inc., allots Channel 256C to Gackle, ND, as the community's first local aural service. *See* 63 FR 71415, December 28, 1998. Channel 256C can be allotted to Gackle in compliance with the Commission's minimum distance separation requirements without a site restriction at coordinates 46–37–30 NL; 99–08–30. Canadian concurrence in the allotment has been obtained since Gackle is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective August 9, 1999. A filing window for Channel 256C at Gackle will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–231, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under North Dakota, is amended by adding Gackle, Channel 256C.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17080 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–232; RM–9420]

Radio Broadcasting Services; New England, ND

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of High Plains Broadcasting, Inc., allots Channel 239C to New England, ND, as the community's first local aural service. *See* 63 FR 71415, December 28, 1998. Channel 239C can be allotted to New England in compliance with the Commission's minimum distance separation requirements without a site restriction at coordinates 46–32–24 NL; 102–51–48. Canadian concurrence in the allotment has been obtained since New England is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective August 9, 1999. A filing window for Channel 239C at New England will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–232,

adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under North Dakota, is amended by adding New England, Channel 239C.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17081 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–45; RM–9401]

Television Broadcasting Services; El Dorado and Camden, AR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document reallots Channel 49– from El Dorado to Camden, Arkansas, and modifies the authorization of Equity Broadcasting Corporation for Station KKYK–TV, as requested, pursuant to the provisions of Section 1.420(i) of the Commission's Rules. *See* 64 FR 7848, February 17, 1999. The allotment of Channel 49– to Camden will provide a first local television transmission service to the community without depriving El Dorado of local television service. Coordinates used for Channel 49– at Camden are those of the presently authorized transmitter site for Station KKYK–TV at 33–16–19 NL and 92–42–11 WL. With this action, the proceeding is terminated.

EFFECTIVE DATE: August 9, 1999.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 99–45, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 reads as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.606 [Amended]

2. Section 73.606(b), the Table of TV Allotments under Arkansas, is amended by adding Channel 49– at Camden.

3. Section 73.606(b), the Table of TV Allotments under Arkansas, is amended by removing Channel 49– at El Dorado.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17064 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PR Docket No. 92–235; FCC 99–68]

Private Land Mobile Radio Services

AGENCY: Federal Communications Commission.

ACTION: Final rule; petitions for reconsideration.

SUMMARY: This document in PR Docket No. 92–235, addresses petitions for reconsideration of, and clarifies certain decisions made in, the *Second Report and Order* in PR Docket No. 92–235, 62 FR 18834, and, where necessary, makes appropriate modifications to the rules. Specifically, the Commission affirms the decision to limit the eligibility for the Public Safety Pool to those entities that were eligible under the former Public Safety Radio Services or Special Emergency Radio Service (SERS); and modifies the rules to provide that all frequencies—shared and exclusive—assigned to the former Power Radio Service, Petroleum Radio Service, Railroad Radio Service, and Automobile Emergency Radio Service must either be coordinated by the frequency coordinator responsible for the service in question prior to the adoption of the *Second Report and Order,* or be coordinated with that coordinator's prior written concurrence. The Commission also clarifies several aspects of the rules regarding the low power offset channels in the 450–470 MHz band.

DATES: Effective August 5, 1999.

FOR FURTHER INFORMATION CONTACT: Ira Keltz or Michael Wilhelm of the Wireless Telecommunications Bureau, Public Safety and Private Wireless Division, at (202) 418–0680 or via E-mail to "mayday@fcc.gov".

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Memorandum Opinion and Order* in PR Docket No. 92–235, FCC 99–68, adopted April 6, 1999, and released April 13, 1999. The complete text may be purchased from the Commission's copy contractor, International Transcription Services, 1231 20th Street, NW., Washington, DC 20036, telephone (202) 857–3800, facsimile (202) 857–3805. Alternative formats (computer diskette, large print, audio cassette, and Braille) are available to persons with disabilities by contacting Martha Contee at (202) 418–0260, TTY (202) 418–2555, or at mcontee@fcc.gov. The full text of the *Second Memorandum Opinion and Order* is available for inspection and copying during normal business hours in the FCC Reference Center, 1919 M St., NW., Room 239, Washington, DC 20554. It is anticipated that the Reference Center will be relocated to the Commission's Portals Building, 445 12th St., SW., Room CY-A257, during the late spring or early summer of 1999. Accordingly, interested parties are advised to contact the FCC Reference Center at (202) 418–0270 to determine its location. The full text of the *Second Memorandum Opinion and Order* can also be downloaded at: http://www.fcc.gov/Bureaus/Wireless/Orders/1998/fcc9968.txt or http://www.fcc.gov/Bureaus/Wireless/Orders/1998/fcc9968.wp

Summary of the Second Memorandum Opinion and Order

1. The *Second Report and Order* consolidated twenty private land mobile radio (PLMR) services into two pools, a Public Safety Pool consisting of all former Public Safety Radio Services and the Special Emergency Radio Service (SERS), and an Industrial/Business Pool consisting of the former Industrial and Land Transportation Radio Services. It also established provisions designed to facilitate development of centralized trunked systems in the shared PLMR bands below 800 MHz, and adopted an approach for accommodating low power use of the 450–470 MHz band. The Commission received fifteen petitions for reconsideration or clarification of the *Second Report and Order*.

2. The Commission denies a request to expand the categories eligible for the Public Safety Pool to include central station alarm companies, because public safety spectrum is scarce, and the requested expansion would be inconsistent with the definition of public safety in 47 U.S.C. 337(f)(2).

3. The *Second Report and Order* concluded that any frequency in the Industrial/Business Pool could be coordinated by any frequency coordinator designated to coordinate any of the services consolidated into that pool, except that frequencies formerly assigned exclusively to the Power, Petroleum, and Railroad Radio Services could be coordinated only by the coordinators for those services. As requested by those coordinators, the *Second Memorandum Opinion and Order* expands that exception to include frequencies that formerly were shared by any of those services and any other Industrial or Land Transportation Radio Services (except 12.5 kHz and 6.25 kHz channels in the 450–470 MHz band). In the alternative, the power, petroleum, and railroad coordinators may determine that such frequencies may be coordinated by any other Industrial/Business coordinator, provided that written concurrence is first received from the power, petroleum, or railroad coordinator.

4. In addition, the *Second Memorandum Opinion and Order* expands the exception to include frequencies formerly assigned to the Automobile Emergency Radio Service (AERS), but denies requests for similar treatment of other frequencies, because only on the AERS are safety-related communications sufficiently frequent and potentially serious to merit such treatment, which is consistent with the definition of public safety in 47 U.S.C. 309(j)(2).

5. The Commission denies the request of the power and petroleum coordinators to suspend the acceptance of applications for frequencies adjacent to former power and petroleum channels, for there is no evidence of a serious adjacent channel interference problem.

6. After the Commission accepts a proposed channel plan designating specific narrowband (12.5 kHz) offset frequencies in the 450–470 MHz band for low power operations, it will begin accepting full power applications for other the other narrowband offset frequencies in that band. Existing low power licensees may relocate to the designated frequencies, or may remain on the non-designated frequencies, but only on a secondary, non-interference basis. Wideband (25 kHz) operation will be permitted on the designated frequencies only on a secondary basis (unless a waiver is granted).

7. The *Second Memorandum Opinion and Order* classifies as commercial mobile radio services (CMRS) all Industrial/Business Pool licensees that offer to the public for-profit service interconnected to the public switched telephone network. The eligibility requirements for the Industrial/Business Pool are the same as those for the former Business Radio Service (BRS), and BRS licensees that offered for-profit, interconnected service to the public were classified as CMRS. CMRS licensees are subject to part 20 of the Commission's rules and Title II of the Communications Act of 1934, as amended.

8. The *Second Memorandum Opinion and Order* defers to a later date consideration of a request to suspend acceptance of applications for frequencies that formerly were shared by the Power or Petroleum Radio Services and other Industrial or Land Transportation Radio Services, issues associated with the trunking of frequencies in systems which operate below 800 MHz, and the issue of potential interference to medical telemetry systems from PLMR stations operating in the 450–470 MHz band.

Regulatory Flexibility Act

Final Regulatory Flexibility Analysis

9. As required by the Regulatory Flexibility Act (RFA), *see* 5 U.S.C. 603, Initial Regulatory Flexibility Analyses (IRFA) were incorporated in the *Notice of Proposed Rule Making* and the *Further Notice of Proposed Rule Making* in PR Docket 92–235. The Commission sought written public comment on the rule making proposals in the *Notice* and *Further Notice,* including on the respective IRFAs. This present Supplemental Regulatory Flexibility Analysis (Supplemental FRFA) in this *Second Memorandum Opinion and Order* (*Second MO&O*) conforms to the RFA.

10. *Need for, and Objectives of, the Second MO&O.* Our objective is to increase spectrum efficiency and facilitate the introduction of advanced technologies into the 150–174 MHz, 421–430 MHz, 450–470 MHz, and 470–512 MHz private land mobile radio (PLMR) bands. The *Report and Order* in this proceeding modified the Commission's rules to resolve many of the technical issues which inhibited the use of spectrally efficient technologies in these frequency bands. It also stated the Commission's intent to consolidate the twenty existing radio service pools. The *Further Notice* in this proceeding proposed several methods of introducing market based incentives into the PLMR bands, including exclusivity. In the *Second R&O*, the Commission consolidated the radio service frequency pools and addressed related issues such as frequency coordination, trunking, and low power frequencies. This *Second MO&O* address petitions for reconsideration and clarification received in response to the *Second R&O*.

11. The Commission finds that the potential benefits to the PLMR community from the promulgation of rules for this purpose exceed any negative effects that may result. Thus, the Commission concludes that the public interest is served by modifying our rules to consolidate the PLMR services and increase the spectral efficiency of the PLMR bands.

12. *Summary of Significant Issues Raised by Public Comments in Response to the IRFA.* No reconsideration petitions were submitted in direct response to the previous FRFAs. The Commission has, however, reviewed general comments that may impact small businesses. Much of the impact on small businesses arises from the central decision in this proceeding—determining the number of frequency pools and the eligibility criteria for each pool. This affects small businesses in the following way. A smaller number of pools provides a greater number of frequencies available for small businesses that use PLMR systems to meet their coordination needs. Additionally, by creating fewer pools, frequency coordinators will now be subject to competition. Thus, small businesses that use PLMR systems can expect to pay lower prices for frequency coordination while receiving equivalent or better service. Finally, consolidating

the PLMR services provides each frequency coordinator, which currently provides service only for a narrowly defined type of user, with the ability to expand its business base.

13. *Description and Estimate of the Number of Small Entities to Which Rules Will Apply.* The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the rules adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." *See* 5 U.S.C. 601(6). In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. 5 U.S.C. 601(3). A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). 5 U.S.C. 632. A small organization is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field." 5 U.S.C. 601(4). Nationwide, as of 1992, there were approximately 275,801 small organizations. 1992 Economic Census, U.S. Bureau of the Census, Table 6. "Small governmental jurisdiction" generally means "governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000." 5 U.S.C. 601(5). As of 1992, there were approximately 85,006 such jurisdictions in the United States. U.S. Dept. of Commerce, Bureau of the Census, "1992 Census of Governments." This number includes 38,978 counties, cities and towns; of these, 37,566, or 96 percent, have populations of fewer than 50,000. *Id.* The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, the Commission estimates that 81,600 (91 percent) are small entities.

14. Estimates for PLMR Licensees. Private land mobile radio systems serve an essential role in a vast range of industrial, business, land transportation, and public safety activities. These radios are used by companies of all sizes operating in all U.S. business categories. Because of the vast array of PLMR users, the Commission has not developed, nor would it be possible to develop, a definition of small entities specifically applicable to PLMR users. For the purpose of determining whether a licensee is a small business as defined by the Small Business Administration (SBA), each licensee would need to be evaluated within its own business area. The Commission's fiscal year 1994 annual report indicates that, at the end of fiscal year 1994, there were 1,101,711 licensees operating 12,882,623 transmitters in the PLMR bands below 512 MHz. *See* Federal Communications Commission, 60th Annual Report, Fiscal Year 1994 at 120–121. Further, because any entity engaged in a commercial activity is eligible to hold a PLMR license, these rules could potentially impact every small business in the U.S.

15. Estimates for Frequency Coordinators. Neither the Commission nor the SBA have developed a definition of small entities specifically applicable to spectrum frequency coordinators. Therefore, the Commission concluded that the closest applicable definition under SBA rules is Business Associations (SIC 8611). *See Second R&O,* 12 FCC Rcd at 14355. The SBA defines a small business association as an entity with $5.0 million or less in annual receipts. There are 18 entities certified to perform frequency coordination functions under Part 90 of our Rules. However, the Commission is unable to ascertain how many of these frequency coordinators are classified as small entities under the SBA definition. The Census Bureau indicates that 97% of business associations have annual receipts of $4.999 million or less and would be classified as small entities. The Census Bureau category is very broad, and does not include specific figures for firms that are engaged in the frequency coordination. Therefore, for the purposes of this Supplemental FRFA, the Commission estimates that almost all of the 18 spectrum frequency coordinators are small as defined by the SBA.

16. *Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements.* The rules adopted in this *Second MO&O* do not have any general reporting or recordkeeping requirements for PLMR licensees. There are, however, a few compliance requirements. First, frequency coordinators, when recommending frequencies that were formerly allocated on a shared basis to the Petroleum Radio Service, must obtain the concurrence of the former Petroleum Radio Service frequency coordinator. While the Commission wants to remove as many requirements on the licensing process as possible, the Commission believes that this requirement is necessary in order to protect critical safety-related communications systems. The American Petroleum Institute, supported by several commenters, petitioned for protection of existing petroleum stations based upon coverage contours. Rather than institute a complex requirement based on the computation of coverage contours, the Commission believes that the goals of protecting these systems can be achieved through a simple concurrence requirement.

17. Second, the Commission is requiring each of the coordinators that have sole management authority over a group of frequencies to supply supporting reasons for denying any request for frequency coordination on those frequencies. The American Automobile Association petitioned for a clarification that would have held these coordinators to the same coordination procedures as previously were applicable under the former interservice sharing rules. The Commission believes that such procedures would be excessive under the new consolidated pool structure. Therefore, to guard against summary denials and to promote sharing to the greatest degree possible, the Commission believes that requiring the coordinators with sole management authority over certain frequencies to justify any denials of coordination on those frequencies will suffice.

18. *Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered.* The Commission, in this *Second MO&O,* has considered petitions for reconsideration and clarification regarding its *Second R&O* in PR Docket No. 92–235, which consolidated the PLMR radio services below 512 MHz. In doing so, the Commission has adopted several proposals which minimize burdens placed on small entities. First, the Commission adopted a concurrence requirement on frequencies that were allocated to the former Petroleum Radio Service on a shared basis. Based on the need to provide additional protection to entities operating on these frequencies, concurrence is the simplest method of providing this protection. The alternative would be to require applicants and frequency coordinators, including those that are small businesses, to conduct complex and costly contour analyses. Second, the Commission did not expand the number of frequencies on which coordinators have sole management authority. This decision will ensure the continued benefits of consolidation. Namely, entities will have more frequency options than if more frequencies were restricted. The increase in frequency choices will provide a greater likelihood that licensees, including small entities, will share frequencies with fewer systems, enabling them to achieve more

efficiency in their radio systems. Third, the Commission clarifies that a coordinator, at an applicant's request, who determines that the most appropriate frequency is one that is managed solely by another frequency coordinator can forward an application directly to that coordinator. The alternative would be to return applications which would foster inefficiency, add delays to the coordination process, and drive up costs. Fourth, the Commission clarifies and modifies the rules regarding designated low power frequencies to (1) allow existing users of low power systems that are not currently operating on designated low power frequencies to modify their operating frequency to one of the designated frequencies and obtain primary status while still using wideband equipment, and (2) allow new licensees on the designated low power frequencies, all of which are restricted to narrowband operations, to obtain authorizations for wideband equipment on a secondary basis. Many users and manufacturers of low power systems are small businesses and these actions allow for such entities to continue to use existing equipment and for manufacturers to deplete, rather than scrap, existing inventory. Fifth, the Commission amends the rules to require entities to operate in the semi-duplex mode when using former Taxicab Radio Service frequencies in metropolitan areas. Such action ensures that future authorizations on these channels will be compatible with existing taxicab users, many of which are small businesses. Sixth, the Commission amends the rules to extend until 2006, the date by which new licensees operating on the emergency medical (MED) channels must employ equipment capable of operating on all the newly created MED channels. Existing licensees on these channels are grandfathered using their existing radios. This provides relief to licensees, many of which are small businesses, which could not readily comply with the originally proposed rule because of lack of available equipment.

19. The Commission will send a copy of this *Second Memorandum Opinion and Order* including this Supplemental FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, *see* 5 U.S.C. 801(a)(1)(A). In addition, the Commission will send a copy of the *Second Memorandum Opinion and Order*, including Supplemental FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the *Second Memorandum Opinion and Order* and Supplemental FRFA (or summaries thereof) will also be published in the **Federal Register**. *See* 5 U.S.C. 604(b).

List of Subjects in 47 CFR Part 90

Communications equipment, Radio.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

Rule Changes

Part 90 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

The authority citation for Part 90 continues to read as follows:

Authority: 47 U.S.C. 154, 302, 303, and 332, unless otherwise noted.

Section 90.20 is amended by removing the entry for 156.2475 MHz, adding entries for 151.0625 MHz, 151.0775 MHz, 151.1825 MHz, 151.1975 MHz, 151.3025 MHz, and 151.3175 MHz to paragraph (c)(3), revising the entries for 35.02 MHz, 151.070 MHz, 151.190 MHz, 151.310 MHz, 453.025 MHz, 453.03125 MHz 453.075 MHz, 453.0125 MHz, 453.125 MHz, 453.175 MHz, 458.025 MHz, 458.075 MHz, 458.125 MHz, 458.175 MHz, and 470 to 512 MHz of paragraph (c)(3), paragraphs (d)(66)(ii), (d)(66)(iii), and (d)(66)(iv) and adding new paragraphs (d)(66)(v), (d)(66)(vi) and (d)(77) to read as follows:

§ 90.20 Public Safety Pool.

* * * * *

(c) * * *

(3) * * *

PUBLIC SAFETY POOL FREQUENCY TABLE

Frequency or band	Class of stations(s)	Limitations	Coordinator
Megahertz:			
35.02	Mobile	12, 77	PS
* * * * * *	* * *	* * *	
151.0625	do	27, 28	PH
151.070	do	28	PH
151.0775	do	27, 28	PH
* * * * * *	* * *	* * *	
151.1825	do	27, 28	PO
151.190	do	28	PO
151.1975	do	27, 28	PO
* * * * * *	* * *	* * *	
151.3025	do	27, 28	PO
151.310	do	28	PO
151.3175	do	27, 28	PO
* * * * * *	* * *	* * *	
453.0125	Mobile	57, 77	PX
453.025	Central control, fixed base, or mobile	58, 59, 60, 61, 62	PM
453.03125	Base of mobiles	44,59,60,61,62	PM
* * * * * *	* * *	* * *	
453.075	Central control, fixed base, or mobile	58, 59, 60, 61, 62	PM
* * * * * *	* * *	* * *	
453.125	Central control, fixed base, or mobile	58, 59, 60, 61, 62	PM

PUBLIC SAFETY POOL FREQUENCY TABLE—Continued

Frequency or band	Class of stations(s)	Limitations	Coordinator
* * *	* * *	* * *	
453.175	Central control, fixed base, or mobile	58, 59, 60, 61, 62	PM
* * *	* * *	* * *	
458.025	Central control, fixed base, or mobile	58, 59, 61, 62, 63	PM
* * *	* * *	* * *	
458.075	Central control, fixed base, or mobile	58, 59, 61, 62, 63	PM
* * *	* * *	* * *	
458.125	Central control, fixed base, or mobile	58, 59, 61, 62, 63	PM
* * *	* * *	* * *	
458.175	Central control, fixed base, or mobile	58, 59, 61, 62, 63	PM
* * *	* * *	* * *	
470 to 512	Base or mobile	68.	

* * * * *

(d) * * *

(6) * * *

(ii) Except as provided in paragraphs (d)(66)(iv) and (v) of this section, mobile or portable stations licensed prior to July 6, 2000, must employ equipment that is both wired and equipped to transmit/receive, respectively, on each of the following MED frequency pairs with transmitters operated on the 468 MHz frequencies: MED–1, MED–2, MED–3, MED–4, MED–5, MED–6, MED–7, and MED–8.

(iii) Except as provided in paragraphs (d)(66)(v) and (vi) of this section, mobile or portable stations licensed on or after July 6, 2000, must employ equipment that is both wired and equipped to transmit/receive, respectively, on each of the following MED frequency pairs with transmitters operated on the 468 MHz frequencies: MED–1, MED–12, MED–2, MED–22, MED–3, MED–32, MED–4, MED–42, MED–5, MED–52, MED–6 MED–62, MED–7, MED–72, MED–8, and MED–82.

(iv) Except as provided in paragraphs (d)(66)(v) and (vi) of this section, mobile or portable stations licensed on or after January 1, 2006, must employ equipment that is both wired and equipped to transmit/receive, respectively, on each of these MED frequency pairs with transmitters operated on the 468 MHz frequencies.

(v) Portable (hand-held) units operated with a maximum output power of 2.5 watts are exempted from the multi-channel equipment requirements specified in paragraphs (d)(66)(ii), (d)(66)(iii), and (d)(66)(iv) of this section.

(vi) Stations located in areas above line A, as defined in § 90.7 will be required to meet multi-channel equipment requirements only for those frequencies up to the number specified in paragraphs (d)(66)(ii), (d)(66)(iii), and (d)(66)(iv) of this section that have been assigned and coordinates with Canada in accordance with the applicable U.S.-Canada agreement.

* * * * *

(77) Paging operations are not permitted on this frequency.

* * * * *

Section 90.22 is amended by revising the introductory text to read as follows:

§ 90.22 Paging operations.

Unless specified elsewhere in this part, paging operations may be authorized in the Public Safety Pool on any frequency except those assigned under the provisions of § 90.20(d)(77). Paging operations on frequencies subject to § 90.20(d)(77) authorized before August 17, 1974, may be continued only if they do not cause harmful interference to regular operations on the same frequencies. Such paging operations may be renewed indefinitely on a secondary basis to regular operations, except within 125 km (75 mi) of the following urbanized areas:

* * * * *

4. Section 90.35 is amended by revising the entries for 2292 kHz, 25.14 MHz, 30.66 MHz, 30.74 MHz, 30.82 MHz, 150.815 MHz through 150.9725 MHz, 151.490 MHz, 152.870 MHz, 153.035 MHz through 153.4025 MHz, 153.425 MHz through 153.4625 MHz, 153.485 MHz through 153.5225 MHz, 153.545 MHz through 153.5825 MHz, 153.605 MHz through 153.6425 MHz, 153.665 MHz through 153.6875 MHz, 157.470 MHz through 157.5225 MHz, 157.725 MHz, 158.145 MHz through 158.1825 MHz, 158.205 MHz through 158.2425 MHz, 158.265 MHz through 158.3325 MHz, 158.355 MHz through 158.3775 MHz, 158.415 MHz through 158.4375 MHz, 173.250 MHz, 173.300 MHz, 173.350 MHz, 173.39625, 451.175 MHz, 451.225 MHz, 451.275 MHz, 451.375 MHz, 451.425 MHz, 451.475 MHz, 451.525 MHz, 451.550 MHz, 451.575 MHz, 451.600 MHz, 451.625 MHz, 451.650 MHz, 451.675 MHz, 451.700 MHz, 451.750 MHz, 452.325 MHz, 452.375 MHz, 452.425 MHz, 452.475 MHz, 452.525 MHz through 452.61875 MHz, 452.775 MHz, 452.825 MHz, 452.875 MHz, 456.175 MHz, 456.225 MHz, 456.275 MHz, 456.375 MHz, 456.425 MHz, 456.475 MHz, 456.525 MHz, 456.550 MHz, 456.575 MHz, 456.600 MHz, 456.625 MHz, 456.650 MHz, 456.675 MHz, 456.700 MHz, 456.750 MHz, 457.325 MHz, 457.375 MHz, 457.425 MHz, 457.475 MHz, 457.775 MHz, 457.825 MHz, 457.875 MHz, 462.475 MHz, 462.525 MHz, 467.475 MHz, 467.525 MHz, 467.8375 MHz, 469.500 MHz, and 469.550 MHz of paragraph (b)(3), revising paragraphs (b)(2), (c)(6), and (c)(52), and adding paragraphs (c)(79), (c)(80) and (c)(81) to read as follows:

§ 90.35 Industrial/Business Pool.

* * * * *

(b) * * *

(2) Unless otherwise specified, coordination of frequencies in the Industrial/Business pool must be done in accordance with the following:

(i) Unless specified elsewhere in this part, frequencies without any coordinator specified in the Coordinator column of paragraph (b)(3) of this section may be coordinated by any frequency coordinator certified in the Industrial/Business Pool.

(ii) A letter symbol in the Coordinator column of the frequency table in

paragraph (b)(3) of this section designates the mandatory certified frequency coordinator for the associated frequency in the table. However, any certified frequency coordinator in the Industrial/Business Pool may coordinate such frequency provided the prior written consent of the designated coordinator is obtained. Frequencies for which two coordinators are listed may be coordinated by either of the listed coordinators.

(iii) The letter symbols listed in the Coordinator column of the frequency table in paragraph (b)(3) of this section refer to specific frequency coordinators as follows:

IP—Petroleum Coordinator
IW—Power Coordinator
LR—Railroad Coordinator
LA—Automobile Emergency Coordinator

(3) * * *

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE

Frequency or band	Class of stations(s)	Limitations	Coordinator
Kilohertz:			
2292	Base or mobile	4, 5, 7.	
* * * * * * *			
Megahertz:			
25.14	do	3, 4	IP
* * * * * * *			
30.66	do	4, 7.	
* * * * * * *			
30.74	do	4, 7.	
* * * * * * *			
30.82	do	4, 7	
* * * * * * *			
150.815	do		LA
150.830	do	28, 29	LA
150.845	do		LA
150.8525	do	30	LA
150.860	do		LA
150.8675	do	30	LA
150.875	do		LA
150.8825	do	30	LA
150.890	do		LA
150.8975	do	30	LA
150.905	do		LA
150.920	do	28, 29	LA
150.935	do		LA
150.9425	do	30	LA
150.950	do		LA
150.9575	do	30	LA
150.965	do		LA
150.9725	do	30	LA
* * * * * * *			
151.490	do	13, 32.	
* * * * * * *			
152.465	do	79.	
* * * * * * *			
152.870	do.		
* * * * * * *			
153.035	do		IP
153.0425	do	30	IP
153.050	do	4, 7	IP
153.0575	do	4, 7, 30	IP
153.065	do		IP
153.0725	do	30	IP
153.080	do	4, 7	IP

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE—Continued

Frequency or band	Class of stations(s)	Limitations	Coordinator
153.0875	.....do	4, 7, 30	IP
153.095	.....do		IP
153.1025	.....do	30, 80	IP
153.110	.....do	4, 7	IP
153.1175	.....do	4, 7, 30	IP
153.125	.....do		IP
153.1325	.....do	30	IP
153.140	.....do	4, 7	IP
153.1475	.....do	4, 7, 30	IP
153.155	.....do		IP
153.1625	.....do	30	IP
153.170	.....do	4, 7	IP
153.1775	.....do	4, 7, 30	IP
153.185	.....do		IP
153.1925	.....do	30	IP
153.200	.....do	4, 7	IP
153.2075	.....do	4, 7, 30	IP
153.215	.....do		IP
153.2225	.....do	30	IP
153.230	.....do	4, 7	IP
153.2375	.....do	4, 7, 30	IP
153.245	.....do		IP
153.2525	.....do	30	IP
153.260	.....do	4, 7	IP
153.2675	.....do	4, 7, 30	IP
153.275	.....do		IP
153.2825	.....do	30	IP
153.290	.....do	4, 7	IP
153.2975	.....do	4, 7, 30	IP
153.305	.....do		IP
153.3125	.....do	30	IP
153.320	.....do	4, 7	IP
153.3275	.....do	4, 7, 30	IP
153.335	.....do		IP
153.3425	.....do	30	IP
153.350	.....do	4, 7	IP
153.3575	.....do	4, 7, 30	IP
153.365	.....do		IP
153.3725	.....do	30	IP
153.380	.....do		IP
153.3875	.....do	30	IP
153.395	.....do		IP
153.4025	.....do	30	IP
* * * *	* * *		
153.425	.....do	80	IP, IW
153.4325	.....do	30, 80	IP, IW
153.440	.....do	80	IP, IW
153.4475	.....do	30, 80	IP, IW
153.455	.....do	80	IP, IW
153.4625	.....do	30, 80	IP, IW
* * * *	* * *		
153.485	.....do	80	IP, IW
153.4925	.....do	30, 80	IP, IW
153.500	.....do	80	IP, IW
153.5075	.....do	30, 80	IP, IW
153.515	.....do	80	IP, IW
153.5225	.....do	30, 80	IP, IW
* * * *	* * *		
153.545	.....do	80	IP, IW
153.5525	.....do	30, 80	IP, IW
153.560	.....do	30, 80	IP, IW
153.5675	.....do	30, 80	IP, IW
153.575	.....do	80	IP, IW
153.5825	.....do	30, 80	IP, IW

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE—Continued

Frequency or band	Class of stations(s)	Limitations	Coordinator
* * * * * * *			
153.605	.....do	80	IP, IW
153.6125	.....do	30, 80	IP, IW
153.620	.....do	80	IP, IW
153.6275	.....do	30, 80	IP, IW
153.635	.....do	80	IP, IW
153.6425	.....do	30, 80	IP, IW
* * * * * * *			
153.665	.....do	80	IP, IW
153.6725	.....do	30, 80	IP, IW
153.680	.....do	80	IP, IW
153.6875	... ..do	30, 80	IP, IW
* * * * * * *			
157.470	Base or mobile	12	LA
157.4775	.....do	12, 30	LA
157.485	.....do	12	LA
157.4925	.....do	12, 30	LA
157.500	.....do	12	LA
157.5075	.....do	12, 30	LA
157.515	.....do	12	LA
157.5225	.....do	12, 30	LA
* * * * * * *			
157.725	Base or mobile	79	
* * * * * * *			
158.145	.....do		IP, IW
158.1525	.....do	30	IP, IW
158.160	.....do		IP, IW
158.1675	.....do	30	IP, IW
158.175	.....do	81	IP, IW
158.1825	.....do	30, 81	IP, IW
* * * * * * *			
158.205	.....do	81	IP, IW
158.2125	.....do	30, 81	IP, IW
158.220	.....do	81	IP, IW
158.2275	.....do	30, 81	IP, IW
158.235	.....do	81	IP, IW
158.2425	.....do	30, 81	IP, IW
* * * * * * *			
158.265	.....do	81	IP, IW
158.2725	.....do	30, 81	IP, IW
158.280	.....do		IP
158.2875	.....do	30	IP
158.295	.....do		IP
158.3025	.....do	30	IP
158.310	.....do	4, 7	IP
158.3175	.....do	4, 7, 30	IP
158.325	.....do		IP
158.3325	.....do	30	IP
* * * * * * *			
158.355	Base or mobile		IP
158.3625	.....do	30	IP
158.370	.....do	4, 7	IP
158.3775	.....do	4, 7,	IP
* * * * * * *			
158.415	.....do		IP

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE—Continued

Frequency or band	Class of stations(s)	Limitations	Coordinator
158.4225	.....do	30	IP
158.430	.....do	4, 7	IP
158.4375	.....do	4, 7,	IP
* *	* *	* *	*
173.250	Base or Mobile		IP, IW
* *	* *	* *	*
173.300	Base or Mobile		IP, IW
* *	* *	* *	*
173.350	Base or Mobile		IP, IW
* *	* *	* *	*
173.39625	.....do	39, 40, 41, 44	
* *	* *	* *	*
451.175	do		IP, IW
* *	* *	* *	*
451.225	do		IP, IW
* *	* *	* *	*
451.275	.....do		IP, IW
* *	* *	* *	*
451.375	.....do		IP, IW
* *	* *	* *	*
451.425	.....do		IP, IW
* *	* *	* *	*
451.475	.....do		IP, IW
* *	* *	* *	*
451.525	.....do		IP, IW
* *	* *	* *	*
451.550	.....do	4, 7	IP
* *	* *	* *	*
451.575	.....do		IP, IW
* *	* *	* *	*
451.600	.....do	4, 7	IP
* *	* *	* *	*
451.625	.....do		IP, IW
* *	* *	* *	*
451.650	.....do	4, 7	IP
* *	* *	* *	*
451.675	.....do		IP, IW

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE—Continued

Frequency or band	Class of stations(s)	Limitations	Coordinator
* * * * * * *			
451.700	.....do	4, 7	IP
* * * * * * *			
451.750	.....do	4, 7	IP
* * * * * * *			
452.325	.....do		LR
* * * * * * *			
452.375	.....do		LR
* * * * * * *			
452.425	do		LR
* * * * * * *			
452.475	.....do		LR
* * * * * * *			
452.525	.....do		LA
452.53125	.....do	33	LA
452.5375	.....do	30	LA
452.54375	.....do	33	LA
452.550	.....do		LA
452.55625	.....do	33	LA
452.5625	.....do	30	LA
452.56875	.....do	33	LA
452.575	.....do		LA
452.58125	.....do	33	LA
452.5875	.....do	30	LA
452.59375	.....do	33	LA
452.600	.....do		LA
452.60625	.....do	33	LA
452.6125	.....do	30	LA
452.61875	.....do	33	LA
* * * * * * *			
452.775	.....do		LR
* * * * * * *			
452.825	.....do		LR
* * * * * * *			
452.875	.....do		LR
* * * * * * *			
456.175	.....do		IP, IW
* * * * * * *			
456.225	.....do		IP, IW
* * * * * * *			
456.275	.....do		IP, IW
* * * * * * *			
456.375	.....do		IP, IW

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE—Continued

Frequency or band	Class of stations(s)	Limitations	Coordinator
456.425	do		IP, IW
* *	* *	* *	*
456.475	do		IP, IW
* *	* *	* *	*
456.525	do		IP, IW
* *	* *	* *	*
456.550	do		IP
* *	* *	* *	*
456.575	do		IP, IW
* *	* *	* *	*
456.600	do		IP
* *	* *	* *	*
456.625	do		IP, IW
* *	* *	* *	*
456.650	do		IP
* *	* *	* *	*
456.675	do		IP, IW
* *	* *	* *	*
456.700	do		IP
* *	* *	* *	*
456.750	do		IP
* *	* *	* *	*
457.325	do		LR
* *	* *	* *	*
457.375	do		LR
* *	* *	* *	*
457.425	do		LR
* *	* *	* *	*
457.475	do		LR
* *	* *	* *	*
457.775	do		LR
* *	* *	* *	*
457.825	do		LR
* *	* *	* *	*
457.875	do		LR

INDUSTRIAL/BUSINESS POOL FREQUENCY TABLE—Continued

Frequency or band	Class of stations(s)	Limitations	Coordinator
* * * * * * *			
462.475	.....do		IP, IW
* * * * * * *			
462.525	.....do		IP, IW
* * * * * * *			
467.475	.....do		IP, IW
* * * * * * *			
467.525	.....do		IP, IW
* * * * * * *			
467.8375	.....do	11, 12, 30, 35, 60.	
* * * * * * *			
469.500	.....do	10, 34.	
* * * * * * *			
469.550	.....do	10, 34.	

* * * * * * *

(c) * * *

(6) Frequencies may be assigned in pairs with the separation between base and mobile transmit frequencies being 5.26 MHz. A mobile station may be assigned the frequency which would normally be assigned to a base station for single frequency operation. However, this single-frequency operation may be subject to interference that would not occur to a two-frequency system. Base or mobile stations operating wholly within Standard Metropolitan Areas having 50,000 or more population (1950 Census) must be operated in the half-duplex mode.

* * * * *

(52) In Puerto Rico and the Virgin Islands only, this frequency is available to all stations operating in the Industrial/Business Pool and may be coordinated by any frequency coordinator certified in the Industrial/Business Pool.

* * * * *

(79) Frequencies may be assigned in pairs with the separation between base and mobile transmit frequencies being 5.26 MHz. A mobile station may be assigned the frequency which would normally be assigned to a base station for single frequency operation. However, this single-frequency operation may be subject to interference that would not occur to a two-frequency system. Base or mobile stations located 80.5 km (50 miles) or less from the center or any urbanized area of 600,000 or more population (U.S. Census of Population, 1970) must be operated in the half-duplex mode.

(80) Concurrence from the Petroleum Coordinator is required only for applications for this frequency that request authorization for transmitters in Arkansas, Louisiana, Oklahoma, or Texas.

(81) Concurrence from the Petroleum Coordinator is required only for applications for this frequency that request authorization for transmitters in Arkansas, Louisiana, Oklahoma, Oregon, Texas, or Washington.

5. Section 90.135 is amended by removing and reserving paragraph (b)(5), and by revising paragraph (a)(2) and by revising the first sentence in paragraph (d) to read as follows:

§ 90.135 Modification of license.

(a) * * *

(2) Change in the type of emission.

* * * * *

(d) In case of a change listed in paragraphs (b)(1) or (b)(2) of this section, the licensee must notify the Commission immediately. * * *

6. Section 90.173 is amended by revising paragraph (a) and by adding paragraph (j) to read as follows:

§ 90.173 Policies governing the assignment of frequencies.

(a) Except as indicated in paragraph (j) of this section, the frequencies which ordinarily may be assigned to stations in the services governed by this part are listed in subparts B, C and F of this part. Except as otherwise specifically provided in this part, frequencies assigned to land mobile stations are available on a shared basis only and will not be assigned for the exclusive use of any licensee.

* * * * *

(j) Frequencies other than those listed in subparts B and C of this part may be assigned in the 150–174 MHz, 421–430 MHz, 450–470 MHz, and 470–512 MHz bands, provided the following conditions are met:

(1) Such applications must be accompanied by a showing of frequency coordination in accordance with the requirements of § 90.175;

(2) The frequencies must not be available in any other rule part of this chapter; and

(3) The authorized bandwidth of any system operating in accordance with this paragraph must not overlap spectrum available in other rule parts of this chapter unless that spectrum is also allocated in part 90.

* * * * *

7. Section 90.175 is amended by revising the first sentence of the

introductory text and by revising paragraph (b) to read as follows:

§ 90.175 Frequency coordination requirements.

Except for applications listed in paragraph (i) of this section, each application for a new frequency assignment, for a change in existing facilities as listed in § 90.135(a), or for operation at temporary locations in accordance with § 90.137 must include a showing of frequency coordination as set forth below. * * *

* * * * *

(b) *For frequencies between 25 and 470 MHz:* (1) A statement is required from the applicable frequency coordinator as specified in §§ 90.20(c)(2) and 90.35(a)(2) recommending the most appropriate frequency. In addition, concurrence from the applicable frequency coordinator must be obtained on frequencies designated for such a requirement. The coordinator's recommendation may include comments on technical factors such as power, antenna height and gain, terrain, and other factors which may serve to minimize potential interference. In addition:

(2) On frequencies designated for coordination or concurrence by a specific frequency coordinator as specified in §§ 90.20(c)(3) and 90.35(b)(3), the applicable frequency coordinator shall provide a written supporting statement in instances in which coordination or concurrence is denied. The supporting statement shall contain sufficient detail to permit discernment of the technical basis for the denial of coordination or concurrence.

(3) In instances where a frequency coordinator determines that an applicant's requested frequency or the most appropriate frequency is one designated for coordination by a specific frequency coordinator as specified in §§ 90.20(c)(3) and 90.35(b)(3), that frequency coordinator may forward the application directly to the appropriate frequency coordinator. A frequency coordinator may only forward an application as specified above if consent is obtained from the applicant.

* * * * *

8. Section 90.187 is amended by revising paragraphs (b)(2)(i) and the second sentence of (b)(2)(ii) to read as follows:

§ 90.187 Trunking in the bands between 150 and 512 MHz.

* * * * *

(b) * * *

(2) * * *

(i) Stations that have assigned frequencies (base and mobile) that are 15 kHz or less removed from proposed stations that will operate with a 25 kHz channel bandwidth; stations that have assigned frequencies (base and mobile) that are 7.5 kHz or less removed from proposed stations that will operate with a 12.5 kHz bandwidth; or stations that have assigned frequencies (base and mobile) 3.75 kHz or less removed from proposed stations that will operate with a 6.25 kHz bandwidth; and

(ii) * * * Alternatively, applicants may submit an engineering analysis based upon generally accepted engineering practices and standards that demonstrates that the service area of the trunked system does not overlap the service area of any existing station.

* * * * *

Section 90.207 is amended by revising the last sentence in paragraph (l) to read as follows:

§ 90.207 Types of emissions.

* * * * *

(l) * * * Authorization to use digital voice emissions is construed to include the use of F1D, F2D, G1D, or G2D emission subject to the provisions of § 90.233.

§ 90.211 [Removed]

10. Section 90.211 is removed.

11. Section 90.267 is amended by revising paragraph (a)(3) and by adding new paragraphs (b), (c), and (d) to read as follows:

§ 90.267 Assignment and use of frequencies in the 450–470 MHz band for low-power use.

(a) * * *

(3) Stations are limited to 2 watts output power.

* * * * *

(b) Unless specified elsewhere in this part, licensees as of August 5, 1999, licensed for operations with an emission designator wider than 11k25 on frequencies subject to the conditions of paragraph 90.20(d)(20) or paragraph 90.35(c)(30) that have been designated low-power channels pursuant to paragraph (a) of this section may obtain primary status with respect to co-channel licensees, by supplying their coordinates to the Commission. These licensees will continue to operate on a secondary basis with respect to adjacent channel licensees. Additionally, these licensees may continue to operate with an authorized bandwidth wider than 11.25 kHz on frequencies subject to the conditions of paragraph 90.20(d)(20) or paragraph 90.35(c)(30).

(c) Unless specified elsewhere in this part, licensees as of August 5, 1999, licensed for operations with an emission designator wider than 11k25 on frequencies subject to the conditions of paragraph 90.20(d)(20) or paragraph 90.35(c)(30) that have not been designated as low-power channels pursuant to paragraph (a) of this section that otherwise comply with the conditions of paragraph (a) of this section may obtain primary status with respect to co-channel licensees, by modifying their license to a designated low-power channel and supplying their coordinates to the Commission. These licensees will continue to operate on a secondary basis with respect to adjacent channel licensees. Additionally, these licensees may continue to operate with an authorized bandwidth wider than 11.25 kHz on frequencies subject to the conditions of paragraph 90.20(d)(20) or paragraph 90.35(c)(30).

(d) Applicants proposing to operate with an authorized bandwidth wider than 11.25 kHz on designated low-power frequencies that are subject to the conditions of paragraph 90.20(d)(20) or paragraph 90.35(c)(30) that otherwise meet the conditions of paragraph (a) of this section, may be licensed on a secondary, non-interference basis.

Section 90.311 is amended by revising the table in paragraph (a) to read as follows:

§ 90.311 Frequencies.

(a) * * *

Channel Assignment	Urbanized Area	General access pool	
		Base and mobile	Mobile
14	Boston, MA Chicago, IL Cleveland, OH Miami, FL New York/N.E. NJ Pittsburgh, PA	470.30625 to 472.99375	473.30625 to 475.99375

Channel Assignment	Urbanized Area	General access pool	
		Base and mobile	Mobile
	Los Angeles, CA	470.05625 to 472.99375	473.05625 to 475.99375
15	Chicago, IL	476.30625 to 478.99375	479.30625 to 481.99375
	Cleveland, OH		
	Detroit, MI		
	New York/N.E. NJ		
16	Boston, MA	482.30625 to 484.99375	485.30625 to 487.99375
	Dallas/Fort Worth, TX		
	Detroit, MI		
	San Francisco/Oakland, CA		
	Los Angeles, CA (Use is restricted to Public Safety Pool eligibles).	482.00625 to 484.99375	485.00625 to 487.99375
17	Houston, TX	488.30625 to 490.99375	491.30625 to 493.99375
	San Francisco/Oakland, CA		
	Washington, DC/MD/VA		
18	Pittsburgh, PA	494.30625 to 496.99375	497.30625 to 499.99375
	Washington, DC/MD/VA		
19	Philadelphia, PA	500.30625 to 502.99375	503.30625 to 505.99375
20	Los Angeles, CA	506.13125 to 508.99375	509.13125 to 511.99375
	Philadelphia, PA	506.30625 to 508.99375	509.30625 to 511.99375

* * * * * * *

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BILLING CODE 6712–01–U

OFFICE OF PERSONNEL MANAGEMENT

48 CFR Parts 1615, 1632, and 1652

RIN 3206 AI67

Federal Employees Health Benefits (FEHB) Program and Department of Defense (DoD) Demonstration Project; and Other Miscellaneous Changes

AGENCY: Office of Personnel Management.

ACTION: Interim regulation.

SUMMARY: OPM is issuing an interim regulation to implement the portion of the Defense Authorization Act for 1999 that establishes authority for a demonstration project under which certain Medicare and other eligible DoD beneficiaries can enroll in health benefit plans in certain geographic areas under the Federal Employees Health Benefits (FEHB) Program. The demonstration project will run for a period of three years from January 1, 2000, through December 31, 2002. This regulation specifies only the requirements that differ from existing FEHB Program regulations because of unique aspects of the demonstration project.

DATES: The effective date of this regulation is July 6, 1999. Comments must be received on or before September 7, 1999.

ADDRESSES: Comments must be sent to Abby L. Block, Chief, Insurance Policy and Information Division, OPM, Room 3425, 1900 E Street, NW., Washington, DC 20415–0001.

FOR FURTHER INFORMATION CONTACT: Michael W. Kaszynski, (202) 606–0004. You may submit comments and data by sending electronic mail (E-mail) to: *mwkaszyn@opm.gov*.

SUPPLEMENTARY INFORMATION: The purpose of this regulation is to implement the portion of the Defense Authorization Act for 1999, Public Law 105–261, that amended chapter 55 of title 10, United States Code, and chapter 89 of title 5, United States Code, to establish a demonstration project under which certain Medicare and other eligible DoD beneficiaries can enroll in health benefit plans under the FEHB Program. The legislation was signed into law on October 17, 1998. The demonstration project will run for a period of three years from January 1, 2000, through December 31, 2002. DoD, with OPM concurrence, has selected eight geographic areas to serve as demonstration project areas. The legislation requires that between 6 and 10 geographic areas be selected. No more than 66,000 individuals can participate in the demonstration project at any one time. Beneficiaries who are provided coverage under the demonstration project will not be eligible to receive care at a military medical treatment facility or to enroll in a health care plan under DoD's TRICARE program. Individuals who disenroll or cancel enrollment from the demonstration project are not eligible to reenroll in the demonstration project. OPM will establish separate risk pools for developing demonstration project enrollee premium rates. The Government contribution for demonstration enrollees will be paid by DoD and cannot exceed the percentage that the Government would have contributed had the enrollee been enrolled as a regular FEHB enrollee in the same health benefits plan and level of benefits.

The legislation requires OPM and DoD to jointly produce and submit two reports to Congress designed to assess the viability of expanding access to the FEHB Program to certain Medicare and other eligible DoD beneficiaries permanently. The first report is due by April 1, 2001; the second is due by December 31, 2002. The reports will focus on enrollee participation levels, impact on Medicare Part B enrollment, impact on premium rates and costs as compared to regular FEHB enrollees, impact on accessibility of care in military treatment facilities, impact on medical readiness and training in military treatment facilities, impact on the cost, accessibility, and availability of prescription drugs for DoD beneficiaries, and recommendations on eligibility and enrollment.

OPM has determined it necessary to specify certain differences from existing FEHB Program regulations because of the unique features of the demonstration project. This regulation amends chapter 16 of title 48, Code of Federal Regulations (CFR) to enumerate these differences.

When developing premium rates for demonstration project community-rated carriers, OPM will not use similarly sized subscriber group (SSSG) rating methodologies to determine the reasonableness of the carrier's demonstration project premium rates. We are not using SSSG's because we have learned from our consultations with community-rated carriers that

there are no similar employer sponsored groups with which to compare. Instead we are benchmarking premiums against adjusted community-rates if available, Medigap offerings, or other similar products to determine reasonableness. We believe that these data will result in competitively developed premium rates.

We have determined the most cost effective and administratively efficient way for the federal government to track expenditures is to allow experience-rated carriers participating in the demonstration project to draw funds from their existing FEHB Letter of Credit (LOC) account to pay demonstration project benefits costs in the same manner as they do for benefits costs incurred by regular FEHB members. However, experience-rated carriers must account separately for health benefits charges paid using demonstration project funds and regular FEHB funds. Direct administrative costs attributable solely to the demonstration project will be fully chargeable to the demonstration project. Indirect administrative costs associated with the demonstration project will be allocated to the demonstration project based on the percentage obtained by dividing the dollar amount of claims processed under the demonstration project by the total claims processed for FEHB Program activity. This same percentage will also be used to determine the amount of the Carrier's service charge that will be allocated to the demonstration project.

Because of the way premiums are collected from enrollees and annuitants and the way the government distributes them to carriers, there will be a period between the effective date of demonstration project enrollees' coverage and the first payment of premium into experience-rated carriers' LOC accounts. DoD enrollments will become effective on January 1, 2000, and the first demonstration project premiums will be withheld from annuities on February 1, 2000. The enrollees' and Government's share of the premiums are due to OPM from DoD on the first day of each month thereafter through the conclusion of the demonstration project. However, since enrollees will be entitled to coverage for at least a month before the first premium payment, there won't be an opportunity for carriers to build a sufficient cash flow to cover the costs of the demonstration project group during this period. By allowing experience-rated carriers to draw on their existing LOC accounts in the same manner as for regular FEHB claims, this problem is addressed.

Since this is a start-up program with no specific experience, we have determined that experience-rated carrier risk must be mitigated in order to keep premiums as low as possible. Experience rated-carriers will report on demonstration project revenues, health benefits charges, and administrative expenses as directed by OPM and they will perform a final reconciliation of revenue and costs for the demonstration group at the end of the demonstration project. Experience-rated carrier costs in excess of the premiums will be reimbursed first from the carrier's demonstration project Contingency Reserve and then from OPM's Administrative Reserve. Any surplus after the final accounting will be paid by carriers to OPM's Administrative Reserve. Should the program be extended beyond the three year demonstration project period, we will regulate to address any necessary changes to these provisions.

We also have made minor editorial changes to clarify title 48, CFR.

Waiver of Notice of Proposed Rule Making

Pursuant to section 553(b)(3)(B) of title 5 of the United States Code, I find that good cause exists for waiving the general notice of proposed rulemaking. The notice is being waived because FEHB Program carriers need the information contained in these regulations now in order to have sufficient time to develop reserve accounts and premiums for enrollments to be effective January 1, 2000, as required by Public Law 105–261.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation will only affect health insurance carriers under the Federal Employees Health Benefits Program.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

List of Subjects in 48 CFR Parts 1615, 1632, and 1652

Government employees, Government procurement, Health insurance.

Office of Personnel Management.

Janice R. Lachance,

Director.

For the reasons set forth in the preamble, OPM is amending chapter 16 of title 48, CFR as follows:

CHAPTER 16—OFFICE OF PERSONNEL MANAGEMENT FEDERAL EMPLOYEES HEALTH BENEFITS ACQUISITION REGULATIONS

1. The authority citation for 48 CFR Parts 1615, 1632, and 1652 continues to read as follows:

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

PART 1615—CONTRACTING BY NEGOTIATION

Subpart 1615.8—Price Negotiation

2. In § 1615.802 paragraph (e) is added to read as follows:

1615.802 Policy.

* * * * *

(e) *Exceptions for the 3-Year DoD Demonstration Project (10 U.S.C. 1108).*

(1) Similarly sized subscriber group (SSSG) rating methodologies will not be used to determine the reasonableness of a community-rated carrier's demonstration project premium rates. Carrier premium rates will not be adjusted for equivalency with SSSG rating methodologies. Carriers will benchmark premiums against adjusted community rates if available, Medigap offerings, or other similar products.

(2) Community-rated carriers must propose premium rates with cost or pricing data and rating methodology, and experience-rated carriers must propose premium rates with cost data and rating methodology regardless of group size or annual premiums.

PART 1632—CONTRACT FINANCING

Subpart 1632.1—General

3. In § 1632.170 paragraph (c) is added to read as follows:

1632.170 Recurring premium payments to carriers.

* * * * *

(c) *Exceptions for the 3-Year DoD Demonstration Project (10 U.S.C. 1108).*

(1) Carriers will create and maintain separate risk pools for demonstration project experience and regular FEHB experience for the purpose of establishing separate premium rates.

(2) OPM will create and maintain a demonstration project Contingency Reserve separate from the regular FEHB Contingency Reserve for each carrier participating in the demonstration project.

(3) Experience-rated carriers participating in the demonstration project will draw funds from their Letter of Credit (LOC) account to pay demonstration project benefits costs in the same manner as they do for benefits

costs incurred by regular FEHB members. Experience-rated carriers will account separately for health benefits charges paid using demonstration project funds and regular FEHB funds. Direct administrative costs attributable solely to the demonstration project will be fully chargeable to the demonstration project. Indirect administrative costs associated with the demonstration project will be allocated to the demonstration project based on the percentage obtained by dividing the dollar amount of claims processed under the demonstration project by the total claims processed for FEHB Program activity. This same percentage will also be used to determine the amount of the experience-rated carrier's service charge that will be allocated to the demonstration project.

(4) Carriers will report on demonstration project revenues, health benefits charges, and administrative expenses as directed by OPM. Experience-rated carriers will perform a final reconciliation of revenue and costs for the demonstration group at the end of the demonstration project. Experience-rated carrier costs in excess of the premiums will be reimbursed first from the carrier's demonstration project Contingency Reserve and then from OPM's Administrative Reserve. Any surplus after the final accounting will be paid by experience-rated carriers to OPM's Administrative Reserve.

PART 1652—CONTRACT CLAUSES

Subpart 1652.2—Texts of FEHBP Clauses

4. Section 1652.215–70 is amended by removing "(JAN 1998)" from the clause heading and adding in its place "(JAN 2000)" and by adding a new paragraph (d) to read as follows:

1652.215–70 Rate Reduction for Defective Pricing or Defective Cost or Pricing Data.

* * * * *

(d) *Exception for the 3-Year DoD Demonstration Project (10 U.S.C. 1108).*

Similarly sized subscriber group (SSSG) rating methodologies shall not be used to determine the reasonableness of the carrier's demonstration project premium rates. The Carrier's rates shall not be adjusted for equivalency with SSSG rating methodologies. The Carrier shall benchmark premiums against adjusted community rates if available, Medigap offerings, or other similar products.

5. Section 1652.216–70 is amended by removing "(JAN 1998)" from the clause heading and adding in its place "(JAN 2000)" and by adding a new paragraph (c) to read as follows:

1652.216–70 Accounting and price adjustment.

* * * * *

(c) *Exception for the 3-Year DoD Demonstration Project (10 U.S.C. 1108).*

Similarly sized subscriber group (SSSG) rating methodologies shall not be used to determine the reasonableness of the Carrier's demonstration project premium rates. The Carrier's rates shall not be adjusted for equivalency with SSSG rating methodologies. The Carrier shall benchmark premiums against adjusted community rates if available, Medigap offerings, or other similar products.

6. Section 1652.216–71 is amended by revising the clause to read as follows:

1652.216–71 Accounting and allowable cost.

* * * * *

Accounting and Allowable Cost (FEHBAR 1652.216–71) (JAN 2000)

(a) *Annual Accounting Statements.* (1) The Carrier shall furnish to OPM an accounting of its operations under the contract. In preparing the accounting, the Carrier shall follow the reporting requirements and statement formats prescribed by OPM in the FEHBP Experience-Rated Carrier and Service Organization Audit Guide (Guide).

(2) The Carrier shall have its Annual Accounting Statements and that of its underwriter, if any, audited in accordance with the Guide. The Carrier shall submit the audit report and the Annual Accounting Statements to OPM in accordance with the requirements of the Guide.

(3) Based on the results of the independent audit prescribed by the Guide and/or a Government audit, the Carrier shall adjust its annual accounting statements (i) By amounts found not to constitute actual, reasonable, allowable, or allocable costs; and/or (ii) to reflect prior overpayments or underpayments.

(4) The Carrier shall develop corrective action plans, in accordance with and as defined by the Guide, to resolve all audit findings.

(b) *Definition of costs.* (1) The Carrier may charge a cost to the contract for a contract term if the cost is actual, allowable, allocable, and reasonable. In addition, the Carrier must:

(i) On request, document and provide accounting support for the cost and justify that the cost is reasonable and necessary; and

(ii) Determine the cost in accordance with: (A) The terms of this contract, and (B) Subpart 31.2 of the Federal Acquisition Regulation (FAR) and Subpart 1631.2 of the Federal Employees Health Benefits Program Acquisition Regulation (FEHBAR) applicable on the first day of the contract period.

(2) In the absence of specific contract terms to the contrary, the Carrier shall classify contract costs in accordance with the following criteria:

(i) *Benefits.* Benefit costs consist of payments made and liabilities incurred for covered health care services on behalf of FEHBP subscribers less any refunds, rebates, allowances or other credits received.

(ii) *Administrative expenses.* Administrative expenses consist of all actual, allocable, allowable and reasonable expenses incurred in the adjudication of subscriber benefit claims or incurred in the Carrier's overall operation of the business. Unless otherwise stated in the contract, administrative expenses include, in part: all taxes (excluding premium taxes, as provided in section 1631.205–41), insurance and reinsurance premiums, medical and dental consultants used in the adjudication process, concurrent or managed care review when not billed by a health care provider and other forms of utilization review, the cost of maintaining eligibility files, legal expenses incurred in the litigation of benefit payments and bank charges for letters of credit. Administrative expenses exclude the cost of Carrier personnel, equipment, and facilities directly used in the delivery of health care services, which are benefit costs, and the expense of managing the FEHBP investment program which is a reduction of investment income earned.

(iii) *Investment income.* The Carrier shall invest and reinvest all funds on hand, including any in the Special Reserve or any attributable to the reserve for incurred but unpaid claims, which are in excess of the funds needed to discharge promptly the obligations incurred under the contract. Investment income represents the net amount earned by the Carrier after deducting investment expenses. Investment expenses are those actual, allowable, allocable, and reasonable contract costs which are attributable to the investment of FEHBP funds, such as consultant or management fees.

(iv) *Other charges.* (A) *Mandatory statutory reserve.* Charges for mandatory statutory reserves are not allowable unless specifically provided for in the contract. When the term "mandatory statutory reserve" is specifically identified as an allowable contract charge without further definition or explanation, it means a requirement imposed by State law upon the Carrier to set aside a specific amount or rate of funds into a restricted reserve that is accounted for separately from all other reserves and surpluses of the Carrier and which may be used only with the specific approval of the State official designated by law to make such approvals. The amount chargeable to the contract may not exceed an allocable portion of the amount actually set aside. If the statutory reserve is no longer required for the purpose for which it was created, and these funds become available for the general use of the Carrier, the Carrier shall return to the FEHBP a pro rata share based upon FEHBP's contribution to the total Carrier's set aside in accordance with FAR 31.201–5.

(B) *Premium taxes.* When the term "premium taxes" is used in this contract without further definition or explanation, it means a tax, fee, or other monetary payment directly or indirectly imposed on FEHB premiums by any State, the District of Columbia, or the Commonwealth of Puerto Rico or by any political subdivision or other governmental authority of those entities, with the sole exception of a tax on net income or profit, if that tax, fee, or payment is

applicable to a broad range of business activity.

(c) *Certification of Accounting Statement Accuracy.* (1) The Carrier shall certify the annual accounting statement in the form set forth in paragraph (c)(3) of this clause. The Carrier's chief executive officer and the chief financial officer shall sign the certificate.

(2) The Carrier shall require an authorized agent of its underwriter, if any, also to certify the annual accounting statement.

(3) The certificate required shall be in the following form:

Certification of Accounting Statement Accuracy

This is to certify that I have reviewed this accounting statement and to the best of my knowledge and belief:

1. The statement was prepared in conformity with the guidelines issued by the Office of Personnel Management and fairly presents the financial results of this reporting period in conformity with those guidelines.

2. The costs included in the statement are actual, allowable, allocable, and reasonable in accordance with the terms of the contract and with the cost principles of the Federal Employees Health Benefits Acquisition Regulation and the Federal Acquisition Regulation.

3. Income, rebates, allowances, refunds and other credits made or owed in accordance with the terms of the contract and applicable cost principles have been included in the statement.

4. If applicable, the letter of credit account was managed in accordance with 5 CFR part 890, 48 CFR chapter 16, and OPM guidelines.

Carrier Name: _____

Name of Chief Executive Officer: (Type or Print)

Name of Chief Financial Officer:

Signature of Chief Executive Officer:

Signature of Chief Financial Officer:

Date Signed:

Date Signed:

Underwriter: _____

Name and Title of Responsible Corporate Official: (Type or Print:) _____

Signature of Responsible Corporate Official:

Date Signed: _____

(End of Certificate)

(d) Exceptions for the 3-Year DoD Demonstration Project (10 U.S.C. 1108).

(1) The Carrier shall draw funds from its Letter of Credit (LOC) account to pay demonstration project benefits costs in the same manner as it does for benefits costs incurred by regular FEHB members. The Carrier shall account separately for health benefits charges paid using demonstration project funds and regular FEHB funds. Direct administrative costs attributable solely to the demonstration project shall be fully chargeable to the demonstration project. Indirect administrative costs associated with the demonstration project will be allocated to the demonstration project based on the percentage obtained by dividing the dollar amount of claims processed under the demonstration project by the total claims processed for FEHB Program activity. This same percentage will also be used to determine the amount of the Carrier's service charge that will be allocated to the demonstration project.

(2) The Carrier shall submit a separate annual accounting statement and monthly incurred claims report for demonstration project experience.

(End of Clause)

7. Section 1652.232–71 is amended by removing "(Jan. 1999)" from the clause heading and adding in its place "(JAN 2000)," and adding a new paragraph (f) to read as follows:

1652.232–71 Payments—experience-rated contracts.

* * * * *

(f) *Exception for the 3-Year DoD Demonstration Project (10 U.S.C. 1108).*

The Carrier will perform a final reconciliation of revenue and costs for the demonstration project group at the end of the demonstration project. Costs in excess of the premiums will be reimbursed first from the Carrier's demonstration project Contingency Reserve and then from OPM's Administrative Reserve. Any surplus after the final accounting will be paid by the Carrier to OPM's Administrative Reserve.

(End of Clause)

[FR Doc. 99–16913 Filed 7–2–99; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Final Designation of Critical Habitat for the Rio Grande Silvery Minnow

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), designate critical habitat for the Rio Grande silvery minnow (*Hybognathus amarus*), a species federally listed as endangered under the authority of the Endangered Species Act of 1973, as amended (Act). This species, also referred to herein as silvery minnow or minnow, presently occurs only in the Rio Grande from Cochiti Dam downstream to the headwaters of Elephant Butte Reservoir, New Mexico, approximately five percent of its known historical range. Critical habitat overlays this last remaining portion of occupied range. It encompasses 262 kilometers (km) (163 miles (mi)) of the mainstem Rio Grande from the downstream side of the State Highway 22 bridge crossing the Rio Grande immediately downstream of Cochiti Dam, to the crossing of the Atchison Topeka and Santa Fe Railroad near San Marcial, New Mexico.

EFFECTIVE DATES: This rule becomes effective August 5, 1999.

ADDRESSES: You may inspect the complete file for this rule at the U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna NE., Albuquerque, New Mexico 87113, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Field Supervisor, New Mexico Ecological Services Field Office (See **ADDRESSES** above).

SUPPLEMENTARY INFORMATION:

Background

The Rio Grande silvery minnow is one of seven species in the genus *Hybognathus* found in the United States (Pflieger 1980). The species was first described by Girard (1856) from specimens taken from the Rio Grande near Fort Brown, Cameron County, Texas. It is a stout silvery minnow with moderately small eyes and a small, slightly oblique mouth. Adults may reach 90 millimeters (mm) (3.5 inches (in)) in total length (Sublette *et al.* 1990). Its dorsal fin is distinctly pointed with the front of it located slightly closer to the tip of the snout than to the base of the tail. Life color is silver with emerald reflections. Its belly is silvery white; fins are plain; and barbels are absent (Sublette *et al.* 1990).

This species was historically one of the most abundant and widespread fishes in the Rio Grande Basin, occurring from Espanola, New Mexico, to the Gulf of Mexico (Bestgen and Platania 1991). It was also found in the Pecos River, a major tributary of the Rio Grande, from Santa Rosa, New Mexico, downstream to its confluence with the Rio Grande (Pflieger 1980). It is completely extirpated from the Pecos River and from the Rio Grande downstream of Elephant Butte Reservoir (Bestgen and Platania 1991). Throughout much of its historical range, decline of the silvery minnow may be attributed to modification of stream discharge patterns and channel drying because of impoundments, water

diversion for agriculture, and stream channelization (Cook *et al.* 1992; Bestgen and Platania 1991).

In the Pecos River, the silvery Minnow was replaced by the closely related, introducted plains minnow (*H. placitus*) (Hatch *et al.* 1985; Bestgen *et al.* 1989; Cook *et al.* 1992). It is believed the plains minnow was introduced into the Pecos drainage during 1968, probably the result of the release of "bait minnows" that were collected from the Arkansas River drainage. The displacement that ensured was complete in less than one decade (Cowley 1979). The plains minnow may be more tolerant of modified habitats and, therefore, able to replace the silvery minnow in the modified reaches of the Pecos River. It is also believed that the two species hybridized. Habitat alteration and resulting flow modification could have also contributed to extirpation of the species in the Pecos River.

Decline of the species in the Middle Rio Grande probably began in 1916 when the gates at Elephant Butte Dam were closed. Construction of the dam signaled the beginning of an era of main stream Rio Grande dam construction that resulted in five major main stem dams within the minnow's habitat (Shupe and Williams 1988). These dams allowed manipulation and diversion of the flow of the river. Often this manipulation resulted in the drying of reaches of river and elimination of all fish. Concurrent with construction of the main stream dams was an increase in the abundance of non-native and exotic fish species as these species were stocked into the reservoirs created by the dams (Sublette *et al.* 1990). Once established, these species often completely replaced the native fish fauna (Propst *et al.* 1987). Development of agriculture and the growth of cities within the historical range of the Rio Grande silvery minnow resulted in a decrease in the quality of water that may have also adversely affected the range and distribution of the species.

Historically there were four other small native fish species that are now either extinct or extirpated from the middle Rio Grande; the silvery minnow is the only one surviving today and it has been reduced to only 5 percent of its historical range. Although the minnow is a hearty fish, capable of withstanding many of the natural stresses of the desert aquatic environment, the majority of the individual minnows live only one year. A healthy annual spawn is key to the survival of the species.

The minnow's range has been so greatly restricted that the species is extremely vulnerable to a single naturally occurring chance event. The minnow prefers shallow waters with a sandy and silty substrate that is generally associated with a meandering river that includes sidebars, oxbows, and backwaters. However, physical modifications to the Rio Grande over the last century, including the construction of dams and channelization of the mainstem, have altered much of the historical habitat for the minnow. Channelization has straightened and shortened mainstem river reaches, increased the velocity of the current, and altered riparian vegetation, instream cover, and substrate composition. The spring runoff triggers the minnow's spawn and the eggs produced drift in the water column. Diversion dams prevent the minnow from subsequently being able to move upstream as waters recede or as the minnow approaches inhospitable habitat such as Elephant Butte Reservoir, where the waters are cold, deep and stocked with non-native predatory fish.

During the irrigation season (March 1 to October 31), minnows often become stranded in the diversion channels where they may, although are unlikely to, survive for a while. As the water is used on the fields, the chance for survival of the minnow in the irrigation return flows in slim. Unscreened diversion dams also entrain both adult minnow, fry, and buoyant eggs. Perhaps even more problematic for the minnow are irrigation seasons in drought years, when most or all of the water may be diverted from the two lower-most segments of the river to meet irrigation and other needs. This diversion causes minnows to become stranded in dewatered segments of the river.

Historically, the silvery minnow was able to withstand periods of drought primarily by retreating to pools and backwater refugia, and swimming upstream to repopulate upstream habitats. However, when the river dries too rapidly and dams prevent upstream movement, the minnow becomes trapped in dewatered reaches and generally dies. This becomes particularly significant for the silvery minnow below San Acacia diversion dam, where approximately 70 percent of the current population lives. In the river reaches above (north of) San Acacia Dam, return flows from irrigation and other diversions are returned back into the mainstem of the river, which assures a fairly consistent flow. However, at San Acacia Dam, one irrigation diversions are made the return flows continue in off-river channels until they enter Elephant Butt Reservoir.

Furthermore, because the river is an aggrading system below San Acacia (i.e,. the river bottom is rising due to sedimentation), the bed of the river is now perched above the bed of the 80 km (50 mile) low flow conveyance channel, which is immediately adjacent and parallel to the river channel. Because of this physical configuration, waters in the mainstem of the river tend to be drained into the low flow conveyance channel.

Seventy percent of the remaining minnow population resides between San Acacia diversion dam and the headwaters of elephant butte. In low water years in this reach, all the water in the stream may be diverted into the irrigation system or drained from the mainstem by the low flow conveyance channel. In effect, water is being conveyed to Elephant Butte reservoir through a bypass of the river in the San Acacia reach, resulting in a dry or drying Riverbed.

The designation of critical habitat for the Rio Grande silvery minnow includes 262 river-km (163 river-mi) in the Middle Rio Grande which are the last miles of habitat occupied by the species. The designation involves the mainstem of the Rio Grande or the active river channel including the water column, and its associated channel morphology. Land on either side of, but not within, the designated critical habitat, lies within the administrative boundaries of the Middle Rio Grande Conservancy District. Other landowners, sovereign entities, and managers include: the pueblos of Cochiti, San Felipe, Santo Domingo, Santa Ana, Sandia, and Isleta; the U.S. Bureau of Reclamation (BOR); the Service; the U.S. Bureau of Land Management; New Mexico State Parks Division; New Mexico Department of Game and Fish; New Mexico State Lands Department; and the U.S. Army Corps of Engineers (Corps). The communities of Algodones, Bernalillo, Rio Rancho, Corrales, Albuquerque, Bosque Farms, Los Lunas, Belen, and Socorro also border the length of critical habitat in the Middle Rio Grande Valley.

Previous Federal Action

On February 19, 1991, we mailed approximately 80 pre-proposal notification letters to the six Middle Rio Grande Indian pueblos, various governmental agencies, knowledgeable individuals, and the New Mexico Congressional delegation. The letter informed them of our intent to propose adding the Rio Grande silvery minnow to the Federal list of Endangered and Theratened Wildlife and Plants and solicited their comments and input. We were particularly interested in obtaining

additional status information or information concerning threats. On May 22, 1991, a second informational letter was sent to the New Mexico Congressional delegation. Comments were received from the Service's Dexter, New Mexico, Fisheries Assistance Office; New Mexico Department of Game and Fish City of Albuquerque; Texas Parks and Wildlife Department; U.S. Department of the Interior, Office of Surface Mining; and the New Mexico Interstate Stream Commission. No commenters offered additional information concerning the status of the species or information concerning additional threats. Most commented that the range of the species had been severely reduced and that Federal listing should be considered. The response from the New Mexico interstate Stream Commission included a historical review of water development in the Middle Rio Grande Valley.

The Rio Grande silvery minnow was included in our Animal Notice of Review (56 FR 58804; November 21, 1991) as a Category 1 candidate species. At that time, a Category 1 candidate species was one for which we had on file substantial information on biological vulnerability and threats to support a proposal to list it as an endangered or threatened species.

On March 20, 1992, we held a meeting in Albuquerque, New Mexico, to explore with various interested governmental and private entities any existing or potential flexibility in water delivery schedules that might avoid de-watering the Rio Grande through the area containing the remaining habitat of the silvery minnow. We also requested that attendees provide any information that would add to the knowledge of the current distribution of the species. No New information concerning distribution, abundance, or threats to the species was provided. No flexibility in the management of water in the river or the timing or duration of flows was identified by any meeting participant.

We proposed to list the Rio Grande silvery minnow as an endangered species with critical habitat on March 1, 1993 (58 FR 11821). The comment period, originally scheduled to close on April 30, 1993, was extended until August 25, 1993 (58 FR 19220; April 13, 1993). This extension allowed us to conduct public hearings and to receive additional public comments. Public hearings were held in Albuquerque and Socorro, New Mexico, on the evenings of June 2 and 3, 1993, respectively.

After a review of all comments received in response to the proposed rule, we published the final rule to list the Rio Grande silvery minnow on July 20, 1994 (59 FR 36988). Section 4(a)(3) of the Act requires that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time a species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)(2)) state that critical habitat is not determinable if information sufficient to perform required analyses of the impacts of the designation is lacking or if the biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat. At the time of listing the silvery minnow, we found that critical habitat was not determinable because there was insufficient information to perform the required analyses of the impacts of the designation.

We contracted for an economic analysis of the proposed critical habitat designation in September 1994. Individuals and agencies were notified of the award of the contract on September 30, 1994. On October 27, 1994, we held a meeting with the contractors, inviting representatives from the BOR and Corps, as the two Federal agencies with significant activities within the range of the silvery minnow and the proposed critical habitat; the pueblos of Cochiti, San Felipe, Isleta, Sandia, Santa Ana, and Santo Domingo; the Middle Rio Grande Conservancy District; the Rio Grande Compact Commission; the cities of El Paso, Texas and Albuquerque, New Mexico; the Elephant Butte Irrigation District; and the International Boundary and Water Commission. At the meeting, we and the contractors outlined the approach under consideration to determine if economic impacts arose from critical habitat designation and sought input to the process and participation from these entities. Following the meeting, a paper prepared by the consulting economists on their methodology for estimating economic effects of critical habitat designation was provided to all attendees.

On November 3, 1994, letters soliciting any information considered germane to the economic analysis were sent to attendees of the October 27, 1994, meeting. We scheduled two additional meetings to discuss and clarify any questions of the agencies and entities who were asked to provide information for the economic analysis. Non-Pueblo entities were invited to a June 21, 1995, meeting. At that meeting we reviewed the description and evaluation provided in the proposed rule of activities that might adversely modify critical habitat or that may be affected by such designation. To assist respondents in replying to our information request, the following topics identified in the proposed rule were discussed:

Any action that would lessen the amount of the minimum flow or would significantly alter the natural flow regime;

any activity that would extensively alter the channel morphology of the Rio Grande; and

any activity that would significantly alter the water chemistry in the Rio Grande.

Further, at that meeting we identified activities that may be affected by the designation to include construction, maintenance, and operation of diversion structures; use of the conveyance channel and other canals; and levee and dike construction and maintenance. As detailed below, we have since determined that activities likely to result in a finding of adverse modification of critical habitat for the silvery minnow are also likely to jeopardize the continued existence of the species.

On June 22, 1995, a meeting was held solely for Pueblo representatives to discuss the proposed critical habitat and the process to be employed in determining economic effects of the designation with the content identical to that of the earlier meeting. No Pueblo representative attended.

On July 5, 1995, potential respondent agencies and individuals were provided a copy of a previous report prepared on potential economic consequences of designating critical habitat for fish species in southern Oregon and northern California, in order to familiarize them with the type of approach to be utilized for the silvery minnow. On July 14, 1995, we sent a questionnaire to all known Federal entities in the area of proposed critical habitat seeking their input in developing information on the potential economic consequences of the proposed designation. The entities were specifically requested to evaluate two scenarios. The "no designation" scenario represented the conditions that would exist, given that the Rio Grande silvery minnow has been listed as an endangered species, but assuming there were no designations of critical habitat. The other was the "proposed designation" scenario, which represented conditions that would exist if proposed critical designation was made final. Any difference between activities was to be identified as the designation's impacts. Five Federal agencies did not respond to the questionnaire. Twelve responded that their actions would not change between

the two scenarios. One Federal agency, the BOR, responded that the designation of critical habitat for the silvery minnow in the middle Rio Grande Valley would have a limited impact on activities that it would conduct, authorize, permit, or fund over and above any impact derived from the listing of the species.

Following the compilation and assessment of responses, the draft economic analysis was prepared and provided to us on February 29, 1996. The draft document was then provided to all interested parties on April 26, 1996. That mailing included 164 individuals and agencies, all affected pueblos in the valley, all county commissions within the occupied range of the species, and an additional 54 individuals who had attended the public hearings on the proposed listing and who had requested that they be included on our mailing list. At that time we notified the public that, because of the Congressional moratorium and funding rescission on final listing actions and designations of critical habitat imposed by Public Law 104–6, no work would be conducted on the analysis or on the final decision concerning critical habitat. However, we solicited comments from the public and agencies on the economic analysis for use when such work resumed.

On April 26, 1996, the moratorium was lifted. Following the waiver of the moratorium, we reactivated the listing program that had been shut down for over a year and faced a national backlog of 243 proposed species' listings. In order to address that workload, we published our listing Priority Guidance (LPG) for the remainder of Fiscal Year (FY) 1996 (May 16, 1999; 61 FR 24722). That guidance prioritized all listing actions and identified the designation of critical habitat as the lowest priority upon which we would expend limited funding and staff resources. Subsequent revisions of the LPG for Fiscal Years 1997 (61 FR 64475) and for 1998/1999 (63 FR 25502) retained critical habitat as the lowest priority.

The processing of this final rule designating critical habitat for the minnow does not conform with our current LPG for FY 1998/1999. That guidance gives the highest priority (Tier 1) to processing emergency rules to add species to the Lists of Endangered and Threatened Wildlife and Plants; second priory (Tier 2) to processing final determinations on proposals to add species to the lists, processing new listing proposals, processing administrative findings on petitions (to add species to the lists, delist species, or reclassify listed species), and processing a limited number of proposed and final rules to delist or reclassify species; and third priority (Tier 3) to processing proposed and final rules designating critical habitat. Our Southwest Region is currently working on Tier 2 actions; however, we are undertaking this Tier 3 action in order to comply with the court order in *Forest Guardians and Defenders of Wildlife* v. *Bruce Babbitt,* CIV 97–0453 JC/DIS, discussed below.

On February 22, 1999, the United States District Court for the District of New Mexico in *Forest Guardians and Defenders* ordered us to publish a final determination with regard to critical habitat for the Rio Grande silvery minnow within 30 days of that order. The deadline was subsequently extended by the Court to June 23, 1999 This final rule is issued to comply with that order and has been crafted within the time constraints imposed by the Court's orders. The draft economic analysis performed for the critical habitat designation was drafted in 1996 and represents data gathered from respondent entities about 4 years ago. We reviewed the content of that draft report in the context of Service policy, comments received from the public, and any other new information.

On April 7, 1999, we reopened the public comment period on the proposal to designate critical habitat and announced the availability of two draft documents, the draft Economic Analysis prepared in 1996, and a draft Environmental Assessment on the proposed action of designating critical habitat (64 FR 16890). Also on April 7, 1999, we mailed copies of the notice and the two draft documents to approximately 425 entities known to have an interest in the Rio Grande silvery minnow and its proposed critical habitat. The April 7, 1999, **Federal Register** notice also announced a public hearing to discuss and receive comments on the proposed designation. That hearing was held in Albuquerque, New Mexico, on April 29, 1999.

Parallel to the process of reviewing the critical habitat proposal and the economic consequences of the designation, we initiated recovery planning for the silvery minnow. The Interagency Cooperative Policy Statement, issued jointly by us and the National Marine Fisheries Service on July 1, 1994 (59 CFR 34272), identified the minimization of social and economic impacts caused by implementing recovery actions as a priority of both Services. The Rio Grande Silvery Minnow Recovery Team was appointed pursuant to this guidance and includes both species and habitat experts and community and private interest stakeholders. Many of the representatives of agencies, municipalities, and private interests that were involved in the proposal to list and in the analysis of critical habitat are recovery team members. The draft Final Rio Grande Silvery Minnow Recovery Plan has been prepared and is currently under review.

Critical Habitat

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. With this final rule, critical habitat is being designated for the RIO Grande silvery minnow.

Definition of Critical Habitat

Critical habitat is defined in section 3(5)(A) of the Act as "(i) the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species." The term "conservation," as defined in section 3(3) of the Act, means "to use and the use of all methods and procedures which are necessary to bring an endangered species or threatened species to the point at which the measures provided pursuant to this Act are no longer necessary" (i.e., the species is recovered and removed from the list of endangered and threatened species).

We are required to base critical habitat designations upon the best scientific and commercial data available (50 CFR 424.12) after taking into account economic and other impacts of such designation. In designating critical habitat for the Rio Grande silvery minnow, we have reviewed the overall approach to the conservation of the silvery minnow undertaken by the local, State, Tribal, and Federal agencies operating within the Middle Rio Grande Valley since the species' listing in 1994, and the identified steps necessary for recovery outlined in the draft Final Rio Grande Silvery Minnow Recovery Plan (in review). We have also reviewed available information that pertains to the habitat requirements of this species, including material received during the

initial public comment period on the proposed listing and designation, the information received following the provision of the draft Economic Analysis to the public on April 26, 1996, and the comments and information provided during the 30-day comment period opened on April 7, 1999, including the public hearing.

Effect of Critical Habitat Designation

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. If a Federal action may affect a list species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

The designation of critical habitat directly affects only Federal agencies, by prohibiting actions they fund, authorize, or carry out from destroying or adversely modifying critical habitat. Individuals, firms and other non—Federal entities are not affected by the designation of critical habitat so long as their actions do not require support by permit, license, funding, or other means from a Federal agency.

An understanding of the interplay of jeopardy and adverse modification standards is necessary to evaluate the likely outcomes of consultation under section 7, and to evaluate the environmental, economic and other impacts of any critical habitat designation. Implementing regulations (50 CFR part 402) define "jeopardize the continued existence of" (a species) and "destruction or adverse modification of" (critical habitat) in virtually identical terms. "Jeopardize the continued existence of" means to engage in an action "that reasonably would be expected * * * to reduce appreciably the likelihood of both the survival and recovery of a listed species." "Destruction or adverse modification" means a direct or indirect alteration that "appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species."

Common to both definitions is an appreciable detrimental effect on both survival and recovery of a listed species. Thus, for most species, actions likely to result in destruction or adverse modification of critical habitat are nearly always found to jeopardize the species concerned, and in most cases the existence of a critical habitat designation does not materially affect the outcome of consultation. This is often in contrast to the public perception that the adverse modification standard sets a lower threshold for violation of section 7 than the jeopardy standard. In fact, biological opinions that conclude that a Federal agency action is likely to adversely modify critical habitat but not to jeopardize the species for which it is designated are extremely rare historically and none have been issued in recent years.

The duplicative nature of the jeopardy and adverse modification standards is true for the Rio Grande silvery minnow as well. Since the species was listed in 1994, there have been a number of consultations that included a determination of potential impacts to proposed critical habitat. Implementing regulations of the act found at 50 CFR 402.10 direct that each Federal agency shall confer with the Service on any action which is likely to jeopardize the continued existence of any proposed species or result in the destruction or adverse modification of proposed critical habitat. No additional restrictions resulted from these conferences. We do not anticipate that when the designation is finalized we will need to impose additional restrictions relative to critical habitat that were not previously in place due to the listing of the species.

In some cases, critical habitat may assist in focusing conservation activities by identifying areas that contain essential habitat features (primary constituent elements), regardless of whether they are currently occupied by the listed species. This alerts the public and land managing agencies to the importance of an area in the conservation of that species. Critical habitat also identifies areas that may require special management or protection.

Section 4(b)(8) of the Act requires us to describe in any proposed or final regulation that designates critical habitat, those activities involving a Federal action that may adversely modify such habitat or that may be affected by such designation. Activities that may destroy or adversely modify critical habitat include those that alter the primary constituent elements (defined below) to an extent that the value of designated critical habitat for both the survival and recovery of the silvery minnow is appreciably reduced. We note that such activities may also jeopardize the continued existence of the species. Because the area that is being designated as critical habitat represents the remaining 5 percent of its historical range and is currently occupied by the species, loss of habitat that would result in a finding of adverse modification would also significantly reduce the likelihood of survival and recovery of the species, which is the definition of jeopardy.

Federal activities that may be affected by critical habitat designation include construction, maintenance, and operation of diversion structures; management of the conveyance channel; and levee and dike construction and maintenance. Again, these types of activities have already been examined under consultation with us upon listing the species as endangered. No additional restrictions to these activities as a result of critical habitat designation are anticipated.

Recent consultations undertaken with the BOR and Corps have recognized and allowed for occasional drying of portions of the lower reaches of the minnow's occupied habitat. We anticipate that, in times of severe water shortages, similar actions must be permissible after the designation of critical habitat becomes final, as long as a managed reduction ion surface flows allows the minnow to remain in the water column and retreat upstream, minimizing mortality. However, any such circumstance would require consultation under section 7 of the Act, and adequate monitoring would be required to ensure that the action would not result in jeopardy to the species, adversely modify its critical habitat, or result in unpermitted taking of individuals. See the discussion on Primary Constituent Elements and our response to Issue 33, below.

The minnow does not need a large quantity of water to survive but it does need some water. The minnow requires habitat with sufficient flows through the irrigation season to avoid excessive mortality in downstream reaches, plus a spike in flow in the late spring or early summer to trigger spawning, and a relatively constant winter flow. Alterations of the primary constituent elements are evaluated to determine whether Federal activities are destroying or adversely modifying critical habitat; the identification of primary constituent elements for the minnow is not intended to create a high-velocity, deep flowing river. The minnow does not require such habitat characteristics.

Primary Constituent Elements

In identifying areas as critical habitat, 50 CFR 424.12 provides that we consider those physical and biological

attributes that are essential to a species' conservation, and that may require special management considerations or protection. Such physical and biological features, as outlined in 50 CFR 424.12, include, but are not limited to, the following:

Space for individual and population growth, and for normal behavior;

Food, water, or other nutritional or physiological requirements;

Cover or shelter;

Sites for breeding, reproduction, or rearing of offspring; and

Habitats that are protected from disturbances or are representative of the historical geographical and ecological distributions of a species.

Primary constituent elements of critical habitat required to sustain the Rio Grande silvery minnow include:

Stream morphology that supplies sufficient flowing water to provide food and cover needed to sustain all life stages of the species;

Water of sufficient quality to prevent water stagnation (elevated temperatures, decreased oxygen, carbon dioxide build-up, etc.); and

Water of sufficient quality to prevent formation of isolated pools that restrict fish movement, foster increased predation by birds and aquatic predators, and congregate pathogens.

All areas within the designated stretch of the Rio Grande are occupied by the Rio Grande silvery minnow. Areas within the designated stretch either contain, or are capable of containing, these primary constituent elements. Areas within the designated critical habitat that may not have minnows present at a given point in time are capable of supporting these constituent elements because habitat conditions can change rapidly in response to flows and other factors, such as the development of sand bars, shifting of islands within the channel, and creation and disappearance of pools.

Land Ownership

The area designated as critical habitat for the Rio Grande silvery minnow is the only area where the species has been collected in the recent past and where it is currently known to exist. Within this 160 mi (262 km) stretch of river, there are four identified reaches delineated to reflect the management of water and habitat. From its upstream end at the Highway 22 bridge to its downstream terminus at the railroad trestle, critical habitat is within the Cochiti, Angostura, Isleta, and San Acacia reaches.

Critical habitat for the silvery minnow includes only the active channel of the mainstem Rio Grande. Ownership of the channel itself is unclear. However, most of the land in the middle river valley that abuts critical habitat is within the administrative boundaries of the Middle Rio Grande Conservancy District. The Middle Rio Grande Conservancy District is the subdivision of the State of New Mexico which provides for irrigation, flood control, and drainage of the Middle Rio Grande valley in New Mexico, from Cochiti Dam downstream 150 mi (285 km) to the northern boundary of the Bosque del Apache del Apache National Wildlife Refuge. Within these 150 mi are also the lands of the communities of Algodones, Bernalillo, Corrales, Albuquerque, Los Lunas, Belen, Socorro, and a number of smaller incorporated and unincorporated communities. Within the upper third of the middle valley of the Rio Grande are six Indian pueblos: Cochiti, Santo Domingo, San Felipe, Santa Ana, Sandia, and Isleta. Approximately 45 river mi (86 km) of critical habitat run through Pueblo lands.

Summary of Economic and Other Impacts

The Act requires that we designate critical habitat after taking into consideration the economic impact, and any other relevant impact, of specifying any particular area as critical habitat. We may exclude an area from designation if the benefits of its exclusion outweigh the benefits of its inclusion in critical habitat, unless failure to designate the area would result in extinction of the species concerned. We utilized the draft economic analysis prepared for the proposed critical habitat designation, in addition to our assessment of other impacts, to assist in our determination of whether any incremental economic effects of designation exist beyond the effects of the listing. The draft economic analysis, along with comments and other information available to us, allowed us to assess the benefits of exclusion versus inclusion for the area identified in the proposed rule.

Regional Economic Profile

The study area for the draft economic analysis included the strip of land adjacent to the Rio Grande, stretching from the Santa Fe metropolitan area, at the northern edge of the proposed designation to the El Paso, Texas metropolitan area, lying about 150 miles downstream from the southern terminus of the proposed critical habitat designation. This area embraces the designated habitat area and the majority of the economic activity that directly interacts with resources potentially affected by the designation. This area includes nine counties in two states and four metropolitan areas: Santa Fe, Albuquerque, Las Cruces, and El Paso. Albuquerque and El Paso, each with a population of about 650,000, are considerably larger than the others.

Irrigated agriculture accounts for more than 80 percent of permitted water use in the Middle Rio Grande Valley. Total private-sector employment in the agricultural industry in 1993 was 14,078, about two percent of total employment in the study area. Agricultural employment is a higher percentage of total employment in the two non-metropolitan counties (Socorro and Sierra counties in the lower reaches of designated critical habitat) than in the metropolitan areas, and a higher percentage in the Las Cruces metropolitan area than in the other metropolitan areas. For the study area as a whole, growth in agricultural employment during the past decade did not keep pace with total employment. In 1993, proprietors and employees in the study area's agricultural industry earned income of about $269 million, or one percent of total income. Agricultural incomes in this area have grown more rapidly than incomes in other sectors during the past decade, largely because farm incomes were depressed throughout the nation in the early 1980s. Nonetheless, average earnings in the agricultural industry are approximately two-thirds of the overall average.

These data indicate that the agricultural industry, the resource-intensive industry primarily associated with the critical habitat of the silvery minnow, generally reflects the national trends for resource-intensive industries. In particular, the data indicate that nationwide this industry is a small component of the overall economy and it is not growing as rapidly as other sectors of the economy.

Although from a geographic perspective the landscape surrounding the critical habitat for the silvery minnow is predominantly non-metropolitan, the economy of the study area is highly concentrated in the area's four metropolitan centers: Santa Fe, Albuquerque, Las Cruces, and El Paso. Approximately 98 percent of the population in the study area resides in the counties that constitute the area's four metropolitan statistical areas. This percentage somewhat overstates the portion of the area's population that actually has a metropolitan residence, because these are large counties and each one contains both urban and non-urban residents.

Economic Impacts and Effects

We reviewed and assessed the draft economic analysis report, which was based on questionnaires to Federal agencies. These questionnaires reported Federal agencies' own assessments of the extent to which they would alter their activities in response to critical habitat designation. Most agencies stated that the designation would have no effect. Only one agency, the BOR, indicated that it would alter its activities in response to the proposed designation of critical habitat for the minnow. Specifically, the BOR indicated that it would alter its river maintenance program in the proposed designated critical habitat area from just below Cochiti Dam to just above Elephant Butte Reservoir. Because of numerous uncertainties, however, the BOR was unable to give a specific estimate of the designation's potential impact on its river maintenance activities.

The BOR's response to the questionnaire was their own interpretation of the ramifications of avoiding adverse modification of critical habitat. However, we believe that if the identified activities had an impact on the silvery minnow significant enough to result in a finding of adverse modification of the minnow's critical habitat, we would also find that those activities would jeopardize the continued existence of the species in the absence of designated critical habitat. Thus, the designation of critical habitat should not require any change in the activities identified by the Bureau that were not already changed due to the listing of the minnow, and no economic effects should flow from the designation itself.

No Federal agency that commented during the April–May 1999, public comment period amended or added to its original response about impacts to its operations that would be caused by critical habitat. The BOR, in its May 7, 1999, comments, stated that the designation of critical habitat will likely have minimal impacts on that agency's Endangered Species Act-related activities.

In summary, although the draft economic analysis provided to us identified a perceived economic impact of critical habitat designation, we consider this potential economic impact to be a result of the minnow's listing, not critical habitat designation. In addition, the BOR's original estimate of economic impacts resulting from critical habitat designation discussed ceasing river maintenance; an unlikely occurrence. It is more likely that the Bureau would employ different design and construction techniques to accomplish river maintenance objectives. We have concluded that there are no incremental economic effects associated with the designation of critical habitat above and beyond the effects of listing the species as endangered. We have thus determined that there are no areas within the proposed designation where the benefits of exclusion can be shown to outweigh any benefits of inclusion.

Secretarial Order 3206

Secretarial Order 3206 was issued to clarify the responsibilities of the component agencies, bureaus, and offices of the Department of the Interior and the Department of Commerce, when actions taken under authority of the Act and associated implementing regulations affect, or may affect, Indian lands, Tribal trust resources, or the exercise of American Indian Tribal rights. In keeping with the trust responsibility and government-to-government relationships, we recognize our responsibility to consult with affected tribes and provide written notice to them as far in advance as practicable of conservation restrictions that we consider necessary to protect listed species.

If a proposed conservation restriction is directed at a Tribal activity that could raise the potential issue of direct (directed) take under the Act, then meaningful government-to-government consultation shall occur, in order to strive to harmonize the Federal trust responsibility to Tribes, Tribal sovereignty, and the statutory missions of the Departments of the Interior and Commerce. In cases involving an activity that could raise the potential issue of an incidental take under the Act, Tribal notification shall include an analysis and determination that all of the following conservation standards have been met—(i) the restriction is reasonable and necessary for conservation of the species at issue; (ii) the conservation purpose of the restriction cannot be achieved by reasonable regulation of non-Indian activities; (iii) the measure is the least restrictive alternative available to achieve the required conservation purpose; (iv) the restriction does not discriminate against Indian activities, either as stated or applied; and (v) voluntary tribal measures are not adequate to achieve the necessary conservation purpose.

Below we have specifically assessed the designation of critical habitat with respect to the five factors listed in Secretarial Order 3206:

1. The designation of critical habitat is required by law. The initial inclusion of reaches of the Rio Grande within or adjacent to Pueblo boundaries was based solely on biology and the contribution of those reaches of the river to the conservation of the species. Moreover, as discussed previously, critical habitat designation will impose no additional restrictions on activities on Indian lands beyond the prohibitions already in place against jeopardy and unpermitted taking of the species.

2. In the process of designating critical habitat for the Rio Grande silvery minnow, specific biological criteria were applied to all potential river reaches. This critical habitat designation includes a continuous stretch of river that constitutes the remaining 5 percent of the historical range of the species, and that we consider essential to the silvery minnow's conservation. The contiguity of habitats within and among the different reaches of the Rio Grande and the importance of the linkage between upstream and downstream activities and habitats does not allow for the removal from designation of one river section from its adjacent upstream and downstream non-Indian counterparts without potentially decreasing the value of all sections. Additionally, because of the unique relationship existing between the pueblos and the non-Indian Middle Rio Grande Conservancy District (the District is obligated to deliver water to the pueblos; the pueblos are represented on the Board of the District), and the interdependence of Tribal and non-Tribal activities throughout the stretch of critical habitat lying within the District does not facilitate the separation of the two.

3. The critical habitat as designated encompasses the last remnant of habitat still occupied by the silvery minnow (approximately 5 percent of the species' historical habitat) and is considered the least amount available with which to achieve the survival and recovery of the species.

4. The designation of critical habitat does not discriminate against Indian activities, either as stated or applied. The identified threats to the habitat of the Rio Grande silvery minnow were based on range-wide information that neither discriminated against nor favored particular land owners. Any "restrictions" which might be derived from the designation would have to arise from the obligation, under the Act, of Federal agencies to ensure that their actions do not result in the destruction or adverse modification of critical habitat. As stated in 1 (above), critical habitat does not create additional

restrictions because the areas are currently occupied, and no increased burdens have been identified.

5. Voluntary Tribal measures are not adequate to achieve the necessary conservation purpose. Tribal representation has been included in the Rio Grande Silvery Minnow Recovery Team and we continue to work with individual pueblos when requested to provide expertise in the rehabilitation and maintenance of aquatic habitats on Pueblo lands. Santa Ana Pueblo has taken a leadership role in forming a broad interest-based consortium, which is seeking funding for recovery projects for the silvery minnow. In addition, Santa Ana is also actively pursuing habitat restoration within the Santa Ana Pueblo boundaries. Both Sandia Pueblo (which is north of Albuquerque on the Rio Grande) and Isleta Pueblo (which is immediately south of Albuquerque on the Rio Grande) have enacted EPA-approved water quality standards as authorized under the Clean Water Act.

Because of the time constrains in rendering this final determination, we have had limited opportunity to engage in consultation with the pueblos adjacent to the designated critical habitat. However, on March 4, 1999, following the receipt of the court order, information was provided to Tribal representatives at the meeting of the Six Middle Rio Grande Basin Pueblos Coalition. Written comments to the proposed critical habitat designation for the Rio Grand silvery minnow were received from Sandia Pueblo (generally supporting the designation), Isleta Pueblo, and the Jicarilla Apache Tribe (both expressing concerns about the effects of the designation). On May 3, 1999, the Service's Regional Director, the Department of the Interior's Office of the Regional Solicitor, and staff met with representatives of and legal counsel for the Pueblo of Santa Ana to discuss critical habitat designation and solicit input from the Pueblo. We will continue to provide assistance to and cooperate with pueblos abutting critical habitat at their request.

Summary of Comments

Following the proposal to list the Rio Grand silvery minnow as an endangered species with critical habitat, we received comments from the public, scientific community, and management and regulatory agencies at the State and Federal levels concerning critical habitat. Additionally, following the provision of the draft Economic Analysis to the entities on our mailing list, we also received comments on the draft document and the economic impacts predicted by that document. Finally, during the public comment period opened from April 7 to May 7, 1999, we received a total of 94 comments concerning the proposal, the draft Economic Analysis document, and the draft Environmental Assessment. Thirty-two comments were provided orally at the public hearing, and we received 62 written comments. All comments on critical habitat and the draft documents, both oral and written, received during the comment period are addressed in the following summary. Comments of a similar nature are grouped into a number of general issues. Issues that were addressed in the final rule to list the Rio Grande silvery minnow may be found in that publication (59 FR 36988).

Issue 1: Considerable discrepancy exists within the comments received related to geographical extent of the proposed designation. Some commenters stated that the extent of critical habitat proposed by the Service is inadequate to address survival and recovery of the species. Others asserted that there is no basis for excluding the river above Cochiti Reservoir (including the Colorado portions of the watershed) from designation. Still others recommended that additional reaches of the Rio Grande should be evaluated, such as the river between Elephant Butte and Caballo reservoirs and downstreams of Caballo Reservoir. Some commented that the reach of the Rio Grande below San Acacia, because of its known episodes of intermittency, should be removed from the proposal. Some commenters recommended that, because the reach upstream from San Acacia Cochiti Reservoir would appear to offer an opportunity to provide critical habitat for the silvery minnow without insurmountable adverse effects on water supply, that we do not designate as critical habitat the reach downstream from San Acacia. Some commenters stated that there were no east-west boundaries identified for critical habitat. Some commenters, misinterpreting the scale of the map prepared for critical habitat, interpreted the proposal to incorporate miles of terrestrial habitat bordering the river throughout the length of the Middle Rio Grande Valley.

Service Response: The areas finalized as critical habitat in this rule meet the designation criteria in 50 CFR part 424. This designation of critical habitat is based on the last remaining area still occupied by the species. The Service considers this area in need of special management and protection and essential for the conservation of the species. The area designated includes the mainstem of the Rio Grande (comprised of the active river channel including the water column), and its associated channel morphology. Although some actions on lands within the floodplain of the river may affect critical habitat, these areas are not included within the designation.

The river reach between San Acacia and Elephant Butte Reservoir is of primary importance because 70 percent of the population currently inhabits that reach. The river above Cochiti Dam was not a significant part of the species' historical range, is colder than the optimal temperature for silvery minnows, and is stocked with predatory non-native fish. The area between Elephant Butte and Caballo reservoirs is also stocked with non-native fish, and its channel morphology is not conductive to silvery minnows. Finally, the river below Caballo Reservoir is not currently occupied by the species. As we progress through the recovery process for the Rio Grande silvery minnow, we may identify areas below the Caballo Reservoir, or other areas, that are suitable for reintroduction. Those areas would first have to be examined to determine why the minnow no longer occurs there, what remedial action would be necessary to reestablish the species, and whether remediation is feasible. However, until we have this information, we believe that the habitat essential to the silvery minnow's conservation is that which we originally proposed. If information becomes available that confirms that additional areas are essential for the species' conservation, we can revise the critical habitat designation. In addition, under section 4 of the Act, persons can petition the Service to modify the designation.

Issue 2: The economic analysis for regional impacts must be able to assess the effects on regional income that result from changes in the natural resource supply such as water. An inter-industry general equilibrium resource assessment model that can account for true resource limits and interdependence in the regional economy should be utilized.

Service Response: Because any finding of adverse modification of critical habitat will also result in a finding of jeopardy to this species, we have determined that there are no incremental economic effects above and beyond any effects associated with the listing of this species. Therefore, we believe that there is no need for further economic analysis as suggested by these commentors.

Immediately following initiation of the draft economic analysis, we arranged a meeting for all interested

agencies to meet with the consulting economists and to discuss the approach and methodology that was to be utilized in the determination of economic impacts. Those commenters who expressed their desire to interact with the economists were invited to the meeting. A second meeting was also held with agencies prior to the provision of the questionnaire; interested parties were invited to these meetings and also provided informational copies of the questionnaire that was sent to Federal entities for response.

Issue 3: We must evaluate the direct and indirect impacts of critical habitat. Indirect costs are associated with the societal implications on small communities in the middle Rio Grande valley dependent upon adequate flows from the Rio Grande to sustain the practice of irrigated agriculture. Designation of critical habitat could limit the ability of municipalities and other water providers in the middle valley to provide water to residents and affect the agricultural economy.

Service Response: As indicated in the proposal, the designation of critical habitat would affect only Federal agency actions that would adversely modify or destroy that habitat. As stated previously, actions that would destroy or adversely modify critical habitat would also result in jeopardy to the species. The draft economic analysis discussed the possibility that cessation or alternation of Federal actions in order to avoid jeopardy to the species or adverse modification or destruction of critical habitat might affect water availability to irrigators, cities, and other water rights holders. It also stated that complete cessation might have far reaching impacts on the viability of conveyance structures linked to and dependent upon the maintenance of the channel of the Rio Grande. The draft economic analysis further included the BOR's estimates of increased costs of river maintenance, and possible loss of water caused by an equivalent reduction in river maintenance capability as a worst case scenario based on the Bureau's interpretation of critical habitat.

In commenting on the draft report, the BOR has clarified that those actions under its control within the boundaries of critical habitat would not necessarily cease, rather the Bureau would likely employee different design and construction techniques to accomplish river maintenance objectives. Additionally, the BOR, in its commenting letter of May 7, 1999, said that the designation of critical habitat will likely have minimal impacts on that agency's Endangered Species Act-related activities.

Issue 4: The draft Economic Analysis is incomplete and flawed. The draft Environmental Assessment, relying on the conclusions of the economic analysis, is also flawed and inadequate. The Service should prepare a thorough economic analysis with necessary studies to adequately assess the requirements of the silivery minnow and the impact of the critical habitat designation. The Service is strongly encouraged to provide adequate time for public review and comment on studies to determine the impact of the critical habitat designation and a final rule should not be issued until this new information has been fully considered.

Service Response We have reviewed the draft economic analysis, draft Environmental Assessment, and all comments relieved on those documents and the proposal to designate critical habitat. We considered all comments in the final preparation of this designation. We believe that designation of critical habitat will have no incremental effects beyond those resulting from listing the species as endangered. The absence of impacts attributable to critical habitat designation is clearly and adequately explained in both this final rule and in the environmental assessment prepared for this action. Further, while we welcome and encourage additional studies on the biological requirements of the silvery minnow, we believe the best available information has been used in defining the primary constituent elements necessary for the species' conservation.

Issue 5: The Service should place the silvery minnow critical habitat designation on hold in order to establish a coordinating committee composed of interests above and below Elephant Butte Reservoir to develop a full-scale report on the existing data available on the silvery minnow, with several subcommittees, one of which would be charged with evaluation of the overall impact of the designation on other significant environmental interests.

Service Response: The Act does not allow the indefinite suspension of determination of critical habitat. It does, however, allow for a 1-year delay in designation if we find that critical habitat is not determinable. We stated in the final listing rule that we would need an additional year to determine the economic and other impacts of designation.

The Act requires that we determine the extent of critical habitat and the economic and other relevant impacts of such a determination using the best scientific and commercial information available at that time. We believe that considerable information is available on the silvery minnow, including numerous scientific studies on the species and on the hydrology of the Rio Grande. In addition, a recovery plan has been drafted by a team of experts and is currently under review. This recovery plan represents a compilation and analysis of the existing data on the species and its habitat. Within the constraints imposed by the Act and, in this instance, time constraints from the Court, we have attempted to contact all knowledgeable and interested entities to gather information for use in the determination of critical habitat and in the analysis of the economic and other relevant impacts that might arise from its designation.

Issue 6: The proposed rule provided no data or factors that were considered concerning economic and other impacts.

Service Response: The proposed designation of critical habitat was based solely on biological information concerning the needs and potential conservation of the silvery minnow. Economic data were not required for the proposal, nor were the economic data developed at the time the proposed rule was published. The economic analysis of impacts from the proposed designation was initiated in September 1994. The draft economic analysis was shared with all interested parties in April 1996, and its availability announced along with the reopening of the public comment period on the proposal in April 1999, giving interested parties ample opportunity to comment on the draft economic analysis.

Issue 7: An Environmental Impact Statement is required and must be provided before critical habitat can be designated.

Service Response: We have determined that an Environmental Impact Statement, as defined by the National Environmental Policy Act (NEPA) of 1969, need not be prepared in connection with actions under section 4 of the Endangered Species Act, including designation of critical habitat. A notice outlining our reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244). However, the Tenth Circuit Court of Appeals ordered compliance with NEPA on critical habitat designation for two fish species in *Catron County Board of Commissioners* v. U.S. Fish and Wildlife Service, 75 F.3d 1429 (10th Cir. 1996). Based on that decision, in order to comply with NEPA, we have completed an Environmental Assessment to delineate those environmental, socio-economic, and other relevant impacts

arising from this designation. That Environmental Assessment resulted in a Finding of No Significant Impact for this action. Under NEPA, an Environmental Impact Statement is not required in instances where a Finding of No Significant Impact is made on an Environmental Assessment.

Issue 8: Several commenters stated their concern that critical habitat would affect water rights. Other stated that while the proposed critical habitat is totally upstream of Elephant Butte. Reservoir, action taken in accordance with the proposal may decrease the amount and delivery of water available for use by the El Paso Water Utilities.

Service Response: We have determined that any alternations of BOR activities due to the prohibition against destruction or adverse modification of critical habitat would also be required under the prohibition of jeopardy to the species. Thus, there are no additional impacts of critical habitat designation. Further, neither the listing of the species nor designation of crucial habitat can or will determine State water rights.

Issue 9: The City of Albuquerque's wasterwater treatment facility discharges into the reach of the Rio Grande designated as critical habitat for the silivery minnow. To avoid significantly altering the water chemistry of the Rio Grande, the City of Albuquerque may have to remove the treated effluent entirely from the river, and to control and treat stormwater runoff.

Service Response: The City of Albuquerque is correct in stating that the Environmental Protection Agency (EPA), as the Federal agency issuing a permit for the City's wasterwater treatment plant under the National Pollutant Discharge Elimination System, would be required to ensure that its action would not destroy or adversely modify critical habitat for the silvery minnow. However, the EPA would be required to ensure that its proposed action would not likely jeopardize the continued existence of the species. Given the similarity of the definition of jeopardy and destruction or adverse modification, no additional restrictions will result from designation of critical habitat.

Issue 10: The designation of critical habitat will require continuous instream flow. The working of the primary constituent element to require a quantity of water sufficient to avoid isolated pools in the river equates to perennial bank to bank flows. The amount of water predicted for critical habitat is unobtainable.

Service Response: We have made no determination that continuous bank-to-bank flow is or will be a requirement to avoid jeopardy to the species or adverse modification of critical habitat. (See discussion above under *Effect of Critical Habitat Designation.*) As an evolutionary product of arid southwest river systems such as the Rio Grande, the silvery minnow has adapted to low flow and intermittent flow conditions. However, complete dewatering of extensive reaches of the only section of river where it now exists are of great concern, particularly when the impacts of dewatering are combined with the inability of the silvery minnow to access stillflowing reaches upstream of diversion dams.

We have made no prediction of the amount of water needed for maintenance of critical habitat. However, since the silvery minnow was listed and critical habitat proposed, the amount of water needed in low-water years to avoid jeopardy to the species ranged from about 17,000 to 58,000 acre-feet, depending upon specific yearly conditions of water use, climate, water availability, and response of the silvery minnow to those river conditions. We do not anticipate that flow management necessary to avoid destruction or adverse modification of critical habitat will be different than what is currently required to avoid jeopardizing the species.

Issue 11: The draft economic analysis displayed a bias against irrigated agriculture and flood control activities. It argues against irrigation subsidies even though society through its congressional representatives has made the decision that such subsidies provide important benefits to society.

Service Response: We disagree with the commenter's interpretation that the report's presentation of economic values and commitments identified for irrigated agriculture and flood control is biased against these activities. The report does not argue for or against subsidies of any kind, it merely notes their existence within the context of economic analysis. The costs and revenues from agriculture in the Rio Grande valley are a matter of record, not generated by the authors of the report, but taken from published data of the U.S. Department of Commerce, Bureau of Economic Analysis, and the New Mexico Cooperative Extension Service.

Issue 12: The draft Economic Analysis should have included some analysis to gauge the impacts if the United States' ability to comply with its treaty obligations to Mexico are compromised. Similarly, if the ability of New Mexico to deliver water to Elephant Butte is hampered, there will be drastic consequences for the water users in southern New Mexico and Texas.

Service Response: We believe that there are alternatives in the delivery of water that will allow the United States and the State of New Mexico to comply with compact and treaty obligations without either jeopardizing the continued existence of the species or destroying or adversely modifying critical habitat. Some commenters are concerned that if water is transported in the river channel instead of the conveyance structures, additional water will be lost. However, we do not believe that the accounting of water transport or carriage losses is of sufficient accuracy and precision; the loss of salvaged surface water could be a loss to only one reach of the river, to the overall system, or merely transported subsurface to Elephant Butte. A better understanding of the hydrology and a more precise accounting system would also aid in the management of flow of the river.

Issue 13: The amount of time and data available to agencies in responding to the economic questionnaire were insufficient to allow for more detailed reporting of economic effects.

Service Responses: The initial contact with the identified agencies that might have actions affected by the designation of critical habitat was in October 1994. Coordination by both ourselves and the consulting economists continued with the agencies to clarify information needs, to provide examples of questionnaires utilized in and reports produced by other economic impact assessments of critical habitat, and to exhaustively discuss what would be considered the components of critical habitat and how adverse modification to those components might be analyzed by the Service. These efforts continued for over seven months. In June 1995, another meeting was held with all involved agencies invited to discuss the process, the information needs, the questionnaire, and the assessment parameters. It was only after that extensive period of coordination that the questionnaire was sent to the agencies for their response. The requested response time was 30 days; based on the discussions and meetings of the preceding seven months, we do not believe that the response time was unreasonably brief.

Issue 14: The authors of the draft economic analysis cannot seriously consider the estimate of 4,000 acre-feet additional depletion to represent the actual impact of the designation of critical habitat.

Service Response: The authors of the draft report utilized the information provided to them from the Federal

agencies who have been managing the Rio Grande for over 90 years. The quantity of 4,000 acre-feet was provided by the BOR. Although the BOR estimated that a potential loss of 4,000 acre feet of surface flow could be realized from the cessation of some of their river maintenance program, it is not known if this amount of water would be lost to the system entirely, or travel subsurface down the channel of the Rio Grande to arrive, in some quantity, at Elephant Butte Reservoir.

Issue 15: If critical habitat is declared there is a real possibility that the BOR will be unable to perform periodic maintenance on the Rio Grande upstream from Elephant Butte Reservoir.

Service Response: This concern was not voiced by the BOR. No data provided by the Bureau indicated that a complete cessation of periodic maintenance would occur if critical habitat were to be designated for the Rio Grande silvery minnow. We concur that river maintenance activities may need to be altered in order to avoid jeopardizing the species or destroying or adversely modifying critical habitat, but the resultant impacts in channel capacity, water conveyance efficiencies, or water conservation have not been provided by the Bureau for such alterations.

Issue 16: The New Mexico Interstate Stream Commission commented that the prior appropriation doctrine in New Mexico does, to some extent, protect instream flows. New Mexico State law and the Rio Grande Compact both ensure delivery of water downstream through the Middle Rio Grande Valley to water users in the Rio Grande Project south of Elephant Butte Dam.

Service Response: Both State law and the Rio Grande Compact require the delivery of water downstream. However, currently the water that is released during the irrigation season is native water plus any waters called for to meet irrigation, municipal, and industrial needs. Additional water to meet Compact deliveries are released during the non-irrigation months in accordance with instructions from the Compact Commission, which is composed of representatives from Colorado, New Mexico, and Texas. Alterations to this plan require consent of the Compact Commission. Release of additional Compact waters during the irrigation season would only be helpful to the minnow if the waters traveled down the riverbed. As discussed above, if water is not transported through the reach of river between San Acadia Dam and Elephant Butte Reservoir, increased water in the system may not result in increased wet habitat for the minnow.

Issue 17: Critical habitat should not be designated until such time as a recovery plan has been developed for the silvery minnow that includes a determination that such designation is necessary for survival and recovery of the species.

Service Response: A recovery plan has been drafted for the silvery minnow and the plan is being reviewed. Although we agree that it would be appropriate to make a detailed determination of habitat needs of listed species during the recovery planning process, the Endangered Species Act does not currently link the designation critical habitat to the development of the recovery plan. The Act requires that, to the maximum extent prudent and determinable, we designate critical habitat when it lists a species. If critical habitat is not considered determinable at the time a final rule is adopted to list a species, it must be designated "to the maximum extent prudent" within 1 additional year. There is no provision in the Act to delay designation of critical habitat until such time as a recovery plan is prepared. The timing of this designation also is in compliance with a court order.

Issue 18: The calculation of the value of the BOR's river maintenance program in the Middle Rio Grande is misleading. The river maintenance program has flood control and drainage purposes and benefits as well as water salvage benefits. The draft report did not evaluate the economic value of these benefits.

Service Response: The BOR did not provide estimates of the value of the benefits identified by the commenter, nor did they provide data that would have allowed us to estimate the value of those benefits. Therefore, economists were not able to include the value of those benefits in the draft economic analysis.

Issue 19: The BOR estimated that the proposed designation of critical habitat would cause the cost of continuing the current level of river maintenance in the Middle Rio Grande to increase by up to 40 percent. This would mean that if funding for river maintenance activities remains stable or declines, what river maintenance activities in the Middle Rio Grande would be decreased. Reclamation did not estimate what percentage reduction in the river maintenance program might occur.

Service Response: We assumed that if the Bureau estimated that costs might increase by 40 percent, an alternative scenario would be that activities might instead decrease by 40 percent. However, as discussed above, the Service has determined that any activities likely to result in destruction or adverse modification of critical habitat would also result in a finding of jeopardy to the species. Therefore, any changes in river maintenance activities are attributed to the listing of the silvery minnow, and are not a result of critical habitat designation.

Issue 20: The draft Economic Analysis does not appear to present facts regarding the values of benefits of designating critical habitat for the silvery minnow. The discussion of recreational fishing benefits does not apply to this section of the Rio Grande.

Service Response: In responding to the questionnaire, the BOR provided estimates of costs identified as resulting from the critical habitat designation, without the amelioration or perceived benefits. As stated previously, we have concluded that no additional restrictions will result from the designation of critical habitat. We also concur that recreational fishing in the mainstem of the Rio Grande within the boundaries of critical habitat is a minimal input to the regional economy. The draft Economic Analysis prepared for our use in determining effects presented some potential benefits to be derived from healthy riverine and riparian systems, but that draft did not quantify the benefits to be derived from designation; nor did it address any mitigative actions that might be employed or implemented to lessen the identified economic impacts.

Issue 21: The minnow has not done well in stretches of the river that have perennial flowing water and has done quite well in some places that are seasonally dry.

Service Response: Although we concur that the distribution of silvery minnow shows low members in areas now receiving flows year round (Cochiti and Albuquerque reaches) and high numbers in stretches of the river subject to low or no flows (Isleta and San Acacia reaches), we disagree with the conclusion that they are doing well in the seasonally dry reaches. The silvery minnows transported from upstream reaches to the Isleta and San Acacia stretches cannot regain the upstream habitat. They are blocked by the diversion dams. Their presence does not necessarily indicate that the species is doing well in the lower portions of the river. Their presence indicates that they are vulnerable to the dewatering of these important habitats.

Issue 22: It is not water depletion that threatens the silvery minnow, but the structural changes that have narrowed and confined the channel.

Service Response: We concur that it is not one action or factor that is solely responsible for the endangerment of the

silvery minnow. The morphology of the channel, the quality of the water in the channel, and the provision of some flows to avoid dewatering are all important and, thus, have been identified as constituent elements of the species' critical habitat.

Issue 23: In order to justify the determination of no difference between critical habitat and listing, the Service should limit the components of critical habitat so that there is no difference between critical habitat and listing.

Service Response: We believe that the primary constituent elements identified for critical habitat—channel morphology, water quality, and water quantity—are the attributes needed in the river for the silvery minnow's survival and recovery. It is these attributes that we evaluate whether conducting section 7 consultation on the species with or without critical habitat.

Issue 24: Critical habitat in the Middle Rio Grande is dependent on restoring the low-velocity flows at locations within some reaches of the Middle Rio Grande. The required habitat for the recovery of the Rio Grande silvery minnow in the Middle Rio Grande does not include the entire 163-mile segment from Cochiti Dam to the headwaters of Elephant Butte Reservoir, nor does it include the entire cross section of the river at the locations designated for critical habitat. Only those reaches below the present, modified, or future diversion structures should be considered in arriving at locations designated for the critical habitat for this species.

Service Response: We concur that not every cross section of the river within the 163 miles of designated critical habitat may provide all constituent elements at any moment in time. However, within this relatively short reach of river, habitat conditions change in response to flows and other factors: sand bars develop, islands shift within the channel; pools are created and then filled in. The interconnectedness of the habitat is also vitally important to its value for the survival and recovery of the species. We believe that a continuum of habitat, rather than disjunct reaches, is the best way to maximize the probability of the species' survival and recovery.

Issue 25: The Service is rushing to designate critical habitat with inadequate information; both Secretary of the Interior Bruce Babbitt and Service Director Jamie Rappaport Clark conceded that the Service has insufficient information to declare critical habitat for the minnow and that additional time is required. Judge Conway granted additional time and may grant even more time if an environmental impact statement is required.

Service Response: The Act requires that, to the extent prudent, critical habitat be designated concurrently with a species' listing. Further, the Act requires that the designation be based on the best available information, even if the information is incomplete. Further, the court ordered us to make a determination concerning the designation of critical habitat within a specific time frame. This final rule, therefore, complies with both the Act and the court order. As we stated earlier, we have determined that an Environmental Impact Statement is not required for this action.

Although there is always additional information we would like to have concerning a species, there has been considerable research done on the Rio Grande silvery minnow and on the hydrology of the Middle Rio Grande. In addition, a recovery plan has been prepared and is currently being reviewed, which compiles and analyzes the existing data for the species. In the preparation of this final rule designating critical habitat for the minnow, we used the best scientific and commercial data available.

Issue 26: If it is the Fish and Wildlife Service's conclusion that there is little or no difference in benefit or effect between the No Action and Preferred Action alternatives, the Service should conclude that the designation of critical habitat for the Rio Grande silvery minnow is not needed at this time.

Service Response: This final rule complies with the Act and the court order that we make a final determination on critical habitat for the Rio Grande silvery minnow. A more complete discussion of the Service's view on this designation is found in *Effect of the Critical Habitat Designation* above.

Issue 27: The statement in the Economic Analysis that "If the designation will have no impact on the activities of Federal agencies, then it will have no economic impact" is not true. Although the designation of critical habitat only directly curtails the actions of Federal agencies, it does not follow that no private entities are affected by the Federal agencies' actions or lack thereof.

Service Response: We acknowledge that private entities could be affected if Federal actions are curtailed by the designation of critical habitat. However, the Federal agencies responded that critical habitat would not or would very minimally affect their actions. Thus, we believe that there will be no change from what has occurred in the Federal arena for the past 4 years since the species was listed and critical habitat proposed. Critical habitat, based on the responses received from the Federal agencies, will not "curtail" their actions. Critical habitat will have no incremental affect on their actions over and above that resulting from listing of the Rio Grande silvery minnow.

Issue 28: The economic report is not site-specific. An economic model that does not take local land and water use into account does not benefit the Fish and Wildlife Service.

Service Responses: The economic analysis was specific to the Middle Rio Grande Valley and utilized all information provided by the Federal. State, and local, and Native American respondents operating in the valley. Baseline information concerning the regional economy was provided that dealt specifically with the Middle Rio Grande.

Issue 29: Not only is the Fish and Wildlife Service's conclusion that Rio Grande silvery minnow population declines are due to habitat loss questionable, but the assertion that these declines are the result of agricultural dewatering between 1987 and 1992 are also suspect. Salt cedar and municipal and industrial water use could also be causative factors. The natural flow regime referenced in the proposed critical habitat designation has not existed since irrigation began in the basin over 800 years ago. The drying of the river for days, weeks, and months has been in place for at least 100 years.

Service Responses: As indicated in the proposed and final rules to list the Rio Grande silvery minnow, the species is no longer found in 95 percent of its historical range. This range-wide constriction predates the status of the species between 1987 and 1992 in the Middle Rio Grande Valley. We agree that many factors, in addition to diversions for agricultural use, that contribute to the dewatering of the river may be responsible for the imperiled status of the silvery minnow. The intensity of impact of diversions and water management has certainly grown with the ability to control the river. Diversions 800 years ago did not have the capacity to affect the river to the extent that modern management structures can . As management and manipulation of the river have intensified in the past 100 years, not only in the Middle Rio Grande Valley, but throughout the range of the silvery minnow, the species has been lost from 95 percent of its historical range. Moreover, the contraction in the

minnows' range makes it must more vulnerable to adverse conditions locally, where previously it could have recolonized areas temporarily depopulated from areas where conditions were more favorable.

Issue 30: The Fish and Wildlife Service found an economic impact arising from critical habitat for the Mexican spotted owl. For the Rio Grande silvery minnow, it found no effect attributable to critical habitat. On what basis has the Fish and Wildlife Service's interpretation of critical habitat and its associated impacts been modified?

Service Response: There has been no modification, but we must judge the impacts of individual and specific critical designations based upon the case-specific information before us. The impacts can differ between species and habitats, based on the effects of designation on Federal activities. In the case of the Mexican spotted owl, effects were identified. In the case of the Rio Grande silvery minnow, we found no effects from designation. As we have gained more experience with critical habitat, it has become increasingly apparent that its designation has little, if any, influence on the outcome of section 7 consultations. This has been true of consultations involving the silvery minnow that included a conference on proposed critical habitat. We do not anticipate that the outcome of section 7 consultations will be materially changed upon final critical habitat designation.

Issue 31: The draft Environmental Assessment provides no clarification regarding whether or how the Service believes the designation of critical habitat will affect the BOR's operation of the San Juan-China Project and how such an action may impact trust resources, tribally-owned fee lands, or the exercise of tribal rights for the Jicarilla Apache Tribe.

Service Response: We have been working with the BOR to manage flows for the Rio Grande silvery minnow since the species was listed and critical habitat was proposed. Those management scenarios involved consideration of the San Juan-Chama Project. We do not anticipate a change in that process with the final critical habitat designation, nor do we foresee an impact on trust resources, tribally-owned fee lands, or the exercise of tribal, rights for the Jicarilla Apache.

Issue 32: The economic documents do not evaluate the economic impact of the constituent elements or of the various activities that may adversely affect critical habitat: channelization, impoundment, deprivation of substrate source and riparian destruction, and any activity that would significantly alter the water chemistry in the Rio Grande.

Service Response: The economic analysis evaluated the effect critical habitat designation could be expected to have on the activities mentioned in this comment. The analysis of impacts of a particular action on critical habitat under section 7 will take into account the effects of that action on the primary constituent elements. Any consultation on the effects of an action on the species would also consider the effects on habitat attributes identified as the primary constituent elements.

Issue 33: No attempt has been made to establish a relationship between abundance of Rio Grande silvery minnow and flow conditions.

Service Response: It is correct that specific flow amounts needed for numeric population goals have not been identified. However, data are available to describe habitats, including flow conditions where most Rio Grande silvery minnows have been found. Additionally, data are available to show that a spring pulse is necessary for reproduction of the silvery minnow, and flows sufficient to produce low-velocity habitats are required for the young to survive and be recruited into the population. Flows are necessary to provide habitat to allow survival of this year's fish to next year so that they can spawn and thus contribute to the population. Investigations have not yet been conducted to determine the specific volume of a spring pulse to trigger spawning or to determine the amount of water and its rate of flow to ensure the provision of habitats for the survival of the species.

Issue 34: The primary constituent elements of the critical habitat designation create hydrological operating criteria which add an entirely new component of regulation beyond those imposed by the listing of the minnow. In essence, the constituent elements require the entire length of the river designated as critical habitat to be wet from bank to bank at all times. Because of the carriage losses in the system, to attain a constant flow at San Marcial (just above Elephant Butte Reservoir) would require the release of a quantity of water upstream that would virtually destroy, rather than create habitat for the minnow, which tends to like low-flows over sandy river bottoms. The Service should also identify the source of the water to be used for the minnow.

Service Response: The minnow does not need a large quantity of water but it does need some water to survive. We agree that the minnow could be sustained with low flows in the summer and late spring. In the spring and summer, runoff generally triggers spawning. The primary constituent elements we have described are intended to require the provision of these low flows to create habitat throughout the existing range of the species, not to change the hydrography to a raging, high flowing river.

The Service has not stated the exact flow regime needed to sustain the minnow nor has it required a minimum cubic feet per second flow at any point in the river system. There are a multiplicity of variables to be taken into account at any given time on any point in the river and there may be an equal number of ways to solve the problem of ensuring adequate flows. Not only has the Recovery Team (which includes interested parties in addition to scientific experts) been meeting since the species was listed, but a number of different stakeholders continue to explore possible solutions to the problem. Potential solutions include establishing a conservation pool from which to draw in low-water years; conserving water which might then be used to support the minnow and other life in the river; creating and enhancing silvery minnow habitat upstream and increasing populations upstream; purchasing or leasing unused contract water for use in the mainstem; passing downstream during the irrigation season some of the water used to meet Compact deliveries; creating ways to get some flows returned to the mainstem of the river below the San Acacia Dam; and engaging in a full-scale water rights adjudication on the entire Rio Grande. To limit the methods of assuring the survival of the minnow—such as by requiring a stated minimum flow or a source of water—might not only have unintended consequences to the minnow and the ecosystem, but it might also prematurely limit development of other methods or combinations of methods for preventing jeopardy and adverse modification to the minnow and its critical habitat.

Required Determinations

Regulatory Planning and Review. In accordance with Executive Order 12866, this action was submitted for review by the Office of Management and Budget. This final rule identifies the areas being designated as critical habitat for the silvery minnow. The designation will not have an annual economic effect of $100 million. Our summary of the economic impacts of designation is discussed earlier in this final rule. This rule will create inconsistencies with other agencies' actions. This rule will

not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. This rule will not raise novel legal or policy issues. Proposed and final rules designating critical habitat for listed species are issued under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Critical habitat regulations are issued under procedural rules contained in 50 CFR part 424.

Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act. As explained previously in the final rule, the designation will not have economic effects above and beyond the listing of the species. This is because the prohibition against destroying or adversely modifying critical habitat is essentially duplicative of the prohibition against jeopardizing the continued existence of the species, and therefore there are no additional economic effects that are not already incurred by the listing of the species.

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2)). This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rue does not have an annual effect on the economy of $100 million or more. As explained in this rule, we do not believe that the designation will have economic effects above and beyond the listing of the species. This rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, because the designation will not have economic effects above and beyond the listing of the species. This rule does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. Proposed and final rules designating critical habitat for listed species are issued under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). The prohibition against destruction or adverse modification of critical habitat applies only to actions authorized, funded, or carried out by Federal agencies. Competition, employment, investment productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises are not affected by a final rule designating critical habitat for this or any other species.

Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*). This rule will not significantly affect small governments because this rule will not place additional burdens on small governments beyond any burdens that may have been a result of listing the species as endangered. This rule will not produce a Federal mandate of $100 million or greater in any year, i.e. it is not a significant regulatory action under the Unfunded Mandates Reform Act.

Takings. In accordance with Executive Order 12630, this rule does not have significant takings implications. A takings implication assessment is not required. This final rule will not "take" private property and will not alter the value of private property. Critical habitat designation is only applicable to Federal lands, or to private lands if a Federal nexus exists (i.e., if a Federal agency authorizes or funds an action on private land). The regulatory impacts of this rule are small to non-existent and will not result in a taking of private property rights.

Federalism. This final rule will not affect the structure or role of states, and will not have direct, substantial, or significant effects on states as defined in Executive Order 12612. As previously stated, critical habitat is only applicable to Federal lands. Other lands only become subject to the provisions of critical habitat if a Federal nexus exists.

Civil Justice Reform. In accordance with Executive Order 12988, the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and does meet the requirements of sections 3(a) and 3(b)(2) of the Order. The final designation of critical habitat for the Rio Grande silvery minnow has been reviewed extensively. Every effort has been made to ensure that the rule contains no drafting errors, provides clear standards, simplifies procedures, reduces burden, and is clearly written such that litigation risk is minimized.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule does not contain any information collection requirements for which Office of Management and Budget approval under the Paperwork Reduction Act is required.

National Environmental Policy Act. It is our position that, outside the Tenth Circuit, environmental analyses as defined by the National Environmental Policy Act of 1969, (NEPA) need not be prepared in connection with listing species under the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County* v. *Babbitt*, 48 F.3d 1495 (9th Cir. Ore. 1995), *cert. Denied*, 116 S. Ct. 698 (1996). However, when the range of the species includes States within the Tenth Circuit, such as that of the Rio Grande silvery minnow, the Service, pursuant to the Tenth Circuit ruling in *Catron County Board of Commissioners v. U.S. Fish and Wildlife Service*, 75 F.3d 1429 (10th Cir. 1996), is to undertake a NEPA analysis for critical habitat designations. We have completed that analysis through an Environmental Assessment and Finding of No Significant Impact.

Government-to-Government Relationship with Tribes. In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM2:

We understand that federally-recognized Indian Tribes maintain a Government-to-Government relationship with the United States. The 1997 Secretarial Order on Native Americans and the Act clearly states that Tribal lands should not be designated unless absolutely necessary for the conservation of the species. According to the Secretarial Order, "Critical habitat shall not be designated in any such areas [an area that may impact Tribal trust resources] unless it is determined essential to conserve a listed species. In designating critical habitat, the Services shall evaluate and document the extent to which the conservation needs of a listed species can be achieved by limiting the designation to other lands." The designation of critical habitat for the Rio Grande silvery minnow contains Tribal lands belonging to the pueblos of Cochiti, San Felipe. Santo Domingo, Santa Ana, Sandia, and Isleta.

On October 27, 1994, we held a meeting with the economic analysis contractors and invited Federal agencies, the pueblos of Cochiti, San Felipe, Isleta, Sandia, Santa Ana, and Santo Domingo, and other entities. At the meeting, the Service and our contractors outlined the approach under consideration to define the economic impacts of critical habitat designation and sought input to the process and participation from these entities. On June 22, 1995, a meeting was held solely for Pueblo representatives to discuss the proposed critical habitat and the process to be employed in determining economic effects of the designation with the content identical to that of the earlier meeting. No Pueblo representatives attended. Following the compilation and assessment of

responses to questionnaires, we transmitted the draft analysis to the pueblos on April 26, 1996. Finally, on March 4, 1999, we met with Pueblo officials to discuss the impending designation of critical habitat. Thus, we have sought to consult with tribes on Government to Government basis.

References Cited

A complete list of all references cited herein, as well as others, is available upon request from the New Mexico Ecological Services Field Office (see **ADDRESSES** above).

Author: The primary author of this final rule is Jennifer Fowler-Propst (see **ADDRESSES**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and record keeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—(AMENDED)

1. The authority citation for Part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

§ 17.11 [Amended]

2. Amend section 17.11(h) by revising the entry in the Critical habitat column of the entry for the minnow, Rio Grande silvery, under FISHES, to read "17.95(e)".

3. Section 19.95(e) is amended by adding critical habitat of the Rio Grande silvery minnow (*Hybognathus amarus*), in the same alphabetical order as the species occurs in 17.11(h).

§ 17.95 Critical habitat—fish and wildlife.

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(e) * * *

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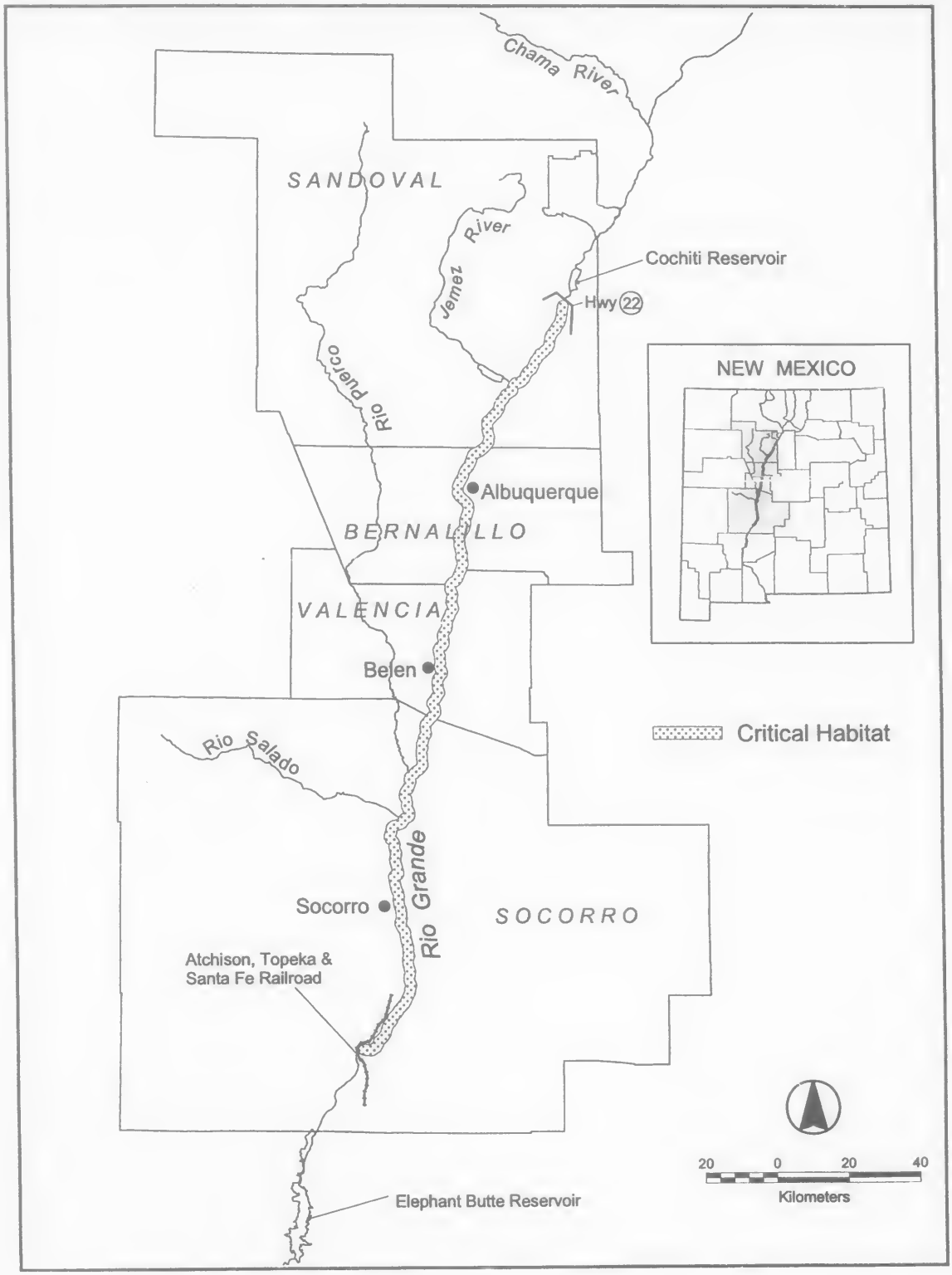
RIO GRANDE SILVERY MINNOW (*Hybognathus Amarus*).

New Mexico: Socorro, Valencia, Bernalillo, and Sandoval Counties. Rio Grande from the downstream side of State highway 22 bridge crossing of the Rio Grande, immediately downstream of Cochiti Dam, NW¼ sec. 17, T. 16N., R. 15 E. of the New Mexico Meridian, extending downstream approximately 163 mi (260 km) to where the Atchison Topeka and Santa Fee Railroad crosses the river near San Marcial, Lat 33°40′50″, long 106°59′30″, Socorro County.

Primary constituent elements for the Rio Grande silvery minnow include stream morphology that supplies sufficient flowing water to provide food and cover needed to sustain all life stages of the species; water of sufficient quality to prevent water stagnation (elevated temperatures, decreased oxygen, carbon dioxide build-up, etc); and water of sufficient quantity to prevent formation of isolated pools that restrict fish movement, foster increased predation by birds and aquatic predators, and congregate pathogens.

BILLING CODE 4310–55–M


Chama River
SANDOVAL
Jemez River
Cochiti Reservoir
Hwy 22
Rio Puerco
NEW MEXICO
Albuquerque
BERNALILLO
VALENCIA
Belen
Critical Habitat
Rio Salado
Rio Grande
Socorro
SOCORRO
Atchison, Topeka &
Santa Fe Railroad
20 0 20 40
Kilometers
Elephant Butte Reservoir

Dated June 22, 1999.

Stephen C. Saunders,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 99–16985 Filed 6–30–99; 10:26 am]

BILLING CODE 4310–55–C

Proposed Rules

Federal Register
Vol. 64, No. 128
Tuesday, July 6, 1999

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 72

RIN 3150–AF98

Reporting Requirements for Nuclear Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend the event reporting requirements for nuclear power reactors: to update the current rules, including reducing or eliminating the reporting burden associated with events of little or no safety significance; and to better align the rules with the NRC's needs for information to carry out its safety mission, including revising reporting requirements based on importance to risk and extending the required reporting times consistent with the time it is needed for prompt NRC action. Also, a draft report, NUREG–1022, Revision 2, is being made available for public comment concurrently with the proposed amendments.

DATES: Submit comments on or before September 20, 1999. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. ATTN: Rulemakings and Adjudications Staff.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. Federal workdays.

Electronic comments may be provided via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). From the home page, select "Rulemaking" from the tool bar at the bottom of the page. The interactive rulemaking website can then be accessed by selecting "Rulemaking Forum." This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received, the transcripts of public meetings held, the draft regulatory analysis and the draft report NUREG–1022, Revision 2 may be examined at the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking web site established by NRC for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Dennis P. Allison, Office of Nuclear Reactor Regulation, Washington, DC 20555–0001, telephone (301) 415–1178, e-mail dpa@nrc.gov.

SUPPLEMENTARY INFORMATION:

Contents

I. Background

Section 50.72 has been in effect, with minor modifications, since 1983. Its essential purpose is "* * * to provide the Commission with immediate reporting of * * * significant events where immediate Commission action to protect the public health and safety may be required or where the Commission needs timely and accurate information to respond to heightened public concern." (48 FR 39039; August 29, 1983).

Section 50.73 has also been in effect, with minor modification, since 1983. Its essential purpose is to identify "* * * the types of reactor events and problems that are believed to be significant and useful to the NRC in its effort to identify and resolve threats to public safety. It is designed to provide the information necessary for engineering studies of operational anomalies and trends and patterns analysis of operational occurrences. The same information can be used for other analytic procedures that will aid in identifying accident precursors." (48 FR 33851; July 26, 1983).

II. Rulemaking Initiation

Experience has shown a need for change in several areas. On July 23, 1998 (63 FR 39522) the NRC published in the **Federal Register** an advance notice of proposed rulemaking (ANPR) to announce a contemplated rulemaking that would modify reporting requirements for nuclear power reactors. Among other things, the ANPR requested public comments on whether the NRC should proceed with rulemaking to modify the event reporting requirements in 10 CFR 50.72, "Immediate notification requirements for operating nuclear power reactors," and 50.73, "Licensee event report system," and several concrete proposals were provided for comment.

A public meeting was held to discuss the ANPR at NRC Headquarters on August 21, 1998. The ANPR was also discussed, along with other topics, at a public meeting on the role of industry in nuclear regulation in Rosemont, Illinois on September 1, 1998. The public comment period on the ANPR closed on September 21, 1998. A comment from the Nuclear Energy Institute (NEI) proposed conducting "table top exercises" early in the development and review process to test key parts of the requirements and guidance for clarity and consistency. That comment was accepted and a third public meeting was held on November 13, 1998 to discuss issues of clarity and consistency in the contemplated approach. Transcripts of these meetings are available for inspection in the NRC Public Document Room or they may be viewed and downloaded electronically via the interactive rulemaking web site established by NRC for this rulemaking, as discussed above under the heading

ADDRESSES. Single copies may be obtained from the contact listed above under the heading **FOR FURTHER INFORMATION CONTACT.**

III. Analysis of Comments

The comment period for the ANPR expired September 21, 1998. Twenty-one comment letters were received, representing comments from sixteen nuclear power plant licensees (utilities), two organizations of utilities, two States and one public interest group. A list of comment letters is provided below. The comment letters expressed support for amending the rules along the general lines of the objectives discussed in the ANPR. Most of the letters also provided specific recommendations for changes to the contemplated amendments discussed in the ANPR. In addition to the written comments received, the ANPR has been the subject of three public meetings as discussed above under the heading BACKGROUND, and comments made at those meetings have also been considered.

The resolution of comments is summarized below. This summary addresses the principal comments (i.e., comments other than those that are: minor or editorial in nature; supportive of the approach described in the ANPR; or applicable to another area or activity outside the scope of sections 50.72 and 50.73).

Comment 1: Several comments recommended amending 10 CFR 50.73 to allow 60 days (instead of the current 30 days) for submittal of Licensee Event Reports (LERs). They indicated that this would allow a more reasonable time to determine the root causes of events and lead to fewer amended reports.

Response: The comments are accepted for the reason stated above. The proposed rule would change the time limit to 60 days.

Comment 2: Two comments suggested a need to establish starting points for reporting time clocks that are clear and not subject to varied interpretations.

Response: The reporting guidelines in this area have been reviewed for clarity. Some editorial clarifications are proposed in section 2.5 of the draft of Revision 2 to NUREG–1022, which is being made available for public comment concurrently with the proposed rule, as discussed below under the heading "Revisions to Reporting Guidelines in NUREG–1022."

Comment 3: Many comments opposed adopting a check the box approach for human performance and other information in LERs (as was proposed in the ANPR, with the objective of reducing reporting burden). They indicated that adopting a check the box approach would result in substantial implementation problems, and recommended continuing to rely on the narrative description which provides adequate information. One comment opposed the idea of a check the box approach on the grounds that it would make LERs more difficult for the general public to understand. A few comments supported the check the box approach.

Response: The intent of the check the box approach was to reduce the effort required in reporting; however, the majority of comments indicate this would not be the case. Accordingly, the proposed rule does not reflect adoption of a check the box approach.

Comment 4: Several comments opposed codifying the current guidelines for reporting human performance information in LERs (i.e., adding the detailed guidelines to the rule, as was proposed in the ANPR). They recommended leaving the rule unchanged in this regard, indicating that sufficient information is being provided under the current rule and guidelines.

Response: The comments are partially accepted. The proposed rule would not codify the reporting guidelines (as proposed in the ANPR) for the reasons stated above.

However, the proposed rule would simplify the requirement. It is not necessary to specify the level of detail provided in the current rule. Accordingly, the amended paragraph would simply require a discussion of the causes and circumstances for any human performance related problems that contributed to the event. Details would continue to be provided in the reporting guidelines, as indicated in section 5.2.1 of the draft of Revision 2 to NUREG–1022. This draft report is being made available for public comment concurrently with the proposed rule, as discussed below under the heading "Revisions to Reporting Guidelines in NUREG–1022."

Comment 5: Several comments opposed codifying a list of specific systems for which actuation must be reported (by naming the systems in 10 CFR 50.72 and 50.73, as was proposed in the ANPR). They indicated that a system's contribution to risk can vary widely from plant to plant, which precludes construction of a valid universal list. They recommended that, instead, actuation be reported only for those systems that are specified to be engineered safety features (ESFs) in the final safety analysis report (FSAR).

Response: The proposed rule would include a list of systems for which actuation would be reported. However, the concern is recognized and public comment will be specifically invited on several alternatives to the proposed rule.

Comment 6: Several comments opposed changing the criteria in 10 CFR 50.72 and 50.73 which require reporting any event or condition that alone could have prevented the fulfillment of the safety function of structures or systems * * *. The change proposed in the ANPR would have substituted the phrase "alone or in combination with other existing conditions" for the word "alone" in this criterion. The comments indicated that this would add confusion, the rule as currently worded is sufficiently clear, and the need to consider other existing plant conditions in evaluating reportability is understood and uniformly implemented. They recommended leaving the rule unchanged in this regard.

Response: The comments are partially accepted. The requirement would not be changed by substituting the phrase "alone or in combination with other existing conditions" for the word "alone" in this criterion (as proposed in the ANPR).

However, the proposed amendments would change the rules by deleting the word "alone," so that they would require reporting "any event or condition that could have prevented fulfillment of the safety function of structures or systems * * *." This would simplify the wording, rather than making it more complicated. It is not intended to change the meaning of the requirement, but to make the meaning more apparent in the wording of the rule. The following points, which are relevant to this question, would continue to be made clear in the reporting guidelines. See section 3.2.7 of the draft of Revision 2 to NUREG–1022, which is being made available for public comment concurrently with the proposed rule, as discussed below under the heading "Revisions to Reporting Guidelines in NUREG–1022."

(1) It is not necessary to assume an additional random single failure in evaluating reportability. (If such an assumption were necessary, inoperability of a single train would generally be reportable under this criterion.)

(2) It is necessary to consider other existing conditions in determining reportability. (For example, if Train A fails at a time when Train B is out of service for maintenance, the event is reportable.)

(3) The event is reportable regardless of whether or not a system was called upon to perform its safety function. (For example, if an emergency core cooling system [ECCS] was incapable of performing its specified safety

functions, the event is reportable even if there was no call for the ECCS function.)

(4) The event is reportable regardless of whether or not a different system was capable of performing the safety function. (For example, if the onsite power system failed, the event is reportable even if the offsite power system was available and capable of performing its safety functions.)

Comment 7: Several comments recommended changing 10 CFR 50.72 and 50.73 to exclude reporting an invalid actuation of an ESF. (An invalid actuation is one that does not result from a plant condition that warrants ESF initiation.)

Response: The comments are partially accepted. The proposed amendments would eliminate the requirement for *telephone* notification of an invalid actuation under 10 CFR 50.72. Invalid actuations are generally less significant than valid actuations because they do not involve plant conditions (e.g., low reactor coolant system pressure) conditions that would warrant system actuation. Instead, they result from other causes such as a dropped electrical lead during testing).

However, the proposed amendments would *not* eliminate the requirement for a *written* report of an invalid actuation under 10 CFR 50.73. There is still a need for reporting of invalid actuations because they are needed to make estimates of equipment reliability parameters, which in turn are needed to support the Commission's move towards risk-informed regulation. This is discussed further in a May 7, 1997 Commission paper, SECY–97–101, "Proposed Rule, 10 CFR 50.76, Reporting Reliability and Availability Information for Risk-significant Systems and Equipment," Attachment 3.

Comment 8: Several comments recommended changing 10 CFR 50.72 and 50.73 to limit certain reports to current events and conditions. That is, they recommended that an event or condition that could have prevented the fulfillment of the safety function of structures or systems * * * be reported:

(1) By telephone under 10 CFR 50.72(b)(2)(iii) only if it currently exists, and

(2) By written LER under 10 CFR 50.73(a)(2)(v) only if it existed within the previous two years.

For a "historical" event or condition of this type (i.e., one which might have been significant at one time but has since been corrected) there is less significance than there is for a current event and, thus, immediate notification under 50.72(b)(2)(iii) is not warranted. With regard to 50.73(a)(2)(v), two years encompasses at least one operating cycle. Considerable resources are expended when it is necessary to search historical records older than this to make past operability determinations, and this is not warranted by the lesser significance of historical events older than two years.

Response: The comments are partially accepted, for the reasons stated above. That is, under the proposed rules, an event or condition that could have prevented the fulfillment of the safety function of structures or systems * * * would be reported by telephone under 10 CFR 50.72(b)(2)(iii) only if it exists at the time of discovery. An event or condition that could have prevented the fulfillment of the safety function of structures or systems * * * would be reported by written LER under 10 CFR 50.73(a)(2)(v) only if it existed within the previous three years.

In addition, although not recommended in the comments, under the proposed rule an operation or condition prohibited by the plant's Technical Specifications would be reported under 50.73(a)(2)(i)(B) only if it existed within the previous three years. For this criterion as well, considerable resources are expended when it is necessary to search historical records older than three years to make past operability determinations, and this is not warranted by the lesser significance of historical events older than three years.

Three years is proposed, rather than two years as suggested in the comments, because the NRC staff trends plant performance indicators over a period of three years to ensure inclusion of periods of both shut down and operation.

Comment 9: Several comments opposed using the term risk-significant (or significant) in the absence of a clear definition.

Response: The term "significant" would be used in two criteria in the proposed rules. In the first criterion, sections 50.72 and 50.73 would require reporting an unanalyzed condition that significantly affects plant safety. In this context the term "significant" would be defined by examples, five of which are discussed below under the heading "Condition that is outside the design basis of the plant." In the second criterion, section 50.73 would require reporting when a component's ability to perform its safety function is significantly degraded and the condition could reasonably be expected to affect other similar components in the plant. Again, the term "significant" would be defined by examples, six of which are discussed below under the heading "Significantly degraded components."

Comment 10: Several comments recommended changing 10 CFR 50.72 and 50.73 to exclude reporting of an unanalyzed condition that significantly compromised plant safety on the basis that it is redundant to other reporting criteria.

Response: The comment is not accepted. Several types of worthwhile reports have been identified that could not readily be captured by other criteria as discussed further below under the heading "Condition that is outside the design basis of the plant."

Comment 11: Several comments recommended amending 10 CFR 50.72 and 50.73 to exclude reporting of a seriously degraded principal safety barrier on the basis that it is redundant to other reporting criteria.

Response: The comments are not accepted. This criterion captures some worthwhile reports that would not be captured by other criteria, such as significant welding or material defects in the primary coolant system. However, some clarifications are proposed in Section 3.2.4 of the draft reporting guidelines, to better indicate which events are serious enough to qualify for reporting under this criterion.

Comment 12: One comment recommended that, with regard to a condition or operation prohibited by the plant's Technical Specifications, reporting should be eliminated for violation of all administrative Technical Specifications.

Response: The comment is partially accepted. The proposed rule would eliminate reporting for Technical Specifications that are administrative in nature. The reporting guidelines would not change. As stated in the current reporting guidelines in NUREG–1022, Revision 1, failure to meet administrative Technical Specifications requirements is reportable only if it results in violations of equipment operability requirements, or had a similar detrimental effect on a licensee's ability to safely operate the plant. For example, operation with less than the required number of people on shift would constitute operation prohibited by the Technical Specifications. However, a change in the plant's organizational structure that has not yet been approved as a Technical Specification change would not. An administrative procedure violation or failure to implement a procedure, such as failure to lock a high radiation area door, that does not have a direct impact on the safe operation of the plant, is generally not reportable under this criterion.

Comment 13: One comment recommended changing 10 CFR 50.73 to require that LERs identify: (1) How many opportunities to detect the problem were missed and (2) corrective actions to prevent future misses.

Response: No changes are proposed. If missed opportunities are identified and are significant to the event, they should be captured by the current requirements to provide a comprehensive description of the event and to describe corrective actions if they are significant to the event.

Comment 14: With regard to design issues, one comment recommended including language in the rules or their statements of considerations encouraging a voluntary report under 10 CFR 50.9 for a newly discovered design issue which is not otherwise reportable at the plant where first discovered (because the affected systems can still perform their specified safety functions) but which might have a significant impact on generic design issues at other plants.

Response: A statement encouraging submittal of voluntary LERs is included in the reporting guidelines. In addition, the guidelines would indicate that any significant degradation that could reasonably be expected to affect multiple similar components in the plant should be reported.

Comment 15: Several comments opposed placing a condition, related to systematic non-compliance, on the elimination of reporting of late surveillance tests (as proposed in the ANPR) under 10 CFR 50.73. The condition would be burdensome because licensees would need to track instances of missed surveillance tests in given time periods.

Response: The proposed rule does not contain this condition. Reporting for the purpose of identifying systematic non-compliance is not needed because NRC resident inspectors routinely review plant problem lists, and thus would be aware of any systematic non-compliance in this area if it occurs.

Comment 16: One comment recommended changing the rules to allow licensees to rely on notifications made to resident inspectors, which could eliminate the need to make a telephone notification via the emergency notification system (ENS) and/or submit a written LER, at least for some events or conditions. They indicated, for example, this should be adequate where the event is a decision to issue a news release.

Response: No changes are proposed. Telephone notifications to the NRC Operations Center, when required, are needed to ensure that the event can be promptly reviewed. This includes notification of the NRC Headquarters Emergency Officers and the Regional Duty Officer and consideration of whether to activate NRC incident response procedures. Written LERs, when required, are needed to ensure that events can be systematically reviewed for safety significance.

Comment 17: Some comments opposed amending 10 CFR 50.73 to require additional information regarding equipment availability for shutdown events (as proposed in the ANPR) to support staff probabilistic risk assessments (PRAs). They indicated that it is rare that sufficient information is not available in an LER.

Response: The proposed rule would require such information. Frequently, when shutdown events are subjected to a probabilistic risk analysis, it is necessary to call the plant to determine the status of systems and equipment. The proposed rule would eliminate much of that need.

Comment 18: Several comments recommended deleting 10 CFR 50.72(b)(2)(i), "Any event *found while the reactor is shut down,* that, had it been found while the reactor was in operation, would have resulted in the nuclear power plant, including its principal safety barriers, being seriously degraded or being in an unanalyzed condition that significantly compromises plant safety." The comments indicated that because the plant would be shutdown, there is no need for immediate NRC action.

Response: The requirement for telephone reporting would not be entirely eliminated because, if a principal safety barrier is significantly degraded or a condition that significantly affects plant safety exists; the event may be significant enough that the NRC would need to initiate actions [such as contacting the plant to better understand the event and/or initiating a special inspection or investigation] within about a day even if the plant is shutdown.

However, in the proposed rule this specific criterion would be combined with 10 CFR 50.72(b)(1)(ii), "Any event or condition *during plant operation* that results in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded or * * *" Also, the term "unanalyzed condition that significantly compromises plant safety" would be deleted. In combination with other changes, this would result in the following criterion for telephone notification "Any event or condition that results in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded."

Comment 19: Some comments recommended that the NRC use enforcement discretion during the rulemaking process to provide early relief with regard to reporting a condition outside the design basis of the plant and/or a late surveillance test (condition or operation prohibited by Technical Specifications).

Response: The current rules will continue to apply until final revised rules are issued and become effective. However in dispositioning any violation, the risk-and safety-significance of the violation will be an important consideration. Establishing an interim enforcement discretion policy would involve the same critical elements as developing the revised rule and guidance including a provision for public comment. This would complicate the rulemaking process, and essentially constitute a prediction of its final outcome, which may or may not turn out to be correct.

Comment 20: Several comment letters opposed the idea of tying enforcement criteria (i.e., violation severity levels) to reporting criteria. They indicated this could have an unintended adverse effect on reporting and the resources consumed because in matching an event with a reporting criterion, a licensee would essentially be forced to make a preliminary determination of severity level.

Response: The comments are not accepted. The proposed changes to the enforcement criteria, are discussed below under the heading "Enforcement."

Comment 21: As requested by the ANPR, a number of comments identified reactor reporting requirements other than sections 50.72 and 50.73 where changes are warranted.

Response: Comments regarding changes to reactor reporting requirements other than sections 50.72 and 50.73 will be addressed in a separate action. A Commission paper on that subject was submitted on January 20, 1999, SECY–99–022, "Rulemaking to Modify Reporting Requirements for Power Reactors" and the Commission issued a Staff Requirements Memorandum on March 19, 1999 directing the staff to proceed with planning and scheduling.

Comment 22: One comment recommended changing the required initial reporting time for some events to "* * * within 8 hours *or by the beginning of the next business day,*" instead of simply specifying "* * * within 8 hours." The comment indicated it does not appear that the

NRC takes action on these events during non-business hours.

Response: The comment is not accepted. The NRC needs these reports in time to call the plant to find out more about the event and/or initiate a special inspection or an investigation, if warranted, within a day. Sometimes these actions are taken during non-business hours.

Comment 23: One comment recommended that an event or condition that could have prevented fulfillment of the safety function of structures or systems. * * * should be reportable only when the time limits of the TS are exceeded. It indicated that if the time limits are not exceeded the event is not significant enough to warrant reporting.

Response: The comment is not accepted. Generally, standard TS require commencement of shutdown within one hour if an important system, such as emergency ac power, is inoperable. However, the stated reason for allowing one hour before commencing the shutdown is to provide time to prepare for an orderly shutdown. Also, the condition might have lasted much longer than one hour before it was discovered. Finally, an event that results in a safety system failure (or inability to perform its function) is generally significant enough to warrant NRC review.

Comment 24: One comment from the State of Ohio recommended that, although rule changes are not necessary, emphasis should be placed on positive notification of State and local agencies of emergency conditions before calling the NRC.

Response: The comment is accepted. It arose from a weakness in the NRC's response to an event at the Davis-Besse plant. Because there were considerable difficulties in establishing telephone communications with the plant at the time of the event, NRC Operations Center personnel requested that the licensee remain on the line and said that the NRC would notify the State. However, the NRC did not do so in a timely manner. Training and procedure changes have been implemented to ensure this type of problem will not reoccur.

Comment 25: One comment letter, from the State of Illinois, stated the following: "In section 50.72 of the advance notice of proposed rulemaking, seven *non-emergency* events listed as (f), are proposed to be reported in eight hours instead of one hour. Of those seven events, six (specifically, (ii), (iii), (iv), (v), (vi), and (vii)) would probably be classified as emergency events under existing emergency plans at an Illinois site * * *. This will cause reporting confusion during an event at a time when clarity is necessary. These six events should all be reported as emergency events, not non-emergency events. EAL thresholds in licensee emergency plans should be required to reflect them clearly. All of these events would affect the State of Illinois' response and our emergency plans. NRC must reconsider the categories of non-emergency events in the context of the current guidance to licensees for classifying EALs to ensure there is a clear distinction between emergency and non-emergency reportable events."

Response: Section 50.72 has been reviewed, and appears to be clear in this regard. It indicates the following:

(1) Any declaration of an Emergency Class is reportable pursuant to 10 CFR 50.72(a)(1)(i) and (a)(3),

(2) The conditions listed in paragraph (b)(1), "One-hour reports," are reportable pursuant to paragraph (b)(1) *if not reported as a declaration of an Emergency Class under paragraph (a),* and

(3) The conditions listed in paragraph (b)(2), "Eight-hour reports. are reportable pursuant to paragraph (b)(2), *if not reported under paragraphs (a) or (b)(1).*

Comment 26: One comment letter, from the State of Illinois, opposed relaxing the required initial reporting time from 4 hours to 8 hours for the following types of events:

(i) Airborne radioactive release that results in concentrations over 20 times allowable levels in an unrestricted area;

(ii) Liquid effluent in excess of 20 times allowable concentrations released to an unrestricted area;

(iii) Radioactively contaminated person transported to an offsite medical facility for treatment;

(iv) News release or other government agency notification related to the health and safety of the public or onsite personnel, or protection of the environment.

The comment further indicated: "It is of paramount importance that those charged with regulating and monitoring the public impact of radiological releases are being kept informed of unplanned releases in a timely manner. Illinois law requires that we perform independent assessments, decide what actions may be necessary to protect the public, and assist in informing the public regarding any radiological risk. Should follow-up action to a release be necessary, then the less time that has elapsed, the better the state is able to respond in a timely and appropriate manner. We oppose any reduction in notification requirements for unplanned radiation releases from a site regardless of the source or quantity.

Timeliness is also important for items of obvious public interest. News of seemingly small events spreads quickly, particularly in local communities around the power plants. Delayed reporting of such events means that we will be unprepared to respond to queries from local officials, or the media, with a resultant loss of public confidence. Therefore, we also oppose any reduction in notification requirements for newsworthy events."

Response: In the interest of simplicity, the proposed amendments would maintain just three basic levels of required reporting times in 10 CFR 50.72 and 50.73 (1 hour, 8 hours, and 60 days). However, the concern is recognized and public comment is specifically invited on the question of whether additional levels should be introduced to better correspond to particular types of events, as discussed below under the heading "Required Initial Reporting Times." Also, if in a final rule the NRC should relax the time limit to 8 hours, a State would not be precluded from obtaining reports earlier than 8 hours.

Comment 27: Two comment letters addressed coordination with States. The comment letter from Florida Power & Light Company stated "The NRC's Public workshop on August 21, 1998, touched on a number of examples where opportunities exist to reduce reporting burdens. An industry representative commented that licensees sometimes have to report the same event to state agencies and the NRC provided one such example. FPL concurs with the recommendation that the time requirement for reporting an event to the NRC and to the state should be consistent wherever practical and possibly in some cases eliminated."

The comment letter from Northeast Nuclear Energy Company stated "Northeast Nuclear Energy Company agrees with extending the non-emergency prompt notifications to eight hours. This would help to eliminate unnecessary reports and retractions. However, it is necessary to have the individual states closely involved with the rule change since they may have requirements that are more restrictive or conflict with the proposed rulemaking. For example, in Connecticut all 10 CFR 50.72 reports require notification of the state within one hour."

Response: The ANPR specifically requested State input. In addition, a letter requesting input was sent to each State. Written comments were received from the State of Ohio and the State of Illinois. In addition, representatives

from several States attended one of the public meetings on the ANPR. The NRC will continue to solicit State input as the rulemaking process proceeds.

Comment 28: One comment recommended eliminating two of the requirements for immediate followup notification during the course of an event, section 50.72(c)(2)(i), the results of ensuing evaluations or assessments of plant conditions, and section 50.72(c)(2)(ii), the effectiveness of response or protective measures taken. The comment indicated that the requirements continue to apply after the event and that they require reporting even if, for example, the result of a further analysis does not change the initial report.

Response: The comment is not accepted. The requirements for followup reporting apply only during the course of the event. Followup reports are needed while the event is ongoing. For example, if an analysis is completed during an ongoing event, and it confirms an earlier estimate of how long it will take to uncover the reactor core if electric power is not restored, that information may very well be useful for the purpose of evaluating the need for protective measures (evacuation).

Comment 29: One comment recommended clarifying the reporting requirements for problems identified by NRC inspectors.

Response: No changes are proposed. The current reporting guidelines include a paragraph making it clear that an event must be reported via telephone notification and/or written LER, as required, *regardless* of whether it had been discussed with NRC staff personnel or was identified by NRC personnel.

Comment 30: Several comments recommended changing the requirements in 50.46(a)(iii)(2) for reporting errors in or corrections to ECCS analyses.

Response: These comments will be addressed in a separate action (along with other comments on reporting requirements other than sections 50.72 and 50.73).

Comment 31: Some comments raised issues regarding plant-specific reporting requirements contained in Technical Specifications (or other parts of the operating license). One suggestion was that 10 CFR 50.72 and 50.73 should be changed to address these issues. Another suggestion was that a Generic Letter be issued indicating that the NRC would be receptive to requests for license amendments to eliminate specific reporting requirements.

Response: No changes are proposed for sections 50.72 and 50.73, which identify generic reporting requirements. It is not feasible or appropriate to address the specific reporting requirements contained in individual operating licenses in this format.

The idea of issuing a generic communication to specific requests for license amendments will be addressed (along with other comments on reporting requirements beyond the scope of sections 50.72 and 50.73) in a separate action.

Comment 32: One comment recommended that in section 50.72(b)(1)(v), the word "offsite" be added before "communications capability" to make it clear that what must be reported is a loss of communications with outside agencies, not internal plant communications systems.

Response: The comment is accepted. In the proposed rule the word "offsite" would be added.

Comment 33: Several comments suggested that the NRC should define its needs relative to the information provided in LERs.

Response: The essential purpose of the LER rule is to identify the types of reactor events and problems that are believed to be significant and useful to the NRC in its effort to identify and resolve threats to public safety. The rule is designed to provide the information necessary for engineering studies of operational anomalies and trends, and patterns analysis of operational occurrences. To this end, the information required in LERs is generally needed to understand the event, its significance, and its causes in order to determine whether generic or plant specific action is needed to preclude recurrence. Some further specific functions are discussed below.

It is necessary to identify and analyze events and conditions that are precursors to potential severe core damage, to discover emerging trends or patterns of potential safety significance, to identify events that are important to safety and their associated safety concerns and root causes, to determine the adequacy of corrective actions taken to address the safety concerns, and to assess the generic applicability of events.

The NRC staff reviews each LER to identify those individual events or generic situations that warrant additional analysis and evaluation. The staff identifies repetitive events and failures and situations where the frequency or the combined significance of reported events may be cause for concern. The NRC staff reviews past operating history for similar events and initiates a generic study, as appropriate, to focus upon the nature, cause, consequences and possible corrective actions for the particular situation or concern.

The NRC staff uses the information reported in LERs in confirming licensing bases, studying potentially generic safety problems, assessing trends and patterns of operational experience, monitoring performance, identifying precursors of more significant events, and providing operational experience to the industry.

The NRC determines whether events meet the criteria for reporting as an Abnormal Occurrence Report to Congress or for reporting to the European Nuclear Energy Agency (NEA).

The information from LERs is widely used within the nuclear industry, both nationally and internationally. The industry's Institute of Nuclear Power Operation (INPO) uses LERs as a basis for providing operational safety experience feedback data to individual utilities through such documents as significant operating experience reports, significant event reports, significant events notifications, and operations and maintenance reminders. U.S. vendors and nuclear steam system suppliers, as well as other countries and international organizations, use LER data as a source of operational experience data.

Comment 34: Some comments indicated that the licensing basis should be defined.

Response: No changes are proposed. The term "licensing basis" is not explicitly used in the event reporting rules or the draft reporting guidelines. It can come into play, via Generic Letter (GL) 91–18, "Information to Licensees Regarding two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and on Operability," in determining what the "specified safety function" of a system is. This relates to whether an event is reportable as an event or condition that could have prevented the fulfillment of the safety function of structures or systems * * * and/or an operation or condition prohibited by the plant's technical specification (TS). However, any unsettled details regarding exactly which commitments are included in the licensing basis (for example because of differences between the definitions in GL 91–18 and 10 CFR 54.3) are not of a nature that would change the determination of whether or not a system is capable of performing its specified safety functions (i.e., operable).

Comment 35: Several comments recommended conducting tabletop exercises (public meetings) early in the drafting process, involving licensees, inspectors, and headquarters personnel to discuss the draft amendments and associated and guidance.

Response: The Commission agrees. The recommended public meeting was held on November 13, 1998.

Comment 36: Several comments recommended conducting a workshop (public meeting) early during the public comment period to discuss the proposed rule and draft guidance.

Response: The Commission agrees. The recommended workshop has been added to the schedule.

Comment 37: Several comments recommended that the reporting guidelines be revised concurrently with the rules.

Response: The Commission agrees. Draft guidelines are being made available for comment concurrent with the proposed rules.

Comment 38: Several comment letters recommended reviewing enforcement criteria at the same time the rule is being developed to ensure consistent application of enforcement to reporting.

Response: The comment is accepted. The Enforcement Policy is being reviewed concurrently with development of the rule.

IV. Discussion

1. Objectives of Proposed Amendments

The purpose of sections 50.72 and 50.73 would remain the same because the basic needs remain the same. The objectives of the proposed amendments would be as follows:

(1) To better align the reporting requirements with the NRC's current reporting needs. An example is extending the required initial reporting times for some events, consistent with the need for timely NRC action. Another example is changing the criteria for reporting system actuations, to obtain reporting that is more consistent with the risk-significance of the systems involved.

(2) To reduce the reporting burden, consistent with the NRC's reporting needs. An example is eliminating the reporting of design and analysis defects and deviations of little or no risk-or safety-significance.

(3) To clarify the reporting requirements where needed. An example is clarifying the criteria for reporting design or analysis defects or deviations.

(4) To maintain consistency with NRC actions to improve integrated plant assessments. For example, reports that are needed in the assessment process should not be eliminated.

2. Section by Section Discussion of Proposed Amendments

Generol requirements [section 50.72(a)(5)]. The requirement to inform the NRC of the type of report being made (i.e., emergency class declared, non-emergency 1-hour report, or non-emergency 8-hour report) would be revised to refer to paragraph (a)(1) instead of referring to paragraph (a)(3) to correct a typographical error.

Required initial reporting times [sections 50.72(a)(5), (b)(1), (b)(2), and sections 50.73(a)(1) and (d)]. In the proposed amendments, declaration of an emergency class would continue to be reported immediately after notification of appropriate State or local agencies not later than 1-hour after declaration. This includes declaration of an Unusual Event, the lowest emergency class.

Deviations from technical specifications authorized pursuant to 10 CFR 50.54(x) would continue to be reported as soon as practical and in all cases within 1 hour of occurrence. These two criteria capture those events where there may be a need for immediate action by the NRC.

Non-emergency events that are reportable by telephone under 10 CFR 50.72 would be reportable as soon as practical and in all cases within 8 hours (instead of within 1 hour or 4 hours as is currently required). This would reduce the burden of rapid reporting, while still capturing those events where there may be a need for the NRC to contact the plant to find out more about the event and/or initiate a special inspection or investigation within about a day.

Written LERs would be due within 60 days after discovery of a reportable event or condition (instead of within 30 days as is currently required). Changing the time limit from 30 days to 60 days does not imply that licensees should take longer than they previously did to develop and implement corrective actions. They should continue to do so on a time scale commensurate with the safety significance of the issue. However, for those cases where it does take longer than thirty days to complete a root cause analysis, this change would result in fewer LERs that require amendment (by submittal of an additional report).

The Performance Indicator (PI) program and the future risk-based performance indicator program provide valued input to regulatory decisions (e.g. Senior Management Meetings). Adding 30 days to the delivery of data supplying these programs would result in the reduction in the currency and value of these indicators to senior managers. With respect to the Accident Sequence Precursor program, the additional 30 days will add a commensurate amount of time to each individual event assessment since Licensee Event Reports (LERs) are the main source of data for these analyses. The delivery date for the annual Accident Sequence Precursor report would also slip accordingly. The NRC staff would have to make more extensive use of Immediate Notifications (10 CFR 50.72) and event followup to compensate in part for the Licensee Event Report (LER) reporting extension.

In the interest of simplicity, the proposed amendments would maintain just three basic levels of required reporting times in 10 CFR 50.72 and 50.73 (1 hour, 8 hours, and 60 days). However public comment is specifically invited on the question of whether additional levels should be introduced to better correspond or particular types of events. For example, 10 CFR 50.72 currently requires reporting within 4 hours for events that involve low levels of radioactive releases, and events related to safety or environmental protection that involve a press release or notification of another government agency. These types of events could be maintained at 4 hours so that information is available on a more timely basis to respond to heightened public concern about such events. In another example, events related to environmental protection are sometimes reportable to another agency, which is the lead agency for the matter, with a different time limit, such as 12 hours. These types of events could be reported to the NRC at approximately the same time as they are reported to the other agency.

Operation or condition prohibited by TS [section 50.73(a)(2)(i)(B)]. The term "during the previous three years" would be added to eliminate written LERs for conditions that have not existed during the previous three years. Such a historical event would now have less significance, and assessing reportability for earlier times can consume considerable resources. For example, assume that a procedure is found to be unclear and, as a result, a question is raised as to whether the plant was ever operated in a prohibited condition. If operation in the prohibited condition is likely, the answer should be reasonably apparent based on the knowledge and experience of the plant's operators and/or a review of operating records for the past three years. The very considerable

effort required to review all records older than three years, in order to rule out the possibility, would not be warranted.

In addition, this criterion would be modified to eliminate reporting if the technical specification is administrative in nature. Violation of administrative technical specifications have generally not been considered to warrant submittal of an LER, and since 1983 when the rule was issued the staff's reporting guidance has excluded almost all cases of such reporting. This change would make the plain wording of the rule consistent with that guidance.

Finally, this criterion would be modified to eliminate reporting if the event consisted solely of a case of a late surveillance test where the oversight is corrected, the test is performed, and the equipment is found to be functional. This type of event has not proven to be significant because the equipment remained functional.

Condition of the nuclear power plant, including its principal safety barriers, being seriously degraded [current sections 50.72(b)(1)(ii) and (b)(2)(i), replaced by new section 50.72(b)(2)(ii), and section 50.73(a)(2)(ii)]. Currently, 10 CFR 50.72(b)(1)(ii) and (b)(2)(i) provide the following distinction: a qualifying event or condition during operation is initially reportable in one hour; a condition discovered while shutdown that would have qualified if it had it been discovered during operation is initially reportable in four hours. The new 10 CFR 50.72(b)(2)(ii) would eliminate the distinction because there would no longer be separate 1-hour and 4-hour categories of non-emergency reports for this criterion. There would only be 8-hour non-emergency reports for this criterion.

Unanalyzed condition that significantly compromises plant safety [sections 50.72(b)(1)(ii)(A) and (b)(2)(i), and section 50.73(a)(2)(ii)(A); replaced by new section 50.72(b)(2)(ii)(B), and section 50.73(a)(2)(ii)(B)]. Currently, 10 CFR 50.72(b)(1)(ii)(A) and (b)(2)(i) provide the following distinction: a qualifying event or condition during operation is initially reportable in one hour; a condition discovered while shutdown that would have qualified if it had it been discovered during operation is initially reportable in four hours. The new 10 CFR 50.72(b)(2)(ii)(B) would eliminate the distinction because there would no longer be separate 1-hour and 4-hour categories of non-emergency reports for this reporting criterion. There would only be 8-hour non-emergency reports for this criterion.

In addition, the new 10 CFR 50.72(b)(2)(ii)(B) and 50.73(a)(2)(ii)(B) would refer to a condition that significantly affects plant safety rather than a condition that significantly compromises plant safety. This is an editorial change intended to better reflect the nature of the criterion.

Condition that is outside the design basis of the plant [current Section 50.72(b)(2)(ii)(B) and section 50.73(a)(2)(ii)(B)]. This criterion would be deleted. However, a condition outside the design basis of the plant would still be reported if it is significant enough to qualify under one or more of the following criteria.

If a design or analysis defect or deviation (or any other event or condition) is significant enough that, as a result, a structure or system would not be capable of performing its specified safety functions, the condition would be reportable under sections 50.72(b)(2)(v) and 50.73(a)(2)(v) [i.e., an event or condition that could have prevented the fulfillment of the safety function of structures or systems that are needed to: (A) Shut down * * *].

For example, during testing of 480 volt safety-related breakers, one breaker would not trip electrically. The cause was a loose connection, due to a lug that was too large for a connecting wire. Other safety related breakers did not malfunction, but they had the same mismatch. The event would be reportable because the incompatible lugs and wires could have caused one or more safety systems to fail to perform their specified safety function(s).

Another example is as follows. An annual inspection indicated that some bearings were wiped or cracked on both emergency diesel generators (EDGs). Although the EDGs were running prior to the inspection, the event would be reportable because there was reasonable doubt about the ability of the EDGs to operate for an extended period of time, as required.

If a design or analysis defect or deviation (or any other event or condition) is significant enough that, as a result, one train of a multiple train system controlled by the plant's TS is not capable of performing its specified safety functions, and thus the train is inoperable longer than allowed by the TS, the condition would be reportable under section 50.73(a)(2)(i)(B) [i.e., an operation or condition prohibited by TS].

For example, if it is found that an exciter panel for one EDG lacks appropriate seismic restraints because of a design, analysis or construction inadequacy and, as a result, there is reasonable doubt about the EDG's ability to perform its specified safety functions during and after a Safe Shutdown Earthquake (SSE) the event would be reportable.

Or, for example, if it is found that a loss of offsite power could cause a loss of instrument air and, as a result, there is reasonable doubt about the ability of one train of the auxiliary feedwater system to perform its specified safety functions for a certain postulated steam line breaks, the event would be reportable.

If a condition outside the design basis of the plant (or any other unanalyzed condition) is significant enough that, as a result, plant safety is significantly affected, the condition would be reportable under sections 50.72(b)(2)(ii)(B) and 50.73(a)(2)(ii)(B) [i.e., an unanalyzed condition that significantly affects plant safety].

As was previously indicated in the 1983 Statements of Considerations for 10 CFR 50.72 and 50.73, with regard to an unanalyzed condition that significantly compromises plant safety, "The Commission recognizes that the licensee may use engineering judgment and experience to determine whether an unanalyzed condition existed. It is not intended that this paragraph apply to minor variations in individual parameters, or to problems concerning single pieces of equipment. For example, at any time, one or more safety-related components may be out of service due to testing, maintenance, or a fault that has not yet been repaired. Any trivial single failure or minor error in performing surveillance tests could produce a situation in which two or more often unrelated, safety-grade components are out-of-service. Technically, this is an unanalyzed condition. However, these events should be reported only if they involve functionally related components or if they significantly compromise plant safety." [1]

"When applying engineering judgment, and there is a doubt regarding whether to report or not, the Commission's policy is that licensees should make the report." [2]

"For example, small voids in systems designed to remove heat from the reactor core which have been previously shown through analysis not to be safety significant need not be reported. However, the accumulation of voids that could inhibit the ability to adequately remove heat from the reactor core, particularly under natural circulation conditions, would constitute an

[1] 48 FR 39042, August 29, 1983 and 48 FR 33856, July 26, 1983.

[2] 48 FR 39042, August 29, 1983.

unanalyzed condition and would be reportable."[3]

"In addition, voiding in instrument lines that results in an erroneous indication causing the operator to misunderstand the true condition of the plant is also an unanalyzed condition and should be reported."[4]

Furthermore, beyond the examples given in 1983, examples of reportable events would include discovery that a system required to meet the single failure criterion does not do so.

In another example, if fire barriers are found to be missing, such that the required degree of separation for redundant safe shutdown trains is lacking, the event would be reportable. On the other hand, if a fire wrap, to which the licensee has committed, is missing from a safe shutdown train but another safe shutdown train is available in a different fire area, protected such that the required separation for safe shutdown trains is still provided, the event would not be reportable.

If a condition outside the design basis of the plant (or any other event or condition) is significant enough that, as a result, a principal safety barrier is seriously degraded, it would be reportable under sections 50.72(b)(2)(ii)(A) and 50.73(a)(2)(ii)(A) [i.e., any event or condition that results in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded]. This reporting criterion applies to material (e.g., metallurgical or chemical) problems that cause abnormal degradation of or stress upon the principal safety barriers (i.e., the fuel cladding, reactor coolant system pressure boundary, or the containment) such as:

(i) Fuel cladding failures in the reactor, or in the storage pool, that exceed expected values, or that are unique or widespread, or that are caused by unexpected factors.

(ii) Welding or material defects in the primary coolant system which cannot be found acceptable under ASME Section XI, IWB–3600, "Analytical Evaluation of Flaws" or ASME Section XI, Table IWB–3410–1, "Acceptance Standards."

(iii) Steam generator tube degradation in the following circumstances:

(1) The severity of degradation corresponds to failure to maintain structural safety factors. The structural safety factors implicit in the licensing basis are those described in Regulatory Guide 1.121. These safety factors include a margin of 3.0 against gross failure or burst under normal plant operating conditions, including startup, operation in the power range, hot standby, and cooldown, and all anticipated transients that are included in the plant design specification.

(2) The calculated potential primary-to-secondary leak rate is not consistent with the plant licensing basis. The licensing basis accident analyses typically assume [for accidents other than a steam generator tube rupture (SGTR)] a 1 gpm primary-to-secondary leak rate concurrent with the accident to demonstrate that the radiological consequences satisfy 10 CFR Part 100 and GDC–19. In these instances, degradation which may lead to leakage above 1 gpm under accident conditions, other than a SGTR, would exceed the threshold. For some units, the staff has approved accident leakages above 1 gpm subject to updating the licensing basis accident analyses to reflect this amount of leakage and subject to risk implications being acceptable.[5]

(iv) Low temperature over pressure transients where the pressure-temperature relationship violates pressure-temperature limits derived from Appendix G to 10 CFR Part 50 (e.g., TS pressure-temperature curves).

(v) Loss of containment function or integrity, including containment leak rate tests where the total containment as-found, minimum-pathway leak rate exceeds the limiting condition for operation (LCO) in the facility's TS.[6]

Finally, a condition outside the design basis of the plant (or any other event or condition) would be reportable if a component is in a degraded or non-conforming condition such that the ability of a component to perform its specified safety function is significantly degraded and the condition could reasonably be expected to apply to other similar components in the plant. This new criterion is contained in section 50.73(a)(2)(ii)(C) as discussed below.

As a result, these proposed amendments would focus the reporting of conditions outside the design basis of the plant to the safety significant issues while reducing the number of reports under the current rules in order to minimize the reporting of less significant issues. In particular, the proposed amendments will help ensure that significant safety problems that could reasonably be expected to be applicable to similar components at the specific plant or at other plants will be identified and addressed although the specific licensee might determine that the system or structure remained operable, or that technical specification requirements were met. The proposed rules will provide that, consistent with the NRC's effort to obtain information for engineering studies of operational anomalies and trends and patterns analysis of operational occurrences, the NRC would be able to monitor the capability of safety-related components to perform their design-basis functions.

Significantly degraded component(s) [section 50.73(a)(2)(ii)(C)]. This new reporting criterion would require reporting if a component is in a degraded or non-conforming condition such that the ability of the component to perform its specified safety function is significantly degraded and the condition could reasonably be expected to apply to other similar components in the plant. It would be added to ensure that design basis or other discrepancies would continue to be reported if the capability to perform a specified safety function is significantly degraded and the condition has generic implications. On the other hand, if the degradations are not significant or the condition does not have generic implications, reporting would not be required under this criterion.

For example, at one plant several normally open valves in the low pressure safety injection system were routinely closed to support quarterly surveillance testing of the system. In reviewing the design basis and associated calculations, it was determined that the capability of the valves to open in the event of a large break loss-of-coolant accident (LOCA) combined with degraded grid voltage during a surveillance test was degraded. The licensee concluded that the valves would still be able to reopen under the postulated conditions and considered them operable. However, that conclusion could not be supported using the conservative standards established by Generic Letter 89–10. Pending determination of final corrective action, administrative procedures were implemented to preclude closing the valves. The event would be reportable because the

[3] 48 FR 39042, August 29, 1983 and 48 FR 33856, July 26, 1983.

[4] 48 FR 39042, August 29, 1983 and 48 FR 33856, July 26, 1983.

[5] In addition, if the extent of degradation is great (i.e., if many tubes are degraded or defective), a telephone notification and a written LER should be provided. The plant's TS typically provide specific requirements indicating when reporting is required (based on the number of tubes degraded or defective in terms of "percent inspected") and those requirements should be used to determine reportability.

[6] The LCO typically employs La, which is defined in Appendix J to 10 CFR Part 50 as the maximum allowable containment leak rate at pressure Pa, the calculated peak containment internal pressure related to the design basis accident. Minimum-pathway leak rate means the minimum leak rate that can be attributed to a penetration leakage path; for example, the smaller of either the inboard or outboard valve's individual leak rates.

capability of a component to perform its specified safety functions was significantly degraded and the same condition could reasonably be expected to apply to other similar components.

In another example, during a routine periodic inspection, jumper wires in the valve operators for three valves were found contaminated with grease which was leaking from the limit switch gear box. The cause was overfilling of the grease box, as a result of following a generic maintenance procedure. The leakage resulted in contamination and degradation of the electrical components which were not qualified for exposure to grease. This could result in valve malfunction(s). The conditions were corrected and the maintenance procedures were changed. The event would be reportable because the capability of several similar components to perform their specified safety functions could be significantly degraded.

In a further example, while processing calculations it was determined that four motor operated valves within the reactor building were located below the accident flood level and were not qualified for that condition. Pending replacement with qualified equipment, the licensee determined that three of the valves had sufficiently short opening time that their safety function would be completed before they were submerged. The fourth valve was normally open and could remain open. After flooding, valve position indication could be lost, but valve position could be established indirectly using process parameter indications. The event would be reportable because the capability of several similar components to perform their specified safety functions could be significantly degraded.

An example of an event that would not be reportable is as follows. The motor on a motor-operated valve (MOV) burned out after repeated cycling for testing. This event would not be reportable because it is a single component failure, and while there might be similar MOVs in the plant, there is not a reasonable basis to think that other MOVs would be affected by this same condition. On the other hand, if several MOVs had been repeatedly cycled and then after some extended period of time one of the MOVs was found inoperable or significantly degraded because of that cycling, then the condition would be reportable.

Minor switch adjustments on MOVs would not be reported where they do not significantly affect the ability of the MOV to carry out its design-basis function and the cause of the adjustments is not a generic concern.

At one plant the switch on the radio transmitter for the auxiliary building crane was used to handle a spent fuel cask while two protective features had been defeated by wiring errors. A new radio control transmitter had been procured and placed in service. Because the new controller was wired differently than the old one, the drum overspeed protection and spent fuel pool roof slot limit switch were inadvertently defeated. While the crane was found to be outside its design basis, this condition would not be reportable because the switch wiring deficiency could not reasonably be expected to affect any other components at the plant.

Condition not covered by the plant's operating and emergency procedures [section 50.72(b)(2)(ii)(C), and section 50.73(a)(2)(ii)(C)]. This criterion would be deleted because it does not result in worthwhile reports aside from those that would be captured by other reporting criteria such as:

(1) An unanalyzed condition that significantly affects plant safety;

(2) An event or condition that could have prevented the fulfillment of the safety function of structures or systems that are needed to: shut down the reactor and maintain it in a safe shutdown condition; remove residual heat; control the release of radioactive material; or mitigate the consequences of an accident;

(3) An event or condition that results in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded;

(4) An operation or condition prohibited by the plant's TS;

(5) An event or condition that results in actuation of any of the systems listed in the rules, as amended;

(6) An event that poses an actual threat to the safety of the nuclear power plant or significantly hampers site personnel in the performance of duties necessary for the safe operation of the nuclear power plant.

Manual or automatic actuation of any engineered safety feature ESF [current sections 50.72(b)(1)(iv) and (b)(2)(ii), replaced by new sections 50.72(b)(2)(iv), and section 50.73(a)(2)(iv)]. Currently, sections 50.72(b)(1)(iv) and (b)(2)(ii) provide the following distinction: an event that results or should have resulted in ECCS discharge into the reactor coolant system is initially reportable within 1 hour; other ESF actuations are initially reportable within 4 hours. The new 10 CFR 50.72(b)(2)(iv) would eliminate this distinction because there would no longer be separate 1-hour and 4-hour categories of non-emergency reports for this criterion. There would only be 8-hour non-emergency reports for this criterion.

The new section 50.72(b)(2)(iv) would eliminate telephone reporting for invalid automatic actuation or unintentional manual actuation. These events are not significant and thus telephone reporting is not needed. However, the proposed amendments would not eliminate the requirement for a written report of an invalid actuation under 10 CFR 50.73. There is still a need for reporting of these events because they are used in making estimates of equipment reliability parameters, which in turn are needed to support the Commission's move towards risk-informed regulation. (See SECY–97–101, May 7, 1997, "Proposed Rule, 10 CFR 50.76, Reporting Reliability and Availability Information for Risk-significant Systems and Equipment," Attachment 3).

The term "any engineered safety feature (ESF), including the reactor protection system (RPS)," which currently defines the systems for which actuation must be reported in section 50.72(b)(2)(iv) and section 50.73(a)(2)(iv), would be replaced by a specific list of systems. The current definition has led to confusion and variability in reporting because there are varying definitions of what constitutes an ESF. For example, at some plants systems that are known to have high risk significance, such as emergency ac power, auxiliary feedwater, and reactor core isolation cooling are not considered ESFs. Furthermore, in many cases systems with much lower levels of risk significance, such as control room ventilation systems, are considered to be ESFs.

In the proposed amendments actuation would be reportable for the specific systems named in sections 50.72(b)(2)(iv) and 50.73(a)(2)(iv). This would result in *consistent* reporting of events that result in actuation of these *highly risk-significant systems.* Reasonable consistency in reporting actuation of highly risk-significant systems is needed to support estimating equipment reliability parameters, which is important to several aspects of the move towards more risk-informed regulation, including more risk-informed monitoring of plant performance.

The specific list of systems in the proposed rule would also eliminate reporting for events of lesser significance, such as actuation of control room ventilation systems.

The specific list of systems in the proposed rule is similar to the list of systems currently provided in the reporting guidelines in NUREG–1022,

Revision 1, with some minor revisions. It is based on systems for which actuation is frequently reported, and systems with relatively high risk-significance based on a sampling of plant-specific PRAs (see Draft Regulatory Guide DG-1046, "Guidelines for Reporting Reliability and Availability Information for Risk-Significant Systems and Equipment in Nuclear Power Plants," particularly Tables C–1 through C–5).

This proposal to list the systems in the rule is controversial and public comment is specifically invited in this area. In particular, three principal alternatives to the proposed rule have been identified for comment:

(1) Maintain the status quo. Under this alternative, the rule would continue to require reporting for actuation of "any ESF." The guidance would continue to indicate that reporting should include *as a minimum* the system on the list.

(2) Require use of a plant-specific, risk-informed list. Under this alternative, the list of systems would be risk-informed, and plant-specific. Licensees would develop the list based on existing PRA analyses, judgment, and specific plant design. No list would be provided in the rule.

(3) Return to the pre-1998 situation (i.e., before publication of the reporting guidance in NUREG–1022, Revision 1). Under this alternative, the rule would continue to require reporting for actuation of "any ESF." The guidance would indicate that reporting should include those systems identified as ESF's for each particular plant (e.g., in the FSAR).

With regard to this third alternative, it may be noted that this approach has the advantage of clarity and simplicity. There would be no need to develop a new list, and this is the practice that was followed from 1984–1997 without creating major problems. However, the lists of ESFs are not based on risk-significance. For example, emergency diesel generators (EDGs) are known to be highly risk-significant; however, at six plants, the EDGs are not considered to be ESFs. Similarly, auxiliary feedwater (AFW), systems at pressurized water reactors (PWRs) are known to be highly risk-significant; however, at a number of plants these systems are not considered to be ESFs. Also, reactor core isolation cooling (RCIC) systems at boiling water reactors (BWRs) are known to be highly risk significant; however, at a number of plants these systems are not considered to be ESFs. In contrast, at many plants, systems with much lower levels of risk significance, such as control room ventilation systems, are considered to be ESFs.

*Event or condition that could have prevented fulfillment of the safety function of structures or systems that * * * [current sections 50.72(b)(1)(ii) and (b)(2)(i), replaced by new sections 50.72(b)(2)(v) and (vi), and sections 50.73(a)(2)(v) and (vi)]* The phrase "event or condition that alone could have prevented the fulfillment of the safety function of structures or systems.* * *" would be clarified by deleting the word "alone". This clarifies the requirements by more clearly reflecting the principle that it is necessary to consider other existing plant conditions in determining the reportability of an event or condition under this criterion. For example, if one train of a two train system is incapable of performing its safety function for one reason, and the other train is incapable of performing its safety function for a different reason, the event is reportable.

The term "at the time of discovery" would be added to section 50.72(b)(2)(v) to eliminate telephone notification for a condition that no longer exists, or no longer has an effect on required safety functions. For example, it might be discovered that some time ago both trains of a two train system were incapable of performing their safety function, but the condition was subsequently corrected and no longer exists. In another example, while the plant is shutdown, it might be discovered that during a previous period of operation a system was incapable of performing its safety function, but the system is not currently required to be operable. These events are considered significant, and an LER would be required, but there would be no need for telephone notification.

The phrase "occurring within three years of the date of discovery" would be added to section 50.73(a)(2)(v) to eliminate written LERs for conditions that have not existed during the previous three years. Such a historical event would now have less significance, and assessing reportability for earlier times can consume considerable resources. For example, assume that during a design review a discrepancy is found that affects the ability of a system to perform its safety function in a given specific configuration. If it is likely that the safety function could have been prevented, the answer should be reasonably apparent based on the knowledge and experience of the plant's operators and/or a review of operating records for the past three years. The very considerable effort required to review all records older than three years, in order to rule out the possibility, would not be warranted.

A new paragraph, section 50.72(b)(2)(vi) would be added to clarify section 50.72. The new paragraph would explicitly state that telephone reporting is not required under section 50.72(b)(2)(v) for single failures if redundant equipment in the same system was operable and available to perform the required safety function. That is, although *one train* of a system may be incapable of performing its safety function, reporting is not required under this criterion if that *system* is still capable of performing the safety function. This is the same principle that is currently stated explicitly in section 50.73(a)(2)(vi) with regard to written LERs.

Major loss of emergency assessment capability, offsite response capability, or communication capability [current section 50.72(b)(2)(v), new section 50.72(b)(2)(xiii)]. The new section would be modified by adding the word "offsite" in front of the term "communications capability" to make it clear that the requirement does not apply to internal plant communication systems.

*Airborne radioactive release * * * and liquid effluent release * * * [section 50.72(b)(2)(viii) and sections 50.73(a)(2)(viii) and 50.73(a)(2)(ix)].* The statement indicating reporting under section 50.72(b)(2)(viii) satisfies the requirements of section 20.2202 would be removed because it would not be correct. For example, some events captured by section 20.2202 would not be captured by section 50.72(b)(2)(viii). Also, the statement indicating that reporting under section 50.73(a)(2)(viii) satisfies the requirements of section 20.2203(a)(3) would be deleted because it would not be correct. Some events captured by section 20.2203(a)(3) would not be captured by section 50.73(a)(2)(viii).

The proposed extension of reporting deadlines to 8 hours in section 50.72 and 60 days in section 50.73 raises questions about whether similar changes should be made to Parts 20, 30, 40, 70, 72 and 76. The merits of such changes, which may vary for different types of licensees, will be addressed in separate actions.

Contents of LERs [sections 50.73(b)(2)(ii)(F) and 50.73(b)(2)(ii)(J)]. Paragraph (F) would be revised to correct the address of the NRC Library.

Paragraph (J) currently requires that the narrative section include the following specific information as appropriate for the particular event:

"(1) Operator actions that affected the course of the event, including operator

errors, procedural deficiencies, or both, that contributed to the event.

(2) For each personnel error, the licensee shall discuss:

(i) Whether the error was a cognitive error (e.g., failure to recognize the actual plant condition, failure to realize which systems should be functioning, failure to recognize the true nature of the event) or a procedural error;

(ii) Whether the error was contrary to an approved procedure, was a direct result of an error in an approved procedure, or was associated with an activity or task that was not covered by an approved procedure;

(iii) Any unusual characteristics of the work location (e.g., heat, noise) that directly contributed to the error; and

(iv) The type of personnel involved (i.e., contractor personnel, utility-licensed operator, utility non-licensed operator, other utility personnel)."

The proposed amendment would change section 50.73(b)(2)(ii)(J) to simply require that the licensee discuss the causes and circumstances for each human performance related problem that contributed to the event. It is not necessary to specify the level of detail provided in the current rule, which is more appropriate for guidance. Details would continue to be provided in the reporting guidelines, as indicated in section 5.2.1 of the draft of Revision 2 to NUREG–1022. This draft report is being made available for public comment concurrently with the proposed rule, as discussed below under the heading "Revisions to Reporting Guidelines in NUREG–1022."

Spent fuel storage cask problems [current sections 50.72(b)(2)(vii) and 72.16(a)(1), (a)(2), (b) and (c)]. Section 50.72(b)(2)(vii) would be deleted because these reporting criteria are redundant to the reporting criteria contained in sections 72.216(a)(1), (a)(2), and (b). Repetition of the same reporting criteria in different sections of the rules adds unnecessary complexity and is inconsistent with the current practice in other areas, such as reporting of safeguards events as required by section 73.71.

Also, a conforming amendment would be made to section 72.216. This is necessary because section 72.216(a) currently relies on section 50.72(b)(2)(vii), which would be deleted, to establish the time limit for initial notification. The amended section 72.216 would refer to sections 72.74 and 72.75 for initial notification and followup reporting requirements.

Assessment of Safety Consequences [section 50.73(b)(3)]. This section currently requires that an LER include an assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event. It would be modified by adding a requirement to also include the status of components and systems that "are included in emergency or operating procedures and could have been used to recover from the event in case of an additional failure in the systems actually used for recovery." This information is needed to better support the NRC's assessment of the risk-significance of reported events.

Exemptions [section 50.73(f)]. This provision would be deleted because the exemption provisions in section 50.12 provide for granting of exemptions as warranted. Thus, including another, section-specific exemption provision in section 50.73 adds unnecessary complexity to the rules.

3. Revisions to Reporting Guidelines in NUREG–1022

A draft report, NUREG–1022, Revision 2, "Event Reporting Guidelines, 10 CFR 50.72 and 50.73," is being made available for public comment concurrently with the proposed amendments to 10 CFR 50.72 and 50.73. The draft report is available for inspection in the NRC Public Document Room or it may be viewed and downloaded electronically via the interactive rulemaking web site established by NRC for this rulemaking, as discussed above under the heading **ADDRESSES.** Single copies may be obtained from the contact listed above under the heading "For Further Information Contact." In the draft report, guidance that is considered to be new or different is a meaningful way, relative to that provided in NUREG–1022, Revision 1, is indicated by redlining the appropriate text.

4. Reactor Oversight

The NRC is developing revisions to process for oversight of operating reactors, including inspection, assessment and enforcement processes. In connection with this effort, the NRC has considered the kinds of event reports that would be eliminated by the proposed rules and believes that the changes would not have a deleterious effect on the oversight process. Public comment is invited on whether or not this is the case. In particular, it is requested that if any examples to the contrary are known they be identified.

5. Reporting of Historical Problems

As discussed above, provisions would be added to sections 50.73(a)(2)(i)(B) and 50.73(a)(2)(v) to eliminate reporting of a condition or event that did not occur within three years of the date of discovery. (See the response to Comment 8, the discussion under the heading "Operation or condition prohibited by TS," and the discussion under the heading "Event or condition that could have prevented fulfillment of the safety function of structures or systems that * * *") Public comment is invited on whether such historical events and conditions should be reported (rather than being excluded from reporting, as proposed). Public comment is also invited on whether the three year exclusion of such historical events and conditions should be extended to all written reports required by section 50.73(a) (rather than being limited to these two specific reporting criteria, as proposed).

6. Reporting of Component Problems

As discussed above, a new reporting criterion would be added to require reporting if a component is in a degraded or non-conforming condition such that the ability of the component to perform its specified safety function is significantly degraded and the condition could reasonably be expected to apply to other similar components in the plant. (See the response to Comment 14 and the discussion under the heading "Significantly degraded component(s) [section 50.73(a)(2)(ii)(C)].") Public comment is invited on whether this proposed new criterion would accomplish its stated purpose—to ensure that design basis or other discrepancies would continue to be reported if the capability to perform a specified safety function is significantly degraded and the condition has generic implications. Public comment is also invited on whether the proposed new criterion would be subject to varying interpretations by licensees and inspectors.

7. Enforcement

The NRC intends to modify its existing enforcement policy in connection with the proposed amendments to sections 50.72 and 50.73. The philosophy of the proposed changes is to base the significance of the reporting violation on: (1) The reporting requirement, which will require reporting within time frames more commensurate with the significance of the underlying issues than the current rule; and (2) the impact that a late report may have on the ability of the NRC to

fulfill its obligations of fully understanding issues that are required to be reported in order to accomplish its public health and safety mission, which in many cases involves reacting to reportable issues or events. As such, the NRC intends to revise the Enforcement Policy, NUREG–1600, Rev. 1 as follows:

(1) Appendix B, Supplement I.C—Examples of Severity Level III violations.

(a) Example 14 would be revised to read as follows—A failure to provide the required one hour telephone notification of an emergency action taken pursuant to 10 CFR 50.54(x).

(b) An additional example would be added that would read as follows—A failure to provide a required 1-hour or 8-hour non-emergency telephone notification pursuant to 10 CFR 50.72.

(c) An additional example would be added that would read as follows—A late 8-hour notification that substantially impacts agency response.

(2) Appendix B, Supplement I.D—Examples of Severity Level IV violations.

(a) Example 4, would be revised to read as follows—A failure to provide a required 60-day written LER pursuant to 10 CFR 50.73.

These changes in the Enforcement Policy would be consistent with the overall objective of the rule change of better aligning the reporting requirements with the NRC's reporting needs. The Enforcement Policy changes would correlate the Severity Level of the infractions with the relative importance of the information needed by the NRC.

Section IV.D of the Enforcement Policy provides that the Severity Level of an untimely report may be reduced depending on the individual circumstances. In deciding whether the Severity Level should be reduced for an untimely 1-hour or 8-hour non-emergency report the impact that the failure to report had on any agency response would be considered. For example, if a delayed 8-hour reportable event impacted the timing of a followup inspection that was deemed necessary, then the Severity Level would not normally be reduced. Similarly, a late notification that delayed the NRC's ability to perform an engineering analysis of a condition to determine if additional regulatory action was necessary would generally not be considered for disposition at a reduced Severity Level. Additionally, late reports filed in cases where the NRC had to prompt the licensee to report would generally not be subject to disposition at reduced Severity Level and the Severity Level for failure to submit a timely Licensee Event Report (LER) would not be reduced to a minor violation.

In accordance with Appendix C of the Enforcement Policy, " Interim Enforcement Policy for Severity Level IV Violations Involving Activities of Power Reactor Licensees," the failure to file a 60-day LER would normally be dispositioned as a Non-Cited Violation (NCV). Repetitive failures to make LER reports indicative of a licensee's inability to recognize reportable conditions, such that it is not likely that the NRC will be made aware of operational, design and configuration issues deemed reportable pursuant to 10 CFR 50.73, will be considered for categorization at Severity Level III. This disposition may be warranted since such licensee performance impacts the ability of the NRC to fulfill its regulatory obligations.

8. Electronic Reporting

The NRC is currently planning to implement an electronic document management and reporting program, known as the Agency-wide Document Access and Management System (ADAMS), that will in general provide for electronic submittal of many types of reports, including LERs. Accordingly, no separate rulemaking effort to provide for electronic submittal of LERs is contemplated.

9. Schedule

The current schedule is as follows:

08/99—Conduct public workshop to discuss proposed rule and draft reporting guidelines (separate notice with workshop details will be published later this month).
August 5, 1999—Public comments due to OMB
September 7, 1999—Receive OMB approval
September 20, 1999—Public comments due to NRC
10/01/99—Provide final rule and guidelines to NRC staff rulemaking group
11/05/99—Provide final rule and guidelines to the formal concurrence chain
01/14/00—Provide final rule and guidelines to CRGR and ACRS
02/11/00—Complete briefings of CRGR and ACRS
03/10/00—Provide final rule and guidelines to Commission
04/07/00—Publish final rule and guidelines

10. State Input

Many States (Agreement States and Non-Agreement States) have agreements with power reactors to inform the States of plant issues. State reporting requirements are frequently triggered by NRC reporting requirements. Accordingly, the NRC seeks State comment on issues related to the proposed amendments to power reactor reporting requirements.

Plain Language

The President's Memorandum dated June 1, 1998, entitled, "Plain Language in Government Writing," directed that the Federal government's writing be in plain language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed above.

V. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described in categorical exclusion 10 CFR 51.22(c)(3)(iii). Therefore neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

VI. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to information collection and reporting requirements such as those contained in the proposed rule. Therefore, a backfit analysis has not been prepared. However, as discussed below, the NRC has prepared a regulatory analysis for the proposed rule, which examines the costs and benefits of the proposed requirements in this rule. The Commission regards the regulatory analysis as a disciplined process for assessing information collection and reporting requirements to determine that the burden imposed is justified in light of the potential safety significance of the information to be collected.

VII. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room or it may be viewed and downloaded electronically via the interactive rulemaking web site established by NRC for this rulemaking, as discussed above under the heading **ADDRESSES.** Single copies may be obtained from the contact listed above under the heading "For Further Information Contact."

The Commission requests public comment on this draft analysis. Comments on the draft analysis may be

submitted to the NRC as discussed above under the heading **ADDRESSES.**

VIII. Paperwork Reduction Act Statement

This proposed rule would amend information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The public reporting burden for the currently existing reporting requirements in 10 CFR 50.72 and 50.73 is estimated to average about 790 hours per response (i.e., per commercial nuclear power reactor per year) including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. It is estimated that the proposed amendments would impose a one time implementation burden of about 200 hours per reactor, after which there would be a recurring annual burden reduction of about 200 hours per reactor per year. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection contained in the proposed rule and on the following issues:

Is the proposed information collection necessary for the proper performance of the NRC, including whether the information will have practical utility?

Is the estimate of burden accurate?

Is there a way to enhance the quality, utility, and clarity of the information to be collected?

How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Information and Records Management Branch (T–5 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or by Internet electronic mail to BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150AF98), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by August 5, 1999. Comments received after this date will be considered if it is practical to do so, but consideration cannot be ensured for comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

IX. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant econonic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

X. Proposed Amendments

List of Subjects

10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire prevention, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

10 CFR Part 72

Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, and Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR part 50 and 10 CFR part 72.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(D.D.), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. Section 50.72 is amended by revising paragraphs (a) and (b) to read as follows:

§ 50.72 Immediate notification requirements for operating nuclear power reactors.

(a) *General requirements.*[7] (1) Each nuclear power reactor licensee licensed under § 50.21(b) or § 50.22 of this part shall notify the NRC Operations Center via the Emergency Notification System of:

(i) The declaration of any of the Emergency Classes specified in the licensee's approved Emergency Plan; [8] or

(ii) Of those non-Emergency events specified in paragraph (b) of this section.

(2) If the Emergency Notification System is inoperative, the licensee shall make the required notifications via commercial telephone service, other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Operations Center.[9, 10]

(3) The licensee shall notify the NRC immediately after notification of the appropriate State or local agencies and not later than one hour after the time the licensee declares one of the Emergency Classes.

(4) The licensee shall activate the Emergency Response Data System (ERDS) [11] as soon as possible but not later than one hour after declaring an emergency class of alert, site area emergency, or general emergency. The ERDS may also be activated by the licensee during emergency drills or exercises if the licensee's computer

[7] Other requirements for immediate notification of the NRC by licensed operating nuclear power reactors are contained elsewhere in this chapter, in particular §§ 20.1906, 20.2202, 50.36, 72.74, 72.75, and 73.71.

[8] These Emergency Classes are addressed in Appendix E of this part.

[9] Commercial telephone number of the NRC Operations Center is (301) 816–5100.

[10] [Reserved]

[11] Requirements for ERDS are addressed in Appendix E, Section VI.

system has the capability to transmit the exercise data.

(5) When making a report under paragraph (a)(1) of this section, the licensee shall identify:

(i) The Emergency Class declared; or

(ii) Either paragraph (b)(1), "One-Hour Report," or paragraph (b)(2) "Eight-Hour Report," as the paragraph of this section requiring notification of the Non-Emergency Event.

(b) *Non-emergency events*—(1) *One-Hour reports.* If not reported as a declaration of the Emergency Class under paragraph (a) of this section, the licensee shall notify the NRC as soon as practical and in all cases within one hour of the occurrence of any deviation from the plant's Technical Specifications authorized pursuant to § 50.54(x) of this part.

(2) *Eight-hour reports.* If not reported under paragraphs (a) or (b)(1) of this section, the licensee shall notify the NRC as soon as practical and in all cases within eight hours of the occurrence of any of the following:

(i) The initiation of any nuclear plant shutdown required by the plant's Technical Specifications.

(ii) Any event or condition that results in:

(A) The condition of the nuclear power plant, including its principal safety barriers, being seriously degraded; or

(B) The nuclear power plant being in an unanalyzed condition that significantly affects plant safety.

(iii) Any natural phenomenon or other external condition that poses an actual threat to the safety of the nuclear power plant or significantly hampers site personnel in the performance of duties necessary for the safe operation of the plant.

(iv)(A) Any event or condition that results in intentional manual actuation or valid automatic actuation of any of the systems listed in paragraph (b)(2)(iv)(B) of this section, except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(B) The systems to which the requirements of paragraph (b)(2)(iv)(A) of this section apply are:

(1) Reactor protection system (reactor scram, reactor trip).

(2) Emergency core cooling systems (ECCS) for pressurized water reactors (PWRs) including: high-head, intermediate-head, and low-head injection systems and the low pressure injection function of residual (decay) heat removal systems.

(3) ECCS for boiling water reactors (BWRs) including: high-pressure and low-pressure core spray systems; high-pressure coolant injection system; feedwater coolant injection system; low pressure injection function of the residual heat removal system; and automatic depressurization system.

(4) BWR isolation condenser system and reactor core isolation cooling system.

(5) PWR auxiliary feedwater system.

(6) Containment systems including: containment and reactor vessel isolation systems (general containment isolation signals affecting numerous valves and main steam isolation valve [MSIV] closure signals in BWRs) and containment heat removal and depressurization systems, including containment spray and fan cooler systems.

(7) Emergency ac electrical power systems, including: emergency diesel generators (EDGs) and their associated support systems; hydroelectric facilities used in lieu of EDGs at the Oconee Station; safety related gas turbine generators; BWR dedicated Division 3 EDGs and their associated support systems; and station blackout diesel generators (and black-start gas turbines that serve a similar purpose) which are started from the control room and included in the plant's operating and emergency procedures.

(8) Anticipated transient without scram (ATWS) mitigating systems.

(9) Service water (standby emergency service water systems that do not normally run).

(v) Any event or condition that at the time of discovery could have prevented the fulfillment of the safety function of structures or systems that are needed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material, or

(D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (b)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant equipment in the same system was operable and available to perform the required safety function.

(vii) [Reserved]

(viii)(A) Any airborne radioactive release that, when averaged over a time period of 1 hour, results in concentrations in an unrestricted area that exceed 20 times the applicable concentration specified in appendix B to part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time of 1 hour, exceeds 20 times the applicable concentration specified in appendix B to part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(ix) Any event that poses an actual threat to the safety of the nuclear power plant or significantly hampers site personnel in the performance of duties necessary for the safe operation of the nuclear power plant including fires, toxic gas releases, or radioactive releases.

(x) Any event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

(xi) Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made. Such an event may include an onsite fatality or inadvertent release of radioactively contaminated materials.

(xii) Any event that results in a major loss of emergency assessment capability, offsite response capability, or offsite communications capability (e.g., significant portion of control room indication, Emergency Notification System, or offsite notification system).

* * * * *

3. Section 50.73 is amended by revising sections (a), (b)(2)(ii)(F), (b)(2)(ii)(J), (b)(3), (d), and (e) and by removing and reserving paragraph (f) to read as follows:

§ 50.73 Licensee event report system.

(a) *Reportable events.* (1) The holder of an operating license for a nuclear power plant (licensee) shall submit a Licensee Event Report (LER) for any event of the type described in this paragraph within 60 days after the discovery of the event. Unless otherwise specified in this section, the licensee shall report an event regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

(2) The licensee shall report:

(i)(A) The completion of any nuclear plant shutdown required by the plant's Technical Specifications.

(B) Any operation or condition occurring within three years of the date of discovery which was prohibited by the plant's Technical Specifications, except when:

(*1*) The technical specification is administrative in nature; or

(*2*) The event consists solely of a case of a late surveillance test where the oversight is corrected, the test is performed, and the equipment is found to be capable of performing its specified safety functions.

(C) Any deviation from the plant's Technical Specifications authorized pursuant to § 50.54(x) of this part.

(ii) Any event or condition that resulted in:

(A) The condition of the nuclear power plant, including its principal safety barriers, being seriously degraded;

(B) The nuclear power plant being in an unanalyzed condition that significantly affects plant safety; or

(C) A component being in a degraded or non-conforming condition such that the ability of the component to perform its specified safety function is significantly degraded and the condition could reasonably be expected to affect other similar components in the plant.

(iii) Any natural phenomenon or other external condition that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant.

(iv)(A) Any event or condition that resulted in manual or automatic actuation of any of the systems listed in paragraph (a)(2)(iv)(B) of this section, except when:

(*1*) The actuation resulted from and was part of a pre-planned sequence during testing or reactor operation; or

(*2*) The actuation was invalid and;

(*i*) Occurred while the system was properly removed from service; or

(*ii*) Occurred after the safety function had been already completed.

(B) The systems to which the requirements of paragraph (a)(2)(iv)(A) of this section apply are:

(*1*) Reactor protection system (reactor scram, reactor trip).

(*2*) Emergency core cooling systems (ECCS) for pressurized water reactors (PWRs) including: high-head, intermediate-head, and low-head injection systems and the low pressure injection function of residual (decay) heat removal systems.

(*3*) ECCS for boiling water reactors (BWRs) including: high-pressure and low-pressure core spray systems; high-pressure coolant injection system; feedwater coolant injection system; low pressure injection function of the residual heat removal system; and automatic depressurization system.

(*4*) BWR isolation condenser system and reactor core isolation cooling system.

(*5*) PWR auxiliary feedwater system.

(*6*) Containment systems including: containment and reactor vessel isolation systems (general containment isolation signals affecting numerous valves and main steam isolation valve [MSIV] closure signals in BWRs) and containment heat removal and depressurization systems, including containment spray and fan cooler systems.

(*7*) Emergency ac electrical power systems, including: emergency diesel generators (EDGs) and their associated support systems; hydroelectric facilities used in lieu of EDGs at the Oconee Station; safety related gas turbine generators; BWR dedicated Division 3 EDGs and their associated support systems; and station blackout diesel generators (and black-start gas turbines that serve a similar purpose) which are started from the control room and included in the plant's operating and emergency procedures.

(*8*) Anticipated transient without scram (ATWS) mitigating systems.

(*9*) Service water (standby emergency service water systems that do not normally run).

(*v*) Any event or condition occurring within three years of the date of discovery that could have prevented the fulfillment of the safety function of structures or systems that are needed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant equipment in the same system was operable and available to perform the required safety function.

(vii) Any event where a single cause or condition caused at least one independent train or channel to become inoperable in multiple systems or two independent trains or channels to become inoperable in a single system designed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(viii)(A) Any airborne radioactive release that, when averaged over a time period of 1 hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeded 20 times the applicable concentration limits specified in appendix B to part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time period of 1 hour, exceeds 20 times the applicable concentrations specified in appendix B to part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(ix) Any event that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant including fires, toxic gas releases, or radioactive releases.

(b) * * *

(2) * * *

(ii) * * *

(F)(*1*) The Energy Industry Identification System component function identifier and system name of each component or system referred to in the LER.

(*i*) The Energy Industry Identification System is defined in: IEEE Std 803–1983 (May 16, 1983) Recommended Practice for Unique Identification in Power Plants and Related Facilities—Principles and Definitions.

(*ii*) IEEE Std 803–1983 has been approved for incorporation by reference by the Director of the Federal Register.

(*2*) A notice of any changes made to the material incorporated by reference will be published in the **Federal Register**. Copies may be obtained from the Institute of Electrical and Electronics Engineers, 345 East 47th Street, New York, NY 10017. IEEE Std 803–1983 is available for inspection at the NRC's Technical Library, which is located in the Two White Flint North building, 11545 Rockville Pike, Rockville, Maryland; and at the Office of the Federal Register, 1100 L Street, NW, Washington, DC.

* * * * *

(J) For each human performance related problem that contributed to the event, the licensee shall discuss the cause(s) and circumstances.

* * * * *

(3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of systems or components that:

(i) Could have performed the same function as the components and systems that failed during the event, or

(ii) Are included in emergency or operating procedures and could have been used to recover from the event in case of an additional failure in the systems actually used for recovery.

* * * * *

(d) *Submission of reports.* Licensee Event Reports must be prepared on Form NRC 366 and submitted within 60 days of discovery of a reportable event or situation to the U.S. Nuclear Regulatory Commission, as specified in § 50.4.

(e) *Report legibility.* The reports and copies that licensees are required to submit to the Commission under the provisions of this section must be of sufficient quality to permit legible reproduction and micrographic processing.

(f) [Reserved]

* * * * *

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

4. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224, (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

5. Section 72.216 is revised to read as follows:

§ 72.216 Reports.

(a) [Reserved]

(b) [Reserved]

(c) The general licensee shall make initial and written reports in accordance with §§ 72.74 and 72.75.

Dated at Rockville, Maryland, this 25th day of June, 1999.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99–16934 Filed 7–2–99; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–CE–67–AD]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company 300 and 400 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 75–23–08 R5, which currently requires repetitively inspecting and replacing or repairing the exhaust system on certain Cessna Aircraft Company (Cessna) 300 and 400 series airplanes. The proposed AD would replace the inspections and replacements that are required by AD 75–23–08 R5 with inspections and replacements containing new simplified procedures for all 300 and 400 series airplanes (models affected by the current AD plus additional models). The proposed AD would also revise the inspection intervals and would require replacing certain unserviceable parts and removing the exhaust system for detailed inspections at regular intervals. The proposed AD is the result of numerous incidents and accidents relating to the exhaust systems on Cessna 300 and 400 series airplanes dating from the middle 1970's to the present, including six incidents since issuance of AD 75–23–08 R5 where exhaust problems were cited. The actions specified by the proposed AD are intended to detect and correct cracks and corrosion in the exhaust system, which could result in exhaust system failure and a possible uncontrollable in-flight fire with pilot and/or passenger injury.

DATES: Comments must be received on or before August 9, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–CE–67–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

FOR FURTHER INFORMATION CONTACT: Paul O. Pendleton, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4143; facsimile: (316) 946–4407.

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 should identify the Rules Docket number and be submitted in triplicate to the address specified above. The FAA believes that the proposed regulation may have a significant economic impact on a substantial number of small businesses. Due to the urgent nature of the safety issues addressed, the FAA has been unable to complete a preliminary regulatory flexibility analysis prior to issuance of the NPRM. A final regulatory flexibility analysis will be completed before, or within 180 days of issuance of, the final rule. To assist in this analysis, the FAA is particularly interested in receiving information on the impact of the proposed rule on small businesses and suggested alternative methods of compliance that reduce or eliminate such impacts. 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 that summarizes 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 No. 97–CE–67–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, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–CE–67–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

AD 75–23–08 R5, Amendment 39–5451, currently requires repetitively inspecting, using visual methods, the exhaust system on certain Cessna 300 and 400 series airplanes; and repairing or replacing any unserviceable parts.

Cessna and the FAA performed extensive investigation and found the following possible causes and effects of these exhaust problems:

—Significant vibration between the beam-mounted engine and the firewall-mounted turbocharger;
—Leaking exhaust gases, which can cause fuel line failure because the fuel lines behind the firewall overheat and rupture. (Most of these fuel lines cannot be isolated or shut-off);
—Reduced structural strength of the engine mount beams and canted bulkheads as a result of exposure to high heat, which could compromise the engine installation; and
—Structural failure of the wing or loss of flight control that results from an in-flight fire.

The FAA issued AD 75–23–08 and five subsequent revisions to this AD, including the current one referenced above, as an attempt to manage these problems through repetitive visual inspections.

Actions Since Issuance of Previous Rule

In the 20 plus years since the issuance of AD 75–23–08, failures of exhaust systems on Cessna 300 and 400 series airplanes have continued to occur and have contributed to fatalities. The FAA, the National Transportation Safety Board (NTSB), and Cessna have conducted numerous tests and analysis on the exhaust system configurations in an attempt to resolve the repeated problems and to alleviate these failures.

The FAA and the NTSB have issued several safety recommendations to provide guidance on how to alleviate problems with the exhaust systems on Cessna 300 and 400 series airplanes. From these recommendations, the FAA has developed new service information (included as an Appendix to this AD) and Cessna has revised the maintenance and service manuals. The FAA believes that this new information should help to reduce the confusion of the requirements in the current action and simplify the procedures.

A recent fatal accident has occurred involving a Cessna Model 421B airplane. While not implicated in the cause of the accident, the FAA and the NTSB have determined that the exhaust system on the accident airplane was in a condition of imminent catastrophic failure. The airplane records indicate that the exhaust system inspection and replacement requirements of AD 75–23–08 R5 had been accomplished.

The FAA's Determination

After examining the circumstances and reviewing all available information related to the incidents described above, including the referenced service information, the FAA has determined that AD action should be taken to detect and correct cracks and corrosion in the exhaust system, which could result in exhaust system failure and a possible uncontrollable in-flight fire. Exposure to these conditions could cause injury to the pilot and passengers during flight.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Cessna 300 and 400 series airplanes of the same type design, the FAA is proposing an AD to supersede AD 75–23–08 R5. The proposed AD would replace the inspections and replacements that are required by AD 75–23–08 R5 with inspections and replacements containing new simplified procedures for all 300 and 400 series airplanes (models affected by the current AD plus additional models). The proposed AD would also revise the inspection intervals and would require replacing certain unserviceable parts and removing the exhaust system for detailed inspections at regular intervals. Provisions of the proposed AD include:

—Prohibiting patch-type repairs; and
—Removing the exhaust system and sending it to a designated facility for metallic identification, airworthiness determinations, and repair or replacement of any unserviceable parts.

Service Information

In the future, Cessna may develop service information or additional maintenance and/or service manual revisions to address this issue. The FAA will issue alternative methods of compliance to this AD if the procedures are deemed acceptable to address the unsafe condition specified in the proposed AD.

Cost Impact

The FAA estimates that 6,500 airplanes in the U.S. registry would be affected by the proposed AD. The cost of the proposed inspections would be as follows at an average labor rate of approximately $60 per hour. The cost of any necessary repair depends on the extent of the rework and replacement needed based on the results of the proposed inspections.

—The proposed repetitive 50-hour time-in-service (TIS) visual inspections of the exhaust system would take approximately 3 workhours to accomplish, with a labor cost of $180 per airplane for each inspection;
—The proposed repetitive 100-hour TIS visual inspections of the removed tailpipes would take approximately 1 workhour per tailpipe to accomplish, with a labor cost of $120 per airplane for each proposed inspection;
—The proposed inspection of the engine beams and canted bulkheads, as a result of damage to the tailpipes, would take approximately 3 workhours to accomplish, with a labor cost of $180 per airplane;
—The proposed inspection of the fuel tubing behind the firewall, as a result of damage to the tailpipes, engine beams, and canted bulkheads, would take approximately 16 workhours to accomplish, with a labor cost of $960 per airplane;
—The proposed replacement of the fuel tubing, if necessary, would take approximately 30 workhours to accomplish, with a labor cost of $1,800 per airplane;
—The proposed 500-hour TIS proposed requirement of removing and shipping the exhaust system to an approved facility would take approximately 8 workhours, with a labor cost of $480. The cost of shipping the exhaust system to the facility and the inspections by the facility is estimated at $500;
—The proposed repetitive pressure test is estimated to take 1 workhour, with a labor cost of $60 per airplane; and
—The proposed V-band clamp replacement is estimated to take 1 workhour, with a labor cost of $60 per airplane.

The total cost impact on the U.S. operators for the proposed initial inspections is estimated to be

$28,210,000, or $4,340 per airplane. The maximum expense for full exhaust parts replacement is estimated to be approximately $60,000 per airplane. These figures do not take into the account the costs of any repetitive inspections or repairs or replacements that would be necessary if the FAA adopted the proposed rule. The FAA has no way of determining the number of repetitive inspections an owner/operator will incur over the life of the airplane, or the extent of the repairs and replacements that may be necessary for any affected airplane.

Compliance Time of This AD

Certain repetitive inspections of the proposed AD are presented in both calendar time and hours time-in-service (TIS). The unsafe condition specified in the proposed AD is a result of the stress cracking and/or corrosion that results over time. Stress corrosion starts as a result of high local stress incurred through operation of the affected part (the exhaust systems). Corrosion can then develop regardless of whether the airplane is in operation. The cracks may not be noticed initially as a result of the stress loads, but could then progress as a result of corrosion. The stress incurred during flight operations (while in-flight) or temperature changes (either while in-flight or on the ground) could then cause rapid crack growth. In order to assure that these stress corrosion cracks do not go undetected, a compliance time of specific hours TIS and calendar time (whichever occurs first) is proposed.

Regulatory Impact

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 action (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) if promulgated, may have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA is currently conducting a Regulatory Flexibility Determination and Analysis and has considered alternatives to the proposed AD that could minimize the impact on small entities.

After careful consideration, the FAA determined that AD action is the best course of action to address the unsafe condition specified in this document; and (2) the situation does not warrant waiting for the completion of the Regulatory Flexibility Determination and Analysis before issuing the NPRM. When completed, a copy of the Regulatory Flexibility Determination and Analysis will be placed in the Docket file and can be obtained at the address specified in 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. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Airworthiness Directive (AD) 75–23–08 R5, Amendment 39–5451, and by adding a new AD to read as follows:

Cessna Aircraft Company: Docket No. 97–CE–67–AD; Supersedes AD 75–23–08 R5, Amendment 39–5451.

Applicability: Models T310P, T310Q, T310R, 320, 320A, 320B, 320C, 320D, 320E, 320F, 320–1, 335, 340, 340A, 321 (Navy OE–2), 401, 401A, 401B, 402, 402A, 402B, 402C, 404, 411, 411A, 414, 414A, 421, 421A, 421B, and 421C airplanes, all serial numbers, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (k) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated in the compliance table in Figure 1 of this AD, unless already accomplished.

To detect and correct cracks and corrosion in the exhaust system, which could result in exhaust system failure and a possible uncontrollable in-flight fire with pilot and/or passenger injury, accomplish the following:

(a) The following paragraphs present the type of individuals who have the authority to accomplish the actions of this AD:

(1) *Repairs:* Required to be accomplished at an FAA-approved repair facility.

(2) *Replacements:* Required to be accomplished in accordance with the appropriate Cessna Service Manual and must be accomplished by a person holding a currently effective mechanic certificate with both an airframe and powerplant (A&P) rating or by an individual authorized to represent an FAA-approved repair station.

(3) *Visual inspections except for paragraphs (f) and (i) of this AD:* Required to be accomplished by a person holding a currently effective mechanic certificate with both an airframe and powerplant (A&P) rating.

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Figure 1 of Docket No. 97-CE-67-AD
Compliance Table

Letters in ( ) correspond with AD paragraphs	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	Throughout the AD
Actions of AD 9*--****	*Visually inspect the exhaust system.*	*Remove the tailpipes and visually inspect for any crack, corrosion, hole, or distortion.*	*Visually inspect the outboard engine beams and canted bulkheads.*	*Perform the inspection and pressure test of the exhaust system.*	*Remove the exhaust system from the slip joints aft to all turbo-charger components in accordance with paragraph (f) of this AD.*	*Replace the V-band clamps.*	*Disassemble and inspect the slip joint for freedom of movement, and if it is seized or frozen, replace the part.*	*Remove the exhaust system from the slip joints aft to all turbo-charger components*	*If any damage is found on any component or part, repair or replace the damaged component or part in accordance with this AD.*
Compliance Time for Airplanes With Inconel Exhaust Systems	Within the next 100 hours time-in-service (TIS) after the effective date of this AD, and thereafter at intervals not to exceed 100 hours TIS.	Not required.	Within the next 100 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 500 hours TIS.	Not required.	Within the next 500 hours TIS after the effective date of this AD or within the next 2 years after the effective date of this AD, whichever occurs first.	Within the next 500 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 500 hours TIS.	Within the next 500 hours TIS, and thereafter at intervals not to exceed 5 years.	Within 2,200 hours TIS after the inspection required in paragraph (f) of this AD, and thereafter at intervals not to exceed 2,200 hours TIS.	Prior to further flight after damage is found.
Compliance Time for Airplanes With Stainless Steel or Mixed Exhaust Systems	Within the next 50 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 50 hours TIS or 6 calendar months, whichever occurs first.	Within the next 100 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 100 hours TIS (see paragraph (c)(3) in the body of this AD).	Within the next 100 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 500 hours TIS.	Within the next 100 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 100 hours TIS or 12 calendar months, whichever occurs first.	Within the next 500 hours TIS after the effective date of this AD or within the next 2 years after the effective date of this AD, whichever occurs first.	Within the next 500 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 500 hours TIS.	Within the next 500 hours TIS after the effective date of this AD, and thereafter at intervals not to exceed 5 years.	Within 2,200 hours TIS after the inspection required in paragraph (f) of this AD, and thereafter at intervals not to exceed 2,200 hours TIS.	Prior to further flight after damage is found.

(b) At the compliance time specified in Figure 1 of this AD, visually inspect the exhaust system for burned areas, cracks, or looseness. If any area of the exhaust system shows damage as defined in the Appendix of this AD, prior to further flight, repair or replace the damaged part.

(c) At the compliance time specified in Figure 1 of this AD, remove the tailpipes and visually inspect for cracks, corrosion, holes, or distortion.

(1) If no crack, corrosion, hole, or distortion is found, continue to visually inspect at intervals indicated in Figure 1 of this AD.

(2) If a crack, corrosion, hole, or distortion is found during any inspection, prior to further flight, repair or replace the tailpipe.

(3) When a new tailpipe is installed after the effective date of this AD, terminate the 100-hour time-in-service (TIS) repetitive inspections required as specified in Figure 1 of this AD until the accumulation of 500 hours TIS or 5 years from the installation date, whichever occurs first, at which time continue the 100-hour TIS inspection intervals.

(d) At the compliance time specified in Figure 1 of this AD, visually inspect the outboard engine beam (adjacent to the tailpipe) and the canted bulkheads for signs of distress, chafing, corrosion, or cracking. Even though some airplanes may have stainless steel engine beams, carefully inspect the areas of contact between the engine beam and canted bulkhead for corrosion.

(1) If damage to the engine beams is found or there is evidence of overheating on the firewall, prior to further flight, replace the firewall and the aluminum fuel lines behind the firewall. Stainless steel fuel lines are available from the Cessna Aircraft Company. Replacement of the fuel lines behind the firewall may require removing and replacing the firewall or accomplishing major repair of the firewall.

(2) Prior to further flight, repair any distress, chafing, corrosion, or cracking on the engine beams or canted bulkheads in accordance with data provided by any individual or facility that is authorized by the FAA to perform the necessary repairs or provide the FAA-approved data to authorized personnel for repair of these items.

(e) At the compliance time specified in Figure 1 of this AD, inspect the exhaust system and perform a pressure test in accordance with the Appendix of this AD. If any condition as specified in the Appendix of this AD is found, prior to further flight, repair or replace the affected parts.

(f) At the compliance time specified in Figure 1 of this AD, remove the exhaust system from the slip joints and aft to all turbocharger-attached components and send to an FAA-approved manufacturing and repair facility that is authorized by the FAA to perform material and condition determinations, and prior to further flight, accomplish any necessary repairs on these items.

Note 2: The following repair facilities have been approved as of the effective date of this AD. A current list of FAA-approved facilities can be obtained from the FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Wichita, Kansas 67209; Attention: Paul O. Pendleton, Aerospace Engineer; telephone: (316) 946–4143; facsimile: (316) 946–4407:

Wall Colmony Corp., 4700 S.E. 59th St., Oklahoma City, OK 73135, (405) 672–1361

Knisley Welding Inc., 3450 Swetzer Road, Loomis, CA 95650, (916) 652–5891

Heliarc Welding Service, 3965 Newport St., 73135 Denver, CO 80207–73135, (303) 672–1361

Note 3: The FAA-approved manufacturing and repair facilities will perform the following and provide information to be utilized for future actions required by this AD:

- Determine the airworthiness of the exhaust system parts;
- Measure for the minimum acceptable material thickness of .025 inch;
- Determine the airworthiness of previous repairs (multi-seam welds and patch-type welds are not considered airworthy);
- Repair or replace all unserviceable parts (no multi-seam or patch-type weld repairs are permitted);
- Determine the material type of the exhaust system (i.e., Inconel or stainless steel); and
- Stamp the material type with an "I" for Inconel or "SS" for stainless steel, the name of the facility making the determination, and the date on the exhaust system.

(g) At the compliance time specified in Figure 1 of this AD, replace all V-band clamps per the appropriate Cessna Service Manual.

(h) At the compliance time specified in Figure 1 of this AD, disassemble and visually inspect the slip joint for freedom of motion. If the slip joint is seized or frozen, prior to further flight, replace the slip joint.

(i) At the compliance time specified in Figure 1 of this AD, remove the exhaust system from the slip joints and aft to all turbo-charger attached components, and send to any FAA-approved exhaust repair facility. The FAA-approved exhaust repair facility will inspect this portion of the exhaust system for serviceable condition and make any necessary repairs to these items. No patch-type or multi-seam weld repairs are permitted.

(j) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished. Isolation of the fuel cross feed lines behind the firewall may be required.

(k) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, 1801 Airport Road, Room 100, Wichita, Kansas 67209.

(1) The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita Aircraft Certification Office.

(2) Alternative methods of compliance approved in accordance with AD 75–23–08 R5 are not considered approved as alternative methods of compliance for this AD.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita Aircraft Certification Office.

(l) Information related to this AD may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(m) This amendment supersedes AD 75–23–08 R5, Amendment 39–5451.

Appendix to Docket No. 97–CE–67–AD—Visual Inspection

(a) Cleaning

In order to properly inspect the exhaust system, components must be clean and free of oil, grease, etc. If required, clean as follows:

(1) Spray engine exhaust components with a suitable solvent (such as Stoddard Solvent), allow to drain, and wipe dry with a clean cloth.

WARNING NEVER USE HIGHLY FLAMMABLE SOLVENTS ON ENGINE EXHAUST SYSTEMS. NEVER USE A WIRE BRUSH OR ABRASIVES TO CLEAN EXHAUST SYSTEMS OR MARK ON THE SYSTEM WITH LEAD PENCILS.

(2) Remove the heat shields from the turbocharger in accordance with the heat shield removal procedures in the appropriate Cessna Aircraft Service Manual.

(3) Remove shields around the exhaust bellows or slip joints, multi-segment "V" band clamps at joints, and other items that might hinder the inspection of the system. Removal of the "V" band clamps may not be necessary.

(4) Using crocus cloth, polish any suspect surfaces to verify that no cracks or pinholes exist in the material. Replace or repair any part where cracks or pinholes exist.

(b) Visual Inspection of Complete System

Note 1. Conduct this inspection when the engine is cool.

(1) Visually inspect exhaust stacks for burned areas, cracks, bulges, and looseness. Make sure the attach bolts are properly torqued, in accordance with the appropriate Cessna Aircraft Service Manual.

Note 2. During this inspection, pay special attention to the condition of the bellows and welded areas along the seams; the welded areas around the bellows; and the welded seams around the exhaust system components.

(2) Visually inspect the flexible connection between the waste-gate and overboard duct (when applicable) for cracks and security.

(3) Visually inspect the exhaust joint springs for correct compression. If the joint is disturbed or if the springs are obviously loose or frozen, proceed with the following inspection (see Figure 1 of this Appendix).

(i) Before removal of the exhaust joint springs, measure the installed length of each spring, and replace the springs compressed to less than .45 inch.

(ii) Remove all the springs and measure the free length. Replace any spring having a free length of less than .57 inch.

Note 3. Add AN960–10 washers under the head of the joint bolts as required to obtain the correct dimension. During installation, the joint bolts should be tightened gradually and spring length checked frequently to prevent over-compression of the springs.

(iii) Reinstall the springs and measure the installed length. The length must be .51 inch (+.00, −.03 inch).

(4) If installed, visually inspect the slip joint(s) for bulges beyond the normal manufacturing irregularities of .03 inches and/or cracks. If any bulges and/or cracks are present, replace the bulged or cracked slip joint(s). (Refer to the appropriate Cessna Aircraft Service Manual) (See Figure 2 of this Appendix).

(c) Inspection of the Multi-Segment "V" Band Clamp(s) (Between Engine and Turbocharger)

(1) Using crocus cloth, clean the outer band of the multi-segment "V" band clamp(s). Pay particular attention to the spot weld area on the clamp(s).

(2) With the clamp(s) properly torqued, progress to the following actions:

(i) Visually inspect the outer band in the area of the spot weld for cracks (see Figure 3 of this Appendix). If cracks are found, replace the clamp(s) with new multi-segment "V" band clamp(s).

(ii) Visually inspect the corner radii of the clamp inner segments for cracks (see Figure 3 of this Appendix). This inspection requires careful use of artificial light and inspection mirrors.

(iii) Visually inspect the flatness of the outer band, especially within 2 inches of the spot welded tabs that retain the T-bolt fastener. This can be done by placing a straight edge across the flat part of the outer band as shown in Figure 4 of this Appendix, then check the gap between the straight edge and the outer band. This gap should be less than 0.062 inch. If deformation exceeds the 0.062-inch limit, replace the clamp(s) with new multi-segment clamp(s). (See Figure 3 of this Appendix). See Cessna maintenance manual(s) and revisions for correct installation procedures.

(iv) Visually inspect the one-piece "V" band clamp (overboard exhaust to turbocharger) with a light and mirror, in the area of the clamp surfaces adjacent to the intersection of the "V" apex and bolt clips, and the entire length of the "V" apex of the clamp for signs of cracks or fractures. If cracks or fractures are visible, replace the clamp (see Figure 5 of this Appendix). See Cessna service manual(s) and revisions for correct installation procedures

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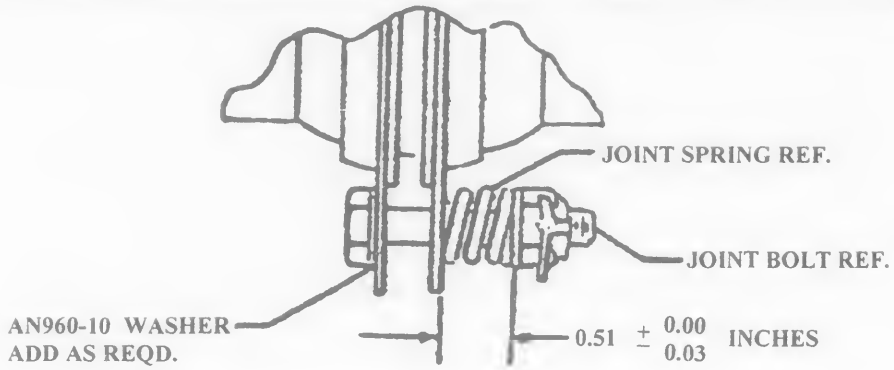


Typical Exhaust Joint Spring Installation

FIGURE 1 to the Appendix

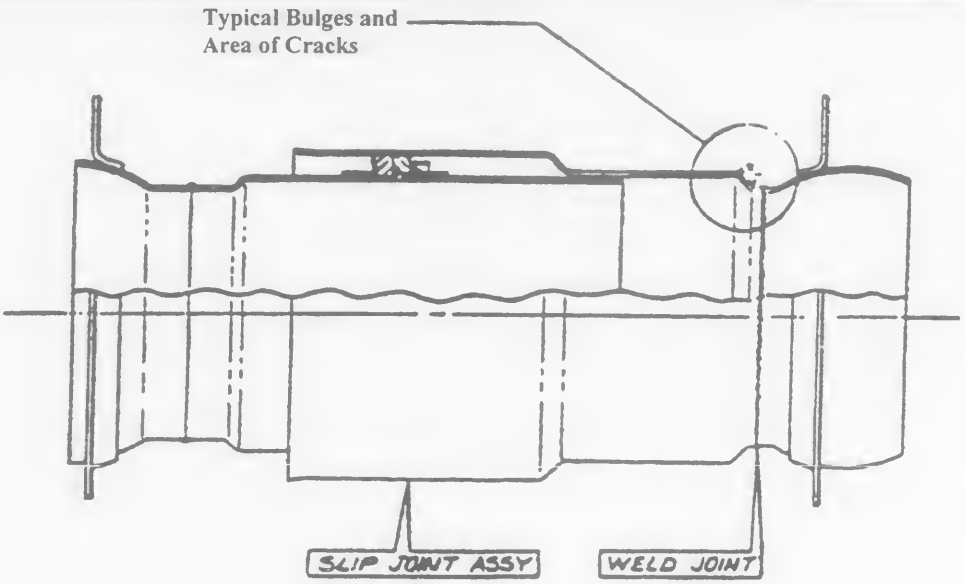
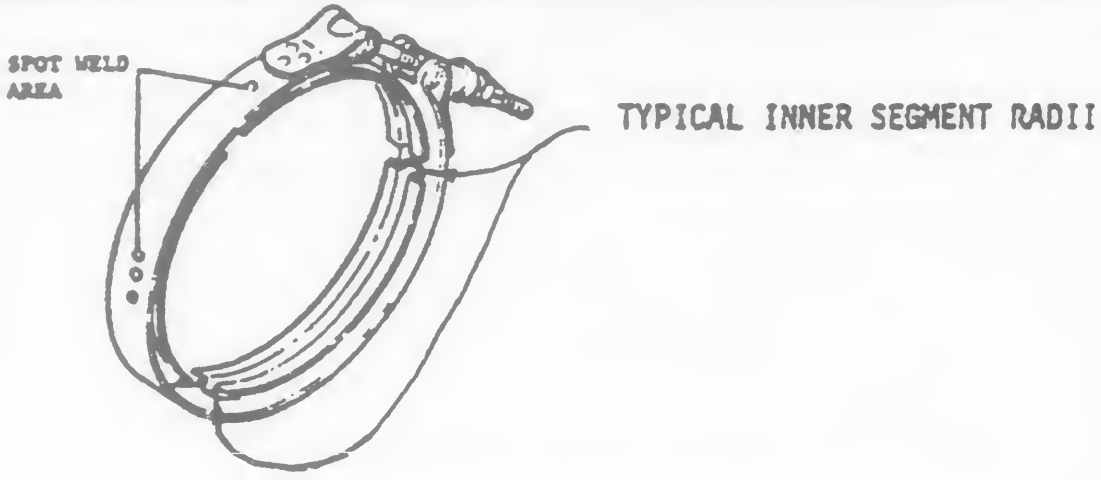
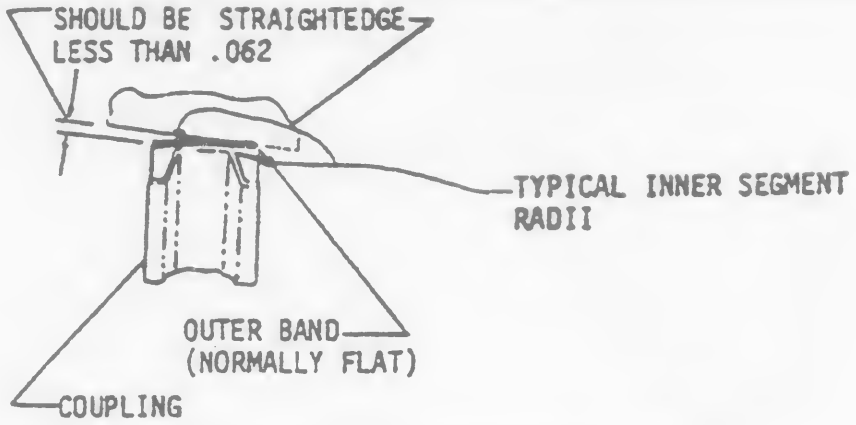


FIGURE 2 to the Appendix



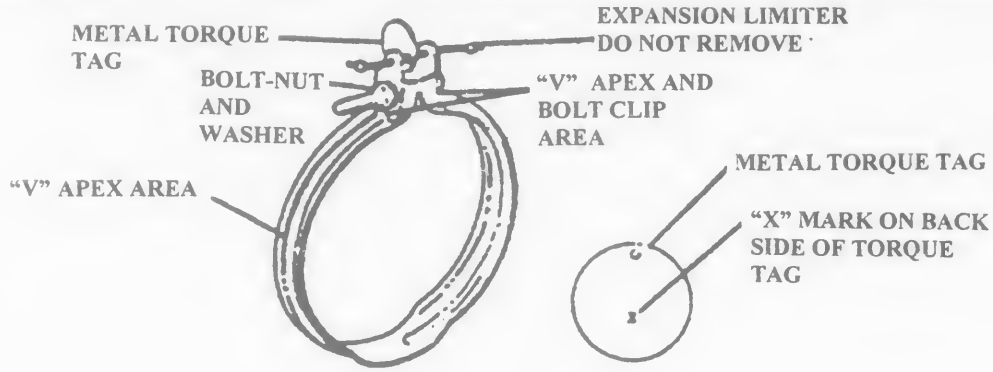
Multi-Segment "V" Band Clamp

FIGURE 3 to the Appendix



Multi-Segment "V" Band Clamp Outer Band Flatness Check

FIGURE 4 to the Appendix



One-Piece "V" Band Type Clamp

FIGURE 5 to the Appendix

BILLING CODE 4910–13–C

Inspection of the Exhaust System AFT of the Slip Joints

(a) Remove all top and bottom engine cowlings, as well as the under-nacelle inspection panels (on aircraft so-equipped). Remove the nacelle-mounted induction air filter canister, slip-joint heat shields, turbocharger heat shields, and any other readily-removable components that facilitate a better view of the exhaust system aft of the slip joints.

(b) Visually inspect each elbow pipe that runs from the slip joint to the wye duct. Carefully inspect the hard-to-see areas where the manifold passes through the canted bulkhead, beneath the clamp-on heat shields, and around the flange and V-band clamp, where it joins the wye. Use a flashlight and mirror to inspect the areas that cannot be seen directly.

(1) Look for evidence of exhaust stains, bulges, cracks, or pinholes.

(2) Exhaust stains or evidence of heat-induced corrosion on any portion of the engine mount beams or canted bulkhead should be grounds for removing the elbow pipe for closer inspection.

(3) Inspect for cracks, bulges, pinholes, or corrosion on the elbow (manifold) pipe, and if any of this damage is found, replace the elbow pipe.

(c) Visually inspect each wye duct beneath the turbo charger for leakage, stains, cracks, or pinholes, and, if damaged, repair or replace. Carefully inspect the hard-to-see area between the duct and firewall.

(1) Carefully inspect the turbo-charger and waste-gate flanges and welded seams between the ducts and the firewall for evidence of exhaust stains on the wye or the firewall, bulges, cracks, or pinholes.

(2) If exhaust stains, bulges, cracks or pinholes are found, repair or replace the damaged part.

Pressure Test

(a) Pressurize the exhaust system with air regulated to 20 PSI or below.

(b) Apply this air pressure to the tailpipe. Fabricate shop fixtures as required to accomplish this.

(c) Seal off the waste-gate pipe.

(d) Check the tailpipe, elbow pipes and the wye duct for leaks by spraying leak check fluid (bubbling) on these parts and looking for the appearance of bubbles. Some air leakage is normal at the joints and flanges, but none should be seen anywhere else.

(e) Pay special attention to any weld repairs, and various hard-to-see areas described previously.

(f) If the tailpipes, elbow pipes, or the wye ducts fail the pressure test, repair or replace the distressed component.

Issued in Kansas City, Missouri, on June 25, 1999.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–16752 Filed 7–2–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05–98–111]

RIN 2115–AE47

Drawbridge Operation Regulations; Debbies Creek, NJ

AGENCY: Coast Guard, DOT.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes a supplemental change to the regulations governing the operation of the Monmouth County highway bridge, at mile 0.4, across Debbies Creek, at Manasquan, New Jersey.

The new proposal would continue to provide the current opening schedule, except that from January 1 through March 31, from 4:30 p.m. to 8 a.m., a 4-hour advance notice would be required. At all other times the bridge will continue to provide openings on signal. This change is intended to relieve the bridge owner of the burden of having a bridge tender staff the bridge during periods when there are few or no requests for openings, while still providing for the reasonable needs of navigation. In addition, the Coast Guard proposes enumeration and rewording of the current regulation to ensure clarity and consistency.

DATES: Comments must reach the Coast Guard on or before September 7, 1999.

ADDRESSES: You may mail comments to the Commander (Aowb), Fifth Coast Guard District, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704–5004, or they may be hand-delivered to the same address between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398–6222. Comments and documents as indicated in this preamble will become part of this docket and will be available for inspection and copying at the above address.

FOR FURTHER INFORMATION CONTACT: Ann Deaton, Bridge Administrator, Fifth Coast Guard District, (757) 398–6222.

SUPPLEMENTARY INFORMATION: .

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written views, comments, data, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD05–98–111) and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgement of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposed rule in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the address listed under **ADDRESSES.** The request should include reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register.**

Regulatory History

On January 22, 1999, the Coast Guard published a Notice of Proposed Rulemaking (NPRM) entitled "Drawbridge Operation Regulations; Debbies Creek, New Jersey" in the **Federal Register** (64 FR 3464). The Coast Guard received 10 letters commenting on the proposed rulemaking. No public hearing was requested and none was held.

Background and Purpose

The Monthmouth County highway bridge is owned and operated by the Board of Chosen Freeholders of the County of Monmouth (BCFCM) in New Jersey. Title 33 Code of Federal Regulations (CFR), § 117.715 requires the bridge to open on signal, except that, from Memorial Day through Labor Day from 7 a.m. to 8 p.m., the draw need be opened only on the hour and the half hour if any vessels are waiting to pass.

The BCFMC has initially requested a change in the regulation by requiring a 24-hour advance notice for bridge openings from January 1 through March 31. Bridge logs from 1989 through 1997 revealed a total of 496 bridge openings in the months of January, February and March. During this period, bridge tenders received an average of approximately 18 bridge-opening requests per month. Considering the minimal number of openings identified by the bridge logs, the Coast Guard believed that the initial proposal would more fairly balance the competing needs of vehicular and vessel traffic. However, the Coast Guard received 10 comments objecting to this proposal. Additionally, after further discussions with BCFCM, the Coast Guard has determined that

since vessel use between January 1 and March 31 is primarily during the daylight hours, an alternative proposal should be considered. The Coast Guard also believes that enumeration and rewording would clarify the current regulation.

Discussion of Comments and Changes

The Coast Guard received 10 comments on the NPRM in opposition to a 24-hour advance notice for vessel openings from January 1 to March 31. Eight of the comments opposed the imposition of any changes to the current regulation as unreasonable and unfair. The remaining two comments suggested an advance notice for vessel openings be conducted from January 1 to March 31, between the hours of 4 p.m. to 8 a.m. All commenters generally indicated that a 24-hour advance notice would be an inconvenience and excessive due to the unpredictable weather conditions. The Coast Guard considered these comments and responded by suggesting that a supplemental alternative proposal be further analyzed and reissued as soon as possible.

Further review of the bridge logs from 1995 through 1997 revealed a total of 61 bridge openings for vessels from January 1 to March 31, from 4:30 p.m. to 8 a.m. During the same hours, bridge logs from 1989 to 1997 showed a total of 104 vessel openings. In view of these statistics, the Coast Guard is proposing a supplemental change to the regulation by reducing the advance notice call from 24 to 4 hours and requiring the 4-hour notice to be established from January 1 to March 31 between the hours of 4:30 p.m. and 8 a.m. Considering the minimal number of openings identified by the bridge logs, the Coast Guard believes that the supplemental changes will more fairly balance the competing needs of vehicular and vessel traffic.

Discussion of Proposal

On January 22, 1999, the Coast Guard issued a Notice of Proposed Rulemaking to amend 33 CFR 117.715 by inserting a provision to require a 24-hour advance notice for bridge openings from January 1 through March 31.

Upon receiving opposition to this proposal and after further discussions with BCFCM, the Coast Guard now proposes to amend 33 CFR 117.715 by inserting a new provision requiring a 4-hour advance notice for bridge openings from January 1 through March 31, between the hours of 4:30 p.m. to 8 a.m. Additionally, to ensure clarity and consistency of the operating regulations, the text of the current 33 CFR 117.715 would be enumerated and reworded.

Regulatory Evaluation

This supplemental proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

The Coast Guard expects the economic impact of this supplemental proposed change to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

The Coast Guard reached this conclusion based on the fact that the supplemental proposed change will not prevent mariners from transiting the bridge, but merely require mariners to plan their transits and to contact the bridge tender to provide the 4 hour advance notice.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the U.S. Coast Guard considered whether this supplemental proposed rule, if adopted, will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this supplemental proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities. If, however, you think that your business or organization may be impacted, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and in what way and to what degree this supplemental proposed rule will economically affect it.

Unfunded Mandates

Under section 201 of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531), the Coast Guard assessed the effects of this supplemental proposed rule on State, local, and tribal governments, in the aggregate, and the private sector. The Coast Guard determined that this regulatory action requires no written statement under section 202 of the UMRA (2 U.S.C. 1532) because it will not result in the expenditure of $100,000,000 in any one year by State, local, or tribal governments, in the aggregate, or the private sector.

Collection of Information

This supplemental proposed rule does not provide for a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this supplemental proposed rule under the principles and criteria contained in Executive Order 12612 and has determined that this supplemental proposed rule does not have sufficient implications for federalism to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this supplemental proposal and concluded that under figure 2–1, paragraph (32)(e) of the Commandant Instruction M16475.1C, this supplemental proposed rule is categorically excluded from further environmental documentation based on the fact that this is a promulgation of an operating regulation for a drawbridge. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons discussed in the preamble, the Coast Guard proposed to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); Section 117.255 also issued under the authority of Pub. L. 102–4587, 106 Stat. 5039.

2. Section 117.715 is revised to read as follows:

§ 117.715 Debbies Creek.

The draw of the Monmouth County highway bridge, mile 0.4 at Manasquan, shall open on signal, except as follows:

(a) From January 1 through March 31, from 4:30 p.m. to 8 a.m., the draw need open only if at least four-hours advance notice is given.

(b) From Memorial Day through Labor Day from 7 a.m. to 8 p.m., the draw need open only on the hour and half hour if any vessels are waiting to pass.

(c) The owners of the bridge shall provide and keep in good legible

condition two board gages painted white with black figures not less than eight inches high to indicate the vertical clearance under the closed draw at all stages of the tide. The gages shall be so placed on the bridge that they are plainly visible to operators of vessels approaching the bridge either up or downstream.

Dated: June 18, 1999.

Thomas E. Bernard,

Captain, U.S. Coast Guard, Fifth Coast Guard District, Acting District Commander.

[FR Doc. 99–17055 Filed 7–2–99; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, 411, 412, 413, 419, 489, 498, and 1003

[HCFA–1005–4N]

RIN 0938–AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services; Extension of Comment Period

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

ACTION: Notice of extension of comment period for proposed rule.

SUMMARY: This notice extends the comment period for the fourth time on a proposed rule published in the **Federal Register** on September 8, 1998, (63 FR 47552). In that rule, as required by sections 4521, 4522, and 4523 of the Balanced Budget Act of 1997, we proposed to eliminate the formula–driven overpayment for certain outpatient hospital services, extend reductions in payment for costs of hospital outpatient services, and establish in regulations a prospective payment system for hospital outpatient services (and for Medicare Part B services furnished to inpatients who have no Part A coverage.)

DATES: The comment period is extended to 5 p.m. on July 30, 1999.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1005–P, P.O. Box 26688, Baltimore, MD 21207–0488.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1005–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to:

Health Care Financing Administration. Office of Information Services, Standards And Security Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: John Burke HCFA–1005–P

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Janet Wellham, (410) 786–4510.

SUPPLEMENTARY INFORMATION: On September 8, 1998, we issued a proposed rule in the **Federal Register** (63 FR 47552) that would do the following:

- Eliminate the formula–driven overpayment for certain hospital outpatient services.
- Extend reductions in payment for costs of hospital outpatient services.
- Establish in regulations a prospective payment system for hospital outpatient services, for partial hospitalization services furnished by community mental health centers, and for certain Medicare Part B services furnished to inpatients who have no Part A coverage.
- Propose new requirements for provider departments and provider-based entities.
- Implement section 9343(c) of the Omnibus Budget Reconciliation Act of 1986, which prohibits Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under an arrangement with the hospital.
- Authorize the Department of Health and Human Services' Office of Inspector General to impose a civil money penalty against any individual or entity who knowingly presents a bill for nonphysician or other bundled services not provided directly or under such an arrangement.

The comment period for the proposed rule initially closed on November 9, 1998. Because of the scope of the proposed rule, hospitals and numerous professional associations requested more time to analyze the potential consequences of the rule. Therefore, we published a notice on November 13, 1998, (63 FR 63429), which extended the comment period until January 8, 1999. Because of further requests from hospitals and professional associations, we published another notice on January 12, 1999, (64 FR 1784) extending the comment period to March 9, 1999. Due to additional requests for more time to analyze the potential consequences of the proposed rule on March 12, 1999,(64 FR 12277) we again extended the comment period until June 30, 1999.

On June 30, 1999 we published a correction notice (64 FR 35258) in the **Federal Register** that corrects a number of technical and typographical errors contained in the September 8, 1998 proposed rule. The correction notice is entitled "Medicare Program; Prospective Payment System for Hospital Outpatient Services; Correction Notice." Due to the publication of the correction notice and our wish to provide potential commenters adequate time to analyze the potential consequences of the proposed rule, we are again extending the comment period to July 30, 1999.

Numerous hospital industry groups, in preparing to comment on the proposed rule, had asked for extensive information on the databases used to develop the proposed prospective payment system for hospital outpatient services. These requests included detailed programming specifications and analysis of individual proposed rates, including underlying data. Because the correction notice reflecting these corrected data was not published until June 30, 1999 and because these data will engender additional analysis by interested parties, we believe that further extending the current comment period is appropriate.

Published elsewhere in this issue of the **Federal Register** is a notice extending the comment period for the proposed rule published in the June 12, 1998, **Federal Register** in which we propose to rebase Medicare payment rates and update the list of approved procedures for ambulatory surgical centers (ASCs) (63 FR 32290). We are

extending the comment period for the June 12, 1998, ASC proposed rule to be concurrent with the extended comment period for the September 8, 1998, hospital outpatient proposed rule because Medicare payments to ASCs are closely linked to the manner in which Medicare proposes to pay hospitals under a prospective payment system for surgical services furnished on an outpatient basis.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 24, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: June 30, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–17026 Filed 6–30–99; 2:00 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416 and 488

[HCFA–1885–6N]

RIN 0938–AH81

Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Procedures for Ambulatory Surgical Centers Effective October 1, 1998; Extension of Comment Period

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

ACTION: Notice of extension of comment period for proposed rule.

SUMMARY: This notice extends the comment period for the sixth time on a proposed rule published in the **Federal Register** on June 12, 1998, (63 FR 32290). In that rule we proposed to make various changes, including changes to the ambulatory surgical center (ASC) payment methodology and the list of Medicare covered procedures.

DATES: The comment period is extended to 5 p.m. on July 30, 1999.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1885–P, P.O. Box 26688, Baltimore, MD 21207–0488.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1885–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890)).

For comments that relate to information collection requirements, mail a copy of comments to:

Health Care Financing Administration, Office of Information Services, Standards And Security Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: John Burke HCFA–1885–P

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Terri Harris, (410) 786–6830.

SUPPLEMENTARY INFORMATION: On June 12, 1998, we issued a proposed rule in the **Federal Register** (63 FR 32290) that would do the following:

- Update the criteria for determining which surgical procedures can be appropriately and safely performed in an ASC.
- Make additions to and deletions from the current list of Medicare covered ASC procedures based on the revised criteria.
- Rebase the ASC payment rates using cost, charge, and utilization data collected by a 1994 survey of ASCs.
- Refine the ratesetting methodology that was implemented by a final notice published on February 8, 1990, in the **Federal Register**.
- Require that ASC payment, coverage, and wage index updates be implemented annually on January 1 rather than having these updates occur randomly throughout the year.
- Reduce regulatory burden.
- Make several technical policy changes.

The proposed rule would also implement requirements of section 1833(i)(1) and (2) of the Social Security Act. We indicated that comments would be considered if we received them by August 11, 1998.

We received requests from numerous ASCs and professional associations for more time to analyze the potential consequences of the rule. We issued a notice in the **Federal Register** on August 14, 1998, (63 FR 43655) announcing extension of the public comment period to September 10, 1998.

On September 8, 1998, we published a proposed rule in the **Federal Register** entitled "Medicare Program; Prospective Payment System for Hospital Outpatient Services" (63 FR 47552). We received additional requests from ASCs and professional associations for more time to analyze the impact of the hospital outpatient proposed rule, and for a delay in the implementation of the ASC final rule to be concurrent with implementation of the hospital outpatient prospective payment system.

On October 1, 1998, we reopened the comment period for the June 12, 1998 ASC proposed rule until November 9, 1998, to coincide with the comment period for the September 8, 1998, hospital outpatient proposed rule. We also gave notice in the October 1, 1998, **Federal Register** (63 FR 52663) of a delay in the adoption of the provisions of the June 12, 1998 ASC proposed rule as a final rule to be concurrent with the adoption as final of the hospital outpatient prospective payment system as soon as possible after January 1, 2000. In the November 13, 1998 **Federal Register** (63 FR 63430), we further extended the comment period until January 8, 1999. In the January 12, 1999, **Federal Register** (64 FR 1785), we again extended the comment period until March 9, 1999. In the March 12, 1999 **Federal Register** (64 FR 12278), we again extended the comment period to June 30, 1999 due to further requests from the industry. On June 30, 1999, we published a correction notice (64 FR 35258) in the **Federal Register** that corrects a number of technical and typographical errors contained in the September 8, 1998 hospital outpatient PPS proposed rule. The correction notice is entitled "Medicare Program; Prospective Payment System for Hospital Outpatient Services; Correction Notice." Due to the publication of the correction notice and our wish to provide potential commenters to have adequate time to analyze the potential consequences of the proposed rule and because Medicare payments to ASCs are

closely linked to the way Medicare proposes to pay hospitals under a prospective payment system for surgical services furnished on an outpatient basis, we find it appropriate to extend the current comment period. Therefore, we are again extending the comment period to July 30, 1999 to be concurrent with the hospital outpatient PPS proposed rule. Also published elsewhere in this issue of the **Federal Register** is a notice extending the comment period for the September 8, 1998 hospital outpatient proposed rule, (63 FR 47552) until July 30, 1999.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 24, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: June 30, 1999.

Donna E. Shalala

Secretary.

[FR Doc. 99–17027 Filed 6–30–99; 2:00 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–239; RM–9658]

Radio Broadcasting Services; Johannesburg and Edwards, CA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed on behalf of Adelman Communications, Inc., licensee of Station KEDD(FM) (formerly Station KRAJ(FM)), Channel 280B1, Johannesburg, California, requesting the substitution of Channel 280A for Channel 280B1 at Johannesburg, the reallotment to Channel 280A to Edwards, California, as that community's first local aural transmission service, and modification of its authorization accordingly, pursuant to the provisions of Section 1.420(i) of the Commission's Rules. Coordinates used for this proposal are 34–59–40 NL and 117–59–32 WL. Additionally, as Edwards is located within 320 kilometers (199 miles) of the U.S.-Mexico border, the Commission must obtain the concurrence of the Mexican government to this proposal.

DATES: Comments must be filed on or before August 16, 1999, and reply comments on or before August 31, 1999.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: David M. Hunsaker and John C. Trent, Esqs., Putbrese, Hunsaker & Trent, P.C., 100 Carpenter Drive, Suite 100, P.O. Box 217, Sterling, VA 20167–0217

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–239, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17070 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–236, RM–9644]

Radio Broadcasting Services; Madisonville, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Leon Hunt d/b/a Hunt Broadcasting proposing the allotment of Channel 267A at Madisonville, Texas. The channel can be allotted to Madisonville in compliance with the Commission's spacing requirements at coordinates 31–01–20 NL and 95–55–00 WL. There is a site restriction 8.09 kilometers (5.0 miles) north of the community.

DATES: Comments must be filed on or before August 16, 1999, and reply comments on or before August 31, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Leon Hunt, 102 West Main Street, Madisonville, Texas 77864.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–236, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17074 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–235, RM–9643]

Radio Broadcasting Services; Ingram, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Ingram Radio Broadcasting Company proposing the allotment of Channel 243A at Ingram, Texas. The channel can be allotted to Ingram in compliance with the Commission's spacing requirements at coordinates 30–04–30 NL and 99–14–06 WL. Concurrence of the Mexican government will be requested for the allotment of Channel 243A at Ingram, Texas.

DATES: Comments must be filed on or before August 16, 1999, and reply comments on or before August 31, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Robert Lewis Thompson, Taylor Thiemann & Aitken, L.C., 908 King Street, Suite 300, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–235, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17073 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–234, RM–9645]

Radio Broadcasting Services; Hunt, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Hunt Radio Broadcasting proposing the allotment of Channel 260A at Hunt, Texas. The channel can be allotted to Hunt in compliance with the Commission's spacing requirements at coordinates 30–07–18 NL and 99–25–39 WL. Concurrence of the Mexican government will be requested for the allotment of Channel 260A at Hunt, Texas.

DATES: Comments must be filed on or before August 16, 1999, and reply comments on or before August 31, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Robert Lewis Thompson, Taylor Thiemann & Aitken, L.C., 908 King Street, Suite 300, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–234, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17072 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–232; RM–9321]

Radio Broadcasting Services; Fort Bridger, WY and Hyrum, UT

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by L. Topaz Enterprises, Inc., proposing the downgrade from Channel 256C1 to Channel 256C3 at Fort Bridger, Wyoming, the reallotment of Channel 256C3 from Fort Bridger to Hyrum, Utah, and the modification of the Station KNYN(FM)'s construction permit accordingly. Channel 256C3 can be allotted to Hyrum in compliance with the Commission's minimum

distance separation requirements with a site restriction of 0.7 kilometers (0.4 miles) north at petitioner's requested site. The coordinates for Channel 256C3 at Hyrum are 41–38–35 North Latitude and 111–51–10 West Longitude. In accordance with the provisions of § 1.420(i) of the Commission's rules, we will not accept competing expressions of interest in the use of Channel 256C3 at Hyrum, or require petitioner to demonstrate the availability of an additional equivalent class channel for use by such parties.

DATES: Comments must be filed on or before August 16, 1999, reply comments on or before August 31, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Dale A. Ganske, President, 5546–3 Century Avenue, Middleton, Wisconsin 53562 (Petitioner); M. Kent Frandsen, PO Box 570, Logan, Utah 84321 (Assignee of Station KNYN(FM)).

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–232, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 1231 20th Street, NW., Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17067 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–233, RM–9662]

Radio Broadcasting Services; Graham, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Graham Tollway Broadcasting Company proposing the allotment of Channel 253A at Graham, Texas. The channel can be allotted to Graham in compliance with the Commission's spacing requirements at coordinates 33–02–30 NL and 98–39–00 WL.

DATES: Comments must be filed on or before August 16, 1999, and reply comments on or before August 31, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Audrey P. Rasmussen, O'Connor & Hannan, L.L.P., 1919 Pennsylvania, Avenue, NW, Suite 800, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–233, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17071 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 99–237, RM–9663]

Radio Broadcasting Services; Medina, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Medina Radio Broadcasting Company proposing the allotment of Channel 296A at Medina, Texas. The channel can be allotted to Medina in compliance with the Commission's spacing requirements at coordinates 29–47–41 NL and 99–15–27 WL. There is a site restriction .9 kilometers (.6 miles) west of the community. Mexican concurrence will be requested for the allotment of Channel 296A at Medina.

DATES: Comments must be filed on or before August 16, 1999, and reply comments on or before August 31, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Robert Lewis Thompson, Taylor Thiemann & Aitken, L.C., 908 King Street, Suite 300, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–237, adopted June 16, 1999, and released June 25, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the

Commission's Reference Center, 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–17075 Filed 7–2–99; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[I.D. 062399B]

RIN 0648–AK89

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Amendment 9 to the Fishery Management Plan (FMP) for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (Amendment 9)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of Amendment 9 to the FMP for the coastal migratory pelagic resources of the Gulf of Mexico and South Atlantic; request for comments.

SUMMARY: NMFS announces that the Gulf of Mexico and South Atlantic Fishery Management Councils have submitted Amendment 9 to the Fishery Management Plan for Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP) for review, approval, and implementation by NMFS. The purpose of Amendment 9 is to enhance the socioeconomic benefits from the commercial quotas for Gulf group king mackerel and to assure a more equitable distribution of these benefits among fishery participants, to reduce the harvest of immature king mackerel and minimize the possibility of recreational king mackerel fishery allocation overruns, and to increase revenue and decrease waste in the king and Spanish mackerel fisheries. Amendment 9 is made available for public comment.

DATES: Written comments must be received on or before September 7, 1999.

ADDRESSES: Comments must be mailed to Mark Godcharles, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Requests for copies of Amendment 9, which includes an environmental assessment, a regulatory impact review (RIR), and an initial regulatory flexibility analysis (IRFA), may be obtained from the Gulf of Mexico Fishery Management Council (Gulf of Mexico Council), Suite 1000, 3018 U.S. Highway 301 North, Tampa, FL 33619; Phone: 813–228–2815; Fax: 813-225-7015; E-mail: gulf.council@noaa.gov; or from the South Atlantic Fishery Management Council (South Atlantic Council), Southpark Building, One Southpark Circle, Suite 306, Charleston, SC 29407–4699; Phone: 843–571–4366; Fax: 843–769–4520; E-mail: safmc@noaa.gov.

FOR FURTHER INFORMATION CONTACT: Mark Godcharles or Steve Branstetter, NMFS, St. Petersburg, FL; Phone: 727–570–5305; Fax: 727–570–5583.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires Regional Fishery Management Councils to submit any proposed FMP or FMP amendment to NMFS for review, approval, and implementation. The Magnuson-Stevens Act also requires that NMFS, upon receiving such FMP or FMP amendment, immediately publish a document in the **Federal Register** stating that the FMP or FMP amendment is available for public review and comment.

Amendment 9 was prepared and submitted by the Gulf of Mexico and South Atlantic Councils. Amendment 9 contains 10 proposed conservation and management measures. For the commercial fisheries for Gulf group king mackerel in the eastern zone (the zone comprising both coasts of Florida), Amendment 9 proposes seven actions to: (1) Create two new subzones (northern and southern) for the commercial hook-and-line fishery in the Florida west coast subzone; (2) establish separate commercial hook-and-line fishery quotas for the proposed northern and southern subzones in the Florida west coast subzone; (3) reallocate the eastern zone commercial quota between the Florida east and west coast subzones to provide for commercial hook-and-line fishery quotas for the proposed new northern and southern Florida west coast subzones; (4) implement a moratorium on issuing any new gillnet endorsements for commercial vessel king mackerel permits in the run-around gillnet fishery in the proposed southern Florida west coast subzone; (5) establish eligibility criteria to reissue gillnet endorsements for commercial vessel king mackerel permits only to traditional fishermen in the run-around gillnet fishery in the proposed southern Florida west coast subzone; (6) restrict the transfer of gillnet endorsements for commercial vessel king mackerel permits in the run-around gillnet fishery in the proposed southern Florida west coast subzone only to the family members of vessel owners; and (7) restrict the operational area for vessels harvesting king mackerel under the run-around gillnet quota to the proposed southern Florida west coast subzone.

Amendment 9 also proposes three additional actions to: (1) Establish a 3,000–lb (1,361–kg) daily trip limit for the commercial vessels harvesting Gulf group king mackerel under the quota for the western zone (Texas through Alabama); (2) increase the minimum size limit from 20 inches to 24 inches (50.8 to 61.0 cm) fork length for both the Gulf and Atlantic groups of king mackerel; and (3) allow the sale of cut-off (damaged) fish from both the Gulf and Atlantic groups of king and Spanish mackerel as long as the cut-off fish meet or exceed the appropriate minimum size limit and are possessed within the established commercial trip limits.

The specific proposed management measures, their supporting rationale, and analyses of potential impacts are contained in Amendment 9. Amendment 9 is intended to enhance the socioeconomic benefits from the commercial quotas for Gulf group king mackerel and to assure a more equitable distribution of these benefits among fishery participants. Measures proposed for fisheries in the eastern zone would equitably distribute the quota among participants using hook-and-line gear and prevent expansion of the run-around gillnet sector while the Gulf of

Mexico and South Atlantic Councils consider future management strategies. The proposal to establish a trip limit for the western zone is expected to prevent derby fishing, extend the harvest season, and increase the exvessel value of the catch. Proposals to increase king mackerel minimum size limits would reduce harvest of immature fish and the likelihood of overrunning recreational fishery allocations. The proposed measures regarding the possession and sale of cut-off (damaged) king and Spanish mackerel would increase fishery revenue, decrease wastage, and improve the accuracy of fishing mortality estimates.

Availability of and Opportunity to Comment on Amendment 9

NMFS has prepared a proposed rule to implement Amendment 9. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine if it is consistent with Amendment 9, the Magnuson-Stevens Act, and other applicable law. If that determination is affirmative, NMFS will publish a proposed rule in the **Federal Register** for public review and comment.

NMFS will consider comments received by September 7, 1999, whether specifically directed to Amendment 9 or its proposed rule in its decision to approve, disapprove, or partially approve Amendment 9. NMFS will not consider comments received after that date in this decision. NMFS will address all comments received on Amendment 9 or on its proposed rule during their respective comment periods in the preamble of the final rule.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 29, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–17060 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 64, No. 128
Tuesday, July 6, 1999

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

National Agricultural Statistics Service

Notice of Intent To Seek Approval To Conduct an Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13) and Office of Management and Budget (OMB) regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the intent of the National Agricultural Statistics Service (NASS) to request approval for a new information collection, the Agricultural Economics and Land Ownership Survey.

DATES: Comments on this notice must be received by September 9, 1999 to be assured of consideration.

ADDITIONAL INFORMATION OR COMMENTS: Contact Rich Allen, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, Room 4117 South Building, Washington, DC 20250–2000, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: 1999 Agricultural Economics and Land Ownership Survey.

Type of Request: Intent to seek approval to conduct an information collection.

Abstract: The 1999 Agricultural Economics and Land Ownership Survey (AELOS) will be conducted by the National Agricultural Statistics Service. This national survey will obtain data to describe the economic status of the U.S. farm operations and farm households. Data collected will provide information on agricultural land ownership, financing, and inputs by farm operators and landlords. The AELOS is designed to provide data that are valid for each state and the U.S. as a whole. The AELOS will be conducted in 2000 for the 1999 calendar year. The last AELOS covered the 1988 calendar year. The respondent universe consists of two populations. First, is the official USDA farm population which is defined as "all establishments that sold or would have normally sold at least $1,000 of agricultural products during the year." Second are the landlords of farm operators selected for the survey. These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 51 minutes per response.

Estimated Number of Respondents: 65,000.

Estimated Total Annual Burden on Respondents: 55,250 hours.

Copies of this information collection and related instructions can be obtained without charge from Larry Gambrell, the Agency OMB Clearance Officer, at (202) 720–5778.

Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Larry Gambrell, Agency OMB Clearance Officer, U.S. Department of Agriculture, 1400 Independence Avenue SW, Room 4162 South Building, Washington, DC 20250–2000. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Signed at Washington, DC, June 14, 1999.

Rich Allen,

Associate Administrator, National Agricultural Statistics Service.

[FR Doc. 99–16948 Filed 7–2–99; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Proposed Change to Section IV of the Field Office Technical Guide (FOTG) of the Natural Resources Conservation Service in Kentucky

AGENCY: Natural Resources Conservation Service (NRCS) in Kentucky, U.S. Department of Agriculture.

ACTION: Notice of availability of proposed changes in Section IV of the FOTG of the NRCS in Kentucky for review and comment.

SUMMARY: It is the intention of the NRCS in Kentucky to issue revised conservation practice standards: Agrichemical Handling Facility (Code 998), Filter Strip (Code 393), Manure Transfer (Code 634), Pond (Code 378), Riparian Forest Buffer (Code 391A), Roof Runoff Management System (Code 558), Sinkhole Protection (Code 725I), Stream Crossing (Code 576), Waste Field Storage (Code 749), Waste Storage Facility (Code 313), Waste Treatment Lagoon (Code 359), and Well Decommissioning (Code 351.)

DATES: Comments will be received for a 30-day period commencing with the date of this publication.

FOR FURTHER INFORMATION CONTACT: Inquire in writing to David G. Sawyer, state conservationist, Natural Resources Conservation Service (NRCS), 771 Corporate Drive, Suite 110, Lexington, KY 40503–5479. Copies of the practice standards are made available upon written request.

SUPPLEMENTARY INFORMATION: Section 343 of the Federal Agriculture Improvement and Reform Act of 1996 states that revisions made after enactment of the law to NRCS State Technical Guides used to carry out highly erodible land and wetland provisions of the law shall be made

available for public review and comment. For the next 30 days the NRCS in Kentucky will receive comments relative to the proposed changes. Following that period a determination will be made by the NRCS in Kentucky regarding deposition of those comments and a final determination of change will be made.

David G. Sawyer,

State Conservationist, Natural Resources Conservation Service.

[FR Doc. 99–16777 Filed 7–2–99; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–602]

Final Results of Expedited Sunset Review: Aspirin From Turkey

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of expedited sunset review: aspirin from Turkey.

SUMMARY: On March 1, 1999, the Department of Commerce ("the Department") initiated a sunset review of the antidumping duty order on aspirin from Turkey (64 FR 9970) pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). On the basis of a notice of intent to participate and substantive comments filed on behalf of the domestic industry and inadequate response (in this case, no response) from respondent interested parties, the Department determined to conduct an expedited review. As a result of this review, the Department finds that revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the *Final Results of Review* section of this notice.

FOR FURTHER INFORMATION CONTACT: Scott E. Smith or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482–6397 or (202) 482–1560, respectively.

EFFECTIVE DATE: July 6, 1999.

Statute and Regulations

This review was conducted pursuant to sections 751(c) and 752 of the Act. The Department's procedures for the conduct of sunset reviews are set forth in *Procedures for Conducting Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) ("*Sunset Regulations*"). Guidance on methodological or analytical issues relevant to the Department's conduct of sunset reviews is set forth in the Department's Policy Bulletin 98:3—*Policies Regarding the Conduct of Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin,* 63 FR 18871 (April 16, 1998) ("*Sunset Policy Bulletin*").

Scope

The product covered by this review is acetylsalicylic acid (aspirin) from Turkey, containing no additives, other than inactive substances (such as starch, lactose, cellulose, or coloring material), and/or active substances in concentrations less than that specified for particular non-prescription drug combinations of aspirin and active substances as published in the *Handbook of Non-Prescription Drugs,* eighth edition, American Pharmaceutical Association, and is not in tablet, capsule, or similar forms for direct human consumption. This product is currently classifiable under the Harmonized Tariff Schedule ("HTS") of the United States item numbers 2918.22.10 and 3003.90.00.[1] The HTS item numbers are provided for convenience and customs purposes only. The written description remains dispositive.

History of the Order

On July 1, 1987, the Department issued a final determination of sales at less than fair value with respect to imports of aspirin (acetylsalicylic acid) from Turkey.[2] The antidumping duty order on aspirin was issued by the Department on August 25, 1987, and, in the order, the dumping margins that were found in the final determination were confirmed.[3] Since the imposition of this order, the Department has conducted one administrative review.[4] The order remains in effect for all manufacturers and exporters of the subject merchandise.

This review covers all producers and exporters of aspirin from Turkey.

Background

On March 1, 1999, the Department initiated a sunset review of the antidumping order on aspirin from Turkey (64 FR 9970), pursuant to section 751(c) of the Act. The Department received a Notice of Intent to Participate on behalf of Rhodia on March 15, 1999, within the deadline specified in section 351.218(d)(1)(i) of the *Sunset Regulations.* We received a complete substantive response from Rhodia on March 31, 1999, within the 30-day deadline specified in the *Sunset Regulations* in section 351.218(d)(3)(i). Rhodia claimed interested party status under section 771(9)(C) of the Act as a U.S. producer of the domestic like product.

Additionally, Rhodia stated that it was not a participant in either the original investigation nor the lone administrative review conducted by the Department. However, Rhodia stated that, of the four domestic producers originally involved in the investigation, two—Sterling Drug and Norwich-Eaton—have since ceased production of subject aspirin. The other two producers, Monsanto Chemical Company and Dow Chemical U.S.A., had their aspirin production taken over by Rhone-Poulenc S.A. Rhodia is the subsidiary of Rhone-Poulenc S.A. responsible for bulk aspirin production and is the successor in interest to Monsanto, which was the original petitioner.

We did not receive a substantive response from any respondent interested party to this proceeding. As a result, pursuant to section 351.218(e)(1)(ii)(C) of the *Sunset Regulations,* the Department determined to conduct an expedited, 120-day, review of this order.

Determination

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the

[1] In its substantive response, Rhodia noted that the written description of the scope of the order indicated that this product was covered under not only under HTS item number 2918.22.10, but also item number 3003.90.00. The Department agrees. Although this item number has not been previously included in the scope section of prior Department determinations in this case, we confirmed with the U.S. Customs Service that both HTS item numbers were appropriate (*see* Memo to File; Re: HTS Item Numbers for Aspirin). Therefore, we have included HTS item number 3003.90.00.

[2] *See Final Determination of Sales at Less Than Fair Value; Acetylsalicylic Acid From Turkey,* 52 FR 24492 (July 1, 1987).

[3] *See Acetylsalicylic Acid From Turkey; Antidumping Duty Order,* 52 FR 32030 (August 25, 1987).

[4] *See Acetylsalicylic Acid From Turkey; Final Results of Antidumping Duty Administrative Review,* 63 FR 34146 (June 23, 1998), and *Termination of Antidumping Duty Administrative Review: Acetylsalicylic Acid From Turkey,* 58 FR 11208 (February 24, 1993).

Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping order, and shall provide to the International Trade Commission ("the Commission") the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department's determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. In addition, Rhodia's comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act ("URAA"), specifically the Statement of Administrative Action ("the SAA"), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt.1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its *Sunset Policy Bulletin* providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its *Sunset Policy Bulletin*, the Department indicated that determinations of likelihood will be made on an order-wide basis (*see* section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping order is likely to lead to continuation or recurrence of dumping when (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (*see* section II.A.3).

In addition to considering guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping when a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the *Sunset Regulations*, this constitutes a waiver of participation.

In its substantive response, Rhodia argued that revocation of the order will likely lead to continuation or recurrence of dumping of aspirin from Turkey. Rhodia stated that compelling evidence supporting this conclusion includes: (1) The cessation of Turkish imports following the issuance of the order; (2) increased imports of bulk aspirin from other countries; (3) downward pricing pressure resulting from intense competition in the U.S. market from Chinese imports; and (4) continuing interest in the U.S. market by Turkish producers as evidenced by the temporary resumption of Turkish imports in 1997.

With respect to whether imports of the subject merchandise ceased after the issuance of the order, Rhodia, citing data from the United States Census Bureau, argued that imports of Turkish aspirin declined significantly with the imposition of dumping duties in 1987. Specifically, Rhodia stated that, in 1987, the year immediately following imposition of the order, import volumes from Turkey declined dramatically, decreasing from 1.3 million pounds to just over 200,000 pounds. Rhodia stated that imports of aspirin from Turkey continued to decline until they completely ceased in 1990. Further, Turkish imports remained at zero until 1997 when imports rose to just over 5,000 pounds. The 1997 shipment, Rhodia argues, was the basis for the sole administrative review of the order, conducted for the 1996–1997 time period. Therefore, Rhodia argues, the decline and cessation of Turkish import volumes of bulk aspirin following the imposition of the antidumping duty order provides a strong indication that, absent an order, dumping would be likely to recur, because the evidence would indicate that the exporter needs to dump to sell at pre-order volumes. (*See* Substantive Response of Rhodia at 10.)

Additionally, Rhodia also argues that, because of the nature of the market for bulk aspirin, were Turkish producers to reenter the U.S. market, they would have to dump in order to compete. Rhodia argues that bulk aspirin is a commodity and, as such, competition is based primarily on price. Further, recent imports of bulk aspirin from other countries, most notably China, have increased and, as import volumes have increased, prices have fallen. Therefore, Rhodia argues that the only way that Turkish producers would realistically be able to reenter the U.S. market would be to meet the price competition posed by the low Chinese import prices.

Consistent with section 752(c) of the Act, the Department has considered whether dumping continued at any level above de minimis after the issuance of the order. In the administrative review covering the 1996–1997 period, the Department determined that no dumping margin existed for Atabay Kimya Sanayi ve Ticaret A.B. ("Atabay") (63 FR 34146, June 23, 1998) and, therefore, a cash deposit rate of zero was imposed for Atabay. Because neither Proces Kimya Sinayi ve Ticaret ("Proces"), one of the two companies examined in the original investigation, nor any other companies, other than Atabay, have been examined in the course of administrative review, the deposit rates for all companies, other than Atabay, continue to be the margins of dumping found in the original investigation—38.60 percent for Proces and 32.98 percent for all others. Therefore, we determine that although there was no dumping found for Atabay in the 1997 review period, the same cannot be said for other Turkish producers/exporters.

Consistent with section 752(c) of the Act, the Department also considered the volume of imports before and after issuance of the order. The import statistics on imports of the subject merchandise from pre-order 1986 to 1998 (as provided by the domestic industry and confirmed by the Department by United States Census Bureau IM146 data) demonstrate that imports of the subject merchandise declined dramatically immediately following the imposition of the order, and continued to decline until 1990 when imports ceased. The only imports of bulk aspirin from Turkey since 1990 involved just over 5,000 pounds in 1997. We agree with Rhodia that imports from Turkey have declined substantially since the imposition of the order in 1987 and, therefore, we determine that, although dumping was eliminated by Atabay, its export volumes have declined significantly since the issuance of the order.

As set forth in the *Sunset Policy Bulletin* (section II.A.3), and consistent with the SAA at 889–90 and the House Report at 63, the Department normally will find that revocation of the antidumping duty order likely will lead to continuation or recurrence of dumping when dumping margins continued at any level after the issuance of the order or when dumping was eliminated after the issuance of the order and import volumes of the subject merchandise declined significantly or ceased. With respect to Atabay, although dumping was eliminated in 1997, shipments of the subject merchandise have declined dramatically. Further, with respect to all

other Turkish producers/exporters, antidumping duty deposit rates remain in effect and we have no reason to believe that dumping has been eliminated. On the basis of this analysis, in conjunction with the fact that respondent interested parties have waived their right to participate in this review before the Department, and, absent argument and evidence to the contrary, the Department determines that dumping is likely to continue if the order were revoked.

Magnitude of the Margin

In the *Sunset Policy Bulletin,* the Department stated that it normally will provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the "all others" rate from the investigation. (*See* section II.B.1 of the *Sunset Policy Bulletin.*) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations. (*See* sections II.B.2 and 3 of the *Sunset Policy Bulletin.*)

The Department, in its final determination of sales at less than fair value, published weighted-average dumping margins for two Turkish producers/exporters of the subject merchandise, Atabay and Proses, and for all other producers/exporters (52 FR 24492, July 1, 1987). The margins calculated in that determination were 27.35 percent for Atabay, 38.60 percent for Proses, and an "all others" rate of 32.98 percent. Atabay, as mentioned above, received a zero margin during the sole administrative review for the 1996–1997 review period (63 FR 34146, June 23, 1998). We note that, to date, we have not issued any duty absorption findings in this case.

In its substantive response, Rhodia argued that the Department, consistent with its *Sunset Policy Bulletin,* should provide the Commission with the company-specific and all others rates from the original investigation as the magnitude of the margin likely to prevail if the order were revoked. Alternatively, Rhodia suggested that the Department could conclude that higher margins would prevail if the order were revoked. In this case, Rhodia suggests that, using Turkish import and export statistics coupled with average U.S. import statistics, the Department could calculate a new margin of 63.14 percent.

Consistent with section II.B.1 of the *Sunset Policy Bulletin,* the Department finds that the rates from the original investigation are probative of the behavior of producers/exporters without the discipline of the order. As a result, the Department determines, absent argument and evidence to the contrary, that the margins from the original investigation are the ones most likely to prevail if the order were revoked. As such, we will report to the Commission the company-specific and all others rates contained in the Final Results of Review section of this notice.

Final Results of Review

As a result of this review, the Department finds that revocation of the antidumping order would likely lead to continuation or recurrence of dumping at the margins listed below:

Manufacturer/exporter	Margin (percent)
Atabay Kimya Sanayi ve Ticaret	27.35
Proces Kimya Sanayi ve Ticaret	38.60
All Others	32.98

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department's regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year ("sunset") review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–17051 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–855]

Initiation of Antidumping Duty Investigation: Certain Non-Frozen Apple Juice Concentrate From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: July 6, 1999.

FOR FURTHER INFORMATION CONTACT: Suresh Maniam or Vincent Kane, Import Administration, International Trade Administration, U.S. Department of Commerce, Room 3099, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–0176 or 482–2815, respectively.

INITIATION OF INVESTIGATION:

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 as amended ("the Act") by the Uruguay Round Agreements Act ("URAA"). In addition, unless otherwise indicated, all citations to the Department of Commerce's ("the Department's") regulations are to the provisions codified at 19 CFR Part 351 (1998).

The Petition

On June 7, 1999, the Department received a petition filed in proper form by Tree Top, Inc.; Knouse Foods Cooperative, Inc.; Green Valley Packers; Mason County Fruit Packers; and Coloma Frozen Foods, Inc., hereinafter collectively referred to as "the petitioners. On June 17 and 25, 1999, at the request of the Department, petitioners provided public summaries for certain business proprietary information contained in the petition. On June 23, 1999, petitioners supplied information relating to their standing as petitioners and on June 25, 1999, petitioners clarified their calculation concerning industry support of the petition.

In accordance with section 732(b) of the Act, the petitioners allege that imports of certain non-frozen apple juice concentrate ("NFAJC") from the People's Republic of China ("PRC") are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are both materially injuring and threatening material injury to an industry in the United States.

The Department finds that the petitioners filed this petition on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated that they account for at least 25 percent of the total production of the domestic like product and more than 50 percent of the production of the domestic like product produced by that portion of the industry

expressing support for, or opposition to, the petition (*see* "Determination of Industry Support for the Petition" section, below).

Scope of the Investigation

For purposes of this investigation, the product covered by the scope is non-frozen concentrated apple juice having a Brix value of 40 or greater, whether or not containing added sugar or other sweetening matter. Excluded from the scope of this investigation are: frozen concentrated apple juice, non-frozen concentrated apple juice fortified with vitamins or minerals, non-frozen concentrated apple juice that has been fermented, and non-frozen concentrated apple juice to which spirits have been added.

The merchandise subject to this investigation is classified in the Harmonized Tariff Schedule of the United States ("HTSUS") at subheading 2009.70.20. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

As discussed in the preamble to the Department's regulations (62 FR 27323 February 26, 1997), we are setting aside a period for parties to raise issues regarding product coverage. The Department encourages all parties to submit such comments within 20 days of publication of this notice in the **Federal Register**. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of our preliminary determination.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) at least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

Section 771(4)(A) of the Act defines the "industry" as: "the producers as a whole of a domestic like product." Thus, to determine whether the petition has the requisite industry support, the statute directs the Department to look to producers and workers who account for production of the domestic like product. The International Trade Commission ("ITC"), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product, they do so for different purposes and pursuant to separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to the law.[1] Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this subtitle." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation," *i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition.

The domestic like product referred to in the petition is the single domestic like product defined in the "Scope of Investigation" section, above. The Department has no basis on the record to find this definition of the domestic like product to be inaccurate. The Department, therefore, has adopted this domestic like product definition.

In this case, the Department has determined that the petition and supplemental information contained adequate evidence of sufficient industry support; therefore, polling was not necessary. *See* Initiation Checklist dated June 28, 1999 (public versions on file in the Central Records Unit of the Department of Commerce, Room B–099). To the best of the Department's knowledge, the producers who support the petition account for more than 50 percent of the production of the domestic like product. Additionally, no person who would qualify as an interested party pursuant to section 771(b)(A), (C), (D), (E) or (F) of the Act has expressed opposition on the record to the petition. Accordingly, the Department determines that this petition is filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

A potential respondent in this proceeding requested that the Department poll the U.S. industry to determine industry support and check the validity of petitioners' calculations of their percent of U.S. production. We addressed this respondent's concerns in the June 28, 1998 initiation checklist.

Export Price and Normal Value

The following is a description of the allegation of sales at less than fair value upon which our decision to initiate this investigation is based. Should the need arise to use any of this information in our preliminary or final determination for purposes of facts available under section 776 of the Act, we may re-examine the information and revise the margin calculations, if appropriate.

The petitioners have based U.S. price on export price ("EP") because information obtained by the petitioners indicates that PRC producers sold NFAJC outside the United States to unaffiliated importers in the United States prior to importation. As a basis for its EP calculation, the petitioners have used an invoice price for sale of the subject merchandise by an unaffiliated U.S. distributor to an unaffiliated purchaser in the United States in the last quarter of 1998. The petitioners calculated a net U.S. price by subtracting from the invoice price the U.S. distributor's markup, ocean freight, and insurance. The petitioners based the cost of ocean freight and insurance on the difference between the C.I.F. price and the F.A.S. price of NFAJC from the PRC as reflected in the IM–145 statistics published by the U.S. Bureau of the Census. The petitioners used the IM–145 statistics for the month in which the U.S. sale occurred for calculating ocean freight and insurance. Petitioners based the distributor's markup on an affidavit attesting to the standard distributor markup in the industry.

Because the PRC is considered a nonmarket economy (NME) country under section 771(18) of the Act, the petitioners based normal value (NV) on the factors of production valued in a surrogate country, in accordance with section 773(c)(3) of the Act. The petitioners selected India as the most appropriate surrogate market economy. For the factors of production, the petitioners relied upon the factor usage rates of what it claimed was the world's most efficient NFAJC producer.

The petitioners first derived a cost for apple juice and then, based on this cost,

[1] *See Algoma Steel Corp. Ltd.*, v. *United States*, 688 F. Supp. 639, 642–44 (CIT 1988); *High Infarmatian Cantent Flat Panel Displays and Display Glass from Japan: Final Determination; Rescission of Investigation and Partial Dismissal of Petition*, 56 FR 32376, 32380–81 (July 16, 1991).

they derived a cost of apple juice concentrate. The cost of apples was based on the current price of juice apples in India as reported in a market research study included in the petition. Labor was valued using the methodology described by the Department in 19 CFR 351.408(c)(3). For energy, the petitioners used data from *Energy Prices & Taxes*, Fourth Quarter 1998, which shows 1995 electricity rates in India to be Rs. 2.1836 per kwh. They then adjusted this 1995 electricity rate for inflation based on the increase in the wholesale price index in India from 1995 to 1998 as reported in the IMF's *International Financial Statistics*. For natural gas, the petitioners obtained a price of US $1.96 per thousand cubic feet based on the first quarter 1999 report of Enron Corp., a large, publicly traded oil and gas company selling energy products in India. For processing agents, maintenance supplies, and miscellaneous costs, the petitioners used the costs of a U.S. producer because Indian values for these inputs were not reasonably available to them.

Selling, general, and administrative (SG&A) expenses, depreciation, and financial expenses were based on the 1997 financial statements of an Indian NFAJC producer. For packing costs, including drums, liners, and pallets, the petitioners used the costs of a U.S. NFAJC producer because Indian values for these inputs were not reasonably available to them.

Based on a comparison of EP to NV, as adjusted by the Department, the information in the petition and other information reasonably available to the Department indicates dumping margins of 51.69 and 65.64 percent. A description of the adjustments which the Department made to petitioners' calculations of export price and normal value are contained in the June 28, 1999 initiation checklist, a public version of which is available in the Central Records Unit, Room B-099, Main Commerce, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of NFAJC from the PRC are being, or are likely to be, sold at less than fair value.

Allegations and Evidence of Material Injury and Causation

The petition alleges that the U.S. industry producing the domestic like product is being materially injured, and is threatened with material injury, by reason of the imports of the subject merchandise sold at less than NV. The petitioners explained that the industry's injured condition is evident in the declining trends in net operating profits and income, net sales volumes and values, profit to sales ratios, and capacity utilization. The allegations of injury and causation are supported by relevant evidence including U.S. Customs import data, lost sales, and pricing information. The Department assessed the allegations and supporting evidence regarding material injury and causation and determined that these allegations are supported by accurate and adequate evidence and meet the statutory requirements for initiation. *See* Initiation Checklist.

Allegation of Critical Circumstances

The petitioners allege that critical circumstances exist with respect to imports of NFAJC from the PRC and have supported their allegations with the following information.

First, the petitioners claim that the importers knew, or should have known, that NFAJC from the PRC was being sold at less than normal value. Specifically, the petitioners allege that the margins calculated in the petition exceed the 25 percent threshold used by the Department to impute importer knowledge of dumping.

The petitioners also have alleged that imports have been massive over a relatively short period. Alleging that there was sufficient pre-filing notice of this antidumping petition, the petitioners contend that the Department should compare imports during June 1998–October 1998 to imports during November 1998–March 1999 for purposes of this determination. Specifically, petitioners supported this allegation with copies of a news article and a transcript of a television program. The new article appeared in the September 1998 edition of "The Great Lakes Fruit Grower News," which reported that the U.S. Apple Association was considering filing an antidumping action against NFAJC from the PRC. The television program, "The World Today," aired on CNN on October 5, 1998. The program also reported that the U.S. Apple Association was considering filing an antidumping action on NFAJC from the PRC. On October 6, 1998, the Associated Press Newswire carried a story that the apple industry planned to file an antidumping action on NFAJC from the PRC. Accordingly, the petitioners provided import statistics for the periods November 1998–March 1999 and June 1998–October 1998. Based on this comparison, imports of NFAJC from the PRC increased by 111 percent.

Although the ITC has not yet made a preliminary decision with respect to injury, the petitioners note that in the past the Department has also considered the extent of the increase in the volume of imports of the subject merchandise as one indicator of whether a reasonable basis exists to impute knowledge that material injury was likely. In this case, the petitioners allege that the increase in imports was more than double the amount considered "massive." Taking into consideration the foregoing, we find that the petitioners have alleged the elements of critical circumstances and supported them with information reasonably available for purposes of initiating a critical circumstances inquiry. For these reasons, we will investigate this matter further and will make a preliminary determination at the appropriate time, in accordance with section 735(e)(1) of the Act and Department practice (see Policy Bulletin 98/4 (63 FR 55364, October 15, 1998)).

Initiation of Antidumping Investigation

Based upon our examination of the petition, we have found that the petition meets the requirements of section 732 of the Act. Therefore, we are initiating an antidumping duty investigation to determine whether imports of NFAJC from the PRC are being, or are likely to be, sold in the United States at less than fair value. Unless this deadline is extended, we will make our preliminary determination by November 15, 1999.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of the petition has been provided to the representatives of the Government of the People's Republic of China. We will attempt to provide a copy of the public version of the petition to the exporters named in the petition.

International Trade Commission Notification

We have notified the ITC of our initiation of this investigation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will determine by July 22, 1999, whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, by reason of imports of NFAJC from the PRC. A negative ITC determination will result in the investigation being terminated; otherwise, this investigation will proceed according to statutory and regulatory time limits.

This notice is published in accordance with section 777(i) of the Act.

Dated: June 28, 1999.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–17050 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–831–801, A–822–801, A–447–801, A–451–801, A–485–601, A–821–801, A–842–801, A–843–801, A–823–801, A–844–801, A–122–605, A–588–609, A–580–605, A–559–601]

Solid Urea From Armenia, Solid Urea From Belarus, Solid Urea From Estonia, Solid Urea From Lithuania, Solid Urea From Romania, Solid Urea From Russia, Solid Urea From Tajikistan, Solid Urea From Turkmenistan, Solid Urea From Ukraine, Solid Urea From Uzbekistan, Color Picture Tubes From Canada, Color Picture Tubes From Japan, Color Picture Tubes From Korea (South), Color Picture Tubes From Singapore: Extension of Time Limit for Final Results of Five-Year Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce

ACTION: Notice of extension of time limit for final results of five-year ("sunset") reviews

SUMMARY: The Department of Commerce ("the Department") is extending the time limit for the final results of the sunset reviews on the antidumping duty orders on solid urea from Armenia, solid urea from Belarus, solid urea from Estonia, solid urea from Lithuania, solid urea from Romania, solid urea from Russia, solid urea from Tajikistan, solid urea from Turkmenistan, solid urea from Ukraine, solid urea from Uzbekistan, color picture tubes from Canada, color picture tubes from Japan, color picture tubes from Korea (South), and color picture tubes from Singapore. Based on adequate responses from domestic interested parties and inadequate responses from respondent interested parties, the Department is conducting expedited sunset reviews to determine whether revocation of the orders would be likely to lead to continuation or recurrence of dumping. As a result of this extension, the Department intends to issue its final results of its sunset reviews of these orders no later than August 30, 1999.

EFFECTIVE DATE: July 6, 1999.

FOR FURTHER INFORMATION CONTACT: Scott E. Smith, Martha V. Douthit or Melissa G. Skinner, Import Administration, International Trade Administration, U.S. Department of Commerce, Pennsylvania Avenue and 14th Street, NW, Washington, D.C. 20230; telephone: (202) 482–6397, (202) 482–3207 or (202) 482–1560 respectively.

Extension of Final Results

The Department has determined that the sunset reviews of the antidumping duty orders on solid urea from Armenia, solid urea from Belarus, solid urea from Estonia, solid urea from Lithuania, solid urea from Romania, solid urea from Russia, solid urea from Tajikistan, solid urea from Turkmenistan, solid urea from Ukraine, solid urea from Uzbekistan, color picture tubes from Canada, color picture tubes from Japan, color picture tubes from Korea (South), and color picture tubes from Singapore are extraordinarily complicated. In accordance with section 751(c)(5)(C)(v) of the Tariff Act of 1930, as amended ("the Act"), the Department may treat a review as extraordinarily complicated if it is a review of a transition order (*i.e.,* an order in effect on January 1, 1995). *See* section 751(c)(6)(C) of the Act. The Department is extending the time limit for completion of the final results of these reviews until not later than August 30, 1999, in accordance with section 751(c)(5)(B) of the Act.

Dated: June 29, 1999.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–17052 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–833]

Stainless Steel Bar From Japan: Final Results of Antidumping Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Antidumping Administrative Review.

SUMMARY: On March 4, 1999, the Department of Commerce published the preliminary results of administrative review of the antidumping duty order on stainless steel bar from Japan. This review covers one producer/exporter, Aichi Steel Corporation, during the period February 1, 1997, through January 31, 1998.

We gave interested parties an opportunity to comment on the preliminary results. Based on our analysis of the comments received, we have made certain changes for the final results.

EFFECTIVE DATE: July 6, 1999.

FOR FURTHER INFORMATION CONTACT: Minoo Hatten or Robin Gray, Office of AD/CVD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 482–1690 or (202) 482–4023, respectively.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department of Commerce's (the Department's) regulations are to 19 CFR Part 351 (1998).

Background

On March 4, 1999, the Department published in the **Federal Register** the preliminary results of administrative review of the antidumping duty order on stainless steel bar from Japan. *Preliminary Results of Antidumping Duty Administrative Review: Stainless Steel Bar from Japan,* 64 FR 10445 (preliminary results). Al Tech Specialty Steel Corp., Dunkirk, N.Y., Carpenter Technology Corp., Reading, PA, Republic Engineered Steels, Inc., Massillon, OH, Slater Steels Corp., Fort Wayne, IN, Talley Metals Technology, Inc., Hartsville, SC, and the United Steel Workers of America, AFL-CIO/CLC, collectively petitioners in the less-than-fair-value (LTFV) investigation (hereafter petitioners), submitted their case brief on April 5, 1999. Aichi Steel Corporation (Aichi), respondent in this review, also submitted its case brief on April 5, 1999. The petitioners and Aichi submitted rebuttal briefs on April 12, 1999. The Department has conducted this administrative review in accordance with section 751 of the Act.

Scope of Review

The merchandise covered by this review is stainless steel bar (SSB). For purposes of this review, the term "stainless steel bar" means articles of stainless steel in straight lengths that have been either hot-rolled, forged, turned, cold-drawn, cold-rolled or otherwise cold-finished, or ground, having a uniform solid cross section

along their whole length in the shape of circles, segments of circles, ovals, rectangles (including squares), triangles, hexagons, octagons or other convex polygons. SSB includes cold-finished SSBs that are turned or ground in straight lengths, whether produced from hot-rolled bar or from straightened and cut rod or wire, and reinforcing bars that have indentations, ribs, groves, or other deformations produced during the rolling process.

Except as specified above, the term does not include stainless steel semi-finished products, cut-length flat-rolled products (*i.e.*, cut-length rolled products which if less than 4.75 mm in thickness have a width measuring at least 10 times the thickness or if 4.75 mm or more in thickness having a width which exceeds 150 mm and measures at least twice the thickness), wire (*i.e.*, cold-formed products in coils, of any uniform solid cross section along their whole length, which do not conform to the definition of flat-rolled products), and angles, shapes and sections.

The SSB subject to this order is currently classifiable under subheadings 7222.10.0005, 7222.10.0050, 7222 20.0005, 7222.20.0045, 7222.20.0075, and 7222.30.0000 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 order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by interested parties to this administrative review are addressed below.

Comment 1: Level of Trade

Aichi argues that the Department should find five different levels of trade for Aichi's home market. Aichi alleges that the Department found three levels of trade correctly—sales to trading companies, sales to distributors, and sales to end-users—but rejected the consignment/non-consignment distinction within the trading company and distributor levels of trade incorrectly. Aichi argues that, in rejecting this distinction, the Department did not appreciate that consignment is in itself a selling function that affects how Aichi markets its products.

The petitioners argue that the Department should continue to find only three levels of trade for Aichi's home market sales as it did in the preliminary results. According to the petitioners, the verified record demonstrates that the Department's preliminary decision—that only three levels of trade exist—was accurate and is supported by the record in this review. The petitioners contend that a close examination of Aichi's arguments reveals that there is no support to segregate the distributor and trading-company levels of trade into further consignment and non-consignment subcategories, since Aichi holds the title until the merchandise is sold for both consignment and non-consignment sales and Aichi receives payment for the goods only after they are sold to the final customer in both cases.

Department's Position: We do not find that consignment is in itself a selling function. The "consignment" relationship is not necessarily a distinct selling function and, even if it were a distinct selling function, such activities alone may not establish a separate level of trade. See, *e.g.*, *Certain Stainless Steel Wire Rod from India; Preliminary Results of Antidumping Duty Administrative and New Shipper Reviews*, 63 FR 48184, 48186 (Sept. 9, 1998) ("there was not a significant difference in selling functions between sales made through consignment agents and marketing agents, and as such we have made no level of trade distinction"); see also *Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination; Stainless Steel Sheet and Strip in Coils from Germany*, 64 FR 92, 97 (Jan. 4, 1999) ("channels of distribution do not qualify as separate levels of trade when the selling functions performed * * * are sufficiently similar"); *Certain Fresh Cut Flowers from Mexico; Final Results of Antidumping Duty Administrative Review*, 55 FR 12696 (Apr. 5, 1990) ("aside from claiming that flowers are sold to two different types of customers, *i.e.*, retailers and consignment wholesalers in the two markets, the respondent did not provide any evidence indicating that the difference in prices is attributable to different levels of trade"); *Final Determination of Sales at Less Than Fair Value: Certain Fresh Cut Flowers from Costa Rica*, 52 FR 6852 (March 5, 1987) ("we have made no level of trade adjustment. The respondent did not demonstrate that expenses incurred in selling to retailers * * * would not have also been incurred in sales to [consignment] wholesalers"). Thus, the mere existence of a consignment relationship does not necessarily establish a distinct level of trade. There must be sufficient differences in selling functions performed between the consignment accounts and non-consignment accounts.

Based on our analysis of information on the record of this review, we determine, as we did in our preliminary analysis, that there are no differences with respect to selling functions between consignment and non-consignment sales. Specifically, there are no differences between consignment and non-consignment sales with respect to strategic and economic planning, market research, computer, legal, accounting, audit, business systems development assistance, personnel assistance, engineering services, research and development (R&D) technical programs, advertising, procurement and sourcing, sales calls/assistance and post-sale warehousing. As stated in the preliminary results, the distinction between consignment and non-consignment sales is that, in consignment-sales situations, Aichi permits the customer to take possession of the product without requiring that the customer pay for the product until the customer sells the merchandise to its downstream customer. This distinction, however, does not relate to the nature of the selling functions performed. Furthermore, Aichi has not presented evidence establishing any price differences between consignment and non-consignment sales.

Selling functions performed with respect to trading companies included strategic and economic planning, market research, computer, legal and business-systems development, engineering services and post-sale warehousing. In addition to these functions, other functions performed for sales to end-users included R&D technical programs, advertising, and sales calls/assistance. Distributors were also offered personnel training and manpower assistance in addition to the services offered to trading companies and end-users. Based on these differences, we found that the three types of home market customers constituted three different levels of trade.

We found that Aichi made export price (EP) sales of various models of merchandise through unaffiliated trading companies, a channel of distribution similar to the home market channel involving sales to trading companies. As with sales through the trading-company channel of distribution in the home market, Aichi performed only a few selling functions when selling merchandise to trading companies that exported the merchandise to the United States. Thus, we found that the level of trade for this U.S. channel of distribution was the same as the level of trade for the home

market trading-company channel of distribution. Based on the information on the record, the Department determines that only three levels of trade exist in the home market. For a detailed discussion of the Department's position on Aichi's levels of trade, see the preliminary results, 64 FR at 10446.

Comment 2: Research and Development Costs

Aichi disagrees with the Department's inclusion of non-SSB-related R&D costs in the general and administrative expenses for the calculation of Aichi's cost of production. Aichi argues that the record shows that it maintains R&D costs by cost center and is thus able to distinguish the products for which it incurred R&D expenses. Aichi urges that, if a respondent records its R&D expenses on a product-specific basis and there is no evidence that this R&D may benefit the production of subject merchandise, under *Micron Technology, Inc.* v. *United States,* 893 F. Supp. 21 (CIT 1995), *aff'd,* 117 F.3d 1386 (Fed. Cir. 1997), the Department must allocate such expenses according to the respondent's records.

The petitioners agree with the Department's calculation of Aichi's cost of production in the preliminary results. The petitioners assert that the simple fact that Aichi records its R&D expenses by cost center is not convincing evidence that there are true product-specific R&D expenses. They contend that Aichi's R&D expenses provide an overall benefit to all products, including the subject merchandise. Furthermore, the petitioners observe, Aichi's products share a single manufacturing process. Finally, the petitioners state that the record indicates that Aichi itself has merged subject and non-subject products in its R&D activities.

Department's Position: Based on our analysis of the information on the record, it is appropriate to allocate the R&D costs in question across Aichi's total cost of production. As discussed below, where evidence on the record suggests that costs associated with R&D projects serve to benefit subject merchandise, the Department has included such costs, regardless of whether the company's accounting system allocates those costs exclusively to non-subject merchandise. Thus, the existence of product-specific accounting records does not necessarily preclude a finding of cross-fertilization. See *Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors ("SRAMs") from the Republic of Korea,* 63 FR 8934, 8939 (Feb. 23, 1998) ("separate accounting * * * does not necessarily mean that cross-fertilization of scientific ideas does not occur"), and *Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors ("SRAMs") from Taiwan,* 63 FR 8909, 8925 (Feb. 23, 1998), where the Department found that, although respondent maintained product-specific R&D accounting records, allocation of all R&D across all products was appropriate, "given that scientific ideas developed in one semiconductor area can be and have been utilized in the development of other semiconductor products."

In order to substantiate its claim that certain R&D costs do not benefit subject merchandise, Aichi provided a list of R&D projects that it claims relate only to non-subject merchandise. Additionally, Aichi provided a breakdown of R&D costs by department. However, as detailed in the analyst's memorandum to file regarding R&D expenses (containing business proprietary information), dated June 23, 1999, Aichi has not submitted a breakdown of costs by project. Thus, as a preliminary matter, we are unable to determine the specific costs for each project to segregate project-specific costs. Therefore, even if we were to determine that some projects do not benefit the production of subject merchandise, we would not be able to segregate and exclude those project-specific costs.

Furthermore, based upon evidence in the record we have identified projects where R&D from one type of product could benefit another type of product. See the June 23, 1999, memorandum to file regarding R&D expenses. As such, because the record shows that at least some of the claimed projects may influence the production of subject merchandise and because we are unable to segregate the remaining projects, we have continued to include all R&D expenses in the cost of production.

Comment 3: Model-Match Error

Aichi argues that the Department should correct a clerical error in the model-match section of the calculations. Aichi asserts that, instead of matching first to contemporaneous sales, the Department first matched cost deviation (*i.e.,* matching to identical and similar physical characteristics) and level of trade (*i.e.,* matching to sales with similar functions) of the home market. As a result, Aichi contends, the identical or most similar home market model in the most contemporaneous month did not always match to each U.S. sale. Aichi argues that the Department should correct this error to comply with its well-established practice of matching contemporaneous sales as a higher matching priority than level of trade or cost deviation.

The petitioners argue that the Department conducted its model-match exercise correctly and that Aichi's suggested approach is not in accordance with the Department's long-standing practice. Citing *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from France, Germany, Italy, Japan, Singapore and the United Kingdom; Final Results of Antidumping Duty Administrative Reviews (AFBs),* 62 FR 2081, 2128 (Jan. 15, 1997), and *Stainless Wire Rods from France: Final Results of Antidumping Duty Administrative Review,* 61 FR 47874, 47879 (Sept. 11, 1996), the petitioners argue that the appropriate model-match hierarchy is cost deviation first, level of trade second, and contemporaneity last.

Department's Position: We did not make a clerical error in our model-match exercise. Contrary to Aichi's assertion, pursuant to section 771(16) of the Act, it has been the Department's practice to compare the subject merchandise sold to the United States first to products with identical physical characteristics sold in the exporting-country market. See, e.g., AFBs, 62 FR at 2128 ("[a]fter selecting the most comparable product match according to the statute, we attempt to find contemporaneous sales of that product at the same level of trade, if possible"). When products sold to the United States do not have identical matches in the foreign market, the statute directs us to use similar merchandise which meets the requirements set forth under section 771(16)(B) of the Act. For the current review, when determining appropriate product comparisons for U.S. sales, we compared U.S. sales to contemporaneous home market sales of the comparison model that were physically "most similar" and which passed the twenty-percent difference-in-merchandise test. We use the results of the model-match exercise to find the "most similar" home market sale within our 90/60 day contemporaneity guideline. After disregarding below-cost sales, we may not find a contemporaneous sale of an identical or similar product. In such situations, we compare the U.S. sale to constructed value. This methodology is consistent with Department practice. See, *e.g., Certain Welded Carbon Steel Pipes and Tubes from Thailand: Final Results of Antidumping Duty Administrative Review,* 61 FR 56515, 56520 (November 1, 1996). Aichi's suggestion could lead us to selecting comparison sales which occurred in the same month as the U.S.

sale but which are less similar than other sales within the 90/60 day contemporaneity guideline. This would not be consistent with the statute's direction to find the best physical comparison in the home market.

Comment 4: Model-Matching Criteria, Type

The petitioners argue that the Department should disregard the distinction Aichi made between hot-rolled SSB and hot-forged SSB within the first element of the model-match criteria, type. They contend that hot-forged products do not reflect a unique physical difference of the finished product. Therefore, they contend, both hot-rolled and hot-forged products should be considered to be hot-finished SSB as identified in the Department's questionnaire. In addition, the petitioners assert, the choice of alternative production processes and different costs is not reason enough for the establishment of different physical characteristics to use in selecting comparable products. In order to correct the respondent's inappropriate segregation of products by type of finish, the petitioners request that the Department consolidate hot-finished and hot-forged products and recalculate various costs affected by Aichi's segregation.

Aichi contends that the rolled/forged distinction warrants the identification of separate products for model-matching purposes. Aichi states that it uses the forging process to produce SSB when the dimensions or grades requested by the customer do not permit use of the rolling process. Therefore, Aichi argues, forging results in different physical characteristics. Aichi argues further that the cost-of-production information it submitted to the Department proves that cost differences exist between items produced using these two processes. For these reasons, Aichi requests that the Department compare home market and U.S. sales using all of the physical criteria Aichi identified in its response.

Department's Position: We find that it is appropriate to reflect the rolled/forged distinction of the products in our model-match methodology. In accordance with sections 771(16)(A) and (B) of the Act, we attempt to match the subject merchandise with products that are identical or similar in physical characteristics and that are approximately equal in commercial value. See, *e.g., Notice of Final Determination of Sales at Less Than Fair Value: Emulsion Styrene-Butadiene Rubber from the Republic of Korea,* 64 FR 14865, 14872 (March 29, 1999) ("mooney viscosity" is an appropriate matching criterion because "it is an essential product characteristic that defines the grade" and "there are cost and price differences between th[e] two grades * * *"); *Extruded Rubber Thread from Malysia: Final Results of Antidumping Duty Administrative Review,* 62 FR 62547, 62558 (Nov. 24, 1997) (the Department found "color" to be an appropriate model-match criterion because the Department had used that criterion consistently in the investigation and following reviews and because color could "materially affect cost and be important to the customer and the use of the product"); *Notice of Final Determination of Sales at Less Than Fair Value: Certain Pasta from Italy,* 61 FR 30326 (June 14, 1996) (the Department found "wheat quality" to be an appropriate matching criterion because there were differences in physical characteristics and because the cost was materially more for the segregated product).

Evidence on the record of this review demonstrates that the forging process results in meaningful differences in physical characteristics. In addition, certain cost differences exist between products manufactured using the rolling and forging process. Therefore, we have used Aichi's information on the forging process in our model-match methodology because it ensures that we make the best match.

Comment 5: Model-Matching Criteria, Shape

The petitioners contend that the Department should disregard Aichi's additional sub-codes for shape and consolidate the shape sub-codes accordingly for model-matching purposes. According to the petitioners, the Department's practice is to develop additional sub-coding for model-matching purposes only if there are physical differences, pricing differences as a result of physical differences, and market reactions to the physical differences. The petitioners contend that Aichi's sub-codes for shape do not meet this standard. In addition, the petitioners assert that Aichi does not distinguish between the shape differences that it submitted in its questionnaire response in the information that it maintains internally (*e.g.,* price-extras list) and disseminates externally (*e.g.,* Aichi product brochures). According to the petitioners, Aichi did not substantiate that additional sub-codes are required within the shape criteria. They request that the Department consolidate the shapes, as appropriate, and recalculate the various weighted-average costs to reflect the consolidation.

Aichi argues that the distinction between various shapes of flat bar in the response is justified and that the petitioners are confused about Aichi's codes. Aichi asserts that the relevant shape codes are those listed in the column "ShapeH" on page 5 of its Exhibit 2, Section B response. Aichi also states that, although it collapsed the square-bar products, the flat-bar distinctions it used are appropriate since the flat-bar products' physical characteristics differ, price differences are evident from the home market sales list, customers request different products, and Aichi has issued special brochures advertising some of these products. Therefore, Aichi contends, record evidence demonstrates that the flat-bar shape distinctions Aichi identified and segregated for model-matching purposes are justified.

Department's Position: It appears that the petitioners may have referred to the wrong variable in their analysis of the shape distinction. Notwithstanding this possibility, we disagree with Aichi that its additional segregation of products is warranted in matching models. As discussed in response to comment 4 above, the Department has discretion to select appropriate model-matching criteria which account for meaningful differences in physical characteristics, cost, and use. See, *e.g., Notice of Final Determination of Sales at Less Than Fair Value: Certain Pasta from Italy,* 61 FR 30326 (June 14, 1996), Koyo Seiko v. *United States,* 66 F.3d 1204 (Fed. Cir. 1995) (Final Results of Adm. Rev.) (the Department has the discretion to "choose the manner in which "such or similar merchandise" shall be selected"), and Certain Cold-Rolled Carbon Steel Flat Products From Germany; Final Results of Antidumping Duty Administrative Review, 60 FR 65264, 65271 (Dec. 19, 1995) (the Department has the discretion to choose "such or similar" merchandise).

As such, it is also not necessary that the Department segregate every claimed difference in characteristics if those differences are not meaningful for matching purposes. See *Certain Cold-Rolled Carbon Steel Flat Products From Germany,* 60 FR at 65271 ("[b]asing its product matching criteria on commercially meaningful characteristics permits the Department to draw reasonable distinctions between products for matching purposes, without attempting to account for every possible difference inherent in certain classes or kinds of merchandise * * *. As such, the Department may define certain products as being "identical" within the meaning of section 771(16)(A), even though they contain

minor differences * * *. Similarly, the Department need not account for every conceivable physical characteristic of a product in its hierarchy. Thus, as a range of products may be considered "identical" within the meaning of the statute"); *Final Determination of Sales at Less Than Fair Value; Gray Portland Cement and Clinker From Mexico,* 55 FR 29244 (July 18, 1990) (the Department determined that products within same ASTM standard would be deemed "identical in physical characteristics to the merchandise sold in [the home market]"); *Circular Welded Non-Alloy Steel Pipe and Tube From Mexico: Final Results of Antidumping Duty Administrative Review,* 63 FR 33041 (June 17, 1998) (Final Results of Adm. Rev.) (pickling, oiling and varnishing were only "packing treatments" and did not "transform the finished merchandise into a different product for purposes of merchandise comparison under 771(16)(A) and (B) of the Act").

With respect to Aichi's additional claimed shape distinction, upon reviewing the record, we find that the additional characteristics do not provide meaningful differences for matching purposes. Aichi's breakdown of flat bar segregates only minor differences in physical shape which do not affect our model-match comparison materially. See analyst's memorandum to file on the Issue of Model-Matching Criteria, Shape (containing business proprietary information), dated June 23, 1999. As we explained in *Circular Non-Alloy Steel Pipe and Tube from Mexico,* where the finishing process does not "transform the finished merchandise * * * for purposes of * * * [our] comparison," we generally will not distinguish such criteria (63 FR 33041 (June 17, 1998)). Thus, we have not accepted Aichi's additional claimed sub-codes for shape.

Comment 6: Warehousing Expenses

The petitioners argue that the Department should deduct home market warehousing expenses only for non-consignment and non-pre-sale-warehoused sales. They allege that the Department confirmed at verification Aichi's statement in its response that warehousing expenses do not apply to warehousing costs incurred on products prior to sale or to consignment sales. The petitioners comment that, in the preliminary results, the Department indicated that it intended to adjust the warehousing expenses, but it did not apply the warehousing expenses adjustment correctly and instead deducted warehousing expenses from consignment sales inadvertently.

Aichi argues that the Department should deduct warehousing expenses from all home market sales because, in accordance with 19 CFR 351.401(e)(2), the Department no longer makes the distinction between pre-sale and post-sale warehousing in granting this adjustment. The fact that warehousing occurred before sale date on consignment sales is irrelevant according to Aichi. Therefore, Aichi requests that the Department apply the warehousing adjustment to all home market sales.

Department's Position: In our preliminary results we added warehousing expenses to movement expenses on consignment sales unintentionally although we intended to add warehousing expenses to movement expenses for non-consignment sales. However, we did not confirm at verification, as the petitioners contend, that the warehousing expenses do not apply to products warehoused prior to sale. At verification we confirmed that, as Aichi stated in its Section B questionnaire response, page 36, the warehousing-expense adjustment applies only to non-consignment transactions. See analysts' Verification Report dated Dec. 21, 1998, in Room B099 of the main Commerce building. Furthermore, Aichi states that it has reported information to distinguish between invoice numbers for consignment sales and invoice numbers for sales involving pre-sale warehousing. In its questionnaire response, Section B, page 12 (May 12, 1998), Aichi provided information which indicates clearly that pre-sale warehousing did not occur on any consignment sales. We examined the home market database and found this to be the case. In addition, in Section A of its response, page 29, the respondent stated that it did not incur post-sale warehousing expenses for consignment sales. Therefore, in our calculations we have added warehousing expenses to the build-up of movement expenses for all sales except consignment sales, as we intended to do in the preliminary results of review.

Comment 7: Miscellaneous Programming Error

The petitioners contend that, in assigning exchange rates to all home market sales, the Department neglected to consolidate the home market dates of sale. It urges the Department to correct this error and provides a suggestion for doing so.

Aichi argues that, contrary to the petitioners' argument, there is no error in the Department's application of exchange rates. Although the Department introduces the exchange-rate database early in the computer program, Aichi states that it is appropriate that the Department never merges the exchange-rate database with the home market database and merges it with the U.S. sales database at a later stage in the program.

Department's Position: There was no error in our exchange-rate calculations. Since we do not merge the exchange-rate database with the home market database, no error occurs. Rather, we merge the exchange rates with the U.S. sales database at a later stage in the program. As a result, no change is necessary.

Final Results of Review

As a result of our analysis of the comments received, we determine a weighted-average margin of 6.62 percent for Aichi for the period February 1, 1997, through January 31, 1998.

The Customs Service will assess antidumping duties on all appropriate entries. The Department will issue appraisement instructions directly to the Customs Service. We have calculated an exporter/customer-specific assessment value for subject merchandise based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of sales examined.

Furthermore, the following deposit requirement shall be effective upon publication of this notice of final results of review for all shipments of SSB from Japan, entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) The cash-deposit rate for Aichi Steel Corporation will be 6.62 percent; (2) for previously investigated or reviewed companies not listed above, the cash-deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this or any previous reviews or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash-deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash-deposit rate will continue to be 61.47 percent, the "all-others" rate established in the LTFV investigation (59 FR 66930, December 28, 1994).

The deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice serves as a final reminder to importers of their responsibility

under 19 CFR 351.402(f) 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 notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this determination in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 25, 1999.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–17049 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Applications for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 a.m. and 5:00 p.m. in Room 4211, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 99–016. *Applicant:* Purdue University, BRWN/WTHR Chemistry Building, W. Lafayette, IN 47907–1393. *Instrument:* ICP Mass Spectrometer, Model PlasmaQuad 3. *Manufacturer:* VG Elemental, United Kingdom. *Intended Use:* The instrument is intended to be used to chemically characterize samples of geologic materials—both terrestrial and extraterrestrial—and meteoric water samples. Geologic samples will be quantified as received (i.e. as solids, either powdered, as polished slabs or as thin sections) or as solutions, after their acid dissolution. Water samples will be analyzed without further processing. In addition, the instrument will be used for educational purposes in undergraduate research. Application accepted by Commissioner of Customs: June 16, 1999.

Docket Number: 99–017. *Applicant:* The Burnham Institute, 10901 North Torrey Pines Road, La Jolla, CA 92037. *Instrument:* Cryo Electron Microscope, Model Tecnai 12 Twin. *Manufacturer:* FEI Company, The Netherlands. *Intended Use:* The instrument is intended to be used for training postdoctoral scientists in the use of electron cryo-microscopy to examine tissue samples during research focusing on image reconstruction of actin filaments decorated with cytoskeletal proteins. All the projects will involve electron cryo-microscopy and image analysis, fitting of crystal structures to the em maps. Application accepted by Commissioner of Customs: June 18, 1999.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 99–17048 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of Connecticut, et al.; Consolidated Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instruments described below, for such purposes as each is intended to be used, is being manufactured in the United States.

Docket Number: 99–005. *Applicant:* University of Connecticut, Storrs, CT 06269–1020. *Instrument:* Fiber Electrode Manipulator System. *Manufacturer:* Thomas Recording, Germany. *Intended Use:* See notice at 64 FR 23056, April 29, 1999. *Reasons:* The foreign instrument provides: (1) capability to position seven microelectrodes for independent manipulation within a small volume of tissue (inter-electrode distances of 256 µm) and (2) microelectrodes having a maximum shaft diameter of only 80 µm. Advice received from: National Institutes of Health, June 8, 1999.

Docket Number: 99–008. *Applicant:* University of California, San Diego, La Jolla, CA 92093–0515. *Instrument:* Operant Testing System. *Manufacturer:* CeNeS Ltd., United Kingdom. *Intended Use:* See notice at 64 FR 27516, May 20, 1999. *Reasons:* The foreign instrument provides: (1) A 9-hole nosepoke panel to permit randomized positioning of stimuli in a 5-choice serial reaction time task for rats and (2) 4.0 cm-deep ports to minimize undesirable head orientation. Advice received from: National Institutes of Health, June 8, 1999.

The National Institutes of Health advises in its memoranda that (1) the capabilities of each of the foreign instruments described above are pertinent to each applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value for the intended use of each instrument.

We know of no other instrument or apparatus being manufactured in the United States which is of equivalent scientific value to either of the foreign instruments.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 99–17047 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–DS–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Taiwan

June 29, 1999.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: July 8, 1999.

FOR FURTHER INFORMATION CONTACT: Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs website at http://www.customs.ustreas.gov. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted, variously, for swing, special shift, special swing and carryforward used.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 63 FR 71096, published on December 23, 1998). Also see 63 FR 69057, published on December 15, 1998.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

June 29, 1999.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 8, 1998, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Taiwan and exported during the twelve-month period which began on January 1, 1999 and extends through December 31, 1999.

Effective on July 8, 1999, you are directed to adjust the current limits for the following categories, as provided for under the terms of the current bilateral textile agreement:

Category	Adjusted twelve-month limit [1]
Group I	
200–224, 225/317/326, 226, 227, 229, 300/301/607, 313–315, 360–363, 369–L/670–L/870 [2], 369–S [3], 369–O [4], 400–414, 464–469, 600–606, 611, 613/614/615/617, 618, 619/620, 621–624, 625/626/627/628/629, 665, 666, 669–P [5], 669–T [6], 669–O [7], 670–H [8] and 670–O [9], as a group.	617,719,704 square meters equivalent.
Sublevels in Group I	
225/317/326	41,139,054 square meters.
611	3,340,709 square meters.
619/620	15,205,500 square meters.
625/626/627/628/629	19,816,003 square meters.
Within Group I Subgroup	
604	224,360 kilograms.
Group II	
237, 239, 330–332, 333/334/335, 336, 338/339, 340–345, 347/348, 349, 350/650, 351, 352/652, 353, 354, 359–C/659–C [10], 359–H/659–H [11], 359–O [12], 431–444, 445/446, 447/448, 459, 630–632, 633/634/635, 636, 638/639, 640, 641–644, 645/646, 647/648, 649, 651, 653, 654, 659–S [13], 659–O [14], 831–844, and 846–859, as a group.	716,060,966 square meters equivalent.
Sublevels in Group II	
331	535,239 dozen pairs.
336	139,547 dozen.
338/339	990,141 dozen.
340	1,288,035 dozen.
345	119,356 dozen.
347/348	1,494,066 dozen of which not more than 1,288,567 dozen shall be in Categories 347–W/348–W [15].
435	26,636 dozen.
436	5,253 dozen.
438	29,652 dozen.
443	44,801 numbers.
444	63,807 numbers.
445/446	142,903 dozen.
638/639	6,495,826 dozen.
640	946,906 dozen of which not more than 281,710 dozen shall be in Category 640–Y [16].
642	889,729 dozen.
647/648	5,351,981 dozen of which not more than 5,088,804 dozen shall be in Categories 647–W/648–W [17].
Within Group II Subgroup	
342	169,016 dozen.
351	413,338 dozen.
447/448	21,865 dozen.
636	395,471 dozen.
651	438,722 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1998.

[2] Category 870; Category 369–L: only HTS numbers 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3016, 4202.92.6091 and 6307.90.9905; Category 670–L: only HTS numbers 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3031, 4202.92.9026 and 6307.90.9907.

[3] Category 369–S: only HTS number 6307.10.2005.

[4] Category 369–O: all HTS numbers except 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3016, 4202.92.6091, 6307.90.9905 (Category 369–L); and 6307.10.2005 (Category 369–S).

[5] Category 669–P: only HTS numbers 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020 and 6305.39.0000.

[6] Category 669–T: only HTS numbers 6306.12.0000, 6306.19.0010 and 6306.22.9030.

[7] Category 669–O: all HTS numbers except 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020, 6305.39.0000 (Category 669–P); 6306.12.0000, 6306.19.0010 and 6306.22.9030 (Category 669–T).

[8] Category 670–H: only HTS numbers 4202.22.4030 and 4202.22.8050.

[9] Category 670–O: all HTS numbers except 4202.22.4030, 4202.22.8050 (Category 670–H); 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3031, 4202.92.9026 and 6307.90.9907 (Category 670–L).

[10] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010 ; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[11] Category 359–H: only HTS numbers 6505.90.1540 and 6505.90.2060; Category 659–H: only HTS numbers 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090 and 6505.90.8090.

[12] Category 359–O: all HTS numbers except 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025, 6211.42.0010 (Category 359–C); 6505.90.1540 and 6505.90.2060 (Category 359–H).

[13] Category 659–S: only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020.

[14] Category 659–O: all HTS numbers except 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017, 6211.43.0010 (Category 659–C); 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090, 6505.90.8090 (Category 659–H); 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020 (Category 659–S).

[15] Category 347–W: only HTS numbers 6203.19.1020, 6203.19.9020, 6203.22.3020, 6203.22.3030, 6203.42.4005, 6203.42.4010, 6203.42.4015, 6203.42.4025, 6203.42.4035, 6203.42.4045, 6203.42.4050, 6203.42.4060, 6203.49.8020, 6210.40.9033, 6211.20.1520, 6211.20.3810 and 6211.32.0040; Category 348–W: only HTS numbers 6204.12.0030, 6204.19.8030, 6204.22.3040, 6204.22.3050, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.62.4055, 6204.62.4065, 6204.69.6010, 6204.69.9010, 6210.50.9060, 6211.20.1550, 6211.20.6810, 6211.42.0030 and 6217.90.9050.

[16] Category 640–Y: only HTS numbers 6205.30.2010, 6205.30.2020, 6205.30.2050 and 6205.30.2060.

[17] Category 647–W: only HTS numbers 6203.23.0060, 6203.23.0070, 6203.29.2030, 6203.29.2035, 6203.43.2500, 6203.43.3500, 6203.43.4010, 6203.43.4020, 6203.43.4030, 6203.43.4040, 6203.49.1500, 6203.49.2015, 6203.49.2030, 6203.49.2045, 6203.49.2060, 6203.49.8030, 6210.40.5030, 6211.20.1525, 6211.20.3820 and 6211.33.0030; Category 648–W: only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4038, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.69.2560, 6204.69.6030, 6204.69.9030, 6210.50.5035, 6211.20.1555, 6211.20.6820, 6211.43.0040 and 6217.90.9060.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 99–16939 Filed 7–2–99; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF ENERGY

Notice of Intent To Establish the Nonproliferation and National Security Advisory Committee

In accordance with Section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and in accordance with Title 41 of the Code of Federal Regulations, sections 101–6.1015(a), this notice of intent to establish the Nonproliferation and National Security Advisory Committee. This intent to establish follows consultation with the Committee Management Secretariat of the General Services Administration, pursuant to 41 CFR Subpart 101–6.10.

The purpose of the Committee is to provide the Secretary of Energy and the Assistant Secretary for Nonproliferation and National Security with advice, information, and recommendations on national research needs and priorities. The Committee will provide an organized forum for the scientific community to provide input to nonproliferation research and development programs.

Committee members will be chosen to ensure an appropriately balanced membership to bring into account a diversity of viewpoints including representatives from universities, industry, and others who may significantly contribute to the deliberations of the Committee. Advance notice of all meetings of this Committee will be published in the **Federal Register**.

The establishment of the Nonproliferation and National Security Advisory Committee has been determined to be compelled by considerations of national security, essential to the conduct of Department of Energy business, and in the public interest.

Further information regarding this Committee may be obtained from Mr. Robert Waldron, Director of the Office of Research and Development, U.S. Department of Energy, Washington, D.C. 20585, phone (202) 586–2400.

Issued in Washington, D.C., on June 30, 1999.

James N. Solit,

Advisory Committee Management Officer

[FR Doc. 99–17024 Filed 7–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket No. EA–147–A]

Application To Export Electric Energy; Aquila Energy Marketing Corporation

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: Aquila Energy Marketing Corporation (AEM) has applied for renewal of its authority to transmit electric energy from the United States to Mexico pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before July 21, 1999.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Im/Ex (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Steven Mintz (Program Office) 202–586–9506 or Michael Skinker (Program Attorney) 202–586–6667.

SUPPLEMENTARY INFORMATION: On June 19, 1997, the Office of Fossil Energy (FE) of the Department of Energy (DOE) authorized AEM to transmit electric energy from the United States to Mexico as a power marketer using the international electric transmission facilities owned and operated by Comision Federal de Electricidad (the national electric utility of Mexico), Central Power & Light Company, El Paso Electric Company, and San Diego Gas & Electric Company. That two-year authorization expired on June 19, 1999. On June 18, 1999, AEM filed an application with FE for renewal of this export authority and requested that the Order be issued for an additional two-year term. AEM also has requested expedited processing of this application.

Procedural Matters

Any person desiring to become a party to this proceeding or to be heard by filing comments or protests to this application should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the date listed above.

Comments on the AEM request to export to Mexico should be clearly marked with Docket EA–147–A. Additional copies are to be filed directly with Mr. David Stevenson, Aquila Energy Marketing Corporation, P.O. Box 11739, 10700 East 350 Highway, Kansas City, MO 64138, and Kathryn A. Flaherty, Blackwell Sanders Peper Martin, 13710 FNB Parkway, Suite 200, Omaha, NB 68154.

DOE notes that the circumstances described in this application are virtually identical to those for which export authority had previously been granted in FE Order EA–147. Consequently, DOE believes that it has adequately satisfied its responsibilities under the National Environmental Policy Act of 1969 through the documentation of a categorical exclusion in the FE Docket EA–147 proceeding.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at http://www.fe.doe.gov. Upon reaching the Fossil Energy Home page, select "Regulatory Programs," then "Electricity Regulation," and then "Pending Proceedings" from the options menus.

Issued in Washington, D.C., on June 28, 1999.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Im/Ex, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 99–17020 Filed 7–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket No. EA–148–A]

Application To Export Electric Energy; Aquila Energy Marketing Corporation

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: Aquila Energy Marketing Corporation (AEM) has applied for renewal of its authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before August 5, 1999.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Im/Ex (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Steven Mintz (Program Office) 202–586–9506 or Michael Skinker (Program Attorney) 202–586–6667.

SUPPLEMENTARY INFORMATION: On August 13, 1997, the Office of Fossil Energy (FE) of the Department of Energy (DOE) authorized AEM to transmit electric energy from the United States to Canada as a power marketer using the international electric transmission facilities owned and operated by Basin Electric Power Cooperative, Bonneville Power Administration, Citizens Utilities, Detroit Edison, Eastern Maine Electric Cooperative, Joint Owners of the Highgate Project, Maine Electric Power Company, Maine Public Service Company, Minnesota Power, Inc., Minnkota Power, New York Power Authority, Niagara Mohawk Power Corp., Northern States Power, and Vermont Electric Transmission Company. That two-year authorization will expire on August 13, 1999. On June 18, 1999, AEM filed an application with FE for renewal of this export authority and requested that the Order be issued for an additional two-year term.

Procedural Matters

Any person desiring to become a party to this proceeding or to be heard by filing comments or protests to this application should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the date listed above.

Comments on the AEM request to export to Canada should be clearly marked with Docket EA–148–A. Additional copies are to be filed directly with Mr. David Stevenson, Aquila Energy Marketing Corporation, P.O. Box 11739, 10700 East 350 Highway, Kansas City, MO 64138, and Kathryn A. Flaherty, Blackwell Sanders Peper Martin, 13710 FNB Parkway, Suite 200, Omaha, NB 68154.

DOE notes that the circumstances described in this application are virtually identical to those for which export authority had previously been granted in FE Order EA–148. Consequently, DOE believes that it has adequately satisfied its responsibilities under the National Environmental Policy Act of 1969 through the documentation of a categorical exclusion in the FE Docket EA–148 proceeding.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at http://www.fe.doe.gov. Upon reaching the Fossil Energy Home page, select "Regulatory Programs," then "Electricity Regulation," and then "Pending Proceedings" from the options menus.

Issued in Washington, D.C., on June 28, 1999.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Im/Ex, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 99–17021 Filed 7–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Albany Research Center; Inventions Available for Licensing

AGENCY: Department of Energy (DOE), Albany Research Center.

ACTION: Notice.

SUMMARY: The United States Department of Energy, Albany Research Center (ALRC) announces that the inventions listed below are available for licensing in accordance with 35 U.S.C. 207–209 to achieve expeditious commercialization of results of federally funded research and development. Foreign patents rights have been retained on selected inventions to extend market coverage and may also be available for licensing. A copy of issued patents may be obtained by download from the U.S. Patent and Trademark Office Website, *http://www.uspto.gov/patft/index.html;* or for a modest fee, from the U.S. Patent and Trademark Office, Washington, DC 20231.

ADDRESSES: George J. Dooley, III, Director, U.S. Department of Energy, Albany Research Center, 1450 Queen Avenue SW, Albany, OR 97321–2198.

FOR FURTHER INFORMATION CONTACT: William Riley, Chief of Technology Transfer, U.S. Department of Energy, Albany Research Center, 1450 Queen Avenue, SW, Albany, Oregon 97321–2198; Telephone (541) 967–5851; OR Mark P. Dvorscak, Assistant Chief Counsel, Office of Intellectual Property Law, U.S. Department of Energy, Chicago Operations Office, 9800 S. Cass Ave., Argonne, IL 60439; Telephone (630) 252–2393; E-mail:mark.dvorscak@ch.doe.gov.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 207 authorizes licensing of Government-owned inventions. Implementing regulations are contained in 37 CFR Part 404. 37 CFR 404.7(a)(1) authorizes exclusive licensing of Government-owned inventions under certain circumstances, provided that notice of the invention's availability for licensing has been announced in the **Federal Register**.

Issued Patents

Number and Title

5,593,593 Process for Removing Sulfate Anions from Waste Water
5,680,996 Gas Fluidized-Bed Stirred Media Mill
5,613,244 Process for Preparing Liquid Wastes
5,564,620 Forming Metal-Intermetallic or Metal-Ceramic Composites by Self-Propagating High-Temperature Reactions
5,560,420 Process for Casting Hard-Faced, Lightweight Camshafts and Other Cylindrical Products
5,799,238 Method of Making Multilayered Titanium Ceramic Composites
5,788,736 Recovery of Titanium Values from Titanium Grinding SWARF by Electric Furnace Smelting
5,259,862 Continuous Production of Granular or Powder Ti, Zr, and Hf or Their Alloy Products
5,265,664 Fixture for Forming Evaporative Pattern Casting (EPC) Process Patterns

Patent Applications Filed

Synergic System for Solvent Extraction of Germanium
Recovery of Titanium Values from Titanium Grinding SWARF by Electric Furnace Smelting
Process for Zinc Recovery from Organic Extractants with Carbon Dioxide

Dated: June 17, 1999.

George J. Dooley,

Director, ALRC.

[FR Doc. 99–17023 Filed 7–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Albany Research Center Intent To Grant Exclusive Patent License

AGENCY: Department of Energy (DOE), Albany Research Center (ALRC).

ACTION: Notice.

SUMMARY: Notice is hereby given of an intent to grant to MSE Technology Applications, Inc., of Butte, Montana, an exclusive license to practice the invention described in U.S. Patent No. 5, 560,420 titled "Process for Casting Hard-Faced, Lightweight Camshafts and Other Cylindrical Products." The invention is owned by the United States of America, as represented by the Department of Energy (DOE). The proposed license will be exclusive, subject to a license and other rights retained by the U.S. Government, and other terms and conditions to be negotiated.

DOE intends to grant the license, upon a final determination in accordance with 35 U.S.C. 209(c), unless within 60 days of publication of this Notice the Deputy Chief Counsel, Office of Intellectual Property Law, Department of Energy, Chicago Operations Office, 9800 S. Cass Ave, Argonne, IL 60439, receives in writing any of the following, together with the supporting documents:

(i) A statement from any person setting forth reasons why it would not be in the best interest of the United States to grant the proposed license; or (ii) An application for a nonexclusive license to the invention, in which applicant states that it already has brought the invention to practical application or is likely to bring the invention to practical application expeditiously.

DATES: Written comments or nonexclusive license applications are to be received at the address listed below no later than September 7, 1999.

ADDRESSES: Deputy Chief Counsel, Office of Intellectual Property Law, U.S. Department of Energy, Chicago Operations Office, 9800 S. Cass Ave, Argonne, IL 60439.

FOR FURTHER INFORMATION CONTACT: William Riley, Chief of Technology Transfer, Department of Energy, Albany Research Center, 1450 Queen Avenue, SW, Albany, Oregon 97321–2198; Telephone (541) 967–5851; E-mail: riley@alrc.doe.gov, or: Mark P. Dvorscak, Assistant Chief Counsel, Office of Intellectual Property Law, U.S. Department of Energy, Chicago Operations Office, 9800 S. Cass Ave., Argonne, IL 60439; Telephone (630) 252–2393.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 209(c) provides the Department with authority to grant exclusive or partially exclusive licenses in Department-owned inventions, where a determination can be made, among other things, that the desired practical application of the invention has not been achieved, or is not likely expeditiously to be achieved, under a nonexclusive license. The statute and implementing regulations (37 CFR § 404) require that the necessary determinations be made after public notice and opportunity for filing written objections.

MSE Technology Applications, Inc., of Butte, Montana, has applied for an exclusive license to practice the invention embodied in U.S. Patent Nos. 5, 560,420 and has a plan for commercialization of the invention.

The proposed license will be exclusive, subject to a license and other rights retained by the U.S. Government, and subject to a negotiated royalty. The Department will review all timely written responses to this notice, and will grant the license if, after expiration of the 60-day notice period, and after consideration of written responses to this notice, a determination is made, in accordance with 35 U.S.C. 209(c), that the license grant is in the public interest.

Dated: June 17, 1999.

George J. Dooley, III,

Director, ALRC.

[FR Doc. 99–17022 Filed 7–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–345–001]

Arkansas Western Pipeline, L.L.C; Notice of Tariff Filing

June 29, 1999.

Take notice that on June 23, 1999, Arkansas Western Pipeline, L.L.C. (AWP L.L.C.) tendered for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 1, revised tariff sheets, with an effective date of June 22, 1999.

AWP L.L.C. asserts that the purpose of this filing is to replace the revised sheets filed by AWP L.L.C. on June 22, 1999 in this proceeding because the issuance and effective dates on such sheets were inadvertently omitted.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in section 154.210 of the Commission's Regulations. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16979 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–348–000]

Arkansas Western Pipeline, L.L.C.; Notice of Tariff Filing

June 29, 1999.

Take notice that on June 23, 1999, Arkansas Western Pipeline, L.L.C. (AWP L.L.C.) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, revised tariff sheets, with an effective date of August 1, 1999.

AWP L.L.C. asserts that the purpose of this filing is to comply with Order No. 587–K.

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, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed in accordance with section 154.210 of the Commission's Regulations. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16980 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–52–000]

Columbia Gulf Transmission Company; Notice of Refund Report

June 29, 1999.

Take notice that on June 25, 1999, Columbia Gulf Transmission Company (Columbia Gulf) tendered for filing a refund report to report on the refunding to its firm customers on June 10, 1999, of refunds it received from the Gas Research Institute (GRI) on May 28, 1999.

Columbia Gulf states that it made the refunds by crediting its customers' invoices on June 10, 1999.

Columbia Gulf states that a copy of this report is being provided to all recipients of a share of the refund and all state commissions whose jurisdiction includes the location of any recipient of a refund.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before July 7, 1999. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16977 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–48–000]

East Tennessee Natural Gas Company; Notice of Refund Report

June 29, 1999.

Take notice that on June 25, 1999, East Tennessee Natural Gas Company (East Tennessee) tendered for filing a refund report of refunds issued pursuant to the Commission's April 29, 1998 Order Approving Settlement in Gas Research Institute (GRI) Docket No. RP97–149.

East Tennessee states that East Tennessee received a refund from GRI in the amount of $527,462.

East Tennessee states that it has refunded amounts to firm transportation customers that received non-discounted service during 1998 by adjustments to their June 1999 invoices.

East Tennessee states that copies of this filing have been mailed to each of East Tennessee's customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16973 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–351–000]

Florida Gas Transmission Company; Notice of Tariff Filing

June 29, 1999.

Take notice that on June 25, 1999, Florida Gas Transmission Company (FGT) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, with an effective date of November 1, 1998:

Third Revised Sheet No. 140
Third Revised Sheet No. 650
Second Revised Sheet No. 651
Second Revised Sheet No. 652
Second Revised Sheet No. 653
Third Revised Sheet No. 654

FGT states that on September 1, 1994 it filed a Stipulation and Agreement of Settlement (Settlement) and pro forma tariff sheets setting forth procedures for the interruption of interruptible transportation and the curtailment of firm service during periods of diminished capacity on FGT's system. The Settlement was accepted and clarified by the Commission on January 12, 1995 (70 FERC ¶ 61,017.) The Commission issued an order on rehearing on June 2, 1995. (71 FERC ¶ 61,274.)

The Settlement, as approved and modified by the Commission, establishes procedures in subsections (g)

and (h) of section 17.A.4. of the General Terms and Conditions of FGT's Tariff to review the Exempt Use classifications under FGT's curtailment plan. These procedures require that the Data Verification Committee (DVC) meet triennially. FGT states that the instant filing reflects the results of the DVC vote at the triennial meeting.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426, in accordance with sections 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16965 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–353–000]

Florida Gas Transmission Company; Notice of Tariff Filing

June 29, 1999.

Take notice that on June 25, 1999, Florida Gas Transmission Company (FGT) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, with an effective date July 26, 1999:

Third Revised Sheet No. 16
First Revised Sheet No. 22I
Third Revised Sheet No. 28
Fifth Revised Sheet No. 37
Fifth Revised Sheet No. 45
First Revised Sheet No. 47E
Third Revised Sheet No. 61
First Revised Sheet No. 135A

FGT states that it is filing the revised tariff sheets to clarify, consistent with Commission policy, the specific types of transportation discounts that may be granted by FGT in a manner consistent with FERC-approved discounts on other pipelines. The revised tariff sheets modify the General Terms and Conditions (GTC) of FGT's Tariff which are applicable to the various throughput Rate Schedules, and add a reference to the provisions in the rate schedules. By including this additional language in the GTC, FGT seeks to avoid the need for filing individual discount agreements on the grounds that they contain "material deviations" from the pro forma service agreements, consistent with the Commission's rulings in Natural Gas Pipeline Company of America, 84 FERC ¶ 61,099 (1998) and subsequent orders. The identification of the types of discounts to which FGT and an individual shipper may agree will clarify FGT's flexibility to provide the services required to meet competitive market conditions.

In addition to its ability to agree to a basic discount from the stated maximum rates, FGT proposes to revise the GTC by adding additional language to reflect the various kinds of discounts it may give to meet competitive circumstances. For example,

FGT may provide a specified discounted rate:

(1) To certain specified quantities under the Service Agreement;

(2) If specified quantity levels are actually achieved or with respect to quantities below a specified level;

(3) To production reserves committed by the Shipper;

(4) During specified time periods;

(5) To specified points of receipt, points of delivery, supply areas, transportation paths or defined geographical areas; or

(6) In a specified relationship to the quantities actually transported (i.e., that the rates shall be adjusted in a specified relationship to quantities actually transported).

In all circumstances the discounted rate shall be between the maximum rate and minimum rate applicable to the service provided.

FGT further states these types of discounts are modeled after the same types of discounts that the Commission recently approved in Colorado Interstate Gas Company, 86 FERC ¶ 71,178 (1999); Wyoming Interstate Company, Ltd., 86 FERC ¶ 61,191 (1999); Panhandle Eastern Pipe Line Company, 86 FERC ¶ 61,117 (1999); Trunkline Gas Company, 86 FERC ¶ 61,118 (1999); Tennessee Gas Pipeline Company, 84 FERC ¶ 61,340 (1998); Eastern Shore Natural Gas Company, 85 FERC ¶ 61,048 (1998); ANR Pipeline Company, 85 FERC ¶ 61,333 (1998) and National Fuel Gas Supply Corporation, 85 FERC ¶ 61,126 (1998).

FGT submits that the proposed revisions are consistent with Commission policy and will provide FGT and its customers administrative flexibility and efficiency.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16967 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–46–000]

KN Interstate Gas Transmission Co.; Notice of Refund Report Filing

June 29, 1999.

Take notice that on June 24, 1999, KN Interstate Gas Transmission Co. (KNI) filed a refund report pursuant to the Commission's February 22, 1995 Order issued in Docket No. RP95–124–000.

KN states that the refund report shows the refund received by KNI from Gas Research Institute overcollections in the amount $413,712 and the pro rata allocation of that refund amount to KNI's eligible firm customers.

KNI states that copies of the filing were served upon all affected firm customers of KNI and applicable state agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before

July 7, 1999. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16971 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–320–022]

Koch Gateway Pipeline Company; Notice of Negotiated Rate Filing

June 29, 1999.

Take notice that on June 25, 1999, Koch Gateway Pipeline Company (Koch) filed with the Federal Energy Regulatory Commission (Commission) four (4) contracts for disclosure of recently negotiated rate transactions. As shown on the contracts, Koch requests an effective date of July 1, 1999.

Special Negotiated Rate Between Koch and Unocal Energy Trading, Inc.

Koch states that it has served copies of this filing upon each all parties on the official service list created by the Secretary in this proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in section 154.210 of the Commission's Regulations. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16978 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–50–000]

Mojave Pipeline Company; Notice of Report of GRI Refunds

June 29, 1999.

Take notice that on June 25, 1999, Mojave Pipeline Company (Mojave) submitted its Report of Gas Research Institute (GRI) Refunds for 1998 pursuant to subpart F of part 154 of the Commission's Regulations and ordering paragraph (C) of the Commission's order issued on February 22, 1995 at Docket No. RP95–124–000.

On May 28, 1999, Mojave received a refund from GRI for overcollections for calendar year 1998 in the amount of $314,625. On June 11, 1999, Mojave states that it refunded its eligible firm shippers as required by the February 22, 1995 order by crediting each shipper's applicable transportation invoice.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with section 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16975 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–350–000]

Northern Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

June 29, 1999.

Take notice that on June 25, 1999, tendered for filing Northern Natural Gas Company (Northern), tendered for filing as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets proposed to be effective July 26, 1999.

Sixth Revised Sheet No. 201
Second Revised Sheet No. 303

Northern states that the purpose of the filing is to modify the General Terms and Conditions of its Tariff to clarify, consistent with Commission policy, the types of discounts that Northern may agree to enter into with its shippers.

Northern further states that copies of the filing have been mailed to each of its customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16964 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–349–000]

Northwest Pipeline Corporation; Notice of Tariff Filing

June 29, 1999.

Take notice that on June 23, 1999, Northwest Pipeline Corporation (Northwest) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, to be effective August 1, 1999.

Fifth Revised Sheet No. 201
Sixth Revised Sheet No. 202
Second Revised Sheet No. 210–B
First Revised Sheet No. 210–C
Third Revised Sheet No. 225–C
First Revised Sheet No. 225–E
First Revised Sheet No. 225–F
First Revised Sheet No. 225–G
Original Sheet No. 225–H
Original Sheet No. 225–I
First Revised Sheet No. 232–F
First Revised Sheet No. 232–G
Second Revised Sheet No. 232–H
Fifth Revised Sheet No. 279
Fifth Revised Sheet No. 279–A
Third Revised Sheet No. 279–C
Fourth Revised Sheet No. 281
Seventh Revised Sheet No. 282

Northwest states that the purpose of this filing is to submit tariff sheets to incorporate the Version 1.3 standards promulgated by the Gas Industry Standards Board (GISB) on July 31, 1998 and adopted by the Commission pursuant to Order No. 587–K as section 284.10(b)(1) of the Commission's regulations.

Northwest states that a copy of this filing has been served upon its customers and interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16963 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–45–000]

Northwest Pipeline Corporation; Notice of Refund Report

June 29, 1999.

Take notice that on June 23, 1999, Northwest Pipeline Corporation (Northwest) tendered for filing a report of Gas Research Institute (GRI) refunds made to its customers.

Northwest states that on May 28, 1999 it received a refund from the GRI in the amount of $2,315,734, representing an overcollection of the 1998 GRI Tier 1 funding target level set for Northwest by the GRI. On June 11, 1999, Northwest credited the GRI refund, pro rata, to its eligible firm customers who received nondiscounted transportation service during 1998.

Northwest states that a copy of this filing has been served upon Northwest's affected customers and intereste state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before July 7, 1999. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16970 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EC99–79–000 and ER99–3151–000]

Public Service Electric and Gas Company, PSEG Fossil LLC, PSEG Nuclear LLC and PSEG Energy Resources & Trade LLC; Notice of Filing

June 29, 1999.

Take notice that on June 24, 1999, Public Service Electric and Gas Company (PSE&G), PSEG Fossil LLC, PSEC Nuclear LLC, and PSEC Energy Resources & Trade LLC filed a supplement to their application. The supplement consisted of a copy of the application PSE&G had previously filed with the Nuclear Regulatory Commission in connection with the transfer of its interest in certain nuclear generating facilities.

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, 888 First 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 385.214). All such motions or protests should be filed on or before July 9, 1997. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16969 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–47–000]

Questar Pipeline Company; Notice of Refund Report

June 29, 1999.

Take notice that on June 24, 1999, Questar Pipeline Company (Questar) tendered for filing a Gas Research Institute (GRI) Tier 1 Refund Report in compliance with the Commission's

Opinion No. 18 issued November 12, 1997, in Docket No. RP97–149–002.

Questar states that on May 28, 1999, it received a $56,936 refund from GRI, representing an overcollection of the 1998 GRI Tier 1 funding target level set for Questar by GRI. Questar states that on June 11, 1999, in compliance with Opinion No. 418, it sent the GRI Tier 1 refund, pro rata, to it eligible firm shippers who received nondiscounted transportation service during 1998. Questar further states the GRI refund was exclusive of interest.

Questar further states that a copy of the refund report has been served upon its affected transportation customers who received a refund and the Public Service Commission of Utah and the Wyoming Public Service Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before July 7, 1999. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http:www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16972 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–49–000]

Tennessee Gas Pipeline Company; Notice of Refund Report

June 29, 1999.

Take notice that on June 25, 1999, Tennessee Gas Pipeline Company (Tennessee) filed a refund report of refunds issued pursuant to the Commission's April 29, 1998 Order Approving Settlement in Gas Research Institute (GRI) Docket No. RP97–149.

Tennessee states that Tennessee received a refund from GRI in the amount of $2,221,561.

Tennessee states that it has refunded amounts to firm transportation customers that received non-discounted service during 1998 by adjustments to their June 1999 invoices.

Tennessee states that copies of this filing have been mailed to each of Tennessee's customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 of 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before July 7, 1999. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16974 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–352–000]

Transwestern Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

June 29, 1999.

Take notice that on June 25, 1999, Transwestern Pipeline Company (Transwestern), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets proposed to be effective July 26, 1999:

Fifteenth Revised Sheet No. 48
Twelfth Revised Sheet No. 96
Sheet No. 97

Transwestern states that the purpose of the filing is to modify the General Terms and Conditions of its Tariff to clarify, consistent with Commission policy, the types of discounts that Transwestern may agree to enter into with its shippers.

Transwestern further states that copies of the filing have been mailed to each of its customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16966 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GT99–51–000]

Transwestern Pipeline company; Notice of Report of Refund

June 29, 1999.

Take notice that on June 25, 1999, Transwestern Pipeline Company (Transwestern) tendered for filing a Report of Refund reflecting distribution of a GRI refund received on May 28, 1999 in the amount of $159,621, with Transwestern credited to its eligible firm shippers on June 11, 1999.

Transwestern states that it provided a credit to its eligible firm Shippers on a pro rata basis based on amounts paid by such shippers through GRI surcharges for 1998.

Transwestern states that copies of the filing were served upon all affected parties and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before July 7, 1999. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16976 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–354–000]

Tuscarora Gas Transmission Company; Notice of Tariff Filing

June 29, 1999.

Take notice that on June 25, 1999, Tuscarora Gas Transmission Company (Tuscarora) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, to be effective August 1, 1999.

Third Revised Sheet No. 33
Fourth Revised Sheet No. 37A
Fourth Revised Sheet No. 42

Tuscarora asserts that the purpose of this filing is to comply with Order No. 587–K, issued on April 2, 1999, in Docket No. RM96–1–011. Specifically, Tuscarora has revised Sections 2 and 4 of the General Terms and Conditions of its tariff to include the most recent version of the standards, Version 1.3. These standards establish rules for conducting business practices and electronic communication with interstate natural gas pipelines.

Tuscarora states that copies of this filing were mailed to customers of Tuscarora and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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. 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 in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–16968 Filed 7–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG99–171–000, et al.]

Woodstock Hills, LLC, et al.; Electric Rate and Corporate Regulation Filings

June 28, 1999.

Take notice that the following filings have been made with the Commission:

1. Woodstock Hills LLC

[Docket No. EG99–171–000]

Take notice that on June 18, 1999, Woodstock Hills LLC (Woodstock), 475 E. 4th Street, Cottonwood, Minnesota 56229, tendered for filing with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations. Also take notice that on June 21, 1999, Woodstock tendered for filing in the above referenced proceeding a signed copy of the Certificate of Mailing.

Woodstock will own and operate an approximate 10.2 megawatt windpowered electric generation facility (Facility) in Woodstock, Minnesota. Woodstock will sell the electric output of the Facility exclusively at wholesale. The Facility will be located in proximity to the transmission facilities of Northern States Power Company, and the Facility will include only those interconnecting transmission facilities necessary to effect sales of electric energy at wholesale.

Comment date: July 8, 1999, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. HL Power Company Limited Partnership

[Docket No. EC99–89–000]

Take notice that on June 22, 1999, HL Power Company Limited Partnership (HLP), a California limited partnership, tendered for filing an application, pursuant to 18 CFR part 33, seeking authority under Section 203 of the Federal Power Act for the Sale of (i) a 60 KV electric transmission line used to deliver electric energy from the Honey Lake small power production facility, located in Lassen County, California, to a substation known as the Milwood Substation and (ii) the Milwood Substation, which includes various items of interconnection equipment and the parcel of real property upon which such equipment is located, all of which was constructed and is currently owned by HLP to Lassen County Municipal Utility District.

HLP has requested expedited consideration of the application in light of the fact that no changes in the rates charged by HLP will occur and that there will be no impact on the relevant competitive markets.

Comment date: July 22, 1999, in accordance with Standard Paragraph E at the end of this notice.

3. West Texas Renewables Limited Partnership

[Docket No. EG99–172–000]

Take notice that on June 18, 1999, West Texas Renewables Limited Partnership, a limited partnership formed under the laws of the State of Delaware, filed with the Federal Energy Regulatory Commission (the Commission) an application for determination of exempt wholesale generator status. West Texas Renewables Limited Partnership will be engaged directly and exclusively in the business of owning and operating a 6.6 MW wind generation facility (the Project) located in Howard County, Texas which will be an eligibility facility within the meaning of section 32(a)(2) of the Public Utility Holding Company Act of 1935, as amended. All of the electricity produced by the Project will be sold at wholesale to the Texas Utilities Electric Company, a Texas corporation (TU Electric) pursuant to a long-term contract.

Comment date: July 8, 1999, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. Public Service Company of New Mexico

[Docket Nos. ER96–1551–005, OA96–202–000 and OA96–202–002]

Take notice that on June 22, 1999, Public Service Company of New Mexico (PNM), tendered for filing a Compliance Report regarding refunds to affected

ancillary services customers, for mandatory ancillary services fees collected (by PNM) in excess of PNM's proposed settlement agreement rate approved by the Federal Energy Regulatory Commission in its April 6, 1999 letter order. The affected customers are:

Aquila Power Company
Arizona Public Service Company
Citizen's Power Sales
Vitol Gas & Electric Company
Duke Energy Trading
Enron Power Marketing, Inc.
Electric Clearinghouse, Inc.
El Paso Electric Company
El Paso Energy Marketing
E Prime, Inc.
City of Gallup
Idaho Power Company
Illinova Energy Partners, Inc.
Kirtland Air Force Base
Los Alamos County
Reliant Energy Services
PacifiCorp Electric Operations
Public Service Company of Colorado
Salt River Project Agricultural Improvement and Power District
Southwestern Public Service Company
Tucson Electric Power Company
Texas-New Mexico Power Company
Williams Energy Services Company

Copies of the filing have been provided to all parties to this proceeding, and the filing is available for public inspection at PNM's offices in Albuquerque, New Mexico.

Comment date: July 12, 1999, in accordance with Standard Paragraph E at the end of this notice.

5. Cinergy Services, Inc.

[Docket No. ER99–1662–000]

Take notice that on June 23, 1999, Cinergy Services, Inc., acting as agent for and on behalf of The Cincinnati Gas & Electric Company and PSI Energy, Inc., tendered for filing an amended Service Agreement for firm point-to-point transmission service entered into between Cinergy and itself under Cinergy's Open Access Transmission Tariff.

Pursuant to the Commission's letter order dated May 24, 1999 in this proceeding, Cinergy's filing was amended to include a specific point of receipt and capacity reservation for the receipt/delivery point combination.

Cinergy states that it has served copies of its filing upon all parties of record in this proceeding.

Comment date: July 13, 1999, in accordance with Standard Paragraph E at the end of this notice.

6. Duke Energy Corporation

[Docket No. ER99–2285–000]

Take notice that on June 23, 1999, Duke Energy Corporation (Duke), tendered for filing an amendment to its firm point-to-point transmission service agreement filed in the above-referenced docket.

Comment date: July 13, 1999, in accordance with Standard Paragraph E at the end of this notice.

7. Electric Clearinghouse, Inc. and Illinois Power Company

[Docket No. ER99–3322–000]

Take notice that on June 21, 1999, Electric Clearinghouse, Inc. (ECI) and Illinois Power Company (Illinois Power), jointly tendered for filing pursuant to Rule 205, 18 CFR 385.205, revisions to their respective rate schedules related to sales of energy and capacity at market-based rates to each other.

ECI and Illinois Power request waiver of the Commission's 60-day prior notice requirement in order to permit their respective revisions to become effective on June 22, 1999.

Comment date: July 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

8. Ohio Valley Electric Corporation and Indiana-Kentucky Electric Corporation

[Docket No. ER99–3326–000]

Take notice that on June 22, 1999, Ohio Valley Electric Corporation (including its wholly-owned subsidiary, Indiana-Kentucky Electric Corporation) (OVEC), tendered for filing a Service Agreement for Non-Firm Point-To-Point Transmission Service, dated May 25, 1999 (the Service Agreement) between Constellation Power Source, Inc. (Constellation Power) and OVEC. The Service Agreement provides for non-firm transmission service by OVEC to Constellation Power. In its filing, OVEC states that the rates and charges included in the Service Agreement are the rates and charges set forth in OVEC's Open Access Transmission Tariff.

OVEC proposes an effective date of May 25, 1999 and requests waiver of the Commission's notice requirement to allow the requested effective date.

Copies of this filing were served upon the Public Service Commission of Maryland, the Public Service Commission of District of Columbia and Constellation Power.

Comment date: July 12, 1999, in accordance with Standard Paragraph E at the end of this notice.

9. FirstEnergy System

[Docket No. ER99–3327–000]

Take notice that on June 22, 1999, FirstEnergy System tendered for filing a Service Agreement to provide Firm Point-to-Point Transmission Service for Carolina Power & Light Company, the Transmission Customer. Services are being provided under the FirstEnergy System Open Access Transmission Tariff submitted for filing by the Federal Energy Regulatory Commission in Docket No. ER97–412–000.

The proposed effective date under this Service Agreement is June 10, 1999, for the above mentioned Service Agreement in this filing.

Comment date: July 12, 1999, in accordance with Standard Paragraph E at the end of this notice.

10. Maine Electric Power Company

[Docket No. ER99–3328–000]

Take notice that on June 22, 1999, Maine Electric Power Company (MEPCO), tendered for filing a service agreement for Short-Term Firm Point-to-Point Transmission Service entered into with PP&L EnergyPlus Company Service will be provided pursuant to MEPCO's Open Access Transmission Tariff, designated rate schedule MEPCO-FERC Electric Tariff, Original Volume No.1, as supplemented.

Comment date: July 12, 1999, in accordance with Standard Paragraph E at the end of this notice.

11. UtiliCorp United Inc.

[Docket No. ER99–3329–000]

Take notice that on June 22, 1999, UtiliCorp United Inc. (UtiliCorp), tendered for filing a service agreement with Enron Power Marketing, Inc., for service under its Short-Term Firm Point-to-Point open access service tariff for its operating division, WestPlains Energy-Colorado.

Comment date: July 12, 1999, in accordance with Standard Paragraph E at the end of this notice.

12. TXU Energy Trading Company

[Docket No. ER99–3333–000]

Take notice that on June 22, 1999, TXU Energy Trading Company tendered for filing a Notice of Succession pursuant to Section 35.16 of the Commission's Regulations, 18 CFR 35.16. As a result of a name change, TXU Energy Trading Company is succeeding to the Rate Schedule No. 1 and Supplement No. 1 to Rate Schedule No. 1 of Enserch Energy Services, Inc., effective June 14, 1999.

Comment date: July 12, 1999, in accordance with Standard Paragraph E at the end of this notice.

13. Maine Electric Power Company

[Docket No. ER99–3334–000]

Take notice that on June 22, 1999, Maine Electric Power Company (MEPCO), tendered for filing a service

agreement for Long Term Firm Point-to-Point Transmission Service entered into with Engage Energy US, L.P. Service will be provided pursuant to MEPCO's Open Access Transmission Tariff, designated rate schedule MEPCO—FERC Electric Tariff, Original Volume No. 1, as supplemented. This service represents a reassignment of transmission rights currently held by Central Maine Power Company (CMP) under FERC Rate Schedule Vol. 1, Service Agreement No. 5.

Comment date: July 12. 1999, in accordance with Standard Paragraph E at the end of this notice.

14. Rocky Road Power, LLC

[Docket No. ER99–3335–000]

Take notice that on June 22, 1999, Rocky Road Power, LLC, tendered for filing a Power Purchase Agreement for short-term transactions between Rocky Road Power, LLC and Electric Clearinghouse, Inc., to be in effect as of May 24, 1999.

Comment date: July 12, 1999, in accordance with Standard Paragraph E at the end of this notice.

15. Northeast Utilities Service Company

[Docket No. ER99–3336–000]

Take notice that on June 23, 1999, Northeast Utilities Service Company (NUSCO), tendered for filing a Service Agreement with TransAlta Energy Marketing (U.S.) Inc. (TransAlta) under the NU System Companies' Sale for Resale Tariff No. 7.

NUSCO states that a copy of this filing has been mailed to TransAlta.

NUSCO requests that the Service Agreement become effective July 1, 1999.

Comment date: July 13, 1999, in accordance with Standard Paragraph E at the end of this notice.

16. Florida Power & Light Company

[Docket No. ER99–3337–000]

Take notice that on June 23, 1999, Florida Power & Light Company (FPL), tendered for filing proposed service agreements with Electric Clearinghouse, Inc., for Short-Term Firm transmission service under FPL's Open Access Transmission Tariff.

FPL requests that the proposed service agreements be permitted to become effective on June 1, 1999.

FPL states that this filing is in accordance with Part 35 of the Commission's Regulations.

Comment date: July 13, 1999, in accordance with Standard Paragraph E at the end of this notice.

17. Penobscot Hydro, LLC

[Docket No. ER99–3338–000]

Take notice that on June 23, 1999, Penobscot Hydro, LLC (Penobscot), tendered for filing with the Commission an executed Transitional Power Sales Agreement (TSA) between Penobscot and Bangor Hydro-Electric Company (Bangor) to replace the unexecuted agreement previously accepted for filing by the Commission on April 23, 1999, in this docket.

Comment date: July 13, 1999, in accordance with Standard Paragraph E at the end of this notice.

18. California Independent System Operator Corporation

[Docket No. ER99–3339–000]

Take notice that on June 23, 1999, the California Independent System Operator Corporation (ISO), tendered for filing a proposed amendment (Amendment No. 19) to the ISO Tariff. Amendment No. 19, would modify the ISO Tariff to implement the ISO's New Generator Interconnection Policy, which sets forth the obligations and responsibilities of Generating Units requesting interconnection to the ISO Controlled Grid and the procedures and requirements for processing such interconnection requests.

The ISO states that this filing has been served upon the Public Utilities Commission of California, the California Energy Commission, the California Electricity Oversight Board, and all parties with effective Scheduling Coordinator Service Agreements under the ISO Tariff.

Comment date: July 13, 1999, in accordance with Standard Paragraph E at the end of this notice.

19. Joe Bob Perkins

[Docket No. ID–3184–003]

Take notice that on June 23, 1999, Mr. Joe Bob Perkins, a former officer and director of El Dorado Energy, LLC, tendered for filing with the Federal Energy Regulatory Commission (Commission) a notice of withdrawal from interlocking positions pursuant to Section 305(b) of the Federal Power Act, Section 45.5(b) of the Commission's Regulations, 18 CFR 45.5(b), and the Commission's Order in El Dorado Energy, LLC, 85 FERC ¶ 61,006 (1998).

Comment date: July 13, 1999, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First 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 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 these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/ online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 99–16981 Filed 7–2–99; 8.45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6371–8]

Agency Information Collection Activities: Proposed Collection; Comment Request; Construction Grants Delegation to States

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB): Construction Grants Delegation to States Information Collection Request, EPA ICR No. 0909.06 and Control No. 2040–0095, current expiration date December 31, 1999. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before September 7, 1999.

ADDRESSES: Gajindar Singh, Office of Wastewater Management, Mail Code 4204, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Interested persons may obtain a copy of the ICR without charge by writing to the preceding address.

FOR FURTHER INFORMATION CONTACT: Gajindar Singh, Telephone Number: (202) 260–4266 /Facsimile Number: (202) 260–1827/E-mail: singh.gajindar@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Comments: Comments shall be submitted to Gajindar Singh, Mail Code 4204, Environmental Protection Agency, Office of Wastewater Management, 401 M Street, SW, Washington, DC 20460. Commenters who want EPA to acknowledge receipt of their comments should enclose a self-addressed stamped envelope. Comments may also be submitted electronically to *singh.gajindar@epamail.epa.gov.*

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and forms of encryption. Electronic comments must be identified by the use of words "Construction Grants Comments." No Confidential Business Information (CBI) should be submitted through e-mail. Comments and data will also be accepted on disks in Corel Word Perfect 8 format or ASCII file format. Electronic comments on this notice may be filed online at many Federal Depository Libraries. The record for this proposed ICR renewal has been established in the Office of Wastewater Management, Municipal Assistance Branch and includes supporting documentation as well as printed, paper versions of electronic comments. It does not include any information claimed as CBI. The record is available for inspection from 9 am to 4 pm, Monday through Friday, excluding legal holidays, at the Municipal Assistance Branch, Northeast Mall Room 2104–6, 401 M Street, SW, Washington, DC 20460. For access to the docket materials, please call (202) 260–4266 to schedule an appointment.

Affected entities: Entities potentially affected by this action are States which administer elements of the construction grants program under a delegation agreement with EPA and municipalities which received construction grants from EPA.

Title: Construction Grants Delegation to States; OMB No. 2040 0095; EPA ICR No. 0909.06 expiring 12/31/99.

Abstract: The purpose of this ICR is to revise and extend the current clearance for the collection of information under the Construction Grants Program Delegation to States, 40 CFR part 35 Subpart J, and Title II of the Clean Water Act (CWA). While the Construction Grants Program is being phased out and replaced by the State Revolving Loan Fund (SRF) program, collection activities for the Construction Grants Program must continue until program completion. The program includes reporting, monitoring and program requirements for municipalities and delegated States.

The information collection activities described in this ICR are authorized under section 205(g) of the Clean Water Act as amended, 33 U.S.C. 1251 *et seq.*, and under 40 CFR part 35 Subpart J. The requested information provides the minimum data necessary for the Federal government to maintain appropriate fiscal accountability for use of section 205(g) construction grant funds. The information is also needed to assure an adequate management overview of those State project review activities that are most important to fiscal and project integrity, design performance, Federal budget control, and attainment of national goals.

Managers at the State and Federal levels both rely on the information described in this ICR. State managers rely on the information for their own program and project administration. Federal managers rely on this information to assess, control, and predict the impacts of the construction grants program on the Federal Treasury and future budget requirements. Federal managers also use this information to respond to OMB and Congressional requests and to maintain fiscal accountability.

In addition, builders of wastewater treatment plants use the information discussed in this ICR. The builders of these plants assess and use the information in the Innovative/Alternative Technology Data Base File to obtain technical information on innovative or alternative wastewater treatment systems.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR part 15.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: Respondents: States and municipalities.

Estimated Number of Respondents: 31.

Frequency of Response: 91 per year.

Responses Per Respondent: 3.0 per year.

Estimated Total Annual Hour Burden: 5,678 hours.

Average Burden Hours Per Response: 62.4.

Estimated Total Annualized Cost Burden: $213,152.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: June 23, 1999.

Michael B. Cook,

Director, Office of Wastewater Management.

[FR Doc. 99–17031 Filed 7–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6371–4]

Agency Information Collection Activities Pesticides; Submission of EPA ICR No. 0601.06 to OMB

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of submission to OMB.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the Information Collection Request (ICR) entitled: "FIFRA Section 29 Annual Report on Conditional Registrations," (EPA ICR No. 0601.06, OMB No. 2070–0026) has been forwarded to the Office of Management and Budget (OMB) for review and approval pursuant to the OMB procedures in 5 CFR 1320.12. The ICR, which is abstracted below, describes the nature of the information collection and its estimated cost and burden. The Agency is requesting that OMB renew

for 3 years the existing approval for this ICR, which is scheduled to expire on June 30, 1999. A **Federal Register** document announcing the Agency's intent to seek OMB approval for this ICR and a 60-day public comment opportunity, requesting comments on the request and the contents of the ICR, was issued on March 3, 1999 (64 FR 10290). EPA received several comments on this ICR during the comment period. Additional comments may be submitted on or before August 5, 1999.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer by phone at 202–260–2740, or via e-mail at "farmer.sandy@epa.gov", or using the address indicated below. Please refer to EPA ICR No. 0601.06 and OMB Control No. 2070–0026.

ADDRESSES: Send comments, referencing EPA ICR No. 0601.06 and OMB Control No. 2070–0026, to the following addresses:

Ms Sandy Farmer, U.S. Environmental Protection Agency, Regulatory Information Division (Mail Code: 2137), 401 M Street, SW, Washington, DC 20460;

and to:

Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

SUPPLEMENTARY INFORMATION:

Review Requested: This is a request to renew a currently approved information collection pursuant to 5 CFR 1320.12.

ICR Numbers: EPA ICR No. 0601.06; OMB Control No. 2070–0026.

Current Expiration Date: Current OMB approval expires on June 30, 1999. EPA is currently seeking a 90 day extension, which will move the expiration date to September 30, 1999.

Title: FRA Section 29 Annual Report on Conditional Registrations

Abstract: EPA is responsible for the regulation of pesticides as mandated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). FIFRA section 29 requires the EPA Administrator to submit an annual report to Congress before February 16 of each year. The section 29 Report is to include the total number of applications for conditional registration filed under sections 3(c)(7)(B) and 3(c)(7)(C) of the Act during previous fiscal year. Of those applications approved, the report must also identify the Administrator's findings in each case, the conditions imposed and any modification of such conditions in each case, and the quantities produced of such pesticides. All of this information, except production volume data, is obtained from Agency files. EPA must rely on outside sources for this data. Therefore, EPA asks registrants with conditionally registered pesticides to provide production volume data from the preceding fiscal year.

Burden Statement: For each use of a conditional registration, EPA requires registrants to submit an annual report to the EPA on the amount (gallons or pounds) of the pesticide produced during the preceding fiscal year. Each October, OPP compiles all information on conditional registrations filed with the Agency during the previous fiscal year including initial conditions of registration and any modifications. Registrants with conditional registrations generally submit the required information automatically. However, if the production volume data has not been received within thirty days of the due date, then EPA will send a fax or phone the registrants requesting submittal of the annual pesticide volume information. EPA compiles the submitted data and internal information to prepare a section 29 Report. The Report includes: The number of conditional registrations, their conditions of registration, any changes in conditional registration status or conditions, and the conditionally registered pesticide production volume data. The Report also includes updated information to identify those conditional registrations that have been canceled or have attained full registration, and name changes of chemical firms.

The annual respondent burden for this collection includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of this estimate, which is only briefly summarized in this document. The annual public burden for the section 29 reporting information collection is estimated to average 1.4 hours per response. The following is a summary of the estimates taken from the ICR:

Respondents/Affected Entities: Pesticide registrants with conditional registrations.

Estimated total number of potential Respondents: 30.

Frequency of Response: Annually.

Estimated total/average number of responses for each Respondents: 2.

Estimated total annual burden hours: 84.

Estimated total annual burden costs: $6,612.

Changes in Burden Estimates: The registrant burden estimate for this information collection has remained at 84 hours per year with the number of respondents reporting and number of conditional registrations each remaining the same. The individual burden per product for reporting has remained constant at 1.4 hours, while the burden per registrant has remained constant at 2.8 hours with two products per registrant.

According to the procedures prescribed in 5 CFR 1320.12, EPA has submitted this ICR to OMB for review and approval. Any comments related to the renewal of this ICR should be submitted within 30 days of this document, as described above.

Dated: June 29, 1999.

Richard T. Westlund,

Acting Director, Regulatory Information Division.

[FR Doc. 99–17033 Filed 7–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6371–2]

Notice of Open Meeting of the Environmental Financial Advisory Board on August 9–10, 1999

The Environmental Protection Agency's (EPA) Environmental Financial Advisory Board (EFAB) will hold an open meeting of the full Board in San Francisco, California on August 9–10, 1999. The meeting will be held at the World Trade Center, Ferry Building, in the International Room. The Monday, August 9 session will run from 9:00 a.m. to 5:00 p.m. and the August 10 session will begin at 8:30 a.m. and end at approximately 12:00 p.m.

EFAB is charted with providing analysis and advice to the EPA Administrator on environmental finance. The purpose of this meeting is to discuss progress with work products under EFAB's current strategic action agenda and to develop an action agenda to direct the Board's activities through 2000. Environmental financing topics expected to be discussed include: Clean Water Action Plan, environmental and multi-state revolving funds, cost-

effective environmental management community-based environmental protection, brownfields redevelopment, international environmental financing, and small business access to capital.

The meeting is open to the public, but seating is limited. For further information, please contact Alecia Crichlow, EFAB Coordinator, U.S. EPA on (202) 564–5188, or Joanne Lynch, U.S. EPA on (202) 564–4999.

Dated: June 29, 1999.

Michael W.S. Ryan,

Comptroller.

[FR Doc. 99–17030 Filed 7–2–99; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00612; FRL–6090–4]

FIFRA Scientific Advisory Panel; Open Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of open meeting.

SUMMARY: There will be a 4-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Food Quality Protection Act (FQPA) Scientific Advisory Panel (SAP) to review a set of scientific issues being considered by the Agency in connection with *Burkholderia cepacia*: risk assessment of a biopesticide and possible human opportunistic pathogen; a consultation on protocol design to assess acute neurotoxicity following oral administration of pesticides; issues pertaining to the assessment of exposure to pesticides in residential and other non-occupational settings; higher tier ecological risk assessment for chlorfenapyr; and pesticide spray drift--review of proposed pesticide deposition curves. The meeting is open to the public. Seating at the meeting will be on a first-come basis. Individuals requiring special accommodations at this meeting, including wheelchair access, should contact either Larry Dorsey or Paul Lewis at the address listed under "FOR FURTHER INFORMATION CONTACT" at least 5 business days prior to the meeting so that appropriate arrangements can be made.

DATES: The meeting will be held on Tuesday, July 20; Wednesday, July 21; Thursday, July 22; and Friday, July 23, 1999, from 8:30 a.m. to 5:30 p.m.

ADDRESSES: The meeting will be held at: Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA. The telephone number for the hotel is: (703) 486–1111.

By mail, submit written comments (one original and 40 copies) to: The Public Information and Records Integrity Branch (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by delivery service, bring comments to: Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202; telephone: (703) 305–5805.

Comments and data also may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. No Confidential Business Information (CBI) should be submitted through e-mail. Additional information on electronic submissions can be found under Unit V. of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Larry C. Dorsey or Paul I. Lewis, Designated Federal Officials, FIFRA Scientific Advisory Panel (7101C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; Office location: Rm. 117T, CM #2, 1921 Jefferson Davis Highway, Arlington, VA; telephone: (703) 305–5369; e-mail: dorsey.larry@ epa.gov or lewis.paul@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose of the Meeting

This SAP meeting includes five distinct sessions. The first session will be the review of a risk assessment of a biopesticide and possible human opportunistic pathogen. Some microorganisms used for controlling pests may be opportunistic human pathogens, or closely related to opportunistic pathogens. Opportunistic pathogens are microbes that are capable of causing disease only in people who are immunocompromized or are otherwise especially susceptible. A critical issue concerns the pathogenic strains proposed for registration as biopesticides, since these strains are typically isolated from the environment, for example agricultural fields, rather than as clinical specimens. As such, these strains have no history of actually causing disease and may not be able to do so. Criteria for relatedness between clinical strains and biocontrol strains and the ability to predict pathogenicity of the biocontrol strains is therefore vital.

The Agency requests the SAP to address the sufficiency of current tests used to consider the risk from opportunistic pathogens to immunocompromized populations. *Burkholderia cepacia*, a biopesticide which may cause fatal infections with cystic fibrosis and chronic granulomatous disease, will be used as a test case to examine the adequacy of animal models, taxonomic criteria, and criteria using known virulence genes as predictors of the pathogenic potential of individual strains, as well as issues related to the importance of levels of exposure and the nature of susceptible populations.

The second session will be a consultation on a study protocol design to assess acute neurotoxicity studies following oral administration of pesticides. Recently, several acute neurotoxicity studies have been submitted to the Agency employing this protocol design. This novel design deviates from the standard Agency acute developmental neurotoxicity protocols. The primary difference is that the test substance is administered in the diet compared to being administered as a bolus dose in the standard Agency study design. The purpose of this session is to consult with the SAP regarding issues pertaining to this new design.

The third session will be a review of issues pertaining to the assessment of exposure to pesticides in residential and other non-occupational settings. When estimating aggregate exposure to a pesticide substance, the Agency includes exposures that may occur following use of the pesticide in residential or other non-occupational settings. This session will focus on several key issues that pertain to improving procedures for estimating exposure to pesticides from use in residential or other non-occupational settings and in revising its standard operating procedures for residential exposure assessments. The issues include: (1) Calculating percent dislodgeability of available pesticide residues from lawns, indoor surfaces, and pets; (2) use of choreographed activities as surrogates for estimating children's dermal exposure; (3) characterizing hand (or object)-to-mouth activities; (4) calculating exposure to pesticides that may result from track-in, drift, bathing or showering; and (5) calculating exposure from use of pesticides in schools, day-care centers, and other public places.

The fourth session concerns the review of the Agency's chlorfenapyr ecological risk assessment. In December, 1994, the Agency received a request for registration for the use of the pyrrole insecticide chlorfenapyr on cotton. The Agency is seeking SAP input regarding the use of available data to characterize the risk of chlorfenapyr use on cotton to birds in cotton agroenvironments. The Agency requests SAP comments on its assessment of avian risks and is seeking

SAP suggestions for how the Agency might use probabilistic risk assessment techniques to improve its risk assessment. Specifically, the Agency is seeking guidance on the geographic scale of a probabilistic risk assessment. The SAP will be queried on what data on chlorfenapyr fate, residues, effects and cotton agroenvironments would be necessary to accommodate extrapolations of risks to scales beyond the treated agroenvironment to much larger scales.

The final session will be a review of pesticide spray drift data from ground hydraulic and orchard air blast applications. The purpose of this session is to examine the validity of an approach developed to place bounds on the Spray Drift Task Force data for ground hydraulic boom and orchard air blast spraying applications. Curves developed from bounds are intended to be used in environmental exposure assessments to estimate deposition over a range of distances, replacing the use of a fixed estimate. The proposed bounding method is intended to be adaptable to allow the addition of data from new or existing application methods.

II. Availability of Review Materials

A meeting agenda is currently available, and copies of EPA background documents for the meeting will be available no later than July 6, 1999. The meeting agenda and EPA primary background documents will be available on the EPA web site -- http://www.epa.gov/pesticides/SAP/ or may be obtained by contacting the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; Office location: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA; telephone: (703) 305–5805.

III. Written Comments and Oral Presentations at the Meeting

Members of the public wishing to submit comments should contact either Larry Dorsey or Paul Lewis at the address or the telephone number given under "FOR FURTHER INFORMATION CONTACT" to confirm that the meeting date and the agenda have not been modified or changed. Interested persons are permitted to file written statements before the meeting. To the extent that time permits and upon advanced written request to either Larry Dorsey or Paul Lewis, interested persons may be permitted by the Chair of the Scientific Advisory Panel to present oral statements at the meeting. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector, chalkboard, etc). There is no limit on the length of written comments for consideration by the Panel, but oral statements before the Panel are limited to approximately 5 minutes. The Agency also urges the public to submit written comments in lieu of oral presentations. Persons wishing to make oral and/or written statements should notify either Larry Dorsey or Paul Lewis and submit 40 copies of the summary information. The Agency encourages that written statements be submitted before the meeting to provide Panel Members the time necessary to consider and review the comments.

IV. Panel Report

Copies of the Panel's report of their recommendations will be available approximately 30 working days after the meeting and may be obtained by contacting the Public Information and Records Integrity Branch at the address or telephone number listed in "ADDRESSES" at the beginning of this document.

V. Public Docket and Submission of Electronic Comments

A public record has been established for this notice under docket control number "OPP–00612" (including comments and data submitted electronically). A public version of this record, including printed versions of electronic comments, which does not include information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch at the address listed in "ADDRESSES" at the beginning of this document.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data also will be accepted on disks in WordPerfect in 5.1/6/7/8.0 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number "OPP–00612." Electronic comments may be filed online at many Federal Depository Libraries.

The official record for this notice, as well as the public version described above, will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Information submitted as a comment in response to this notice may be claimed confidential by marking any part or all of that information as CBI. Information marked CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. An edited copy of the comment that does not contain the CBI material must be submitted for inclusion in the public docket. Information not marked confidential will be included in the public docket. All comments and materials received will be made part of the public record and will be considered by the Panel.

List of Subjects

Environmental protection.

Dated: June 29, 1999.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

[FR Doc. 99–17005 Filed 7–2–99; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of information collection to be submitted to OMB for review and approval under the Paperwork Reduction Act of 1995.

SUMMARY: In accordance with requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the FDIC hereby gives notice that it plans to submit to the Office of Management and Budget (OMB) a request for OMB review and approval of the information collection system described below.

Type of Review: Renewal of a currently approved collection.

Title: Notification of Performance of Bank Services.

Form Number: 6120/06.

OMB Number: 3064–0029.

Annual Burden:

Estimated annual number of respondents: 150.

Estimated time per response: ½ hour.
Average annual burden hours: 75 hours.

Expiration Date of OMB Clearance: July 31, 1999.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503.

FDIC Contact: Tamara R. Manly, (202) 898–7453, Office of the Executive Secretary, Room F–4058, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

Comments: Comments on this collection of information are welcome and should be submitted on or before August 5, 1999 to both the OMB reviewer and the FDIC contact listed above.

ADDRESSES: Information about this submission, including copies of the proposed collection of information, may be obtained by calling or writing the FDIC contact listed above.

SUPPLEMENTARY INFORMATION: Form 6120/06 is used by insured state nonmember banks to notify the FDIC of the existence of a relationship with a bank service corporation as required by section 7 of the Bank Service Company Act (12 USC 1867).

Federal Deposit Insurance Corporation.

James LaPierre,

Deputy Executive Secretary.

[FR Doc. 99–17058 Filed 7–2–99; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1277–DR]

Iowa; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Iowa, (FEMA–1277–DR), dated May 21, 1999, and related determinations.

EFFECTIVE DATE: June 7, 1999.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3772.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Iowa is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 21, 1999:

Montgomery County for Public Assistance.

Scott County for Individual Assistance.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

Laurence W. Zensinger,

Division Director, Response and Recovery Directorate.

[FR Doc. 99–17035 Filed 7–2–99; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1277–DR]

Iowa; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Iowa, (FEMA–1277–DR), dated May 21, 1999, and related determinations.

EFFECTIVE DATE: June 23, 1999.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3772.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Iowa is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 21, 1999:

Chickasaw County for Public Assistance.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

Lacy E Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 99–17036 Filed 7–2–99; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

Partially Open Meeting, Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice of partially open meeting.

SUMMARY: In accordance with section 10 (a) (2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, FEMA announces the following committee meeting:

Name: Board of Visitors for the National Fire Academy.

Dates of Meeting: August 3–5, 1999.

Place: Building J, Room 103, National Emergency Training Center, Emmitsburg, Maryland.

Time: August 3, 1999, 1:30 p.m.–5:00 p.m. (Open Meeting); August 4, 1999, 8:30 a.m.–10:30 a.m. (Closed Meeting); August 4, 1999, 11:00 a.m.–9:00 p.m. (Open Meeting); August 5, 1999, 8:30 a.m.–12 noon (Open Meeting).

Proposed Agenda: August 3, 1999, Review National Fire Academy Program Activities. August 4, 1999 (Closed Meeting From 8:30 a.m.—10:30 a.m., to review Fiscal Year 1999, 2000, and 2001 budgetary and procurement recommendations.) August 4, 1999, 11:00 a.m.–9:00 p.m., and August 5, 1999, 8:30 a.m.–12 noon, Finish Review of National Fire Academy Program Activities.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public (except as noted above) with seating available on a first-come, first-served basis. Members of the general public who plan to attend the meeting should contact the Office of the Superintendent, National Fire Academy, U.S. Fire Administration, 16825 South Seton Avenue, Emmitsburg, MD 21727, (301) 447–1117, on or before July 26, 1999.

Minutes of the meeting will be prepared and will be available for public viewing in the Office of the Administrator, U.S. Fire Administration, Federal Emergency Management Agency, Emmitsburg, Maryland 21727. Copies of the minutes will be available upon request within 60 days after the meeting.

Dated: June 24, 1999.
Richard A. Marinucci,
Acting Chief of Operations.
[FR Doc. 99–17034 Filed 7–2–99; 8:45 am]
BILLING CODE 6718–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediaries pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of the Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel-Operating Common Carrier Ocean Transportation Intermediary Applicants

Bayworld Int'l Corp., 1031 W. Manchester Blvd., #B, Inglewood, CA 90301, Officer: William Chao, President (Qualifying Individual)

Commercial Department Containers Caribe, Inc., 954 Ponce De Leon Avenue, CCND. Miramar Plaza, Suite 15–C, San Juan, PR 00907, Officers: Massimo Lolli, President (Qualifying Individual), Marco Orlandi, Vice President

DSL Transportation Services, Inc., 5011 Firestone Place, South Gate, CA 90280, Officers: Paul C. Grantham, Chief Executive Officer (Qualifying Individual), Darse Crandall, Executive Vice President

Newport Air Express Inc., 1231 West Broadway, Hewlett, NY 11557, Officers: Jerry Lo, Vice President (Qualifying Individual), Hang Wong, President

R.T. Express International, Inc., 1004 W. Hillcrest Blvd., Inglewood, CA 90301, Officers: Ricky Tong, President (Qualifying Individual), Ann Tong, Secretary

Sea Air Surface Distribution Inc., 4694 Coffee Port Road, Brownsville, TX 78521, Officer: Frank Parker, Jr., President (Qualifying Individual)

Ten-Fly Corporation, 17870 Castleton Street, Suite 122, City of Industry, CA 91748, Officer: Ellen Y. Yan, President (Qualifying Individual)

Trans Service Line (USA), Inc., 50 Broadway, Suite 1603, New York, NY 10004, Officers: Jean-Francois Pinson, President (Qualifying Individual), Richard K. Bernstein, Secretary

World Transportation Services, Inc., 2723 Yale Street, Houston, TX 77008, Officers: Pam Garifalos Holdrup, Secretary (Qualifying Individual), Jim Shaw, President

Worldwide Freight System Inc., 2801 NW 74 Avenue, Suite 225, Miami, FL 33122, Officers: Michael Liu, Vice President (Qualifying Individual), David Ting, Chairman

Merzario USA Inc., 17 Battery Place, #1630, New York, NY 10004, Officers: Giovanni Bisignani, Director, Claudion Quaranta, Exec. Vice President (Qualifying Individual)

Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants

Straight Air Service (USA), Inc., 161–15 Rockaway Blvd., Rm. 213, Jamaica, NY 11434, Officer: Chan Joe Loong, Managing Director (Qualifying Individual)

Servitrans, Inc., 1116 Oliver Street, Houston, TX 77007, Officers: Rafael A. Struve, President, J. Gregorio Diaz, Vice President (Qualifying Individual)

Caribbean Freight Systems, Inc., 1484 N.W. 153rd Avenue, Pembroke Pines, FL 33028, Officers: Jose A. Espinosa, Jr., Director (Qualifying Individual) Peter Achim, Director

Sea Gate Logistics, Inc., 182–11 150th Road, Suite 205, Jamaica, NY 11413, Officers: Vi Hung Vuong, President (Qualifying Individual), Renbo Lee, Secretary

Ocean Freight Forwarders—Ocean Transportation Intermediary Applicants

IGC, Inc., 7956 Clyo Road, Centerville, OH 45459, Officers: Ater Chokr, President, Patricia S. White, Corporate Secretary (Qualifying Individual)

Jones & Carroll Shipping, L.L.C., 1655 State Street, New Orleans, LA 70118, Officers: John Walker Jones, Jr., President (Qualifying Individual), Eleanor G. Carroll, Vice President

Global Logistics Services Company, 2063 South Atlantic Blvd., Suite 2–B, Monterey Park, CA 91754, Larry Li, Sole Proprietor

Dated: June 30, 1999.
Bryant L. VenBrakle,
Secretary.
[FR Doc. 99–16998 Filed 7–2–99; 8:45 am]
BILLING CODE 6730–01–M

FEDERAL TRADE COMMISSION

[Docket No. 9910075]

Shaw's Supermarkets, Inc., et al.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.
ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before September 7, 1999.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Phillip Broyles, FTC/S–2105, 601 Pennsylvania Avenue, NW Washington, DC 20580, (202) 326–2805.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, § 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for June 28th, 1999), on the World Wide Web, at "http://www.ftc.gov/os/actions97.htm." A paper copy can be obtained from the FTC Public Reference Room, Room H–130, 600 Pennsylvania Avenue, N.W., Washington, DC 20580, either in person or by calling (202) 326–3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Avenue, NW, Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and

copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii).

Analysis of the Draft Complaint and Proposed Consent Order To Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission") has accepted for public comment from J Sainsbury plc, owner of Shaw's Supermarkets, Inc. ("Shaw's") and Star Markets Holdings, owner of Star Markets Company ("Star") (collectively "the Proposed Respondents") an Agreement Containing Consent Order ("the proposed consent order"). The Proposed Respondents have also reviewed a draft complaint contemplated by the Commission. The proposed consent order is designed to remedy likely anitcompetitive effects arising from Shaw's proposed acquisition of all of the outstanding voting stock of Star.

II. Description of the Parties and the Proposed Acquisition

Shaw's Supermarkets, Inc., a Massachusetts corporation headquartered in Bridgewater, Massachusetts, is a wholly owned subsidiary of J Sainsbury plc, a United Kingdom company. Shaw's operates 126 supermarkets in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. All of Shaw's supermarkets operate under the "Shaw's" trade name. Shaw's total sales for its 1998 fiscal year were approximately $2.8 billion. Shaw's is the second largest supermarket chain operating in Greater Boston. After the merger, Shaw's will become the number one supermarket chain in Greater Boston, controlling almost 40% of all supermarket sales.

Star is a Massachusetts corporation headquartered in Cambridge, Massachusetts. Star operates 53 supermarkets in Massachusetts, forty-nine under the "Star" trade name and four under the "Wild Harvest" trade name. Star also operates a wholesale food business that serves mostly small independent supermarket customers throughout New England and New York State. Star's wholesale customer base includes 11 supermarkets that contractually use the "Star Markets" trade name though Star has no ownership interest in them. Star's revenues for fiscal year 1998 are more than $1 billion, $966 million of which are from its retail operations. With its 53 supermarkets, Star is the third largest supermarket chains operating in Greater Boston.

On November 25, 1998, J Sainsbury plc, Star Markets Holdings, Inc., Star Markets Company, Inc. and certain stockholders of Star Markets Holdings Inc., entered into a Stock Purchase Agreement for J Sainsbury plc to acquire all of the outstanding voting securities of Star Markets Holdings, Inc. The value of the transaction is approximately $490 million.

III. The Draft Complaint

The draft complaint alleges that the relevant line of commerce (i.e., the product market) is the retail sale of food and grocery items in supermarkets. Supermarkets provide a distinct set of products and services for consumers who desire to one-stop shop for food and grocery products. Supermarkets carry a full line and wide selection of both food and nonfood products (typically more than 10,000 different stock-keeping units ("SKUs")), as well as an extensive inventory of those SKUs in a variety of brand names and sizes. In order to accommodate the large number of nonfood products necessary for one-stop shopping, supermarkets are large stores that typically have at least 10,000 square feet of selling space.

Supermarkets compete primarily with other supermarkets that provide one-stop shopping for food and grocery products. Supermarkets base their food and grocery prices primarily on the prices of food and grocery products sold at nearby supermarkets. Most consumers shopping for food and grocery products at supermarkets are not likely to shop elsewhere in response to a small price increase by supermarkets.

Retail stores other than supermarkets that sell food and grocery products, such as neighborhood "mom & pop" grocery stores, limited assortment stores, convenience stores, specialty food stores (e.g., seafood markets, bakeries, etc.), club stores, military commissaries, and mass merchants, do not effectively constrain prices at supermarkets. The retail format and variety of items sold at these other stores are significantly different than that of supermarkets. None of these other retailers offer a sufficient quantity and variety of products to enable consumers to one-stop shop for food and grocery products.

The draft complaint alleges that the relevant sections of the country (i.e., the geographic markets) in which to analyze the acquisition are the areas in or near the following incorporated cities or towns in Massachusetts: (a) Waltham area that includes Waltham, Auburndale, Watertown, Newton, West Newton, Weston, and Lexington; (b) Quincy-Dorchester area that includes Quincy, N. Quincy, Milton, Dorchester, Boston, S. Boston, Braintree, and Weymouth; (c) Norwood area that includes Norwood, Walpole, Westwood, Dedham, Wrentham, and Sharon; (d) Milford area that includes Milford, Hopedale, Mendon, and Upton; (e) Salem-Lynn area that includes Salem, Lynn, Peabody, Swampscott, Danvers, Nahant, and Marblehead; (f) Norwell area that includes Norwell, Hanover, Rockland, Pembroke, Hanson, Scituate, Halifax, Hingham, Weymouth, Cohasset, and Hull; (g) Hudson-Stow area that includes Stow, Hudson, Sudbury, Marlborough, and Bolton; and (h) Saugus-Melrose-Stoneham area that includes Saugus, Melrose, Stoneham, and Wakefield.

J Sainsbury through its Shaw's subsidiary and Star Markets are actual and direct competitors in the all of the relevant markets.

The draft complaint alleges that the post-merger markets would all be highly concentrated, whether measured by the Herfindahl-Hirschman Index (commonly referred to as "HHI") or four-firm concentration ratios. The acquisition would substantially increase concentration in each market. The post-acquisition HHIs in the geographic markets range from 2205 points to 5136 points.

The draft complaint further alleges that entry is difficult and would not be timely, likely, or sufficient to prevent anticompetitive effects in the relevant geographic markets.

The draft complaint also alleges that Shaw's acquisition of all of the outstanding voting securities of Star, if consummated, may substantially lessen competition in the relevant line of commerce in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by eliminating direct competition between supermarkets owned or controlled by Shaw's and supermarkets owned and controlled by Star; by increasing the likelihood that Shaw's will unilaterally exercise market power; and by increasing the likelihood of, or facilitating, collusion or coordinated interaction among the remaining supermarket firms. Each of these effects increases the likelihood that the prices of food, groceries or services will increase, and the quality and selection of food, groceries or services will decrease, in the geographic markets alleged in the complaint.

IV. The Terms of the Agreement Containing Consent Order ("the Proposed Consent Order")

The proposed consent order will remedy the Commission's competitive concerns about the proposed acquisition. Under the terms of the proposed consent order Shaw's and Star must divest ten supermarkets, seven stores operating under the "Star Markets" trade name and three under the "Shaw's" trade name.

In the eight relevant markets, the Proposed Respondents will divest either all of the Shaw's or Star supermarkets to buyers who do not currently operate supermarkets in these markets. Divesting all of one party's assets in a particular market achieves the goals that the proposed consent order is designed to achieve—ensuring that the merger will not increase concentration in any relevant market and maintaining the number of firms in the market that existed before the merger.

Seven of the supermarkets to be divested are being sold to two experienced up-front buyers, firms that the Commission has pre-evaluated for their competitive and financial viability. The Commission's evaluation process consisted of analyzing the financial condition of the proposed acquirers and the locations of their current supermarkets to ensure that divestitures to them would not increase concentration or decrease competition in the relevant markets, as well as, determining that these purchasers are well qualified to operate the divested stores. The remaining three supermarkets are to be divested by the Proposed Respondents within three months of the date on which they signed the proposed consent agreement, to an acquirer approved by the Commission and in a manner approved by the Commission. Public comments may address the suitability of the designated up-front buyers to acquire supermarkets under the proposed consent order.

The following is a discussion of the two up-front buyers, Victory Super Markets ("Victory") and Foodmaster Super Markets, Inc. ("Foodmaster"). Victory, headquartered in Massachusetts and founded by the DiGeronimo family in 1923, will acquire five supermarkets from Shaw'—Shaw's Supermarket stores No. 193 in Waltham, No. 196 in North Quincy, and No. 122 in Norwood; and Star Markets Stores No. 169 in Milford, and No. 128 in Norwell, MA. Foodmaster, headquartered in Chelsea, Massachusetts, will acquire two supermarkets from Shaw's—Star Markets No.144 in Lynn and No. 129 in Swampscott.

The proposed consent order further requires Shaw's and Star to divest three additional supermarkets, Star Markets No. 152 in Stow, Star Markets No. 118 in Sudbury, and Star Markets No. 173 in Saugus to a proposed buyer that will be selected by Shaw's and approved by the Commission within three months of the date on which the Proposed Respondents sign the proposed consent agreement.

Paragraph II.A. of the proposed consent order requires that the divestiture to Victory must occur no later than the earlier of (1)20 days from when the merger is consummated, or (2) four months after the Commission accepts the agreement for public comment.[1] Paragraph II.B. of the proposed consent agreement requires that Shaw's divest the two supermarkets to Foodmaster within ten days of the date on which the proposed consent order becomes final. If Shaw's consummates the divestitures to Victory and Foodmaster during the public comment period, and if, at the time the Commission decides to make the order final, the Commission notifies Shaw's that Victory or Foodmaster is not an acceptable acquirer or that the asset purchase agreement with Victory or Foodmaster is not an acceptable manner of divestiture, then Shaw's must immediately rescind the transaction in question and divest those assets to another buyer within three months of the date the order becomes final. At that time, Shaw's must divest those assets only to an acquirer that receives the prior approval of the Commission and only in a matter that receives the prior approval of the Commission. In the event that any Commission-approved buyer is unable to take or keep possession of any of the supermarkets identified for divestiture, a trustee that the Commission may appoint has the power to divest any assets that have not been divested to satisfy the requirements of the proposed consent order.

The proposed consent order also enables the Commission to appoint a trustee to divest any supermarkets or sites identified in the order that Shaw's and Star have not divested to satisfy the requirements of the proposed consent order. In addition, the proposed order enables the Commission to seek civil penalties against Shaw's for non-compliance with the proposed consent order.

Among other requirements related to maintaining operations at the supermarkets identified for divestiture, the proposed consent order also specifically requires the Proposed Respondents to: (1) Maintain the viability, competitiveness and marketability of the assets to be divested; (2) not cause the wasting or deterioration of the assets to be divested; (3) not sell, transfer, encumber, or otherwise impair their marketability or viability; (4) maintain the supermarkets consistent with past practices; (5) use best efforts to preserve existing relationships with suppliers, customers, and employees; and (6) keep the supermarkets open for business and maintain the inventory at levels consistent with past practices.

The proposed consent order also prohibits Shaw's from acquiring, without providing the Commission with prior notice, any supermarkets, or any interest in any supermarkets, located in the county or counties that include the incorporated cities and towns in Massachusetts: Waltham, Auburndale, Watertown, Newton, West Newton, Weston, Lexington, Quincy, N. Quincy, Milton, Dorchester, Boston, S. Boston, Braintree, Hopedale, Mendon, Upton, Salem, Lynn, Peabody, Swampscott, Danvers, Nahant, Marblehead, Norwell, Hanover, Rockland, Pembroke, Hanson, Scituate, Halifax, Hingham, Cohasset, Hull, Stow, Hudson, Sudbury, Marlborough, Bolton, Saugus, Melrose, Wakefield, and Stoneham for ten years. These are the areas for which the supermarkets to be divested draw customers. The provisions regarding prior notice are consistent with the terms used in prior Orders. The proposed consent order does not, however, restrict the Proposed Respondents from constructing new supermarkets in the above listed areas; nor does it restrict the Proposed Respondents from leasing facilities not operated as supermarkets within the previous six months.

The proposed consent also prohibits Shaw's, for a period of ten years, from entering into or enforcing any agreement that restricts the ability of any person acquiring any location used as a supermarket, or interest in any location used as a supermarket on or after January 1, 1998, to operate a supermarket at that site if that site was a formerly owned or operated by Shaw's or Star Markets in any of the areas listed in the paragraph above. In addition, the Proposed Respondents are prohibited from removing fixtures or equipment from a store or property owned or leased

[1] Acceptance of the proposed consent agreement for public comment terminates the HSR waiting period and enables Shaw's to immediately acquire all of the outstanding voting securities of Star Markets.

by Shaw's in any of the cities or town listed above that is no longer operated as a supermarket, except (1) prior to a sale, sublease, assignment, or change in occupancy or (2) to relocate such fixtures or equipment in the ordinary course of business to any other supermarket owned or operated by the Proposed Respondents.

The Proposed Respondents are required to file compliance reports with the Commission, the first of which is due within thirty days of the date on which Proposed Respondents signed the proposed consent, and every thirty days thereafter until the divestitures are completed, and annually for ten years.

The proposed consent order also has a provision relating to the settlement agreement negotiated by the State of Massachusetts. If the State of Massachusetts fails to approve any divestiture that has not been completed, even though the parties are in compliance with the other provisions of the proposed consent agreement, the time period in which the divestiture must be completed will be extended 60 days during which the parties must exercise utmost good faith and best efforts to resolve the concerns of that particular state.

V. Opportunity for Public Comment

The proposed consent order has been placed on the public record for 60 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 60 days, the Commission will again review the proposed consent order and the comments received and will decide whether it should withdraw from the agreement or make the proposed consent order final.

By accepting the proposed consent order subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the proposed consent order, including the proposed sale of supermarkets to Victory and Foodmaster, in order to aid the Commission in its determination of whether to make the proposed consent order final. This analysis is not intended to constitute an official interpretation of the proposed consent order nor is it intended to modify the terms of the propsed consent order in any way.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 99–16993 Filed 7–2–99;8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Account Number: 4151–04]

Office of the Assistant Secretary for Planning and Evaluation; Cooperative Agreement With the Manpower Demonstration Research Corporation

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE).

The Office of the Assistant Secretary for Planning and Evaluation's (ASPE) Office of Human Services Policy announces that it will award an unsolicited cooperative agreement to the Manpower Demonstration Research Corporation (MDRC) in support of the Project on Devolution and Urban Change.

The purpose of this cooperative agreement is to support research to understand the impacts of welfare reform and welfare to work programs on low-income individuals, families, and the communities in which they live, with an emphasis on urban areas.

ASPE will have substantial involvement in all stages of the project, including: identifying potential questions that could be answered using the data; prioritizing among them based on the available resources; determining appropriate methods of data analysis; reviewing draft papers and reports; and assisting in their dissemination.

The goal of ASPE in entering into this cooperative agreement is to improve our understanding of the impact of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 in urban areas.

Authorizing Legislation

This cooperative agreement is authorized under Section 1110 of the Social Security Act (42 U.S.C. 1310), Section 5001 of the Balanced Budget Act of 1997, and the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1999 (Pub. L. 105–277).

Background

Assistance will be provided to MDRC. No other applications are solicited. ASPE is committed to supporting high-quality research in the area of welfare policy, and has a particular interest in understanding the effects of welfare reform in urban areas. Most welfare reform studies to date have not been in large cities, and thus have not addressed the challenges posed by high levels of unemployment and by concentrated poverty. These questions are critical because caseloads have not declined as much in cities as in other parts of the country, and also because the lessons from urban areas may be applicable elsewhere in the case of an economic downturn.

ASPE believes that MDRC is uniquely qualified to work with ASPE to meet this goal for the following reasons:

1. The Project on Devolution and Urban Change presents a unique opportunity to learn about the implementation and impacts of welfare reform in four large urban areas—Cleveland, Philadelphia, Los Angeles, and Miami. MDRC has an ongoing working relationship with key officials in each city and has already obtained commitments from the state and local governments in these areas to provide extensive longitudinal administrative data for research purposes.

2. This project brings together data from an unusually wide array of sources: longitudinal administrative data for all families receiving AFDC/TANF or Food Stamps dating back to 1992; survey data; an implementation study; neighborhood indicators; an institutional study focusing on local service providers; and an ethnographic study of a limited number of families. This will allow the researchers to capture effects that might be missed in one approach, and to improve our understanding of the strengths and weaknesses of each approach. It is unlikely that this breadth of sources could be replicated. MDRC has assembled a multi-disciplinary team of distinguished researchers to collect and analyze this data.

3. This project leverages a substantial commitment of private sector funding. Of the total $20 million cost of the Project on Devolution and Urban Change, approximately $14 million has already been committed by private funders, with an additional $3 million informally promised. This funding allows for a breadth of research far beyond what could be purchased with the federal support alone.

4. MDRC is one of the pre-eminent institutions in the area of welfare and welfare-to-work research, having conducted projects in over 400 communities in 40 states. MDRC has developed a reputation for objective, high-quality work. This project will involve several of MDRC's senior researchers, as well as consultants who are recognized as leaders in their areas of concentration.

Approximately $800,000 is available in FY 1999 for a one-year project period of this cooperative agreement. A portion of this support is provided by the Administration for Children and Families, HHS, and the Economic

Research Service, U.S. Department of Agriculture.

Where To Obtain Additional Information

If you are interested in obtaining additional information regarding this project, contact Ms. Elizabeth Lower-Basch, Office of Human Services Policy, ASPE, 200 Independence Ave. SW, Room 404E, Washington, DC, 20201 or telephone: 202 690–6808.

Dated: June 28, 1999.

Margaret A. Hamburg,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 99–17009 Filed 7–2–99; 8:45 am]

BILLING CODE 4110–60–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Contract Review Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C., Appendix 2), announcement is made of an Agency for Health Care Policy and Research (AHCPR) Technical Review Committee (TRC) meeting. This TRC's charge is to review contract proposals and to provide recommendations to the Administrator, AHCPR, regarding the technical merit of proposals submitted in response to a Request for Proposals (RFPs) regarding "Computer Decision Support Tools for Evidence Based Medicine", issued on April 28, 1999. The contract will constitute part of AHCPR's participation in the Small Business Innovation Research program.

The upcoming TRC meeting will be closed to the public in accordance with the Federal Advisory Committee Act (FACA), section 10(d) of 5 U.S.C., Appendix 2, implementing regulations, and procurement regulations, 41 CFR 101–6.1023 and 48 CFR 315.604(d). The discussions at this meeting of contract proposals are likely to reveal proprietary and personal information concerning individuals associated with the proposals. Such information is exempt from disclosure under the above-cited FACA provision that protects the free exchange of candid views, and under the procurement rules that prevent undue interference with Committee and Department operations.

Name of TRC: Agency for Health Care Policy and Research SBIR Topic 3000—"Computer Decision Support Tools for Evidence Based Medicine".

Date: July 27, 1999 (Closed to the public).

Place: Agency for Health Care Policy and Research, Conference Center, Conference Room B, 6010 Executive Boulevard, 4th Floor, Rockville, Maryland 20852.

Contact Person: Anyone wishing to obtain information regarding this meeting should contact Kate Rickard, Center for Practice and Technology Assessment, Agency for Health Care Policy and Research, 6010 Executive Boulevard, Suite 300, Rockville, Maryland 20852, 301–594–2431.

Dated: June 28, 1999.

John M. Eisenberg,

Administrator.

[FR Doc. 99–17056 Filed 7–2–99; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Contract Review Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C., Appendix 2), announcement is made of an Agency for Health Care Policy and Research (AHCPR) Technical Review Committee (TRC) meeting. This TRC's charge is to review contract proposals and to provide recommendations to the Administrator, AHCPR, regarding the technical merit of proposals submitted in response to a Request for Proposals (RFPs) regarding "Development and Implementation of the National Measurements Clearinghouse (NMC). The RFP was published in the Commerce Business Daily on April 15, 1999.

The upcoming TRC meeting will be closed to the public in accordance with the Federal Advisory Committee Act (FACA), section 10(d) of 5 U.S.C., Appendix 2, implementing regulations, and procurement regulations, 41 CFR 101–6.1023 and 48 CFR 315.604(d). The discussions at this meeting of contract proposals are likely to reveal proprietary and personal information concerning individuals associated with the proposals. Such information is exempt from disclosure under the above-cited FACA provision that protects the free exchange of candidad views, and under the procurement rules that prevent undue interference with Committee and Department operations.

Name of TRC: The Agency for Health Care Policy and Research—"Development and Implementation of the National Measures Clearinghouse (NMC)".

Date: July 27, 1999 (Closed to the public).

Place: Agency for Health Care Policy and Research, Conference Room 2, 2101 East Jefferson Street, 6th Floor, Rockville, Maryland 20852

Contact Person: Anyone wishing to obtain information regarding this meeting should contact Marge Keyes, Center for Quality Measurement and Improvement, Agency for Health Care Policy and Research, 2101 Executive Boulevard, Suite 502, Rockville, Maryland, 20852, 301–594–1824.

Dated: June 28, 1999.

John M. Eisenberg,

Administrator.

[FR Doc. 99–17057 Filed 7–2–99; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites; Hanford Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on PHS Activities and Research at DOE Sites Hanford Health Effects Subcommittee (HHES).

Times and Dates: 8:30 a.m.–5 p.m., July 22, 1999. 8:30 a.m.–2:30 p.m., July 23, 1999.

Place: DoubleTree Hotel Spokane City Center, North 322 Spokane Falls Court, Spokane, Washington 99201, telephone 509/455–6285.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Background: Under a Memorandum of Understanding (MOU) signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at Doe sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities

such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to receive an update from the Inter-tribal Council on Hanford Health Projects; to review and approve the Minutes of the previous meeting; to receive updates from ATSDR/NCEH and NIOSH: to receive reports from the Outreach, Public Health Assessment, Public Health Activities, and the Studies Workgroups; and to address other issues and topics, as necessary.

Matters to be Discussed: Agenda items include a presentation and discussion on the health effects subcommittee evaluations, Federal Task Order and request for proposal process, the National Academy of Science June 19th meeting, and agency updates. Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Leslie C. Campbell, Executive Secretary HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation ATSDR, 1600 Clifton Road, NE M/S E–56, Atlanta, Georgia 30333, telephone 1–888/42–ATSDR (28737), fax 404/639–6075.

The Director, Management Analysis and Services office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 29, 1999.

Carolyn J. Russell,

Director, Management Analysis and Service Office, Centers for Disease Control and Prevention.

[FR Doc. 99–16986 Filed 7–2–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2080]

Engelhard Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Engelhard Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a solution of 1-naphthalenesulfonic acid, 2-[(2-hydroxy-6-sulfo-1-naphthalenyl)azo]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[4-chloro-5-ethyl-2-sulfophenyl)azo]-6-hydroxy-, strontium salt (1:1) (C.I. Pigment Red 277) as a colorant for polymers intended for use in contact with food.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4667) has been filed by Engelhard Corp., 3400 Bank St., Louisville, KY 40212. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of a solution of 1-naphthalenesulfonic acid, 2-[(2-hydroxy-6-sulfo-1-naphthalenyl)azo]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[4-chloro-5-ethyl-2-sulfophenyl)azo]-6-hydroxy-, strontium salt (1:1) (C.I. Pigment Red 277) as a colorant for polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) 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.

Dated: June 11, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–16944 Filed 7–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

The Food and Drug Administration (FDA) is being restructured to create a more streamlined and efficient Office of the Commissioner that will provide leadership without compromising programmatic effectiveness. More specifically, the goals of this reorganization are to: Create an Office of the Commissioner (OC) for which the principal focus is to provide leadership in building effective, two-way communication between the agency and all of our stakeholders, including patients, consumers, Congress, the Administration, the regulated industry, health care professionals, and other scientific advisors and between agency management and employees; enable FDA to implement agency priorities and to develop agency policy with primary input from the Center Directors and the Associate Commissioner for Regulatory Affairs, and with legal advice from the Chief Counsel; streamline the OC to make the overall agency more effective and efficient with roles and responsibilities clearly delineated; and retain in OC only those staff functions which cannot be reasonably and more effectively performed in the Centers or the Office of Regulatory Affairs (ORA).

The new agency structure will consist of one Deputy Commissioner rather than the current four deputy structure. The Deputy Commissioner position will be established within the immediate OC. The Office of Operations will be abolished and the Center Directors and Associate Commissioner for Regulatory Affairs will report directly to the Commissioner. In addition, the Office of the Chief Counsel, Office of the Administrative Law Judge, and the Office of Equal Opportunity (OEO) (formerly titled the Office of Equal Employment and Civil Rights) will remain in OC. The OEO will assume the agency wide diversity program functions.

A new position will be established in the OC titled the Senior Associate Commissioner. The incumbent will head a new Office of the Senior

Associate Commissioner (OSAC). This Office will be responsible for coordinating all activities within the OC as well as providing advisory committee oversight. This Office will include the Office of the Ombudsman, the Office of Executive Secretariat, the Office of Public Affairs (formerly in the Office of External Affairs (OEA)), the Office of Orphan Products Development (formerly in the Office of Operations (OO)), the Office of Internal Affairs, and the Office of Tobacco Programs (formerly in the Office of Policy (OP)).

The former Office of Policy will be abolished. A new position will be established in the OC titled the Senior Associate Commissioner for Policy, Planning and Legislation. The new Office of Policy, Planning, and Legislation will be comprised of a new Policy office, the Office of Legislation (formerly titled the Office of Legislative Affairs in the OEA), and the Office of Planning (formerly titled the Office of Planning and Evaluation from the Office of Management and Systems), which will include the Management Initiatives Staff.

The Office of External Affairs will be abolished. As a result of the growing importance of international policy and activities, a new Office of International and Constituent Relations will be established. The new Office of International and Constituent Relations will consist of a new Office of International Programs, the Office of Consumer Affairs, the Office of Women's Health and the Office of Special Health Issues, all formerly in the OEA.

The current incumbent's position will be retitled Deputy Commissioner for International and Constituent Relations. This position will be converted to Senior Associate Commissioner when vacated.

The Industry and Small Business Liaison Staff (formerly in the OEA) will be abolished and its staff reassigned; some of its meeting scheduling functions will be realigned to the Office of Public Affairs, OSAC. The Office of Health Affairs (formerly in the OEA) will be abolished. Some of its functions (health assessments, patent term restorations, and scheduling of controlled substances) will be realigned to the Center for Devices and Radiological Health. Responsibility for 21 CFR parts 16 and 12 hearings will be realigned to the Office of the Ombudsman, OSAC.

The Office of Management and Systems will remain relatively unchanged in function except that many of the transactional functions of management will be decentralized to the Centers. The Divisions of Personnel Operations I, II, and III will be decentralized. The Centers and ORA will be functionally responsible for processing their personnel actions. The Office of Human Resources and Management Services will continue to process OC personnel actions. As noted earlier, the Office of Planning and Evaluation will be realigned to the Office of Policy, Planning, and Legislation.

The position title Deputy Commissioner for Management and Systems will be retained until this position is vacated. At such time the position will be converted to Senior Associate Commissioner for Management and Systems.

Part D, Chapter DA, Office of the Commissioner, FDA, of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 60 FR 56605, November 9, 1995, and in pertinent part at (56 FR 29484, June 27, 1991)) is amended to reflect the restructuring of FDA as follows:

Office of the Commissioner (DA): The Commissioner and Deputy Commissioner are responsible for the efficient and effective implementation of the FDA mission.

Office of the Chief Counsel (DAA): Subject to the professional supervision and control of the General Counsel, represents FDA in court proceedings and administrative hearings with respect to programs administered by FDA.

Provides legal advice and policy guidance for programs administered by FDA.

Acts as liaison to the Department of Justice and other Federal departments for programs administered by FDA.

Drafts or reviews all proposed and final regulations and **Federal Register** notices prepared by FDA.

Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to FDA.

Reviews proposed legislation affecting FDA that originates in the Department or on which Congress requests the views of the Department.

Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the Chief Counsel.

Office of Equal Opportunity (DAC): Advises and assists the Commissioner and other key agency officials on Equal Employment Opportunity (EEO) and Civil Rights activities which impact on policy development and execution of program goals.

Serves as the agency focal point and liaison with the Department, and other Federal agencies, State, and local governments, and other organizations regarding EEO and Civil Rights matters.

Develops and recommends policies and priorities designed to implement the intent of the Office of Personnel Management, Equal Employment Opportunity Commission, Office of Civil Rights, Department of Health and Human Services requirements under Executive Orders, regulations, EEO and Civil Rights legislation.

Provides leadership, direction, and technical guidance to the agency on EEO and Civil Rights matters.

Develops plans, programs, and procedures designed to ensure the prompt adjudication of complaints of alleged discrimination based on race, color, sex, age, religion, national origin, handicap, and sexual orientation.

Develops and oversees agency diversity initiatives and the diversity databank.

Provides alternative dispute resolution and mediation services as needed.

Develops and maintains training and technical assistance programs for agency EEO managers, counselors, special emphasis/program representatives, employees, supervisory personnel, and other key agency officials.

Examines the use and impact of administrative mechanisms on work assignments, pay systems, award systems, performance appraisal systems, promotion patterns, reorganization impacts, delegations of authority, management controls, information and documentation systems, and similar functions of management as they impact upon equal employment opportunities for all employees within the agency's representatives, and such other assistance as may be needed for EEO activities.

Develops, implements, and monitors the agency's Affirmative Action Plan and directs the agency's Affirmative Employment Program to achieve specific objectives.

Issues policies, publications and information dissemination services to agency employees including Commissioner Policy Statements, brochures, the EEO Counselors Manual, etc.

Develops labor-management partnerships on EEO matters.

Provides sign language interpreting services and manages the interpreting services contracts.

Office of the Administrative Law Judge (DAD): Schedules and conducts formal evidentiary public hearings under 21 CFR part 12, under the Federal

Food, Drug, and Cosmetic Act, as amended, as well as other related laws and the Administrative Procedure Act (5 U.S.C. 511 *et seq.*).

Issues Initial Decisions containing findings of fact and conclusions of law based on the independent review and evaluation of all evidence of record in formal hearings.

Office of the Senior Associate Commissioner (DAF): Advises the Commissioner and other key agency officials on agency-level activities and issues that affect agency wide programs, projects, strategies, and initiatives.

Coordinates activities involving emergency or crises situations and resolves complex problems and issues related to agency programs that are sensitive and controversial that impact upon agency relations with other Federal agencies and foreign governments.

Oversees and directs the agency's ombudsman, public affairs, tobacco program, orphan products, executive secretariat, and advisory committee functions to ensure coherence in decisionmaking and the efficient operation of these functions internally and across agency jurisdictions.

Provides leadership and direction to assure the efficient and effective planning, performance, and evaluation of oversight activities.

Office of Executive Secretariat (DAFA): Coordinates identification of and expedites development and implementation of the agency's highest program priorities and initiatives for the Commissioner.

Develops and maintains management information necessary for monitoring the Commissioner's and agency's goals and priorities.

Advises the Commissioner and other key agency officials on all activities that affect agency wide programs, projects, and initiatives. Informs appropriate agency staff of the decisions and assignments made by the Commissioner and other key agency officials.

Ensures that materials in support of recommendations presented for the Commissioner's consideration are comprehensive, accurate, fully discussed, and encompass the issues involved.

Provides correspondence control for the Commissioner and controls and processes all agency public correspondence directed to the Commissioner. Develops and operates tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.

Provides direct support to the Commissioner and other key agency officials, including briefing materials, background information for meetings, responses to outside inquiries, and maintenance and control of the Commissioner's working files.

Performs agency wide assignments involving complex problems and issues related to agency programs, strategies and activities, including preparation of special reports for the Department.

Coordinates the agency's communications with the Public Health Service (PHS), DHHS, and the White House including correspondence for the Assistant Secretary for Health and Secretarial signatures.

Office of Public Affairs (DAFB): Advises and assists the Commissioner and other key agency officials on all public information programs; acts as the focal point for disseminating news on FDA activities and as a liaison with PHS and the Department on public information programs.

Plans, develops, implements, and monitors policy and programs on agency media relations and consumer information and education programs conducted through the media, FDA's consumer affairs officers, and other communications sources.

Plans, develops, produces, and publishes agency publications and graphic arts materials.

Coordinates agency implementation of the Freedom of Information (FOI) Act and the Privacy Act.

Processes requests for information under FOI.

Executes FOI denial authority for the agency.

Press Relations Staff (DAFB–1): Advises and assists top level agency officials on print press matters involving mass media communications.

Plans, develops, and implements agency wide print media strategies for disseminating regulatory and educational material to the public through the mass media.

Serves as the agency focal point for preparing, clearing, and disseminating press releases and other print media statements representing agency policy and responding to media inquiries; maintains liaison with news media and pertinent publications.

Establishes policy for and coordinates all print media information activities, including news interviews and responses to inquiries; prepares position and policy statements for use by agency employees in responding to print media questions; tracks issues of potential interest to the media.

Coordinates the research and drafting of major public statements by the Commissioner including transmittal documents and supportive statements for use in transactions with the Department, other agencies, and the White House; provides editorial consultation and review for manuscripts, articles, and speeches written by the staff offices serving the Commissioner to ensure consistency of information and policy interpretation and maintains mailing lists for these documents.

Compiles, publishes, and distributes the weekly FDA Enforcement Report and the FDA Public Calendar; maintains the FDA Daily Clipping Service and FDA's electronic bulletin board; and coordinates the Daily Media Report.

Communications Staff (DAFB–2): Identifies consumer communication and educational requirements for the agency and creates, implements, and coordinates appropriate programs conducted through the media, agency consumer affairs officers, and other communication sources.

Plans, designs, produces, publishes, and disseminates audiovisual materials, exhibits, posters, publications, and periodicals, including *FDA Consumer*, *FDA Today*, and the *FDA Drug Bulletin*; participates in the planning and development of all publications and audiovisual aspects of communications programs directed at mass audiences.

Provides centralized agency graphic arts and editorial services for public information materials.

Acts as the public information liaison with the Department for all publications and audiovisual needs; provides prepublication clearance of publications, exhibits, and audiovisual materials in accordance with procedures established by the agency, PHS, the Department, Office of Management and Budget (OMB), and the White House.

Provides agency wide advice and consultation in the production of audiovisual materials; maintains centralized files of photographs and audiovisual materials for use by all agency components.

Freedom of Information Staff (DAFB–3): Establishes agency wide policy and provides overall direction and leadership for the Freedom of Information (FOI) program and Privacy Act program.

Serves as the agency expert and focal point for Headquarters and field personnel in the development and implementation of effective policies and procedures in accordance with the Freedom of Information Act, the Privacy Act, FDA regulations, and other relevant statutes.

Receives, reviews, controls, coordinates, and routes all FOI requests to the proper action office; designs and implements control mechanisms to

ensure that FOI and Privacy Act inquiries are processed and responded to within established timeframes.

Reviews all recommendations for denials submitted by Headquarters and field FOI Officers. Determines the need for supplemental information and/or changes in the denial recommendation and coordinates required action with the submitting office.

Analyzes, compiles, and prepares reports on privacy and FOI activities in the agency for the annual reports to the Department and for other reporting requirements.

Maintains copies of agency manuals, indexes, and other records required to be on public display.

Operations Staff (DAFB–4): Directs the effective utilization of all management resources by coordinating the management, facilities, budget, and equipment resources for the Office of Public Affairs.

Reviews organizational, management, and administrative policies of the Office to appraise the efficiency and effectiveness of operations.

Identifies potential management problems and/or needs and plans, develops, and conducts management studies.

Broadcast Media Staff (DAFB–5): Advises and assists top level agency officials on electronic media matters involving mass media communications.

Plans, develops, and implements agency wide broadcast media strategies for disseminating regulatory and educational materials to the public through the mass media.

Serves as the agency focal point for preparing, clearing, and disseminating electronic media requests representing agency policy and responding to electronic media inquiries; maintains liaison with broadcast media contacts.

Establishes policy for and coordinates all broadcast media information activities, including on-camera interviews and response to media inquiries; prepares position and policy statements for use by agency employees in responding to broadcast media questions; tracks issues of potential interest to the media.

Plans and coordinates all broadcast media training for the agency.

Office of the Ombudsman (DAFC): Serves as the agency lead on issues involving the administrative processing of product applications for FDA regulated products.

Provides advice and guidance to the Commissioner and other key agency officials regarding premarket approval processes for all FDA regulated products including requirements pertaining to applications, petitions, amendments, and supplements; and product, processing, packaging, and emerging product technologies.

Investigates and resolves internally and externally generated complaints and disagreements regarding the administrative processing of various applications for products regulated by the agency as well as regarding the fair and even handed application of agency policy and procedures in this process.

Represents the Commissioner or other key agency officials and serves as the agency's principal authority and spokesperson to top level agency and departmental officials, regulated industry representatives, scientific and professional organizations and groups, and other professional, and consumer associations concerning critical and significant issues and activities related to FDA regulated products.

Office of Orphan Products Development (DAFD): Manages the implementation of the provisions of the Orphan Drug Act and its amendments and manages a program to encourage the development of drugs of limited commercial value for use in rare or common diseases and conditions.

Develops and communicates agency policy and makes decisions on approval of sponsor requests and incentives, under the Federal Food, Drug, and Cosmetic Act (the act), including orphan drug protocol assistance under section 525 of the act (21 U.S.C. 360aa), orphan drug designation under section 526 (21 U.S.C.360bb), orphan drug exclusivity under section 527 (21 U.S.C.360cc), and orphan drug grants and contracts to support clinical research and other areas of agency policy related to the development of products for rare disorders.

Represents the Commissioner or serves as the agency's principal authority and spokesperson to the PHS Orphan Products Board, other governmental committees, industry, professional and consumer associations, requesting agency participation in orphan product development activities.

Reviews investigational new drug and biologics applications and investigational device exemptions to locate the existence of products under investigational study that show evidence of effectiveness for rare or common diseases but lack commercial sponsorship. Assists sponsors, researchers, and investigators in communicating with agency regulatory officials and expediting solutions to problems in obtaining investigational or market approval status.

Manages an extramural program of clinical research to evaluate safety and effectiveness of orphan products by funding grants and contracts, requesting applications for funding, organizing peer review of applications, monitoring and guiding investigators, and evaluating study results.

Office of Tobacco Programs (DAFE): Serves as the FDA focal point to provide programmatic direction to agency personnel on tobacco matters related to compliance, outreach activities, and product review under the Federal Food, Drug, and Cosmetic Act as amended.

Provides advice, guidance, oversight, and coordination to a variety of substantive activities in response to the FDA's rule to regulate the sale and distribution of cigarettes and smokeless tobacco products.

Establishes and maintains partnerships with Congress, other Federal agencies (e.g., Center for Disease Control and Prevention, Substance Abuse and Mental Health Services Agency, and the National Institutes of Health, etc.), State and local authorities, consumer groups, industry, and other key stakeholders on matters related to cigarettes and smokeless tobacco products.

Designs and implements a regulatory program that specifically addresses cigarettes and smokeless tobacco products.

Provides oversight and coordination for compliance, surveillance, and education programs and develops and disseminates pertinent information related to the FDA's rule to regulate the sale and distribution of cigarettes and smokeless tobacco products.

Provides agency guidance and coordinates technical evaluation of complex, precedent setting regulatory and scientific issues for existing, new, and/or novel tobacco products.

Identifies, plans, and develops policies, strategies, guidelines, programs, research protocols, standards, and educational materials, in cooperation with appropriate agency personnel.

Develops and utilizes methods to evaluate the effectiveness of program operations.

Develops and implements guidelines to ensure advertising, marketing, and youth access restrictions.

Office of Internal Affairs (DAFF): Provides a centralized agency wide investigative resource for the Commissioner and top agency management.

Provides a centralized investigative liaison between FDA and the Office of the Inspector General (OIG).

Serves as a FDA investigative resource to conduct internal FDA investigations and to support OIG investigations.

Conducts special assignments relative to the functions of this Office as requested.

Office of International and Constituent Relations (DAG): Serves as the agency focal point for developing and maintaining international communications and programs.

Advises and assists the Commissioner on health issues that have an impact on policy, direction, and long-range program goals.

Advises and assists the Commissioner on consumer affairs issues. Serves as the agency focal point for coordinating information from the appropriate agency components about significant consumer affairs issues.

Office of International Programs (DAGA): Serves as the agency focal point for international matters.

Advises the Commissioner and other key agency officials on agency formulation and execution and cross cutting and precedent setting issues involving international matters.

Serves as the agency liaison with other U.S. Government components, international and foreign governments (including Washington, DC embassies) for policy formulation and execution impacting FDA and FDA regulated products.

Directs and monitors agency strategic planning, priority-setting, and resource allocation processes for agency international matters.

Provides support to agency program areas for international activities.

Serves as the focal point for the agency international visitor program.

Provides support and issues guidelines for the visiting scientist program.

Serves as the focal point for the agency international travel program.

Serves as the focal point for international-related training (external and internal).

Serves as the focal point for agency technical cooperation and assistance activities.

Serves as the agency focal point for information exchange on international matters to ensure consistency internally and externally.

Provides a focal point for contacts with foreign governments and international organizations (including Washington, DC embassies).

Serves as the agency focal point for planning and coordinating meetings involving international matters.

Office of Consumer Affairs (DAGB): Serves as the agency focal point for coordinating information from the Centers, the Office of Regulatory Affairs, and other agency components about significant or public interest issues; develops mechanisms to gather consumer views for use in developing agency policy on these issues; monitors the development of agency policy on these issues; apprises the Commissioner and other key agency officials on the impact of consumer involvement in resolving these issues.

Serves as the agency focal point for contacting and involving national consumer groups on agency public participation programs; analyzes consumer feedback at the national level to assess potential major health issues, to determine national trends in consumer concerns, and to compile a consumer perspective of agency regulatory policies and activities; informs other agency components of consumer trends.

Serves as the agency focal point for coordinating information from Centers, the Office of Regulatory Affairs, and other agency components about potential public participation opportunities and informs the consumer of these activities.

Designs and administers special community outreach projects to broaden agency interaction with special target audiences, including the economically and educationally disadvantaged and the minorities.

Administers consumer awareness and advocacy skills training programs designed to educate lay consumers and current/potential consumer representatives for advisory committees to enhance their participation in agency regulatory and decisionmaking processes.

Administers the agency selection process for consumer representatives on advisory committees and panels.

Office of Women's Health (DAGC): Serves as the principal advisor to the Commissioner and other key agency officials on scientific, ethical, and policy issues relating to women's health.

Provides leadership and policy direction for the agency regarding issues of women's health and coordinates efforts to establish and advance a women's health agenda for the agency.

Monitors the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and the completion of gender analysis.

Identifies and monitors the progress of crosscutting and multidisciplinary women's health initiatives including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA's mission.

Serves as the agency's liaison with other agencies, industry, and professional associations with regard to the health of women.

Office of Special Health Issues (DAGD): Serves as an information resource to FDA and provides advice to the Commissioner and other key agency officials on matters related to the acquired immune deficiency syndrome (AIDS), cancer, Alzheimer's Disease, and other special health issues.

Coordinates interactions between FDA and consumer and professional groups dealing with AIDS, cancer, Alzheimer's Disease, and other special health issues.

Serves as a liaison point to coordinate contacts between FDA and other Federal agencies to ensure effective coordination and communication on AIDS, cancer, Alzheimer's Disease, and other special health issues.

Provides internal coordination on FDA activities related to AIDS, cancer, Alzheimer's Disease, and other special health issues.

Assists in the planning, administration, development, and evaluation of FDA policies related to AIDS, cancer, Alzheimer's Disease, and other special health issues.

Office of Policy, Planning, and Legislation (DAH): Advises the Commissioner and other key agency officials on matters relating to agency policy, regulations development, legislative issues, and planning and evaluation activities.

Participates with the Commissioner in the formulation of the basic policies and operational philosophy, which guide the Agency in effectively implementing its responsibilities.

Oversees and directs the agency's legislative activities, including legislative needs, pending legislation, and oversight activities.

Oversees and directs the agency's rulemaking activities and regulations development system.

Serves as the agency focal point for developing and maintaining communications, policies, and programs with regard to regulations development.

Oversees and directs FDA's planning and evaluation activities, including the development of programs and planning strategies through analysis and evaluation of issues affecting policies and program performance.

Office of Policy (DAHA): Advises and assists the Commissioner, the Senior Associate Commissioner for Policy, Planning and Legislation and other key agency officials on matters relating to agency policy and regulations development.

Serves as the agency focal point for developing broad agency policy.

Oversees, directs, and coordinates the agency's rulemaking activities and regulations development system.

Serves as the agency focal point for developing and maintaining communications, policies, and programs with regard to regulations development.

Initiates new and more efficient systems and procedures to accomplish agency goals in the rulemaking process.

Regulations Policy and Management Staff (DAHA–1): Serves as the agency focal point for developing and maintaining communications, policies, and programs with regard to regulations development. Directs, manages, and coordinates the agency's rulemaking activities and regulations development system. Initiates new and more efficient systems or procedures to accomplish agency goals in the rulemaking process.

Serves as the agency's focal point with the Department of Health and Human Services, Office of Managament and Budget, and other Federal agencies for policies and programs concerning regulations development.

Reviews proposed regulations, final regulations, and other agency documents to be published in the **Federal Register**. Ensures regulations are necessary; consistent with established agency policy; clearly written; enforceable; coordinated with other agency components, the Office of the General Counsel, and Federal, State, and local government agencies; appropriately responsive to public participation requirements and applicable executive orders; and responsive to any applicable requirements for assessment of economic and environmental effects.

Ensures that all regulations required by statute are issued.

Coordinates, with other agency components, the evaluation of existing regulations to determine whether they are efficiently and/or effectively accomplishing their intended purpose. Identifies regulations that require revision to correspond with current standards and those that should be revoked due to obsolescence. Makes recommendations for disposition of these regulations.

Arbitrates regulatory policy disagreements between agency components during the preparation of **Federal Register** documents.

Regulations Editorial Section (DAHA–11): FDA's official liaison with the Office of the Federal Register. Edits, processes, and prepares finished manuscript material for the issuance of agency proposed and final regulations and other documents published in the **Federal Register**.

Provides all **Federal Register** document development support functions (including cross-referencing, record retention, incorporation by reference, document tracking, and agency master print books of current CFR materials). Controls numbering and organization of agency codified material to insure proper structure of regulations being issued.

Policy Development and Coordination Staff (DAHA–2): Advises and assists the Senior Associate Commissioner for Policy, Planning, and Legislation concerning information that may affect current or proposed FDA policies.

Advises the Senior Associate Commissioner for Policy, Planning, and Legislation and other key agency officials on the formulation of broad agency regulatory policy.

Establishes procedures for agency policy formulation and monitors policy formulation activities throughout the agency.

Negotiates the resolution of policy issues involving more than one component of the agency.

Develops and coordinates the review and analysis of policy.

Initiates and participates in interagency discussions on agency regulations, plans, and policies to improve coordination of Federal regulations. When appropriate, assumes the lead in working with other Federal, State, or local agencies on a specific regulation or in developing an effective alternative regulatory approach.

Serves on agency task forces that are critical elements in the initiation, study, and resolution of priority policy issues.

Serves as the agency liaison for intergovernmental policy development.

Office of Planning (DAHB): Advises and assists the Commissioner and other key agency officials concerning the performance of the FDA planning and evaluation activities.

Develops program and planning strategy through analysis and evaluation of issues affecting policies and program performance.

Develops, installs, and monitors the agency wide planning system including the 5-year plan, strategic plan, and functional plans.

Conducts operations research, economic, and special studies as a basis for forecasting trends, needs, and major problems requiring solutions, and provides assistance and consultation in these areas to operating units.

Evaluates impact of external factors on FDA programs, including industry economics, consumer expectations, and prospective legislation. As necessary, recommends new programs or changes in existing programs and program priorities.

Develops FDA evaluation programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.

Evaluates impact of FDA programs on consumer protection.

Manages the operation of the agency wide Evaluation Review Board.

Coordinates the evaluation reviews of FDA by external groups.

Planning Staff (DAHB–1): Directs the agency long-range planning processes, including strategic and program planning, and coordinates with the Department of Health and Human Services (DHHS) long-range planning process.

Prepares the FDA Forward Plan and Annual Report.

Assists and consults with agency components in their planning.

Analyzes base line data and determines importance of external factors, including consumer safety and regulatory expectations, which affect the agency.

Consults with and supports the Office of Management and Systems in preparation of the agency budget; consults with and supports the Office of Legislation in the preparation of legislative proposals.

Conducts special planning-related studies and critiques as requested.

Coordinates the agency functional (regulatory, research, etc.) planning processes and supports agency staff units in planning, design, preparation, coordination, and execution.

Represents the agency in departmental planning activities.

Conducts analysis of resource requests submitted by agency components in order to develop resource recommendations for the Commissioner, to support the planning process, and to fulfill DHHS requirements.

Designs and operates management communications systems.

Coordinates and presents an annual regulatory development plan.

Conducts the agency manpower management system.

Evaluation Staff (DAHB–2): Performs agency program and policy evaluations and analytical studies. Recommends alternative courses of action to increase effectiveness of agency allocation of resources and to improve program and project performance.

Performs analyses of significantly broad agency issues identified in the planning process. Recommends and/or

implements steps to resolve these issues.

Ensures that appropriate program evaluation activities are taken in agency components. Monitors and coordinates these efforts to assure uniqueness and a contribution to agency program goals.

Develops the annual evaluation plan for the agency and coordinates with DHHS.

Conducts special evaluation, analytical, and economic-related studies in support of agency policy development and in resolution of broad agency problems.

Evaluates impact of external factors on agency programs, including consumer expectations and prospective legislation.

Evaluates the impact of agency operations and policies on regulated industries and other agency constituents.

Evaluates Program Management System (PMS) projects to provide a basis for agency decisionmaking. Recommends PMS project selections for evaluation, conducts the evaluations, and provides written and/or oral reports to the Commissioner and/or program managers.

Approves survey methodology, design, and questionnaires within the agency prior to Office of Management and Budget (OMB) clearance under the Paperwork Reduction Act; reviews Memoranda of Need, which require the collection of health research data and advises agency components on the planning and design of health research studies.

Advises international health organizations (e.g., World Health Organization) on the use of program evaluation to strengthen program operations in member countries.

Economics Staff (DAHB–3): Provides economic analyses as input to and support for decisions regarding agency policy issues.

Serves as the agency focal point for economic analysis assistance and consultation; provides economic analysis assistance to agency components for regulatory and other program functions.

Advises and assists the Commissioner and other key agency officials on a day-to-day basis concerning economic factors relating to current and proposed agency activities.

Provides a resource of economic research material for use by agency officials in preparing testimony before congressional committees and in developing replies to inquiries directed to the agency.

Conducts economic studies of FDA-related industries as a basis for forecasting trends, needs, and major problems affecting the agency.

Provides agency representation to Congress, OMB, DHHS, and others, as appropriate, on economic issues relating to agency regulations and other current and proposed actions.

Management Initiatives Staff (DAHB–4): Provides process expertise to agency components in designing consensus sessions with internal and external stakeholders.

Assists and consults with agency components on the design and execution of key program and process reinventions.

Assists and consults with agency scientific review components to enhance transparency, consistency, accountability, and continuous improvement of review processes.

Facilitates cross organizational sharing of key program and process improvements.

Serves as agency focal point on project management.

Maintains an agency team of interactive management practitioners.

Maintains and manages a facility for interactive management sessions for group problem-solving, action planning, consensus building, and redesign.

Office of Legislation (DAHC): Advises and assists the Commissioner and other key agency officials concerning legislative needs, pending legislation, and oversight activities that affect FDA.

Serves as the focal point for overall legislative liaison activities within FDA and between FDA, the Department, PHS, and other agencies; and analyzes the legislative needs of FDA and drafts or develops legislative proposals, position papers, and departmental reports on proposed legislation for approval by the Commissioner.

Advises and assists members of Congress and congressional committees and staffs in consultation with the Office of the Secretary, on agency actions, policies, and issues related to legislation which may affect FDA.

Congressional Affairs Staff I (DAHC–1): Serves as the agency focal point with Congress, the Department, PHS, and other agencies on all congressional and legislative issues and activities as they pertain to the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the National Center for Toxicological Research, and cross cutting agency organizational components and issues.

Coordinates and prepares agency responses to congressional and legislative inquiries and other sensitive correspondence on various issues that affect the agency including proposed legislation, oversight, investigative, and constituent matters.

Initiates, coordinates, and provides indepth analyses of agency legislative needs and proposed and pending legislation by preparing supporting documents, legislative proposals, and position papers for the Commissioner, other agency officials, Congress, and OMB.

Develops and coordinates testimony for the agency and the Department for presentation to congressional committees; monitors hearings; and edits transcripts of agency testimony.

Provides information on the agency's legislative programs and proposals to consumers and regulated industry.

In collaboration with other FDA and Department offices, initiates and conducts appraisals of regulatory and scientific policies to resolve problems pertaining to FDA programs and policies under existing statutes.

Congressional Affairs Staff II (DAHC–2): Serves as the agency focal point with Congress, the Department, PHS, and other agencies on all congressional and legislative issues and activities as they pertain to the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health.

Coordinates and prepares agency responses to congressional and legislative inquiries and other sensitive correspondence on various issues that affect the agency including proposed legislation, oversight, investigative, and constituent matters.

Initiates, coordinates, and provides indepth analyses of agency legislative needs and proposed and pending legislation by preparing supporting documents, legislative proposals, and position papers for the Commissioner, other agency officials, Congress, and OMB.

Develops and coordinates testimony for the agency and the Department for presentation to congressional committees; monitors hearings; and edits transcripts of agency testimony.

Provides information on the agency's legislative programs and proposals to consumers and regulated industry.

In collaboration with other FDA and Department offices, initiates and conducts appraisals of regulatory and scientific policies to resolve problems pertaining to FDA programs and policies under existing statutes.

Congressional Affairs Support Staff (DAHC–3): Receives, assigns, and tracks all congressional correspondence, reviews written responses for grammar, accuracy, completeness, and general

quality and maintains congressional correspondence files.

Prepares briefing books for congressional hearings, assists in the preparation and finalization of testimony, researches information in response to congressional, department and interagency requests (verbal or written), responds to incoming calls from Congress (subject to knowledge of program area), and provides office automation support.

Office of Management and Systems (DAJ): Advises and assists the Commissioner and other key agency officials on various management and systems activities.

Ensures that the conduct of agency administrative and financial management activities, including budget, finance, personnel, organization, methods, grants and contracts, procurement and property, records, and similar support activities, effectively support program operations.

Coordinates the integration and development of management information systems.

Advises the Commissioner on management information systems policies.

Executive Management Staff (DAJ–1): Advises the Commissioner and other key agency officials in regard to administrative management matters for their components.

Provides a focal point for administrative activities for the Office of the Commissioner.

Develops, coordinates, and facilitates various administrative processes such as personnel, procurement, training, travel, and other pertinent areas as necessary.

Establishes and maintains liaison with administrative officers throughout the serviced components to keep abreast with current issues.

Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations or redelegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: June 28, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–17019 Filed 6–30–99; 12:55 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry that has been developed by the Office of Inspector General in cooperation with, and with input from, the Health Care Financing Administration (HCFA), the Department of Justice (DOJ) and representatives of various trade associations and health care practice groups. The OIG has previously developed and published compliance program guidance focusing on hospitals, clinical laboratories, home health agencies, and third-party medical billing companies. We believe that the development and issuance of this compliance guidance will serve as a positive step towards promoting a higher level of ethical and lawful conduct throughout the entire health care industry.

FOR FURTHER INFORMATION CONTACT: Christine Pullifrone, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidances has been an important undertaking by the OIG in its effort to engage the health care community in combating fraud and abuse. In formulating this compliance guidance, the OIG has worked closely with HCFA, and has received input from interested parties and industry trade associations. The 4 previously-issued compliance program guidances focused on the hospital industry, home health agencies, clinical laboratories and third-party medical billing companies. The development of these types of compliance program guidances are based on our belief that a health care provider can efficiently use internal controls to monitor adherence to applicable statutes, regulations and program requirements.

Guidance for the DMEPOS Industry

On August 7, 1998, the OIG published a solicitation notice (63 FR 42409) seeking information and recommendations for developing guidance for the durable medical equipment, prosthetics, orthotics and supply (DMEPOS) industry. In response to that solicitation notice, the OIG received numerous comments from various parts of the industry and from their representatives. We carefully considered those comments, as well as consulted with DOJ, HCFA and the durable medical equipment regional carriers in developing a draft compliance program guidance for the DMEPOS industry. In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, the draft guidance for the DMEPOS industry was published in the **Federal Register** on January 28, 1999 (64 FR 4436) for further comment and recommendations.

Elements for an Effective Compliance Program

Through experience, the OIG has identified 7 fundamental elements applicable to an effective compliance program. They are:

- Implementing written policies, procedures and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.

Using these 7 elements, the OIG has identified specific areas of DMEPOS industry operations that may prove to be vulnerable to fraud and abuse. Like previously-issued OIG compliance guidance, adoption of the Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry set forth below will be strictly voluntary.

A reprint of the newly-issued compliance program guidance follows:

Office of Inspector General's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry (June 1999)

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human

Services (HHS) continues in its efforts to promote voluntarily developed and implemented compliance programs for the health care industry. The following compliance program guidance is intended to assist suppliers [1] of durable medical equipment,[2] prosthetics,[3] orthotics,[4] and supplies [5] (DMEPOS) and their agents and subcontractors (referred to collectively in this document as DMEPOS suppliers) develop effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State and private health plans.[6] The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, abuse, and waste in these health care plans while at the same time further the fundamental mission of all DMEPOS suppliers, which is to provide quality items, service, and care to patients.

Within this document, the OIG first provides its general views on the value and fundamental principles of DMEPOS suppliers' compliance programs, and then provides the specific elements that each DMEPOS supplier should consider when developing and implementing an effective compliance program. While this document presents basic procedural and structural guidance for designing a compliance program, it is not in itself a compliance program. Rather, it is a set of guidelines to be considered by a DMEPOS supplier interested in implementing a compliance program.

The OIG recognizes the size-differential that exists between operations of the different DMEPOS suppliers and organizations that compose the DMEPOS industry. Appropriately, this guidance is pertinent for all DMEPOS suppliers, regardless of size (in terms of employees and gross revenue); number of locations; type of equipment provided; or corporate structure. The applicability of the recommendations and guidelines provided in this document depends on the circumstances of each individual DMEPOS supplier. However, regardless of a DMEPOS supplier's size or structure, the OIG believes that every DMEPOS supplier can and should strive to accomplish the objectives and principles underlying all of the compliance policies and procedures recommended within this guidance.

Fundamentally, compliance efforts are designed to establish a culture within a DMEPOS supplier that promotes prevention, detection, and resolution of instances of conduct that do not conform to Federal and State law, and Federal, State and private payor health care program requirements, as well as the DMEPOS supplier's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the DMEPOS supplier's commitment to ethical conduct. Benchmarks that demonstrate implementation and achievements are essential to any effective compliance program. Eventually, a compliance program should become part of the fabric of routine DMEPOS supplier operations.

Specifically, compliance programs guide a DMEPOS supplier's owner(s), governing body (e.g., board of directors or trustees), chief executive officer (CEO), president, vice president(s), managers, sales representatives, billing personnel, and other employees in the efficient management and operation of a DMEPOS supplier. They are especially critical as an internal quality assurance control in the reimbursement and payment areas, where claims and billing operations are often the source of fraud and abuse, and therefore, historically have been the focus of Government regulation, scrutiny, prosecution and sanctions.

It is incumbent upon a DMEPOS supplier's owner(s), corporate officers, and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and legal conduct. Employees, managers, and the Government will focus on the words and actions of a DMEPOS supplier's leadership as a measure of the organization's commitment to compliance. Indeed, many DMEPOS suppliers have adopted mission statements articulating their commitment to high ethical standards. A formal compliance program, as an additional element in this process, offers a DMEPOS supplier a further concrete method that may improve quality of service and reduce waste. Compliance programs also provide a central coordinating mechanism for furnishing and disseminating information and guidance on applicable Federal and State statutes, regulations, and Federal, State and private health care program requirements.

Implementing an effective compliance program requires a substantial commitment of time, energy, and resources by senior management and the DMEPOS supplier's governing body.[7] Superficial programs that simply have the appearance of compliance without being wholeheartedly adopted and implemented by the DMEPOS supplier or programs that are hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective and could expose the DMEPOS supplier to greater liability than no program at all. Although it may require significant additional resources or reallocation of existing resources to implement an effective compliance program, the long term benefits of implementing the program significantly outweigh the costs. Undertaking a voluntary compliance program is a beneficial investment that advances both the DMEPOS supplier's organization and the stability and solvency of the Medicare program.

A. Benefits of a Compliance Program

The OIG believes an effective compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, improving operational quality, improving the quality of health care services and reducing the cost of health care. Attaining these goals provides positive results to the DMEPOS supplier, the Government and individual citizens alike. In addition to fulfilling its legal duty to ensure that it is not submitting false or inaccurate claims to Government and private payors, a DMEPOS supplier may gain numerous additional benefits by voluntarily implementing an effective compliance program. These benefits may include:

- The formulation of effective internal controls to assure compliance

[1] The term "supplier" is defined in this document as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered DMEPOS items and meets the Medicare supplier standards. *See* 42 CFR 424.57(a).

[2] The term "durable medical equipment" is applied in this document as defined in 42 U.S.C. 1395x(n).

[3] The term "prosthetics" and "prosthetic devices" are applied in this document as defined in 42 U.S.C. 1395x(s)(9) and (s)(8), respectively.

[4] The term "orthotics" is applied in this document as defined in 42 U.S.C. 1395x(s)(9).

[5] The term "supplies" includes home dialysis supplies and equipment as described in 42 U.S.C. 1395x(s)(2)(f); surgical dressings and other devices as described in 42 U.S.C. 1395x(s)(5); immunosuppressive drugs as described in 42 U.S.C. 1395x(s)(2)(J); and any other items or services designated by the Health Care Financing Administration (HCFA).

[6] The OIG recognizes that not every supplier provides durable medical equipment, prosthetics, orthotics and supplies. However, a compliance program incorporating the elements in this guidance can be used by all suppliers regardless of the items/services they provide.

[7] Recent case law suggests that the failure of a corporate Director to attempt in good faith to institute a compliance program in certain situations may be a breach of a Director's fiduciary obligation. *See, e.g., In re Caremark International Inc. Derivative Litigation,* 698 A.2d 959 (Ct. Chanc. Del. 1996).

with Federal and State statutes, rules, and regulations, and Federal, State and private payor health care program requirements, and internal guidelines;

- A concrete demonstration to employees and the community at large of the DMEPOS supplier's strong commitment to honest and responsible corporate conduct;
- The ability to obtain an accurate assessment of employee and contractor behavior relating to fraud and abuse;
- An increased likelihood of identification and prevention of criminal and unethical conduct;
- The ability to more quickly and accurately react to employees' operational compliance concerns and the capability to effectively target resources to address those concerns;
- Improvement of the quality, efficiency, and consistency of providing services;
- Increased efficiency on the part of employees;
- A centralized source for distributing information on health care statutes, regulations, policies, and other program directives regarding fraud and abuse and related issues;
- Improved internal communication;
- A methodology that encourages employees to report potential problems;
- Procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers, sales representatives, employees, independent contractors, consultants, clinicians and other health care professionals;
- Initiation of immediate, appropriate, and decisive corrective action;
- Early detection and reporting, minimizing the loss to the Government from false claims, and thereby reducing the DMEPOS supplier's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion; [8] and
- Enhancement of the structure of the DMEPOS supplier's operations and the consistency between: any related entities of the DMEPOS supplier; different departments within the DMEPOS supplier; the DMEPOS supplier's different locations; and the DMEPOS supplier's separate business units (e.g., franchises, subsidiaries).

Overall, the OIG believes that an effective compliance program is a sound investment on the part of a DMEPOS supplier.

The OIG recognizes that the implementation of a compliance program may not entirely eliminate fraud, abuse, and waste from the DMEPOS supplier's system. However, a sincere effort by the DMEPOS supplier to comply with applicable Federal and State statutes, rules, and regulations and Federal, State and private payor health care program requirements, through the establishment of an effective compliance program, significantly reduces the risk of unlawful or improper conduct.

B. Application of Compliance Program Guidance

Given the diversity within the industry, there is no single "best" DMEPOS supplier compliance program.[9] The OIG understands the variances and complexities within the DMEPOS supplier industry and is sensitive to the differences among large national and regional DMEPOS supplier organizations, and small independent DMEPOS suppliers. However, elements of this guidance can be used by all DMEPOS suppliers, regardless of size (in terms of employees and gross revenue); number of locations; type of equipment provided; or corporate structure, to establish an effective compliance program. Similarly, a DMEPOS supplier or corporation that owns a DMEPOS supplier or provides DMEPOS supplies may incorporate these elements into its system-wide compliance or managerial structure. We recognize that some DMEPOS suppliers may not be able to adopt certain elements to the same comprehensive degree that others with more extensive resources may achieve. This guidance represents the OIG's suggestions on how a DMEPOS supplier, regardless of size, can best establish internal controls and monitor its conduct to correct and prevent fraudulent activities. By no means should the contents of this guidance be viewed as an exclusive discussion of the advisable elements of a compliance program. On the contrary, the OIG strongly encourages DMEPOS suppliers to develop and implement compliance elements that uniquely address the individual DMEPOS supplier's risk areas.

The OIG believes that input and support by individuals and organizations that will utilize the tools set forth in this document is critical to the development and success of this compliance program guidance. In a continuing effort to collaborate closely with the private sector, the OIG placed a notice in the **Federal Register** soliciting recommendations and suggestions on what should be included in this Compliance Program Guidance.[10] Further, the OIG published the draft Compliance Program Guidance for the DME, Prosthetics, Orthotics, and Supply industry in the **Federal Register** for public comment.[11] In addition, we considered previous OIG publications, such as Special Fraud Alerts, Advisory Opinions,[12] the findings and recommendations in reports issued by OIG's Office of Audit Services and Office of Evaluation and Inspections, as well as the experience of past and recent fraud investigations related to DMEPOS suppliers conducted by OIG's Office of Investigations and the Department of Justice.

As appropriate, this guidance may be modified and expanded as more information and knowledge is obtained by the OIG, and as changes in the statutes, rules, regulations, policies, and procedures of Federal, State, and private health plans occur. The OIG understands DMEPOS suppliers will need adequate time to react to these modifications and expansions and to make any necessary changes to their voluntary compliance programs. New compliance practices may eventually be incorporated into this guidance if the OIG discovers significant enhancements to better ensure an effective compliance program.

The OIG recognizes that the development and implementation of compliance programs in DMEPOS suppliers often raise sensitive and

[8] The OIG, for example, will consider the existence of an *effective* compliance program that pre-dated any governmental investigation when addressing the appropriateness of administrative sanctions. However, the burden is on the DMEPOS supplier to demonstrate the operational effectiveness of a compliance program. Further, the False Claims Act, 31 U.S.C. 3729–3733, provides that a person who has violated the Act, but who voluntarily discloses the violation to the Government within 30 days of detection, in certain circumstances will be subject to not less than double, as opposed to treble, damages. *See* 31 U.S.C. 3729(a). Thus, the ability to react quickly when violations of the law are discovered may materially help reduce a DMEPOS supplier's liability.

[9] This is particularly true in the context of DMEPOS suppliers, which include many small independent DMEPOS suppliers with limited financial resources, staff, and product lines as well as large DMEPOS supplier chains with extensive financial resources, staff, and product lines.

[10] *See* 63 FR 42409 (August 7, 1998), Notice for Solicitation of Information and Recommendations for Developing OIG Compliance Program Guidance for the Durable Medical Equipment Industry.

[11] *See* 64 FR 4435 (January 28, 1999): Draft Compliance Program Guidance for the DME, Prosthetics, Orthotics, and Supply Industry.

[12] The OIG periodically issues Advisory Opinions responding to specific inquiries from members of the public and Special Fraud Alerts setting forth activities that raise legal and enforcement issues. Special Fraud Alerts and Advisory Opinions, as well as the regulations governing the issuance of Advisory Opinions, can be obtained on the Internet at http://www.dhhs.gov/progorg/oig, in the **Federal Register**, or by contacting the OIG's Public Information Desk at 202–619–1142.

complex legal and managerial issues.[13] However, the OIG wishes to offer what it believes is critical guidance for providers who are sincerely attempting to comply with the relevant health care statutes and regulations.

At the end of each section, where applicable, the OIG has included ideas to help aid the small DMEPOS supplier in implementing the principles espoused in this guidance. There is no all inclusive definition of a small DMEPOS supplier. However, as previously mentioned, each DMEPOS supplier should tailor its compliance program according to its resources.

II. Compliance Program Elements

The elements proposed by these guidelines are similar to those of the other OIG Compliance Program Guidances [14] and the OIG's corporate integrity agreements.[15] The OIG believes that every DMEPOS supplier can benefit from the principles espoused in this guidance, which can be tailored to fit the needs and financial realities of a particular DMEPOS supplier.

The OIG believes that every effective compliance program must begin with a formal commitment [16] by the DMEPOS supplier's governing body to include *all* of the applicable elements listed below, which are based on the seven steps of the Federal Sentencing Guidelines.[17] The OIG recognizes full implementation of all elements may not be immediately feasible for all DMEPOS suppliers. However, as a first step, a good faith and meaningful commitment on the part of the DMEPOS supplier, especially the owner(s), governing body, president, vice president(s), CEO, and managing employees, will substantially contribute to the program's successful implementation. As the compliance program is implemented, that commitment should cascade down through the management to every employee of the DMEPOS supplier.

At a minimum, comprehensive compliance programs should include the following seven elements:

(1) The development and distribution of written standards of conduct, as well as written policies and procedures that promote the DMEPOS supplier's commitment to compliance (e.g., by including adherence to the compliance program as an element in evaluating managers and employees) and address specific areas of potential fraud, such as the claims development and submission process, completing certificates of medical necessity (CMNs), and financial relationships with physicians and/or other persons authorized [18] to order DMEPOS;

(2) The designation of a compliance officer and other appropriate bodies, (e.g., a corporate compliance committee), charged with the responsibility for operating and monitoring the compliance program, and who report directly to the CEO and the governing body; [19]

(3) The development and implementation of regular, effective education and training for all affected employees; [20]

(4) The development of effective lines of communication between the compliance officer and all employees, including a process, such as a hotline or other reporting system, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect callers from retaliation;

(5) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problem areas; [21]

(6) The development of appropriate disciplinary mechanisms to enforce standards and the development of policies addressing (i) employees who have violated internal compliance policies, applicable statutes, regulations, or Federal, State or private payor health care program requirements and (ii) the employment of sanctioned and other specified individuals; [22] and

(7) The development of policies to respond to detected offenses and to initiate corrective action to prevent similar offenses.

A. Written Policies and Procedures

Every compliance program should require the development and distribution of written compliance policies, standards, and practices that identify specific areas of risk and vulnerability to the individual DMEPOS supplier. These policies, standards, and practices should be developed under the direction and supervision of the compliance officer and the compliance committee (if such a committee is practicable for the DMEPOS supplier) and, at a minimum, should be provided to all individuals who are affected by the particular policy at issue, including the DMEPOS supplier's agents and independent contractors who may affect billing decisions.[23]

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[13] Nothing stated within this document should be substituted for, or used in lieu of, competent legal advice from counsel.

[14] *See* 63 FR 70138 (December 18, 1998) for the Compliance Program Guidance for Third Party Medical Billing Companies; 63 FR 42410 (August 7, 1998) for the Compliance Program Guidance for Home Health Agencies; 63 FR 45076 (August 24, 1998) for the Compliance Program Guidance for Clinical Laboratories, as revised; 63 FR 8987 (February 23, 1998) for the Compliance Program Guidance for Hospitals. These documents are also located on the Internet at http://www.dhhs.gov/progorg/oig.

[15] Corporate integrity agreements are executed as part of a civil settlement between a health care provider and the Government to resolve a case based on allegations of health care fraud or abuse. These OIG-imposed programs are in effect for a period of three to five years and require many of the elements included in this compliance program guidance.

[16] A formal commitment may include a resolution by the board of directors, owner(s) or president, where applicable. A formal commitment should include the allocation of adequate resources to ensure that each of the elements is addressed.

[17] *See* United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3(k). The Federal Sentencing Guidelines are detailed policies and practices for the Federal criminal justice system that prescribe the appropriate sanctions for offenders convicted of Federal crimes.

[18] In some instances, persons other than the treating physician (e.g., nurse practitioner, physician assistant, clinical nurse specialist) may be authorized to order DMEPOS for Medicare beneficiaries if permitted under State law and in accordance with HCFA policies. A DMEPOS supplier should be aware of any persons, other than the treating physician, who are authorized to order DMEPOS.

[19] The integral functions of the compliance officer and the corporate compliance committee in implementing an effective compliance program are discussed throughout this compliance program guidance. However, the OIG recognizes that the differences in the sizes and structures of DMEPOS suppliers will result in differences in the ways in which compliance programs are set up. It is important that a DMEPOS supplier structures its compliance program in such a way that the program facilitates implementation of the key functions of the corporate compliance officer and the corporate compliance committee discussed within this document. *See* section II.B and accompanying notes.

[20] Education and training programs for DMEPOS suppliers should be detailed and comprehensive. They should cover specific billing procedures, sales and marketing practices, as well as the general areas of compliance. *See* section II.C and accompanying notes.

[21] For example, spot-checking the work of coding and billing personnel periodically and conducting periodic post-payment claim review should be elements of an effective compliance program. *See* section II.E and accompanying notes.

[22] The term "Federal health care program" is applied in this document as defined in 42 U.S.C. 1320a–7b(f), and includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly in whole or in part, by the United States Government (i.e., via programs such as Medicare, Federal Employees' Compensation Act, Black Lung, or the Longshore and Harbor Worker's Compensation Act) or any State health plan (e.g., Medicaid, or a program receiving funds from block grants for social services or child health services). Also, for the purpose of this document, the term "Federal health care program requirements" refers to the statutes, regulations, rules requirements, directives, and instructions governing Medicare, Medicare, Medicaid, and all other Federal health care programs.

[23] According to the Federal Sentencing Guidelines, an organization must have established compliance standards and procedures to be followed by its employees and other agents in order

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In addition to these general policies, it may be necessary to implement individual policies for the different components of the DMEPOS supplier.

1. Standards of Conduct

The OIG recommends that the DMEPOS supplier develop standards of conduct for all affected employees that include a clearly delineated commitment to compliance by the DMEPOS supplier's senior management,[24] including any related entities or affiliated providers operating under the DMEPOS supplier's control,[25] and other health care professionals (e.g., nurses, licensed pharmacists, physicians, and respiratory therapists). The standards of conduct should function in the same fashion as a constitution, i.e., as a foundational document that details the fundamental principles, values, and framework for action within the DMEPOS supplier. The standards should articulate the DMEPOS supplier's commitment to comply with all Federal and State statutes, rules, regulations and Federal, State and private payor health care program requirements, with an emphasis on preventing fraud and abuse. They should explicitly state the organization's mission, goals, and ethical principles relative to compliance and clearly define the DMEPOS supplier's commitment to compliance and its expectations for all DMEPOS supplier owners, governing body members, presidents, vice presidents, corporate officers, managers, sales representatives, employees, and, where appropriate, independent contractors and other agents. These standards should promote integrity, support objectivity, and foster trust. Standards should not only address compliance with statutes and regulations, but should also set forth broad principles that guide employees in conducting business professionally and properly.

The standards should be distributed to, and comprehensible by, all affected employees (e.g., translated into other languages when necessary and written at appropriate reading levels). Further, to assist in ensuring that employees continuously meet the expected high standards set forth in the standards of conduct, any employee handbook delineating or expanding upon these standards should be regularly updated as applicable statutes, regulations, and Federal, State, and private payor health care program requirements are modified and/or clarified.[26]

When employees first begin working for the DMEPOS supplier, and each time new standards of conduct are issued, the OIG suggests employees be asked to sign a statement certifying that they have received, read, understood, and will abide by the standards of conduct. The employee's certification should be retained by the DMEPOS supplier in the employee's personnel file, and available for review by the compliance officer.

The OIG believes all DMEPOS suppliers, regardless of size, should operate professionally and ethically. The OIG recognizes that small DMEPOS suppliers may not have formal written standards of conduct. However, such unwritten standards of conduct (e.g., the manner in which the DMEPOS supplier conducts its business) should be relayed to each employee. Employees should attest, in writing, that they understand and will abide by these standards.

2. Written Policies for Risk Areas

As part of its commitment to compliance, the DMEPOS supplier should establish a comprehensive set of written policies and procedures that take into consideration the particular statutes, rules, regulations, and program instructions applicable to each function of the DMEPOS supplier.[27] In contrast to the standards of conduct, which are designed to be a clear and concise collection of fundamental standards, the written policies should articulate specific procedures personnel should follow.

Consequently, we recommend that the individual policies and procedures be coordinated with the appropriate training and educational programs with an emphasis on areas of special concern that have been identified by the OIG.[28] Some of the special areas of OIG concern include:[29]

- Billing for items or services not provided;[30]
- Billing for services that the DMEPOS supplier believes may be denied;[31]

to receive sentencing credit for an "effective" compliance program. The Federal Sentencing Guidelines define "agent" as "any individual, including a director, an officer, an employee, or an independent contractor, authorized to act on behalf of the organization." See United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3(d).

[24] The OIG strongly encourages high-level involvement by a DMEPOS supplier's owner(s), governing body, CEO, president, vice president(s), as well as other personnel, as appropriate, in the development of the standards of conduct. Such involvement should help communicate a strong and explicit organizational commitment to compliance goals and standards.

[25] E.g., pharmacies, billing services, and manufacturers.

[26] The OIG recognizes that not all statutes, rules, regulations, standards, policies, and procedures need to be communicated to all employees. However, the OIG believes that the bulk of the standards that relate to complying with fraud and abuse laws and other ethical areas should be addressed and made part of all affected employees' training. A DMEPOS supplier must decide whether additional educational programs should be targeted to specific categories of employees based on job functions and areas of responsibility.

[27] A DMEPOS supplier can conduct focus groups, composed of managers from various departments, to solicit their concerns and ideas about compliance risks that may be incorporated into the DMEPOS supplier's policies and procedures. Such employee participation in the development of the DMEPOS supplier's compliance program can enhance its credibility and foster employee acceptance of the program.

[28] A DMEPOS supplier's compliance program should require that the legal staff, compliance officer, or other appropriate personnel carefully consider any and all Special Fraud Alerts and Advisory Opinions issued by the OIG that relate to DMEPOS suppliers. See note 12. Moreover, the compliance program should address the ramifications of failing to cease and correct any conduct criticized in such a Special Fraud Alert or Advisory Opinion, if applicable to the DMEPOS supplier, or to take reasonable action to prevent such conduct from reoccurring in the future. If appropriate, a DMEPOS supplier should take the steps described in section II.G regarding investigations, reporting, and correction of identified problems.

[29] The OIG Work Plan details the various projects the OIG currently intends to address in the fiscal year. It should be noted that the priorities in the Work Plan are subject to modification and revision as the year progresses and does not represent a complete or final list of areas of concern to the OIG. The Work Plan is currently available on the Internet at http://www.dhhs.gov/progorg/oig.

[30] Billing for items or services not provided involves submitting a claim representing that the DMEPOS supplier provided an item or service or part of an item or service that the patient did not receive. It may also include not fulfilling a contractual agreement, for example, when the DMEPOS supplier has agreed to service the rental equipment and does not fulfill this obligation.

[31] Billing for services that may be denied involves seeking reimbursement for a service that is not covered by Medicare or does not meet the Medicare coverage criteria as documented by the patient's current medical condition. See 42 U.S.C. 1395y(a)(1)(A). The OIG recognizes that DMEPOS suppliers cannot make medical necessity determinations and may not be aware if an item or service will be denied in every instance. However, civil money penalties (CMPs) and administrative sanctions may be imposed against any person who submits a claim for services "that [the] person knows or should know are not medically necessary." See 42 U.S.C. 1320a-7a(a). Such conduct may also result in liability under civil and criminal laws. HCFA does allow DMEPOS suppliers to submit claims when the DMEPOS supplier believes the item or service may not be covered, provided, however, that the supplier "note[s] on the claim [its] belief that the service is noncovered and that it is being submitted at the beneficiary's insistence." See *Medicare Carriers Manual*, section 3043. If the DMEPOS supplier believes the item or

- Billing patients for denied chargs without a signed written notice; [32]
- Duplicate billing; [33]
- Billing for items or services not ordered; [34]
- Using a billing agent whose compensation arrangement violates the reassignment rule; [35]
- Upcoding; [36]
- Unbundling items or supplies; [37]
- Billing for new equipment and providing used equipment; [38]
- Continuing to bill for rental items after they are no longer medically necessary; [39]
- Resubmission of denied claims with different information in an attempt to be improperly reimbursed; [40]
- Refusing to submit a claim to Medicare for which payment is made on a reasonable charge or fee schedule basis; [41]
- Inadequate management and oversight of contracted services, which results in improper billing; [42]
- Charge limitations; [43]
- Providing and/or billing for substantially excessive amounts of DMEPOS items or supplies; [44]
- Providing and/or billing for an item or service that does not meet the quality and standard of the DMEPOS item claimed; [45]
- Capped rentals; [46]
- Failure to monitor medical necessity on an on-going basis; [47]
- Delivering or billing for certain items or supplies prior to receiving a physician's order and/or appropriate CMN; [48]
- Falsifying information on the claim form, CMN, and/or accompanying documentation; [49]

service may be denied for any reason (e.g., not covered, not medically necessary), the DMEPOS supplier may have the beneficiary sign a written notice accepting financial responsibility if the item or service is denied (*see Medicare Carriers Manual*, section 7300.5). The DMEPOS supplier should include modifier "GA" on the claim for such item or service. This modifier indicates the beneficiary has signed a written notice. If the beneficiary signed an advance written notice, the DMEPOS supplier may directly bill the beneficiary for the denied item or service. (See section II.A.3.i for further discussion on written notices). *See also* discussion in section II.A.3.a and accompanying notes.

[32] This includes, but is not limited to, billing the patient for items or services denied as not medically necessary by the payor, where there has been no written notice signed by the patient, the written notice has been inappropriately obtained or the written notice was drafted inappropriately. *See Medicare Carrier Manual*, section 7300.5A, regarding the requirements for written notice.

[33] Duplicate billing occurs when more than one claim for payment is submitted for the same patient, for the same service, for the same date of service (by the same or different DMEPOS supplier), or the same claim is submitted to more than one payor as primary Although duplicate billing can occur due to simple error (which does not create civil or criminal liability), fraudulent duplicate billing is often evidenced by systematic or repeated double billing, and creates liability under criminal, civil, and administrative law, particularly if any overpayment is not promptly refunded. *See* note 72.

[34] Billing for items or services not ordered involves seeking reimbursement for items or services provided, but not ordered by the treating physician or other authorized person.

[35] If a billing agent receives payment on behalf of a DMEPOS supplier, the billing agent's compensation may not be related in any way to the dollar amounts billed or collected. *See* 42 U.S.C. 1395u(b)(6); 42 CFR 424.73; *Medicare Carriers Manual*, section 3060.

[36] Upcoding involves selecting a code to maximize reimbursement when such code is not the most appropriate descriptor of the service (e.g., billing for a more expensive piece of equipment when a less expensive piece of equipment is provided).

[37] Unbundling items or supplies involves billing for individual components when a specific HCFA Common Procedure Coding System (HCPCS) code provides for the components to be billed as a unit (*e.g.*, providing a wheelchair and billing the individual parts of the wheelchair, rather than the wheeelchair as a whole).

[38] The DMEPOS supplier must indicate on the Medicare claim form, through the use of modifiers, whether the item provided is new or used. The modifier for providing new equipment is "NU." The modifies for providing used equipment is "UE." A knowing failure to correctly document the item provided would constitute falsifying information on the claim form and many constitute a violation of the False Claims Act. *See* 31 U.S.C. 3729.

[39] Once a rental item is no longer medically necessary, the DMEPOS supplier required to discontinue billing the payor for it. The OIG recognizes that DMEPOS suppliers cannot make medical necessity determinations and may not be aware that a rental item is no longer medically necessary for a particular patient. As a result, the OIG recommends that the DMEPOS supplier periodically contact the treating physician or other authorized person to ensure the rental item continues to be medically necessary. In addition, the OIG recommends that the DMEPOS supplier pick up such equipment from the patient in a timely manner. If the DMEPOS supplier bills for a rental item after it is no longer medically necessary, the DMEPOS supplier is financially responsible for that item and must remit any overpayments for that item. *See* 42 U.S.C. 1320a-7b(a)(3), which provides criminal penalties for failure to disclose an overpayment.

[40] This practice involves the DMEPOS supplier improperly changing information on a previously denied claim and continuing to resubmit the claim in an attempt to receive payment. For example, a DMEPOS supplier may submit a claim using the accurate HCPCS code for the item or service provided and the claim is subsequently denied. It is improper to change the HCPCS code to HCPCS code that the DMEPOS supplier believes is reimbursable, when such item or service was not provided.

[41] This practice involves a DMEPOS supplier not submitting a claim on behalf of the beneficiary for items or services that are Medicare benefits and are reimbursable under the Medicare program. *See* 42 U.S.C 1395w–4(g)(4).

[42] The OIG recommends that the DMEPOS supplier create internal mechanisms to ensure that the use of contractors does not lead to improper billing practices.

[43] A DMEPOS supplier should ensure that its billing personnel are informed of the different payment rules of all the Federal, State, and private health care programs it bills. The supplier should be aware that billing for items or services furnished substantially in excess of the supplier's usual charges may result in exclusion and other sanctions. *See* 42 U.S.C. 1320a–7(b)(6)(A). *See also* OIG Ad. Op. 98–8 (1998).

[44] This practice, which constitutes overulitization, involves providing and/or billing for substantially more items or supplies that are reasonable and necessary for the needs of each individual patient. The OIG recognizes that DMEPOS suppliers cannot make medical necessity determinations. The medical need for an item must be determined by the physician or other authorized person who is treating the patient. However, the DMEPOS supplier must ensure that the patient's condition meets coverage, payment and utilization criteria as established in the payor's medical policies. If the DMEPOS supplier is providing and/or billing for substantially excessive amounts of DMEPOS items or supplies, the DMEPOS supplier is financially responsible for remitting any overpayments relating to those items or supplies. The OIG recommends that if a DMEPOS supplier is providing and billing for a large number of items or supplies for the same patient, it may periodically want to contact the treating physician or other authorized person to confirm the medical necessity of the items or supplies. Such contact with the physician's office should be documented. The practice of billing for substantially excessive amounts of items or supplies may lead to exclusion from Federal health care programs and other sanctions. *See* 42 U.S.C. 1320a–7(b)(6)(B).

[45] This practice involves providing and/or billing for an item or service that does not meet the definition and/or requirement of the item or service ordered by the treating physician or other authorized person. Generally, such items are inferior in quality, and therefore do not meet the definition of what was ordered and/or billed. Sometimes this may mean that certin equipment was never cleared by the Food and Drug Administration, as required by law. This practice may lead to billing for items that are not reasonable and necessary. A DMEPOS supplier should ensure that the iterm or services it furnishes meet professionally recognized minimum standards of health care.

[46] See discussion in section II.A.3.k and accompanying notes.

[47] In order for a patient to continue to receive items or supplies (e.g., rental equipment, supplies for an on-going condition) and for the DMEPOS supplier to receive Medicare reimbursement, the patient must meet the medical necessity criteria for that specific item or supply on an on-going basis. The item or supply furnished by the DMEPOS supplier should be replaced or adjusted, in a timely manner, to reflect changes in the patient's condition. The OIG recognizes that a DMEPOS supplier cannot make medical necessity determinations and may not be aware when a patient's condition changes. However, if a DMEPOS supplier is billing for items or services that are no longer medically necessary, the supplier is financially responsible for remitting any overpayments relating to those items or services. The OIG recommends that if a DMEPOS supplier is providing the same items or supplies to a patient on a regular basis, it may periodically want to contact the treating physician or other authorized person to confirm that the items or supplies continue to be medically necessary. Such contact with the physician's office should be documented.

[48] This practice involves a DMEPOS supplier delivering to the patient, and/or billing the payor for, items or supplies that have not yet been ordered by the treating physician or other authorized person. Medicare requires written orders for certain items before delivery. *See*, e.g., 42 CFR 410.38.

[49] This practice invovles supplying false information to be included on the claim form, the CMN, or other accompanying documentation. The

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- Completing portions of CMNs reserved for completion only by the treating physician or other authorized person; [50]
- Altering medical records; [51]
- Manipulating the patient's diagnosis in an attempt to receive improper payment; [52]
- Failing to maintain medical necessity documentation; [53]
- Inappropriate use of place of service codes; [54]
- Cover letters that encourage physicians to order medically unnecessary items or services; [55]
- Improper use of the ZX modifier; [56]
- Routine waiver of deductibles and coinsurance; [57]
- Providing incentives to actual or potential referral sources (e.g., physicians, hospitals, patients, skilled nursing facilities, home health agencies or others) that may violate the anti-kickback statute or other similar Federal or State statute or regulation; [58]
- Compensation programs that offer incentives for items or services ordered and revenue generated; [59]
- Joint ventures between parties, one of whom can refer Medicare or Medicaid business to the other; [60]
- Billing for items or services furnished pursuant to a prohibited referral under the Stark physician self-referral law; [61]
- Improper telemarketing practices; [62]
- Improper patient solicitation activities and high-pressure marketing of noncovered or unnecessary services; [63]
- Co-location of DMEPOS items and supplies with the referral source; [64]
- Non-compliance with the Federal, State and private payor supplier standards; [65]
- Providing false information on the Medicare DMEPOS supplier enrollment form; [66]
- Not notifying the National Supplier Clearinghouse in a timely manner of changes to the information previously provided on the DMEPOS supplier enrollment form; [67]
- Misrepresenting a person's status as an agent or representative of Medicare; [68]
- Knowing misuse of a supplier number, which results in improper billing; [69]
- Failing to meet individual payor requirements; [70]

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information reported on these documents should accurately reflect the patient's information, including medical information, and the items or services ordere by the treating physician or other authorized person and provided by the DMEPOS supplier. *See*, e.g., 18 U.S.C. 1035, which provides criminal penalties for falsifying information on such documentation.

[50] This practice involves not completing the CMN in compliance with Medicare regulations (i.e., sections B and D should never be completed by the supplier). Instructions for completing the CMN can be found on the back of the form. *See Medicare Carriers Manual*, section 3312, which provides instructions on how to complete the CMN and the CMPs that may be assessed for improper completion of the CMN. *See also* 42 U.S.C. 1395m(j)(2); section II.A.3.c and accompanying notes for further discussion on CMNs. Such conduct may also result in liability under civil and criminal laws.

[51] This practice involves falsifying information on a patient's medical records to justify reimbursement for an item or service.

[52] This practice involves altering the treating physician's or other authorized person's diagnosis in an attempt to receive reimbursement for a particular item or service. A DMEPOS supplier should not claim the patient has a particular medical condition in order to qualify for an item for which the patient would not otherwise qualify.

[53] This practice involves failing to ensure that the medical necessity documentation requirements for the item or service billed are properly met (*e.g.*, failing to maintain the physician orders or CMNs or failing to ensure that CMNs contain adequate and correct information). *See Medicare Carriers Manual*, section 4105.2 for evidence of medical necessity. *See also* sections II.A.3.b and II.A.3.c regarding physician orders and CMNs, respectively.

[54] This practice involves indicating on the claim form that the place of service is a location other than where the service was provided. For example, the patient resides in a skilled nursing facility (SNF) and a DMEPOS supplier submits a claim with the place of service as the patient's home. Provided that the DMEPOS items or services are ordered, provided, reasonable and necessary given the clinical condition of the patient, the items or services may be covered if the beneficiary resides at home. However, such items may not be covered if the beneficiary resides in a SNF. *See Medicare Carriers Manual*, section 2100.3 for the definition of a beneficiary's home.

[55] *See* discussion in section II.A.3.m.

[56] This practice involves the improper use of the ZX modifier, relating to maintaining medical necessity documentation. *See* discussion in section II.A.3.l.

[57] Throughout this document, the term "deductibles and coinsurance" refers to Medicare as well as to any other health insurance program requiring deductibles and coinsurance. *See* discussion in section II.A.3.j and accompanying notes.

[58] Examples of arrangements that may run afoul of the anti-kickback statute include practices in which a DMEPOS supplier pays a fee to a physician for each CMN the physician signs, provides free gifts to physicians for signing CMNs, provides inducements to beneficiaries, and/or provides items or services for free or below fair market value to providers or beneficiaries of Federal health care programs. *See* 42 U.S.C. 1320a–7a(a)(5); 42 U.S.C. 1320a–7b(b); 60 FR 40847 (August 10, 1995). *See also* discussion in section II.A.4 and accompanying notes.

[59] Compensation programs that offer incentives for items or services ordered or the revenue they generate may lead to the ordering of medically unnecessary items or supplies and/or the "dumping" of such items or supplies in a facility or in a beneficiary's home (e.g., mail order supply companies that continue to send the patient supplies when the supplies are no longer medically necessary).

[60] Equally troubling to the OIG is the proliferation of business arrangements that may violate the anti-kickback statute or other similar Federal and State statute or regulation. Such arrangements are generally established between those in a position to refer business, such as physicians, and those providing items or services, such as DMEPOS suppliers, for which a Federal health care program pays. Sometimes established as "joint ventures," these arrangements may take a variety of forms. The OIG currently has a number of investigations and audits underway that focus on such areas of concern. The OIG has also issued a Special Fraud Alert on Joint Venture Arrangements. This Special Fraud Alert can be found at 59 FR 65372 (December 19, 1994) or on the Internet at http://www.dhhs.gov/progorg/oig.

[61] Under the Stark physician self-referral law, if a physician (or an immediate family member of such physician) has a prohibited financial relationship with a DMEPOS supplier, the physician may not make a referral to the DMEPOS supplier and the DMEPOS supplier may not bill for furnishing DMEPOS items or supplies for which payment may be made under the Federal health care programs. *See* 42 U.S.C. 1395nn.

[62] *See* 42 U.S.C. 1395m(a)(17) or Pub.L. 103–432, section 132(a) for the prohibition on telemarketing. *See also* discussion in section II.A.5 and accompanying notes.

[63] The DMEPOS supplier should not utilize prohibited or inappropriate conduct to carry out its initiatives and activities designed to maximize business growth and patient retention. Many cases against DMEPOS suppliers have involved the DMEPOS supplier giving the beneficiary free gifts such as angora underwear, microwaves and air conditioners in exchange for providing and billing for unnecessary items. Any marketing information offered by the DMEPOS supplier should be clear, correct, non-deceptive, and fully informative. *See* discussion in section II.A.5 and accompanying notes.

[64] In this situation, a physician allows a DMEPOS supplier to stock inventory (the storage space may or may not be rented by the DMEPOS supplier) in a physician's office. When such items and supplies are dispensed to the patient, Medicare is then billed. Although such arrangements are not prohibited per se, the OIG believes that such arrangements may potentially raise anti-kickback and self-referral issues, particularly when the DMEPOS supplier pays the physician an amount above fair market value to rent the space.

[65] A DMEPOS supplier should have appropriate personnel acknowledge they have reviewed and will abide by the Medicare supplier standards. In addition, a DMEPOS supplier should ensure it is meeting individual State and private payor supplier standards. *See* 42 CFR 424.57 for the Medicare supplier standards.

[66] Criminal penalties may be imposed against an individual who knowingly and willfully makes or causes to be made any false statements or representations of a material fact in any application for any benefit or payment under a Federal health care program. *See* 42 U.S.C. 1320a-7b(a)(1). *See also* 31 U.S.C. 3729(a) ("any person who * * * knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government * * * is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person * * *")

[67] By signing the DMEPOS supplier enrollment application, a DMEPOS supplier certifies it will notify the Medicare contractor of any changes in its enrollment information within 30 days of the effective date of the change.

[68] It is unlawful for a DMEPOS supplier to represent itself as a Medicare representative. *See* 42 U.S.C. 1320b-10.

[69] This practice may involve, but is not limited to, using another DMEPOS supplier's billing number.

[70] A DMEPOS supplier should be aware of the requirements of any payor they bill, especially in those situations where there is a primary and secondary payor.

• Performing tests on a beneficiary to establish medical necessity; [71]
• Failing to refund overpayments to a health care program; [72]
• Failing to refund overpayments to patients; [73]
• Improper billing resulting from a lack of communication between the DMEPOS supplier, the physician, and the patient; [74]
• Improper billing resulting from a lack of communication between different departments within the DMEPOS supplier; [75] and
• Employing persons excluded from participation in Federal health care programs.[76]

A DMEPOS supplier's prior history of noncompliance with applicable statutes, regulations, and Federal, State or private health care program requirements may indicate additional types of risk areas where the DMEPOS supplier may be vulnerable and that may require policies and procedures to prevent recurrence.[77] Additional risk areas should be assessed by the DMEPOS supplier and incorporated into its written policies and procedures and training programs developed as part of its compliance program.

The OIG believes sound operating policies are essential to all DMEPOS suppliers, regardless of size. The OIG recommends that small DMEPOS suppliers focus on the risk areas most potentially problematic to its business operations. The OIG recognizes some small DMEPOS suppliers may not have the resources to independently develop a comprehensive set of written policies and procedures pertaining to such risk areas. In this case, the OIG recommends that the small DMEPOS supplier create a manual that is accessible to all employees. Such a manual should contain the specific statutes, regulations, and DMERC instructions and bulletins that address the DMEPOS supplier's identified risk areas. The goal of this manual is to provide employees direction so they can properly address any concerns/issues/questions that may arise.

3. Claims Development and Submission

a. Medical Necessity

The OIG recommends that the DMEPOS supplier's compliance program communicate to physicians and other persons authorized to order items and services that claims submitted for items and services will only be paid if the item or service is ordered, provided, covered, reasonable and necessary for the patient, given his or her clinical condition. The DMEPOS suppliers should take all reasonable steps to ensure they are not submitting claims for services that are not: (i) covered; (ii) reasonable; and (iii) necessary.[78] The DMEPOS suppliers must keep the treating physician's or other authorized person's signed and dated order or CMN on file for all DMEPOS items and services.[79] Upon a payor's request, the DMEPOS supplier must be able to provide documentation, such as physician orders, completed original CMNs,[80] proof of delivery, written confirmation of verbal orders and any other documentation to support the medical necessity of an item or service the DMEPOS supplier has provided and billed to a Federal or private health care program.[81] Because the DMEPOS supplier is responsible for producing documentation upon request, the DMEPOS supplier may want to send a written notice to its clients who write orders and refer patients concerning payors' documentation requirements.

As a preliminary matter, the OIG recognizes that physicians and other authorized persons must be able to order any items or services that they believe are appropriate for the treatment of their patients. However, Medicare and other Government and private health care plans will only pay for those services that are covered and that meet the appropriate medical necessity standards (e.g., ordered, provided, reasonable, necessary, and meeting criteria established by medical review policies). "No payment may be made under Part A or Part B for any expenses incurred for items or services * * * which are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member." [82] Therefore, DMEPOS suppliers should be aware that Medicare may deny payment for an item or service that the treating physician or other authorized person believes is appropriate, but which does not meet the Medicare coverage criteria or where the documentation does not support that the item or service was reasonable and necessary for the patient. The OIG recommends that the DMEPOS supplier advise its clients that claims for items or services submitted for Federal, State or private payor reimbursement must meet program requirements [83] or the claims may be denied.

The DMEPOS supplier should take steps to ensure compliance with the applicable statutes, regulations and the requirements of Federal, State and private health plans. The OIG recognizes that DMEPOS suppliers do not and cannot treat patients or make medical necessity determinations. However, the DMEPOS supplier must take steps to ensure that the beneficiary's condition meets coverage, payment and utilization criteria established in medical policies before it submits a claim to Federal, State or private health plans. In order to help

[71] *E.g.*, Medicare does not permit DMEPOS suppliers to perform oxygen tests (e.g., oximetry tests and arterial blood gas tests) to qualify patients for oxygen and oxygen supplies. *See Medicare Caverage Issues Manual*, section 60–4. *See also* discussion in section II.A.3.o.

[72] An overpayment is the amount of money received in excess of the amount due and payable under a health care program. Examples of overpayments include, but are not limited to, instances where a DMEPOS supplier is: (i) paid twice for the same service, for the same beneficiary; or (ii) paid for services that were provided but not ordered by the treating physician or other authorized person. The OIG strongly recommends that the DMEPOS supplier institute procedures to detect overpayments and to promptly remit such overpayments to the affected payor. *See* 42 U.S.C. 1320a-7b(a)(3). *See alsa* 18 U.S.C. 669 and 31 U.S.C. 3729(a)(7).

[73] If a patient is also due money when a DMEPOS supplier identifies an overpayment to a health care program, the DMEPOS supplier should make a prompt refund to the patient. *See* 42 U.S.C. 1395m(j)(4) on limitation of patient liability for non-assigned claims that are denied due to medical necessity. *See alsa* 42 U.S.C. 1395pp(h) on limitation of patient liability for assigned claims that are denied due to medical necessity.

[74] A lack of communication between the DMEPOS supplier, physician, and patient may result in the DMEPOS supplier inappropriately billing for items or supplies (e.g., supplies for an on-going condition or rental equipment that are no longer medically necessary). *See* discussion in section II.A.3.n.

[75] A lack of communication between the different departments of a DMEPOS supplier may result in the DMEPOS supplier filing incorrect claims and/or equipment delivery problems.

[76] This involves hiring or contracting with individuals or entities who have been excluded from participation in Federal health care programs or any other Federal procurement or non-procurement program. *See* section II.F.2.

[77] "Recurrence of misconduct similar to that which an organization has previously committed casts doubt on whether it took all reasonable steps to prevent such misconduct" and is a significant factor in the assessment of whether a compliance program is effective. See United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3(k)(iii).

[78] *See* note 31.

[79] *See Medicare Carrier Manual*, section 3312. *See alsa Medicare Carrier Manual*, section 4105.2 regarding what information must be included on the physician's order.

[80] An original CMN is that in which Section B was completed by the treating physician or other authorized person and contains the original signature of the treating physician or other authorized person.

[81] In order to ensure correct reimbursement, the payor may conduct a post-payment audit of a DMEPOS supplier's claims. Such audits may require that the DMEPOS supplier submit documentation to substantiate that the items or services were ordered by the treating physician or other authorized person, provided, covered, reasonable and necessary. *See* 42 CFR 424.5(a)(6).

[82] *See* 42 U.S.C. 1395y(a)(1)(A).

[83] *See* note 31.

ensure compliance, the OIG recommends that DMEPOS supplier personnel understand the coverage and payment criteria of each payor they bill. To help aid supplier personnel, the DMEPOS supplier's compliance officer may want to create a clear, comprehensive summary of the "medical necessity" standards or coverage criteria and applicable rules of the various Government and private plans. This summary should be disseminated and explained to the appropriate DMEPOS supplier personnel.

We also recommend that DMEPOS suppliers formulate internal control mechanisms through their written policies and procedures to ensure the medical necessity of the items or services they provide. Such policies and procedures may include periodic claim reviews, both prior and subsequent to billing for items and services. Such a procedure will verify that patients are receiving and the DMEPOS supplier is being paid for items and/or services that are ordered, provided, covered, reasonable and necessary. The DMEPOS supplier may choose to incorporate this claims review function into pre-existing quality assurance mechanisms.

b. Physician Orders

The DMEPOS supplier's written policies and procedures should state that the DMEPOS supplier will not bill for an item or service unless and until it has been ordered by the treating physician or other authorized person. For all Medicare reimbursed DMEPOS items or services, the DMEPOS supplier must receive a written order from the patient's treating physician or other authorized person. Such written order must be received prior to billing Medicare. When the DMEPOS supplier receives a verbal order, the DMEPOS supplier should document the verbal order and must have the treating physician or other authorized person confirm it in writing prior to billing.

The written policies and procedures should also state, for items requiring a written order prior to delivery, that the order must be received by the DMEPOS supplier before it delivers the equipment to the patient and before it bills the payor.[84]

c. Certificate of Medical Necessity [85]

For some DMEPOS items and services, the DMEPOS supplier must receive a signed CMN from the treating physician or other authorized person. Currently, CMNs are required for Medicare reimbursement for fourteen items.[86] The CMN must be retained in the DMEPOS supplier's records before it can submit a claim for payment to the Medicare program. Although faxed CMNs are permitted in order to submit the claim, the DMERCs have the authority to request the original CMN from the DMEPOS supplier at any time.[87]

Each CMN has four sections: A, B, C, and D. Section A may be completed by the DMEPOS supplier. Section B may not be completed by the DMEPOS supplier.[88] Section B may only be completed by the treating physician, a non-physician clinician involved in the care of the patient or a physician employee who is knowledgeable about the patient's treatment. If section B is completed by a physician's employee, the section must be reviewed by the treating physician or other person authorized to sign section D of the CMN[89] to ensure the information's accuracy. Section C must be completed by the DMEPOS supplier prior to the CMN being furnished to the treating physician or other authorized person for signature.[90] Section D is the attestation statement and may only be signed by the treating physician or other person authorized to sign section D.[91] The DMEPOS supplier's written policies and procedures on completing CMNs should reflect these standards.

The DMEPOS supplier should take all reasonable steps to ensure that each section of the CMN is completed in accordance with the above guidelines. The OIG recommends that the DMEPOS supplier's written policies and procedures, at a minimum, provide that the DMEPOS supplier:

- Does not forward blank CMNs to the treating physician or other authorized person for signature;
- Does not complete section B (Medical Necessity) of the CMN;
- Does not alter or add any information on the CMN after receiving the completed and signed CMN from the physician or other authorized person;[92]
- Does not sign the CMN for the treating physician or other authorized person;
- Does not urge physicians or other authorized persons to order equipment or supplies that exceed what is reasonable and necessary for the patient;
- Does not deliver an item that requires a written order from the treating physician or other authorized person prior to receiving the written order;[93]
- Does not submit a claim for DMEPOS items or services prior to receiving a written order or CMN from the treating physician or other authorized person;
- Does not submit a claim for DMEPOS items or services until the CMN is properly and correctly completed by the treating physician or other authorized person;
- Maintains completed and signed CMNs in its files;
- Consults with the treating physician or other authorized person who signed the CMN when there is a question on the order;
- Properly complete sections A and C of the CMN and then forward the CMN to the treating physician or other authorized person for his/her review, information, and signature; and
- Only submit claims for services that the treating physician or other authorized person attests in section D are ordered and medically necessary for the patient.

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[84] *See* 42 CFR 410.38.

[85] As defined in 42 U.S.C. 1395m(j)(2)(B). *See also* OIG Special Fraud Alert regarding Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services, 64 FR 1813 (January 12, 1999). Special Fraud Alerts are available on the OIG website.

[86] Items or services requiring CMNs are as follows: Home oxygen therapy (HCFA form 484); Hospital beds (HCFA form 841); Support surfaces (HCFA form 842); Motorized wheelchairs (HCFA form 843) (Section C continuation, HCFA form 854); Manual wheelchairs (HCFA form 844) (Section C continuation, HCFA form 854); Continuous positive airway pressure (CPAP) devices (HCFA form 845); Lymphedema pumps (pneumatic compression devices) (HCFA form 846); Osteogenesis stimulators (HCFA form 847); Transcutaneous electrical nerve stimulators (TENS) (HCFA form 848); Seat lift mechanisms (HCFA form 849); Power operated vehicles (HCFA form 850); Infusion pumps (HCFA form 851); Parenteral nutrition (HCFA form 852); and Enteral nutrition (HCFA form 853).

[87] *See* HCFA Program Memorandum B–99–23 (April 1999).

[88] A supplier who knowingly and willfully completes section B of the form is, at a minimum, subject to a CMP of up to $1,000 for each form or document completed in such manner. *See* 42 U.S.C. 1395m(j)(2). That supplier may also face civil and criminal liability.

[89] *See* HCFA Program Memorandum B–98–47 (November, 1998), which discusses who is authorized to sign section D of the CMN.

[90] A supplier who knowlingly and willfully fails to include, in section C, the fee schedule amount and the supplier's charge for the equipment or supplies being furnished may be subject to a CMP up to $1,000 for each form or document so distributed. *See* 42 U.S.C. 1395m(j)(2).

[91] Physicians or persons authorized to sign section D (see note 89), should only sign CMNs in which sections A-C are completed and correct. Signature and date stamps are not acceptable. *See Medicare Carriers Manual*, section 3312.

[92] There have been many investigations centering on DMEPOS suppliers who alter information in order to affect their reimbursement (e.g., altering diagnosis code, altering HCPCS code of service provided).

[93] *See* 42 U.S.C. 1395m(a)(11)(B). *See also* 42 CFR 410.38.

d. Billing

The DMEPOS supplier should provide in its written policies and procedures that it will only submit to Medicare or other Federal, State or private payor health care plans claims that are properly completed, accurate, and correctly identify the item or service ordered by the treating physician or other authorized person and furnished to the patient. Also, prior to submitting the claim, the DMEPOS supplier should take all reasonable steps to ensure the item or service being claimed was provided, covered, reasonable and necessary.

The written policies and procedures should also clarify that a DMEPOS supplier cannot submit bills or receive payment for drugs used in conjunction with DMEPOS, unless the DMEPOS supplier is licensed to dispense the drug.[94]

e. Selection of HCPCS Codes

The DMEPOS supplier's written policies and procedures should state that only the HCPCS code that most accurately describes the item or service ordered and provided should be billed. The OIG views knowing "upcoding" (i.e., the selection of a code to maximize reimbursement when such a code is not the most appropriate descriptor of the service) as raising, among other things, false claims issues under the Civil False Claims Act.[95] To ensure code accuracy, the OIG recommends that the DMEPOS supplier include a requirement in its policies and procedures that the codes be reviewed (random sample or certain codes) by individuals with technical expertise in coding before claims containing such codes are submitted to the affected payor. If a DMEPOS supplier has questions regarding the appropriate code to be used, it should contact the Statistical Analysis Durable Medical Equipment Carrier's (SADMERC) HCPCS coding help line.[96]

f. Valid Supplier Numbers

The DMEPOS supplier should ensure that appropriate personnel are knowledgeable in (1) completing the HCFA 855S supplier application;[97] and (2) complying with the Federal requirements of 42 CFR 424.57(e) for updating supplier number applications.

The written policies and procedures should state that the DMEPOS supplier should not bill any other Federal, State or private payor health care plan without obtaining the necessary billing numbers and that the billing numbers will be used correctly.[98]

Prior to applying for a valid supplier number, a DMEPOS supplier providing services to Medicare beneficiaries must meet the supplier standards.[99] The DMEPOS supplier should take all affirmative steps to ensure that no claims for Medicare reimbursement are submitted prior to the DMEPOS supplier being issued a valid supplier number by the National Supplier Clearinghouse. A DMEPOS supplier should not have more than one Medicare supplier number unless it is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.[100]

g. Mail Order Suppliers

We recommend that any DMEPOS supplier who engages in the mail order supply business clearly articulate its protocol for this segment of its business in the company's written policies and procedures.

Mail order supplies should only be delivered in accordance with the treating physician's or other authorized person's orders. Regularly shipping supplies without such orders may lead to providing supplies substantially in excess of the patient's needs.[101] We also recommend that the supplier utilize a tracking system so it will be able to determine whether or not the patient received the supplies and will be able to track the location of an item or supply at any given time.

h. Assignment

If a DMEPOS supplier accepts Medicare assignment, its written policies and procedures should state that it will not charge Medicare beneficiaries more than the amounts allowed under the Medicare fee schedule, including coinsurance and deductibles. If the beneficiary pays the DMEPOS supplier prior to the DMEPOS supplier submitting the claim, the DMEPOS supplier should ensure it is not charging the beneficiary more than the coinsurance on the allowed amount under the fee schedule. In the event that the DMEPOS supplier collects excess payments from a Medicare beneficiary, it should have mechanisms in place to promptly refund the overpayment to the beneficiary. The DMEPOS supplier should be knowledgeable about the Medicare rules and instructions for accepting assignment and receiving direct payment from beneficiaries for items or services.

If a DMEPOS supplier chooses not to accept Medicare assignment, it is still responsible for submitting claims to Medicare on behalf of beneficiaries.[102]

If the DMEPOS supplier chooses to utilize a billing agent, the DMEPOS supplier should ensure it is complying with all of the relevant statutes and requirements governing such an arrangement.[103] The OIG strongly recommends that the DMEPOS supplier coordinate closely with the billing company to establish compliance responsibilities. Once the responsibilities have been clearly delineated, they should be formalized in the written contract between the DMEPOS supplier and the billing agent. The OIG recommends that the contract enumerate those functions that are shared responsibilities and those that are the sole responsibility of either the billing agent or the DMEPOS supplier.

i. Liability Issues

The OIG recommends that DMEPOS suppliers avoid submitting claims for items or services that the DMEPOS supplier believes are not covered by Medicare. However, HCFA does permit a DMEPOS supplier to submit a claim for an item or service that the DMEPOS supplier believes is not covered if (i) the beneficiary insists that the DMEPOS supplier submit the claim, and (ii) the DMEPOS supplier notes on the claims its belief that the service is noncovered and that it is being submitted at the beneficiary's insistence (e.g., submitted for a Medicare determination of

[94] *See* Medicare Program Memoranda B–98–6 (February, 1998) and B–98–18 (May, 1998).

[95] *See* 31 U.S.C. 3729, which provides for the imposition of penalties of $5,000 to $10,000 per false claim, plus up to three times the amount of damages suffered by the Federal Government because of the false claim.

[96] The phone number for the SADMERC's HCPCS coding help line is 803–736–6809. The hours of operation are Monday through Friday from 9:00 am to 4:00 pm, EST. Based on the information provided by the DMEPOS supplier, the SADMERC will aid the DMEPOS supplier in choosing the most accurate code for the item or service ordered and supplied. However, the DMEPOS supplier should be aware that assigning a HCPCS code to an item or service does not necessarily guarantee reimbursement.

[97] By signing the certification statement on the enrollment application, the applicant agrees that he/she has read, understood, meets and will continue to meet the supplier standards and will be disenrolled from the program if any standards are not met or violated.

[98] E.g., if a DMEPOS supplier has more than one location, the supplier number of the location that filled the physician's or other authorized person's order will be used on the claim form.

[99] *See* 42 CFR 424.57.

[100] *See* 42 U.S.C. 1395m(j)(1)(D).

[101] *See* note 44.

[102] *See* 42 U.S.C. 1395w–4(g)(4).

[103] *See* 42 U.S.C. 1395u(b)(6); 42 CFR 424.73; *Medicare Carriers Manual*, section 3060. *See also* OIG Ad. Op. 98–1 (1998) and OIG Ad. Op. 98–4 (1998).

coverage and/or to obtain a denial notice in order to bill other insurers).[104]

A DMEPOS supplier or Medicare beneficiary is not liable for payment on assigned claims where the beneficiary did not know, and could not reasonably have been expected to know, that the payment for such services would not be made.[105] However, when the DMEPOS supplier knew, or could have been expected to know, the items or services would be denied, the liability for improperly paid items or services rests with the DMEPOS supplier.[106]

In order to protect itself from financial responsibility in such situations (i.e., situations in which the beneficiary is insisting that a claim be submitted to Medicare notwithstanding the DMEPOS supplier's belief that Medicare does not cover the service), the DMEPOS supplier must inform the patient prior to furnishing the item or service of the DMEPOS supplier's belief that the claim to Medicare will be denied. In this situation, the DMEPOS supplier should ask the patient to sign a written notice.[107] The written notice must be in writing, must clearly identify the particular item or service, must state that the payment for the particular item or service likely will be denied, and must give the reason(s) for the belief that payment is likely to be denied. It is the beneficiary's decision whether or not to sign the written notice. If the beneficiary does sign the written notice, the DMEPOS supplier should: (1) include the appropriate modifier on the claim form; (2) maintain the written notice in its files; and (3) be able to produce the written notice to the DMERC, upon request.

If the DMEPOS supplier improperly bills the beneficiary, Medicare will indemnify the beneficiary for any payments the beneficiary made to the DMEPOS supplier, and collect the indemnification amount from the DMEPOS supplier as an overpayment.

Routine notices to beneficiaries that do no more than state that denial of payment is possible are not considered acceptable evidence of written notice. Notices should not be given to beneficiaries unless there is some genuine doubt regarding the likelihood of payment as evidenced by the reasons stated on the written notice. Giving notice for all claims, items or services is not an acceptable practice.

The OIG recommends that the DMEPOS supplier include the foregoing liability issues in its written policies and procedures.

j. Routine Waiver of Deductibles and Coinsurance

Routine waivers of deductibles and coinsurance may result in false claims, CMPs for inducements to beneficiaries, and violations of the anti-kickback statute or similar Federal or State statute or regulations.[108] In addition to the potential problems regarding kickbacks, false claims, and CMPs, the OIG has programmatic concerns when DMEPOS suppliers routinely waive deductibles and coinsurance. When DMEPOS suppliers forgive financial obligations for reasons other than genuine financial hardship of a particular patient, they may be inducing the patient to use items or services that are unnecessary, simply because they are free. Such usage may also lead to overutilization. DMEPOS suppliers are permitted to waive the Medicare coinsurance amounts for cases of financial need.[109] We recommend that the DMEPOS supplier develop and maintain written criteria documenting its policy for determining financial need and consistently apply this criteria to all cases.[110] A good faith effort must be made to collect deductibles and coinsurance.[111]

The DMEPOS supplier's written policies and procedures should state that it will not routinely waive deductibles and coinsurance for Medicare beneficiaries. The OIG recommends that such policies and procedures should include, but not be limited to, statements that DMEPOS supplier personnel are prohibited from: advertising an intent to waive deductibles or coinsurance for Medicare beneficiaries; advertising an intent to discount services for Medicare beneficiaries; or giving unsolicited advice to Medicare beneficiaries that they need not pay.

k. Capped Rentals

The DMEPOS supplier's written policies and procedures should address Government and private payor requirements when providing rental equipment to beneficiaries (e.g., the purchase option[112] and servicing and maintenance[113]). The DMEPOS supplier must offer a purchase option to beneficiaries during the 10th continuous rental month.[114] The DMEPOS supplier should clearly, accurately, and non-deceptively discuss the pros and cons of the different options with the beneficiary. If the beneficiary does not accept the purchase option, the DMEPOS supplier must continue to provide the item. After the 15th continuous month of receiving rental payments from Medicare, providing the item or service continues to be medically necessary, the DMEPOS supplier must continue to provide the item without charge to the beneficiary or Medicare.

However, the DMEPOS supplier may submit additional claims for the maintenance and servicing fees associated with the rental item.[115] The DMEPOS supplier should ensure it is performing basic safety and operational function checks after use by each patient, and is performing routine and preventative maintenance on equipment. The DMEPOS supplier must ensure it has qualified staff or contractors to service, set up, and instruct the patient on the proper use of the equipment. The DMEPOS supplier should ensure it maintains current service manuals for all the equipment it supplies. In addition, the OIG recommends that the DMEPOS supplier's policies and procedures establish an internal control system that allows the DMEPOS supplier to track the location of each piece of equipment at any given time.

The policies and procedures should also address the guidelines for determining continuous use and criteria for a new rental period.[116] If a beneficiary dies during a rental period, the DMEPOS supplier may receive the entire monthly rental payment.[117] However, if the DMEPOS supplier continues to bill for the item because it did not receive notice of the beneficiary's death until the following

[104] *See Medicare Carriers Manual*, section 3043.

[105] *See* 42 U.S.C. 1395pp.

[106] *Id.*

[107] *See Medicare Carriers Manual*, section 7300.5.

[108] *See* 59 FR 31157 (December 19, 1994) or the OIG website at http://www.dhhs.gov/progorg/oig for the OIG Special Fraud Alert on Medicare Deductibles and Copayments. *See also* 31 U.S.C. 3729–3733; 42 U.S.C. 1320a–7a(a)(5); 42 U.S.C. 1320a–7b.

[109] *See Medicare Carriers Manual*, section 5520

[110] What constitutes "financial need" varies depending on the circumstances. However, the OIG believes it is important that a DMEPOS supplier make determinations of financial need on an individualized, case by case, basis in accordance with a reasonable set of income guidelines uniformly applied in all cases. The guidelines should be based on objective criteria and appropriate for the applicable locality. It is not appropriate to apply inflated income guidelines that result in waivers of copayments for persons not in genuine financial need.

[111] *See* 42 CFR 413.80; *Provider Reimbursement Manual*, Part I, sections 308 and 310.

[112] *See* 42 CFR 414.229(d).

[113] *See* 42 CFR 414.229(e).

[114] DMEPOS suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the DMEPOS supplier first furnishes the item *See* 42 CFR 414.229(d)(1).

[115] *See* 42 CFR 414.229(e).

[116] *See* 42 CFR 414.230.

[117] *See Medicare Carriers Manual*, section 4105.3.

month, any payments received for rental items the month after the beneficiary dies are considered an overpayment and must promptly be refunded. The DMEPOS supplier should create internal mechanisms to ensure the correct rental month appears on the claim and the correct modifier is used.

In addition, the DMEPOS supplier should ensure it is not submitting claims for rental equipment when the beneficiary is residing in an institution. The OIG is aware that some DMEPOS suppliers bring DMEPOS items to beneficiaries residing in an institution, just prior to the beneficiary's discharge, in order to train the beneficiary on how to use the item or to fit the item for the beneficiary. Once the DMEPOS supplier has trained or fitted the beneficiary, the DMEPOS supplier should take the item and deliver it to the beneficiary's home on the date of discharge. As a result, the DMEPOS supplier should file the claim for this item with the date of delivery/date of service as the date the beneficiary is discharged from the institution. If the DMEPOS supplier delivers the item to the beneficiary in the institution prior to the beneficiary's discharge to be used by the beneficiary while in the institution, the item should be included in the institution's cost and the DMEPOS supplier should not submit the claim. The DMEPOS supplier may not submit the claim prior to the beneficiary's date of discharge.

l. ZX Modifier

The ZX modifier is used on the claim form to indicate that the DMEPOS supplier is maintaining medical necessity documentation in its files. Such documentation only needs to be submitted to the DMERC upon request.

The DMEPOS supplier should create internal mechanisms to ensure the proper use of the ZX modifier. Improper use of the modifier may result in the submission of false claims. The OIG recommends that the DMEPOS supplier's written policies and procedures address the DMEPOS supplier's protocol for using the ZX modifier.[118]

m. Cover Letters

Cover letters are commonly used by the DMEPOS supplier as a method of communication between the DMEPOS supplier and the treating physician or other authorized person. The cover letter is not a form required or regulated by the Government. As a result, the DMERCs do not base Medicare denials solely on what may be considered inappropriate use of cover letters. However, the OIG is concerned that cover letters may influence or direct a physician's or other authorized person's answers on the CMN, particularly the questions relating to the patient's medical condition.[119] It is the treating physician's or other authorized person's responsibility to determine both the medical need for, and the utilization of, health care services. The OIG encourages the DMEPOS supplier to include language in its cover letter to remind treating physicians and other authorized persons of their responsibilities in properly completing CMNs.

n. Communication

The OIG suggests that the DMEPOS supplier create mechanisms that increase the communication among treating physicians or other authorized persons who refer business to the DMEPOS supplier, the patients, and the DMEPOS supplier. We recommend that such mechanisms be included in the DMEPOS supplier's written policies and procedures. Such mechanisms may include: (i) the DMEPOS supplier periodically calling the patient to ensure the equipment is still being used and is operating properly; or (ii) periodically calling the treating physician to ensure the provided items continue to be medically necessary for a patient.

In addition, we recommend the DMEPOS supplier create mechanisms to ensure communication between different departments (e.g., sales and billing) in order to prevent the filing of incorrect claims.

o. Oxygen and Oxygen Equipment

The OIG recommends that the written policies and procedures for DMEPOS suppliers furnishing oxygen state that the DMEPOS supplier will ensure that initial claims for oxygen therapy include the written results of an arterial blood gas study or oximetry test (on the CMN) that has been ordered and evaluated by the patient's treating physician. Further, the written policies and procedures should provide for the DMEPOS supplier to maintain such test results and any other independent diagnostic treatment facility (IDTF) documents supporting the patient's medical necessity for the oxygen. The OIG recommends that the DMEPOS supplier have the IDTFs, from which it receives test results, submit, all raw test results to the treating physician for the physician's benefit, and not just a summary of the results. The written policies and procedures should provide that a DMEPOS supplier is not qualified to conduct the blood gas study or to prescribe the oxygen therapy.[120]

The OIG also recommends, for patient safety purposes, that the rental of oxygen include established maintenance safeguards and that steps are taken to ensure the equipment is properly maintained, as maintenance is included in the rental price of the equipment.

When submitting an oxygen or oxygen equipment claim for reimbursement, the DMEPOS supplier must ensure it is complying with the payment rules.[121]

4. Anti-Kickback and Self-Referral Concerns

The DMEPOS supplier should have policies and procedures in place with respect to compliance with Federal and State laws, including the anti-kickback statute, as well as the Stark physician self-referral law.[122] Such policies should provide that:

- All of the DMEPOS supplier's contracts and arrangements with actual or potential referral sources (e.g., physicians) are reviewed by counsel and comply with all applicable statutes and regulations, including the anti-kickback statute and the Stark physician self-referral law; [123]
- The DMEPOS supplier will not submit or cause to be submitted to health care programs claims for patients who were referred to the DMEPOS supplier pursuant to contracts or financial arrangements that were designed to induce such referrals in violation of the anti-kickback statute or similar Federal or State statute or regulation or that otherwise violate the Stark physician self-referral law;

[118] See relevant DMERC supplier manual(s) for guidelines on proper use.

[119] Encouraging physicians or other authorized persons to order unwanted items or supplies may result in submitting claims for items or services that are not reasonable or necessary. The OIG is aware of instances where the DMEPOS supplier has copied the CMN, complieted section B of the copy, and used this completed copy as its cover letter to physicians.

[120] *See Coverage Issues Manual*, section 60–4.

[121] See 42 CFR 414.226.

[122] Towards this end, the DMEPOS supplier should, among other things, obtain copies of all relevant OIG regulations, Special Fraud Alerts, and Advisory Opinions (these documents are located on the Internet at http://www.dhhs.gov/progorg/oig), and ensure that the DMEPOS supplier's policies reflect the guidance provided by the OIG. *See* 42 U.S.C. 1395nn(a) for the Stark physician referral laws. *See also* 42 U.S.C. 1320a–7b for prohibited activities under the anti-kickback statute.

[123] If the DMEPOS supplier questions an arrangement into which it may enter, it should consider asking the OIG for an Advisory Opionion regarding the anti-kickback statute of HCFA for an Advisory Opinion regarding Stark. *See* 62 FR 7350 (February 19, 1997) and 63 FR 38,311 (July 16, 1998) for instructions on how to submit an Advisory Opinion to the OIG. These instructions are also located on the Internet at http://www.dhhs.gov/progorg/oig. *See* 63 FR 1645 (January 9, 1998) on how to submit an Advisory Opinion to HCFA.

• A DMEPOS supplier does not offer a physician or other referral source more than fair market value for space rented to store items or supplies (i.e., consignment closet); and

• The DMEPOS supplier does not offer or provide gifts, free services, or other incentives or things of value to patients, relatives of patients, physicians, home health agencies, nursing homes, hospitals, contractors, assisted living facilities, or other potential referral sources for the purpose of inducing referrals in violation of the anti-kickback statute or similar Federal or State statute or regulation.[124]

Further, the OIG recommends that the written policies and procedures should specifically reference and take into account the OIG's safe harbor regulations, which describe those payment practices that are immune from criminal and administrative prosecution under the anti-kickback statute.[125]

The OIG believes all DMEPOS suppliers, regardless of size, should be concerned with potential anti-kickback and Stark violations. As a result, all DMEPOS suppliers should be knowledgeable about, and compliant with, the anti-kickback statute, the Stark physician self-referral law and other relevant Federal and State statutes or regulations.

Although all DMEPOS suppliers are responsible for ensuring compliance with these provisions, the OIG recognizes that the small DMEPOS supplier may not have the resources to implement the suggestions in this section to the same extent as a large DMEPOS supplier. Therefore, the smaller DMEPOS supplier may need to employ a slightly different mechanism to ensure compliance. For example, the small DMEPOS supplier may want to choose a sample of contracts or financial arrangements to review on a periodic basis.

5. Marketing

Where marketing is permitted, the DMEPOS supplier's compliance program should require honest, straightforward, fully informative and non-deceptive marketing. It is in the best interest of patients, DMEPOS suppliers, physicians and health care programs that physicians or other persons authorized to order DMEPOS fully understand the services offered by the DMEPOS supplier, the items or services that will be provided when ordered, and the financial consequences for Medicare as well as other payors for the items or services ordered. The OIG recommends that if the DMEPOS supplier services a large number of non-English speaking patients, it should ensure that its marketing materials are available in those other languages. The DMEPOS supplier's written policies and procedures should ensure that its marketing information is clear, correct, and fully informative.

Salespeople must not offer physicians, patients or other potential referral sources incentives, in cash or in kind, for their business.[126] Similarly, they must not engage in any marketing activity that either explicitly or implicitly implies that Medicare beneficiaries are not obligated to pay their coinsurance or can receive "free" services.[127] In addition, DMEPOS suppliers must not promote items or services to patients or physicians that are not reasonable or necessary for the treatment of the individual patient. The OIG suggests that the DMEPOS supplier's written policies and procedures create internal mechanisms to avoid these situations.

With respect to marketing and sales, the OIG has a longstanding concern that percentage compensation arrangements for sales and marketing personnel may increase the risk of such persons violating the anti-kickback statute.[128] The OIG recommends that the DMEPOS supplier monitor its sales representatives on a regular basis (e.g., rotate sales staff or send a sales manager on some sales calls).

The DMEPOS suppliers are prohibited from making unsolicited telephone contacts to Medicare beneficiaries.[129] We suggest that the DMEPOS supplier's written policies and procedures reflect this prohibition.

The DMEPOS suppliers are also prohibited from using symbols, emblems, or names in reference to Social Security or Medicare in a manner that they know or should know would convey the false impression that an item is approved, endorsed, or authorized by the Social Security Administration, HCFA, or the Department of Health and Human Services or that the supplier has some connection with, or authorization from, any of these agencies.[130]

The OIG believes marketing strategies employed by all DMEPOS suppliers, regardless of size, should be clear, correct, honest, straightforward, non-deceptive and fully informative. In addition, all DMEPOS suppliers should inform their sales people of potential anti-kickback concerns, the telemarketing law, and the prohibition on inappropriately using references to Social Security and Medicare. Although the small DMEPOS supplier may not have extensive written policies and procedures, every DMEPOS supplier should ensure that its employees are clear on what is permitted and prohibited with regard to marketing.

6. Retention of Records

The DMEPOS supplier's compliance program should provide for the implementation of a records system. The DMEPOS supplier should ensure that records are maintained for the length of time required by Federal and State law and private payors, or by the DMEPOS supplier's record retention policies, whichever is longer. This system should establish policies and procedures regarding the creation, distribution, retention, storage, retrieval, and destruction of documents.[131] The three types of documents developed under this system should include: (1) all records and documentation (e.g., billing and claims documentation) required either by Federal or State law and the program requirements of Federal, State, and private health plans; (2) records listing the persons responsible for implementing each part of the compliance program; and (3) all records necessary to protect the integrity of the DMEPOS supplier's compliance process and confirm the effectiveness of the program.[132] The documentation necessary to satisfy the third requirement includes, but is not limited to: evidence of adequate employee training; reports from the DMEPOS supplier's hotline; results of any investigation conducted as a consequence of a hotline call; modifications to the compliance program; self-disclosure; all written notifications to physicians and payors; [133] and the results of the DMEPOS supplier's auditing and monitoring efforts.

All DMEPOS suppliers, regardless of size, must retain documents required by the health plans in which they

[124] *See* 42 U.S.C. 1320a–7a(a)(5), which provides for CMPs for improper inducements to beneficiaries.

[125] *See* 42 CFR 1001.952. Simply because an arrangement does not meet a safe harbor does not necessarily mean it is illegal.

[126] *See* anti-kickback statute discussion in section II.A.4.

[127] *See* discussion in section II.A.3.j.

[128] *See* e.g., 42 U.S.C. 1320a–7b(B); OIG Ad. Op. 98–10 (1998); section II.A.4.

[129] *See* 42 U.S.C. 1395m(a)(17), Pub.L. 103–432, section 132(a).

[130] *See* 42 U.S.C. 1320b–10.

[131] This records system should be tailored to fit the individual needs and financial resources of the DMEPOS supplier.

[132] The creation and retention of such documents and reports may raise a variety of legal issues, such as patient privacy and confidentiality. These issues are best discussed with legal counsel.

[133] This should include notifications regarding inappropriate claims and overpayments.

participate. In case of a future Government investigation, the OIG recommends that all DMEPOS suppliers retain documents relating to the implementation of their compliance programs.

7. Compliance as an Element of a Performance Plan

The DMEPOS supplier's compliance program should require that the promotion of, and adherence to, the elements of the compliance program be a factor in evaluating the performance of all employees. Employees should be periodically trained in new compliance policies and procedures. In addition, all managers and supervisors should:

- Discuss with all supervised employees and relevant contractors the compliance policies and legal requirements applicable to their function;
- Inform all supervised personnel that strict compliance with these policies and requirements is a condition of employment; and
- Disclose to all supervised personnel that the DMEPOS supplier will take disciplinary action up to and including termination for violation of these policies or requirements.

In addition to making performance of these duties an element in evaluations, the compliance officer or DMEPOS supplier management should include a policy that managers and supervisors will be sanctioned for failing to instruct adequately their subordinates or for failing to detect noncompliance with applicable policies and legal requirements, where reasonable diligence on the part of the manager or supervisor would have led to the discovery of any problems or violations.

The OIG believes all DMEPOS suppliers, regardless of size, should ensure their employees understand the importance of compliance. If the small DMEPOS supplier does not have a formal performance evaluation structure, it should informally convey the employee's compliance responsibilities and the importance of these responsibilities.

B. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every DMEPOS supplier should designate a compliance officer to serve as the focal point for compliance activities. The compliance officer should be a person of high integrity. This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the DMEPOS supplier and the complexity of the task. When a compliance officer has other duties, the other duties should not be in conflict with the compliance goals.[134]

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official in the DMEPOS supplier with direct access to the DMEPOS supplier's owner(s), president or CEO, governing body, all other senior management, and legal counsel.[135] The compliance officer should be highly enough placed in the company so that he or she can exercise independent judgment without fear of reprisal, and so that employees will know that bringing a problem to that person's attention is not a wasted exercise. The compliance officer should have sufficient funding and staff to fully perform his or her responsibilities. Coordination and communication are the key functions of the compliance officer with regard to planning, implementing, and monitoring the compliance program.

The compliance officer's primary responsibilities should include:

- Overseeing and monitoring the implementation of the compliance program; [136]
- Reporting on a regular basis to the DMEPOS supplier's owner(s), governing body, CEO, president, and compliance committee (if applicable) on the progress of implementation, and assisting these components in establishing methods to improve the DMEPOS supplier's efficiency and quality of services, and to reduce the DMEPOS supplier's vulnerability to fraud, abuse, and waste;
- Periodically revising the program in light of changes in the organization's needs, and in the statutes, rules, regulations, and requirements of Federal, State, and private payor health care plans;
- Reviewing employees' certifications that they have received, read, understood, and will abide by the standards of conduct;
- Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeks to ensure that all appropriate employees and managers are knowledgeable of, and comply with, pertinent Federal, State and private payor health care program requirements;
- Ensuring independent contractors and agents who provide services (e.g., billing companies, delivery services and sources of referrals, i.e., physicians and others) to the DMEPOS supplier are aware of the requirements of the DMEPOS supplier's compliance program with respect to coverage, billing, marketing, and kickbacks, among other things;
- Coordinating personnel issues with the DMEPOS supplier's Human Resources/Personnel office (or its equivalent). The OIG recommends that the DMEPOS supplier check the List of Excluded Individuals/Entities,[137] and the General Services Administration's List of Parties Excluded from Federal Procurement and Nonprocurement Programs [138] to ensure employees and independent contractors have not been excluded or debarred from participating in Federal programs.[139] Depending upon State requirements or DMEPOS supplier policy, the Compliance Officer may also conduct a criminal background check of employees;
- Assisting the DMEPOS supplier's financial management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of departments;

[134] E.g., companies should not choose a sales manager who may be pressured to achieve high sales, which might result in a conflict with compliance goals.

[135] The OIG believes that it is not advisable for the compliance function to be subordinate to the DMEPOS supplier's general counsel, comptroller or similar DMEPOS supplier financial officer. Free standing compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the DMEPOS supplier make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

[136] For DMEPOS supplier chains, the OIG encourages coordination with each DMEPOS supplier location through the use of a headquarter's compliance officer, communicating with parallel positions in each facility or regional office, as appropriate.

[137] The List of Excluded Individuals/Entities is an OIG-produced report available on the Internet at http://www.dhhs.gov/progorg/oig. It is updated on a regular basis to reflect the status of individuals and entities who have been excluded from participation in all Federal health care programs (individuals/entities excluded before August 5, 1997 were only excluded from participation in Medicare, Medicaid, Title V and Title XX programs). The DMEPOS supplier can download the List of Excluded Individuals/Entities and the subsequent monthly exclusion and reinstatement supplements or can use the online search feature.

[138] The List of Parties Excluded from Federal Procurment and Nonprocurement programs is a GSA-produced report available on the Internet at http://www.arnet.bov/epls.

[139] The OIG recognizes that a DMEPOS supplier cannot make medical necessity determinations and may not be aware when a patient's condition changes. However, a DMEPOS supplier should be aware that if it submits a claim in which an excluded physician provided the referral, Medicare will deny payment.

• Independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action (e.g., making necessary improvements to DMEPOS supplier policies and practices, taking appropriate disciplinary action, etc.) with all DMEPOS supplier departments, independent contractors, and health care professionals;

• Developing policies and programs that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation; and

• Continuing the momentum of the compliance program and the accomplishment of its objectives long after the initial years of implementation.[140]

The compliance officer must have the authority to review all documents and other information that are relevant to compliance activities, including, but not limited to, patient records (where appropriate), billing records, and DMEPOS supplier records concerning the marketing efforts of the DMEPOS supplier and the DMEPOS supplier's arrangements with other parties, including employees, home health agencies, skilled nursing facilities, and treating physicians or other authorized persons. This policy enables the compliance officer to review contracts and obligations (seeking the advice of legal counsel, where appropriate) that may contain referral and payment provisions that could violate the anti-kickback statute, as well as the Stark physician self-referral prohibition or other statutory or regulatory requirements.

In addition, the compliance officer should be copied on the results of all internal audit reports and work closely with key managers to identify aberrant trends in the coding and billing areas. The compliance officer should ascertain patterns that require a change in policy and forward these issues to the compliance committee to remedy the problem. The compliance officer should have full authority to stop the processing of claims that he or she believes are problematic until such time as the issue in question has been resolved.

The OIG believes all DMEPOS suppliers, regardless of size, should have a compliance officer or contact who possesses a high degree of integrity, is knowledgeable about the rules, regulations, and policies under which the DMEPOS supplier operates and has sufficient authority to exercise independent judgment. A small DMEPOS supplier may not have the need or the resources to hire/appoint a full time compliance officer. However, each DMEPOS supplier should have a person in its organization (this person may have other functional responsibilities) who can oversee the DMEPOS supplier's compliance with respect to applicable statutes, rules, regulations, and policies. The structure and comprehensiveness of the DMEPOS supplier's compliance program will help determine the responsibilities of each individual compliance officer.

2. Compliance Committee

The OIG recommends, where feasible, that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.[141] When assembling a team of people to serve as the DMEPOS supplier's compliance committee, the DMEPOS supplier should include individuals with a variety of skills.[142] The OIG strongly recommends that the compliance officer manage the compliance committee. Once a DMEPOS supplier chooses the people that will accept the responsibilities vested in members of the compliance committee, the DMEPOS supplier must train these individuals on the policies and procedures of the compliance program, as well as how to discharge their duties.

The committee's responsibilities should include:

• Analyzing the organization's regulatory environment, the legal requirements with which it must comply,[143] and specific risk areas;

• Assessing existing policies and procedures that address these risk areas for possible incorporation into the compliance program;

• Working with appropriate DMEPOS supplier departments to develop standards of conduct and policies and procedures that promote allegiance to the DMEPOS supplier's compliance program;

• Recommending and monitoring, in conjunction with the relevant departments, the development of internal systems and controls to carry out the organization's standards, policies, and procedures as part of its daily operations; [144]

• Determining the appropriate strategy/approach to promote compliance with the program and detection of any potential violations, such as through hotlines and other fraud reporting mechanisms;

• Developing a system to solicit, evaluate, and respond to complaints and problems; and

• Monitoring internal and external audits and investigations for the purpose of identifying troublesome issues and deficient areas experienced by the DMEPOS supplier, and implementing corrective and preventive action.

The committee may also address other functions as the compliance concept becomes part of the overall DMEPOS supplier's operating structure and daily routine.

The compliance committee is an extension of the compliance officer and provides the organization with increased oversight. The OIG recognizes that small DMEPOS suppliers may not have the resources or the need to establish a compliance committee. However, when potential problems are identified, the OIG recommends that the small DMEPOS supplier create a

[140] Periodic on-site visits of DMEPOS supplier operations, bulletins with compliance updates and reminders, distribution of audiotapes or videotapes on different risk areas, lectures at management and employee meetings, circulation of recent health care articles covering fraud and abuse, and innovative changes to compliance training are various examples of approaches and techniques the compliance officer can employ for the purpose of ensuring continued interest in the compliance program and the DMEPOS supplier's commitment to its policies and principles.

[141] The compliance committee benefits from having the perspectives of individuals with varying responsibilities in the organization, such as operations, billing, coding, marketing, and human resources, as well as employees and managers of key operating units. These individuals should have the requisite seniority and comprehensive experience within their respective departments to implement any necessary changes to the DMEPOS supplier's policies and procedures as recommended by the committee. A compliance committee for a DMEPOS supplier that is part of another organization (e.g., home health agency) might benefit from the participation of officials from other departments in the organization, such as the accounting and billing departments.

[142] A DMEPOS supplier should expect its compliance committee members and compliance officer to demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, while eliciting the respect and trust of employees of the DMEPOS supplier. The DMEPOS supplier's compliance committee members should also have significant professional experience working with billing, documentation, and auditing principles.

[143] This includes, but is not limited to, the civil False Claims Act, 31 U.S.C. 3729–3733; the criminal false claims statutes, 18 U.S.C. 287, 1001; the fraud and abuse provisions of the Balanced Budget Act of 1997, Pub.L. 105–33; the Health Insurance Portability and Accountability Act of 1996, Pub.L. 104–191; and compliance with the Medicare supplier standards, 42 CFR 424.57.

[144] With respect to national DMEPOS supplier chains, this may include fostering coordination and communication between those employees responsible for compliance at headquarters and those responsible for compliance at the individual supplier branches.

"taskforce," if appropriate, to address the problem. The members of the taskforce may vary depending upon the issue.

C. Conducting Effective Training and Education

1. Initial Training in Compliance

The proper education and training of corporate officers, managers, employees and the continual retraining of current personnel at all levels, are significant elements of an effective compliance program. In order to ensure the appropriate information is being disseminated to the correct individuals, the training should be separated into sessions. All employees should attend the general session on compliance, and employees whose job primarily focuses on submission of claims for reimbursement, or who are involved in sales and marketing, should receive additional training on these particular subjects. In addition, the OIG recommends that the DMEPOS supplier inform physicians, independent contractors, and significant agents that it has implemented a compliance program.

a. General Sessions

The OIG recommends, as part of its compliance program, that the DMEPOS supplier require all affected personnel to attend training on an annual basis, including appropriate training in Federal and State statutes, regulations and guidelines, HCFA manual instructions, DMERC medical review policies, the policies of private payors, and training in corporate ethics. The general training session should emphasize the DMEPOS supplier's commitment to compliance with these legal requirements and policies.

These training programs should include sessions highlighting the DMEPOS supplier's compliance program, summarizing fraud and abuse statutes and regulations, Federal, State and private payor health care program requirements, claim submission procedures and marketing practices that reflect current legal and program standards. The DMEPOS supplier must take steps to communicate effectively its standards and procedures to all affected employees (e.g., by requiring participation in training programs and disseminating publications that explain specific requirements in a practical manner).[145] DMEPOS suppliers may also wish to offer such training sessions to interested independent contractors and physicians. Managers of specific departments can assist in identifying areas that require training and in carrying out such training.[146] Training New employees should be targeted for training early in their employment.[147]

As part of the initial training, the standards of conduct should be distributed to all employees.[148] At the end of this training session, every employee should be required to sign and date a statement that reflects his or her knowledge of and commitment to the standards of conduct. This attestation should be retained in the employee's personnel file.

Further, to assist in ensuring that employees continuously meet the expected high standards of conduct, any employee handbook delineating or expanding upon these standards should be regularly updated as applicable statutes, regulations and Federal health care program requirements are modified.[149] The DMEPOS supplier should provide an additional attestation in the modified standards that stipulates the employee's knowledge of and commitment to the modifications.

b. Claim Development and Billing Training

In addition to specific training in the risk areas identified in section II.A.2, above, primary training to appropriate corporate officers, managers and other claim development and billing staff should include such topics as:

- Specific Government and private payor reimbursement principles;[150]
- Providing and billing DMEPOS items or services without proper authorization;
- Proper documentation of services rendered, including the correct application of official ICD–9 and HCPCS coding rules and guidelines;
- Improper alterations to documentation (e.g., patient records, CMNs);
- Compliance with the Federal, State and private payor supplier standards; and
- Duty to report misconduct.

Clarifying and emphasizing these areas of concern through training and educational programs are particularly relevant to a DMEPOS supplier's billing and coding personnel, in that the pressure to meet business goals may render employees vulnerable to engaging in prohibited practices.

c. Sales and Marketing Training

In addition to specific training in the risk areas identified in section II.A.2, above, primary training to sales and marketing personnel should include such topics as:

- General prohibition on paying or receiving renumeration to induce referrals;
- Routine waiver of deductibles and/or coinsurance;
- Disguising referral fees as salaries;
- Offering free items or services to induce referrals;
- High pressure marketing of noncovered or unnecessary services;
- Improper patient solicitation; and
- Duty to report misconduct.

Clarifying and emphasizing these areas of concern through training and educational programs are particularly relevant to a DMEPOS supplier's sales and marketing personnel, in that the pressure to meet business goals may render employees vulnerable to engaging in prohibited practices.

The OIG believes all DMEPOS suppliers, regardless of size, should ensure that their employees are well trained and are abiding by the applicable statutes, regulations, and policies. Each employee should know the procedures or who to consult when confronted with a particular situation.

2. Format of the Training Program

The OIG suggests that all relevant levels of personnel be made part of various educational and training programs of the DMEPOS supplier.[151]

[145] OIG publications such as Special Fraud Alerts, audit and inspection reports, and Advisory Opinions, as well as the annual OIG Work Plan, are readily available from the OIG and could be the basis for standards, educational courses and programs.

[146] Significant variations in functions and responsibilities of different departments may create the need for training materials that are tailored to the compliance concerns associated with particular operations and duties. instructors may come from outside or inside the organization.

[147] Certain positions, such as those involving developing and submitting claims, as well as sales and marketing, create a greater organizational legal exposure, and therefore require specialized training. The DMEPOS supplier should fill such positions with individuals who have the appropriate educational background, training, experience, and credentials.

[148] Where the DMEPOS supplier has a culturally diverse employee base, the standards of conduct should be translated into other languages and written at appropriate reading levels.

[149] The OIG recognizes that not all standards, policies and procedures need to be communicated to all employees. However, the OIG believes that the bulk of the standards that relate to complying with fraud and abuse laws and other ethical areas should be addressed and made part of all employees' training. A DMEPOS supplier should determine the additional training to provide categories of employees based upon their job responsibilites.

[150] Government, in this context, includes the appropriate Medicare DMERC(s).

[151] In addition, where feasible, the OIG recommends that a DMEPOS supplier afford outside contractors and its physician clients the opportunity to participate in the DMEPOS supplier's compliance training and educational

Continued

Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment obligations.[152] For example, as discussed above, employees involved in billing functions should be required to attend periodic training in applicable reimbursement coverage and documentation of records.[153]

A variety of teaching methods, such as interactive training and training in several different languages, particularly where a DMEPOS supplier has a culturally diverse staff, should be implemented so that all affected employees are knowledgeable about the DMEPOS supplier's standards of conduct and procedures for alerting senior management to problems and concerns.[154] Targeted training should be provided to corporate officers, managers and other employees whose actions affect the accuracy of the claims submitted to the Government, such as employees involved in the coding, billing, sales, and marketing processes. All training materials should be designed to take into account the skills, knowledge and experience of the individual trainees. Given the complexity and interdependent relationships of many departments, it is important for the compliance officer to supervise and coordinate the training program.

The OIG recommends that attendance and participation in training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action, including possible termination, when such failure is serious. Adherence to the provisions of the compliance program, such as training requirements, should be a factor in the annual evaluation of each employee. The DMEPOS supplier should retain adequate records of its training of employees, including attendance logs and material distributed at training sessions.

The OIG recognizes the format of the training program will vary depending upon the resources of the DMEPOS supplier. For example, a small DMEPOS supplier may want to create a video for each type of training session so new employees can receive training in a timely manner.

3. Continuing Education on Compliance Issues

It is essential that compliance issues remain at the forefront of the DMEPOS supplier's priorities. The OIG recommends that the DMEPOS supplier's compliance program address the need for periodic professional education courses for DMEPOS supplier personnel. In particular, the DMEPOS supplier should ensure that coding personnel receive annual professional training on the updated codes for the current year and have knowledge of the SADMERC's HCPCS coding helpline.[155]

In order to maintain a sense of seriousness about compliance in a DMEPOS supplier's operations, the DMEPOS supplier must continue to disseminate the compliance message. One effective mechanism for maintaining a consistent presence of the compliance message is to publish a monthly newsletter to address compliance concerns. This would allow the DMEPOS supplier to address specific examples of problems the company encountered during its ongoing audits and risk analyses, while reinforcing the DMEPOS supplier's firm commitment to the general principles of compliance and ethical conduct. The newsletter could also include the risk areas published by the OIG in its Special Fraud Alerts. Finally, the DMEPOS supplier could use the newsletter as a mechanism to address areas of ambiguity in the coding and billing process and/or its sales and marketing practices. The DMEPOS supplier should maintain its newsletters in a central location to document the guidance offered, and provide new employees with access to guidance previously provided.

The OIG believes it is important that all DMEPOS suppliers, regardless of size, maintain knowledgeable employees. The OIG recognizes that regularly sending employees to continuing education classes or publishing newsletters may not be feasible for small DMEPOS suppliers. Small DMEPOS suppliers may have their employees meet on a regular basis to discuss information in the DMERC's Medicare bulletin (e.g., coding changes, procedural changes, policy changes, etc.). Such regularly held meetings will help demonstrate the DMEPOS supplier's commitment to compliance.

D. Developing Effective Lines of Communication

1. Access to the Compliance Officer

An open line of communication between the compliance officer and DMEPOS supplier employees is equally important to the successful implementation of a compliance program and the reduction of any potential for fraud, abuse, and waste. Written confidentiality and non-retaliation policies should be developed and distributed to all employees to encourage communication and the reporting of incidents of potential fraud.[156] The compliance committee should also develop several independent reporting paths for an employee to report fraud, waste, or abuse so that such reports cannot be diverted by supervisors or other personnel.

The OIG encourages the establishment of a procedure for personnel to seek clarification from the compliance officer or members of the compliance committee in the event of any confusion or question regarding a DMEPOS supplier policy, practice or procedure. Questions and responses should be documented and dated and, if appropriate, shared with other staff so that standards, policies, practices, and procedures can be updated and improved to reflect any necessary changes or clarifications. The compliance officer may want to solicit employee input in developing these communication and reporting systems.

2. Hotlines and Other Forms of Communication

The OIG encourages the use of hotlines,[157] e-mails, written memoranda, newsletters, suggestion boxes, and other forms of information exchange to maintain these open lines of communication.[158] If the DMEPOS

programs, or develop their own programs that complement the DMEPOS supplier's standards of conduct, compliance requirements and other rules and practices.

[152] Currently, the OIG is monitoring a significant number of corporate integrity agreements that require many of these training elements. The OIG usually requires a minimum of one to three hours annually for basic training in compliance areas. Additional training is required for specially fields such as billing, coding, sales and marketing.

[153] Appropriate coding and billing depends upon the quality and completeness of documentation. Therefore, the OIG believes that the DMEPOS supplier must foster an environment where interactive communication is encouraged.

[154] Post training tests can be used to assess the success of training provided and employee comprehension of the DMEPOS supplier's policies and procedures.

[155] *See* note 96.

[156] The OIG believes that whistleblowers should be protected against retaliation, a concept embodied in the provisions of the False Claims Act. *See* 31 U.S.C. 3730(h). In many cases, employees sue their employers under the False Claims Act's *qui tam* provisions out of frustration because of the company's failure to take action when a questionable, fraudulent, or abusive situation was brought to the attention of senior corporate officials.

[157] The OIG recognizes that it may not be financially feasible for a small DMEPOS supplier to maintain a telephone hotline dedicated to receiving calls solely on compliance issues. These companies may want to explore alternative methods, e.g., outsourcing the hotline or establishing a written method of confidential disclosure.

[158] In addition to methods of communication used by current employees, an effective employee exit interview program could be designed to solicit

supplier establishes a hotline, the telephone number should be made readily available to all employees and independent contractors, possibly by circulating the number on wallet cards or conspicuously posting the telephone number in common work areas.[159] Employees should be permitted to report matters on an anonymous basis. Matters reported through the hotline or other communication sources that suggest substantial violations of compliance policies, Federal, State or private payor health care program requirements, regulations, or statutes should be documented and investigated promptly to determine their veracity. A log should be maintained by the compliance officer that records such calls, including the nature of any investigation and its results.[160] Such information should be included in reports to the owner(s), governing body, CEO, president, and compliance committee.[161] Further, while the DMEPOS supplier should always strive to maintain the confidentiality of an employee's identity, it should also explicitly communicate that there may be a point where the individual's identity may become known or may have to be revealed.

The OIG recognizes that assertions of fraud and abuse by employees who may have participated in illegal conduct or committed other malfeasance raise numerous complex legal and management issues that should be examined on a case-by-case basis. The compliance officer should work closely with legal counsel, who can provide guidance regarding such issues.

The OIG recognizes that protecting anonymity may be infeasible for small DMEPOS suppliers. However, the OIG believes all DMEPOS supplier employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know who to consult and should be able to do so without fear of retribution.

E. Auditing and Monitoring

An ongoing evaluation process is critical to a successful compliance program. The OIG believes that an effective program should incorporate thorough monitoring of its implementation and regular reporting to the DMEPOS supplier's corporate officers.[162] Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, should be maintained by the compliance officer and shared with the DMEPOS supplier's corporate officers and the compliance committee. The extent and frequency of the audit function may vary depending on factors such as the size of the DMEPOS supplier, the resources available to the DMEPOS supplier, the DMEPOS supplier's prior history of noncompliance, and the risk factors that are prevalent in a particular DMEPOS supplier.

Although many monitoring techniques are available, one effective tool to promote and ensure compliance is the performance of regular, periodic compliance audits by internal or external auditors who have expertise in Federal and State health care statutes, rules, regulations, and Federal, State and private payor health care program requirements. The audits should focus on the different departments within the DMEPOS supplier, including external relationships with third-party contractors. At a minimum, these audits should be designed to address the DMEPOS supplier's compliance with laws governing kickback arrangements, the physician self-referral prohibition, pricing, contracts, claim development and submission, reimbursement, sales and marketing. In addition, the audits and reviews should examine the DMEPOS supplier's compliance with the Federal, State and private payor supplier standards and the specific rules and policies that have been the focus of particular attention on the part of the Medicare DMERCs, and law enforcement, as evidenced by educational and other communications from OIG Special Fraud Alerts, Advisory Opinions, OIG audits and evaluations, and law enforcement's initiatives.[163] In addition, the DMEPOS supplier should focus on any areas of specific concern identified within that DMEPOS supplier and those that may have been identified by any entity, whether Federal, State, private or internal.

Monitoring techniques may include sampling protocols that permit the compliance officer to identify and review variations from an established baseline.[164] Significant variations from the baseline should trigger a reasonable inquiry to determine the cause of the deviation. If the inquiry determines that the deviation occurred for legitimate, explainable reasons, the compliance officer and DMEPOS supplier management may want to limit any corrective action or take no action. If it is determined that the deviation was caused by improper procedures, misunderstanding of rules, including fraud and systemic problems, the DMEPOS supplier should take prompt steps to correct the problem.[165] Any overpayments discovered as a result of such deviations should be returned promptly to the affected payor. The OIG recommends sending the payor the following information with the overpayment: (1) that the refund is being made pursuant to a voluntary compliance program; (2) a description of the complete causes and circumstances surrounding the overpayment; (3) the methodology by which the overpayment was determined; (4) the amount of the overpayment; and (5) any claim-specific information, reviewed as part of the self-audit, used to determine the overpayment (e.g., beneficiary health insurance claims number, claim number, date of service, and payment date). Inclusion of such information with the overpayment will aid the payor in making the adjustment and may prevent it from requesting additional information.

An effective compliance program should also incorporate periodic (at least annual) reviews of whether the

information from departing employees regarding potential misconduct and suspected violations of DMEPOS supplier policies and procedures.

[159] DMEPOS suppliers should also post in a prominent, available area the HHS-OIG Hotline telephone number, 1–800–447–8477 (1–800–HHS-TIPS), in addition to any company hotline number that may be posted.

[160] To efficiently and accurately fulfill such an obligation, a DMEPOS supplier should create an intake form for all compliance issues identified through reporting mechanisms. The form could include information concerning the date that the potential problem was reported, the internal investigative methods utilized, the results of the investigation, any corrective action implemented, any disciplinary measures imposed, and any overpayments returned.

[161] Information obtained over the hotline may provide valuable insight into management practices and operations, whether reported problems are actual or perceived.

[162] Even when a DMEPOS supplier is owned by a larger corporate entity, the regular auditing and monitoring of the compliance activities of an individual DMEPOS supplier location must be a key feature in any annual review. Appropriate reports on audit findings should be periodically provided and explained to a parent organization's senior staff and officers.

[163] *See also* section II.A.2.

[164] The OIG recommends that when a compliance program is established in a DMEPOS supplier, the compliance officer, with the assistance of department managers, should take a "snapshot" of operations from a compliance perspective. This assessment can be undertaken by outside consultants, law or accounting firms, or internal staff, with authoritative knowledge of health care compliance requirements. This "snapshot," often used as part of benchmarking analyses, becomes a baseline for the compliance officer and other managers to judge the DMEPOS supplier's progress in reducing or eliminating potential areas of vulnerability.

[165] In addition, when appropriate, as referenced in section II.G.2, below, reports of fraud or systemic problems should also be made to the appropriate governmental authority.

program's compliance elements have been satisfied, e.g., whether there has been appropriate dissemination of the program's standards, training, ongoing educational programs, and disciplinary actions, among other elements.[166] This process will verify actual conformance by all departments with the compliance program and may identify the necessity for improvements to be made to the compliance program, as well as the DMEPOS supplier's operations. Such reviews could support a determination that appropriate records have been created and maintained to document the implementation of an effective program.[167] However, when monitoring discloses that deviations were not detected in a timely manner due to program deficiencies, appropriate modifications must be implemented. Such evaluations, when developed with the support of management, can help ensure compliance with the DMEPOS supplier's policies and procedures.

As part of the review process, the compliance officer or reviewers should consider techniques such as:

- Testing billing staff on their knowledge of reimbursement coverage criteria and official coding guidelines (e.g., present hypothetical scenarios of situations experienced in daily practice and assess responses);
- On-site visits to all facilities and locations;
- Ongoing risk analysis and vulnerability assessments of the DMEPOS supplier's operations;
- Assessment of existing relationships with physicians, and other potential referral sources;
- Unannounced audits, mock surveys, and investigations;
- Examination of the DMEPOS supplier's complaint logs;
- Checking personnel records to determine whether any individuals who have been reprimanded for compliance issues in the past are among those currently engaged in improper conduct;
- Interviews with personnel involved in management, operations, sales and marketing, claim development and submission, and other related activities;
- Questionnaires developed to solicit impressions of the DMEPOS supplier's employees;
- Interviews with physicians or other authorized persons who order services provided by the DMEPOS supplier;
- Interviews with independent contractors who provide services to the DMEPOS supplier;
- Reviews of medical necessity documentation (e.g., physicians orders, CMNs), and other documents that support claims for reimbursement;
- Validation of qualifications of physicians or other authorized persons who order services provided by the DMEPOS supplier;
- Evaluation of written materials and documentation outlining the DMEPOS supplier's policies and procedures; and
- Utilization/trend analyses that uncover deviations, positive or negative, for specific HCPCS codes or types of items over a given period.

The reviewers should:

- Possess the qualifications and experience necessary to adequately identify potential issues with the subject matter to be reviewed;
- Be objective and independent of line management;[168]
- Have access to existing audit and health care resources, relevant personnel, and all relevant areas of operation;
- Present written evaluative reports on compliance activities to the owner(s), president, CEO, governing body, and members of the compliance committee on a regular basis, but not less than annually; and
- Specifically identify areas where corrective actions are needed.

We recommend that these audit reports be prepared and submitted to the compliance officer and senior management to ensure they are aware of the results. We suggest the reports specifically identify areas where corrective actions are needed. With these reports, DMEPOS supplier management can take whatever steps are necessary to correct past problems and prevent them from recurring. In certain cases, subsequent reviews or studies would be advisable to ensure that the recommended corrective actions have been implemented successfully.

A DMEPOS supplier should document its efforts to comply with applicable Federal and State statutes, rules, and regulations, and Federal, State and private payor health care program requirements. For example, where a DMEPOS supplier, in its efforts to comply with a particular statute, regulation or program requirement, requests advice from a Government agency (including a Medicare DMERC) charged with administering a Federal health care program, the DMEPOS supplier should document and retain a record of the request and any written or oral response, including the identity and position of the individual providing the response. The DMEPOS suppliers should take the same steps when requesting advice from private payors. This step is extremely important if the DMEPOS supplier intends to rely on that response to guide it in future decisions, actions, or claim reimbursement requests or appeals. A log of oral inquiries between the DMEPOS supplier and third parties will help the organization document its attempts at compliance. In addition, the DMEPOS supplier should maintain records relevant to the issue of whether its reliance was "reasonable" and whether it exercised due diligence in developing procedures and practices to implement the advice.

The OIG recommends that all DMEPOS suppliers, regardless of size, conduct audits to ensure compliance with the applicable statutes, regulations and policies. The OIG recognizes that the small DMEPOS supplier may not have the resources to audit its operations to the extent suggested previously in this section. At a minimum, the OIG recommends that the small DMEPOS supplier conduct an internal audit. The DMEPOS supplier may choose to review a random sample of claims based on the risk areas it identified. We recommend that the DMEPOS supplier conduct an initial baseline audit and periodically conduct follow-up audits. If problems were identified in the baseline audit, the DMEPOS supplier may want to re-audit the same issue, at a later date, in order to measure the effectiveness of any corrective action(s) implemented as a result of the DMEPOS supplier's compliance program. The DMEPOS supplier should document the results of all audits it conducts. The DMEPOS supplier may want to use the OIG's Audit Process handbook to help design the audit.[169]

The extent of a DMEPOS supplier's audit should depend on the DMEPOS supplier's identified risk areas and resources. If the DMEPOS supplier comes under Government scrutiny in the future, the Government will assess whether or not the DMEPOS supplier developed a comprehensive audit based upon identified risk areas and resources.

[166] One way to assess the knowledge, awareness, and perceptions of a DMEPOS supplier's employees is through the use of a validated survey instrument (e.g., employee questionnaires, interviews, or focus groups).

[167] Such records should include, but not be limited to, logs of hotline calls, logs of training attendees, training agenda and materials, and summaries of corrective action and improvements with respect to DMEPOS supplier policies as a result of compliance activities.

[168] The OIG recognizes that DMEPOS suppliers that are small in size and have limited resources may not be able to use internal reviewers who are not part of line management or hire outside reviewers.

[169] The Audit Process handbook can be downloaded from the OIG Office of Audit Services' webpage at http://www.hhs.gov/progorg/oas.

If the Government determines that the DMEPOS supplier failed to develop an adequate audit program, given its resources, the Government will be less likely to afford the DMEPOS supplier favorable treatment under its various enforcement authorities.

F. Enforcing Standards Through Well-Publicized Disciplinary Guidelines

1. Discipline Policy and Actions

An effective compliance program should include guidance regarding disciplinary action for corporate officers, managers, independent agents and other DMEPOS supplier employees who have failed to comply with the DMEPOS supplier's standards of conduct, policies and procedures, Federal and State statutes, rules, and regulations or Federal, State or private payor health care program requirements. It should also address disciplinary actions for those who have engaged in wrongdoing, which has the potential to impair the DMEPOS supplier's status as a reliable, honest, and trustworthy health care provider.

The OIG believes that the compliance program should include a written policy statement setting forth the degrees of disciplinary actions that may be imposed upon corporate officers, managers, independent agents and other DMEPOS supplier employees for failing to comply with the DMEPOS supplier's standards, policies, and applicable statutes and regulations. Intentional or reckless noncompliance should subject transgressors to significant sanctions. Such sanctions could include oral warnings, suspension, termination, or other sanctions, as appropriate. Each situation must be considered on a case-by-case basis to determine the appropriate sanction. The written standards of conduct should elaborate on the procedures for handling disciplinary problems and specify those who will be responsible for taking appropriate action. Some disciplinary actions can be handled by managers, while others may have to be resolved by the owner(s), president or CEO. Disciplinary action may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. Personnel should be advised by the DMEPOS supplier that disciplinary action will be taken on a fair and equitable basis. Managers and supervisors should be made aware that they have a responsibility to discipline employees in an appropriate and consistent manner.

It is vital to publish and disseminate the range of disciplinary standards for improper conduct and to educate corporate officers, managers, and other DMEPOS supplier employees regarding these standards. The consequences of noncompliance should be consistently applied and enforced, in order for the disciplinary policy to have the required deterrent effect. All levels of employees should be subject to the same types of disciplinary action for the commission of similar offenses. The commitment to compliance applies to all personnel levels within a DMEPOS supplier. The OIG believes that corporate officers, managers, and supervisors should be held accountable for failing to comply with, or for the foreseeable failure of their subordinates to adhere to, the applicable standards, statutes, rules, regulations and procedures.

The OIG believes all DMEPOS suppliers, regardless of size, should consistently apply the consequences of non-compliance. The OIG recognizes that small DMEPOS suppliers may not have a written document detailing the disciplinary actions for non-compliance. However, all employees should be clearly informed of such consequences.

2. New Employee Policy

For all new employees who have discretionary authority to make decisions that may involve compliance with the law or compliance oversight, DMEPOS suppliers should conduct a reasonable and prudent background investigation, including a reference check,[170] as part of every such employment application. The application should specifically require the applicant to disclose any criminal conviction, as defined by 42 U.S.C. 1320a-7(i), or exclusion action. Pursuant to the compliance program, the DMEPOS supplier's policies should prohibit the employment of individuals who have been recently convicted of a criminal offense related to health care or who are listed as debarred, excluded, or otherwise ineligible for participation in Federal health care programs (as defined in 42 U.S.C. 1320a-7b(f)).[171] In addition, pending the resolution of any criminal charges or proposed debarment or exclusion, the OIG recommends that such employees should be removed from direct responsibility for, or involvement with, the DMEPOS supplier's business operations related to any Federal health care program. In addition, we recommend that the DMEPOS supplier remove such employee from any position(s) for which the employee's salary or the items or services rendered by the employee are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds.[172] If resolution of the matter results in conviction, debarment, or exclusion, then the DMEPOS supplier should remove the individual from direct responsibility for or involvement with all Federal health care programs. Similarly, if an independent contractor or a referring physician or other authorized person is debarred or excluded from participation in Federal health care programs, and the DMEPOS supplier is aware of it, the DMEPOS supplier should not involve that individual/entity in the Federal health care portion of its business.

The OIG believes all DMEPOS suppliers, regardless of size, should ensure that they do not employ or contract with anyone who has been debarred, excluded or is otherwise ineligible to participate in Federal health care programs.

G. Responding to Detected Offenses and Developing Corrective Action Initiatives

1. Violations and Investigations

Violations of a DMEPOS supplier's compliance program, failures to comply with applicable Federal or State statutes, rules, regulations or Federal, State or private payor health care program requirements, and other types of misconduct threaten a DMEPOS supplier's status as a reliable, honest and trustworthy health care provider. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the DMEPOS supplier. Consequently, upon reports or reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the conduct in question to determine whether a material violation of applicable law, rules or program instructions or the requirements of the compliance program has occurred, and if so, take decisive steps to correct the

[170] *See* notes 137 and 138. Since the employees of DMEPOS suppliers have access to potentially vulnerable people and their property, DMEPOS suppliers should also strictly scrutinize whether they should employ individuals who have been convicted of crimes of neglect, violence or financial misconduct.

[171] Likewise, DMEPOS supplier compliance programs should establish standards prohibiting the execution of contracts with companies that have been recently convicted of a criminal offense related to health care or that are listed by a Federal agency as debarred, excluded, or otherwise ineligible for participation in Federal health care programs. See notes 137 and 138.

[172] Prospective employees who have been officially reinstated into the Medicare and Medicaid programs by the OIG may be considered for employment upon proof of such reinstatement

problem.[173] As appropriate, such steps may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan,[174] a report to the Government,[175] and the return of any overpayments, if applicable.

Where potential fraud or False Claims Act liability is not involved, the OIG recommends that the DMEPOS supplier promptly return any overpayments to the affected payor as they are discovered. However, even if the overpayment detection and return process is working and is being monitored by the DMEPOS supplier, the OIG still believes that the compliance officer needs to be made aware of these overpayments, violations, or deviations that may reveal trends or patterns indicative of a systemic problem.

Depending upon the nature of the alleged violations, an internal investigation will probably include interviews and a review of relevant documents, such as submitted claims and CMNs. The DMEPOS supplier should consider engaging outside auditors or health care experts to assist in an investigation. Records of the investigation should contain documentation of the alleged violation, a description of the investigative process (including the objectivity of the investigators and methodologies utilized), copies of interview notes and key documents, a log of the witnesses interviewed, the documents reviewed, and the results of the investigation (e.g., any disciplinary action taken and any corrective action implemented). Although any action taken as the result of an investigation will necessarily vary depending upon the DMEPOS supplier and the situation, DMEPOS suppliers should strive for some consistency by utilizing sound practices and disciplinary protocols.[176] Further, after a reasonable period, the compliance officer should review the circumstances that formed the basis for the investigation to determine whether similar problems have been uncovered or modifications of the compliance program are necessary to prevent and detect other inappropriate conduct or violations.

If an investigation of an alleged violation is undertaken and the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, those subjects should be removed from their current work activity until the investigation is completed (unless an internal or Government-led undercover operation known to the DMEPOS supplier is in effect). In addition, the compliance officer should take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation. If the DMEPOS supplier determines disciplinary action is warranted, it should be prompt and imposed in accordance with the DMEPOS supplier's written standards of disciplinary action.

The OIG believes all DMEPOS suppliers, regardless of size, should ensure that they are responsive to investigating allegations of potential misconduct.

2. Reporting

If the compliance officer, compliance committee or other management official discovers credible evidence of misconduct from any source and, after a reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law, then the DMEPOS supplier should promptly report the existence of misconduct to the appropriate Federal and State authorities[177] within a reasonable period, but not more than 60 days[178] after determining that there is credible evidence of a violation.[179] Prompt reporting will demonstrate the DMEPOS supplier's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (e.g., penalties, assessments, and exclusion), if the reporting provider becomes the target of an OIG investigation.[180]

When reporting misconduct to the Government, a DMEPOS supplier should provide all evidence relevant to the alleged violation of applicable Federal or State law(s) and potential cost impact. The compliance officer, with advice of counsel, and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, the compliance officer should be required to notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable health care programs or their beneficiaries. If the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the appropriate Federal and State authorities[181] should be notified immediately.

The OIG believes all DMEPOS suppliers, regardless of size, should ensure that they are reporting the results of any overpayments or violations to the appropriate entity.

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[173] Instances of non-compliance must be determined on a case-by-case basis. The existence, or amount, of a *monetary* loss to a health care program is not solely determinative of whether or not the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss at all, but corrective action and reporting are still necessary to protect the integrity of the applicable program and its beneficiaries.

[174] Advice from the DMEPOS supplier's in-house counsel or an outside law firm may be sought to determine the extent of the DMEPOS supplier's liability and to plan the appropriate course of action.

[175] The OIG currently maintains a provider self-disclosure protocol that encourages providers to report suspected fraud. The concept of voluntary self-disclosure is premised on a recognition that the Government alone cannot protect the integrity of the Medicare and other Federal health care programs. Health care providers must be willing to police themselves, correct underlying problems, and work with the Government to resolve these matters. The self-disclosure protocol is located on the OIG's web site at http://www.dhhs.gov/progorg/oig.

[176] The parameters of a claim review subject to an internal investigation will depend on the circumstances surrounding the issue(s) identified. By limiting the scope of an internal audit to current billing, a DMEPOS supplier may fail to identify major problems and deficiencies in operations, as well as be subject to certain liability.

[177] Appropriate Federal and State authorities include the Office of Inspector General, Department of Health and Human Services; the Criminal and Civil Divisions of the Department of Justice; the U.S. Attorney in the relevant district(s); and the other investigative arms for the agencies administering the affected Federal or State health care programs, such as: the State Medicaid Fraud Control Unit; the Defense Criminal Investigative Service; the Department of Veterans Affairs; the Office of Inspector General, U.S. Department of Labor (which has primary criminal jurisdiction over FECA, Black Lung and Longshore programs); and the Office of Inspector General, U.S. Office of Personnel Management (which has primary jurisdiction over the Federal Employee Health Benefits Program).

[178] In contrast, to qualify for the "not less than double damages" provision of the False Claims Act, the report must be provided to the Government within thirty (30) days after the date when the DMEPOS supplier first obtained the information. *See* 31 U.S.C. 3729(a).

[179] The OIG believes that some violations may be so serious that they warrant immediate notification to governmental authorities, prior to, or simultaneous with, commencing an internal investigation, *e.g.*, if the conduct: (1) is a clear violation of criminal law; (2) has a significant adverse effect on the quality of care provided to program beneficiaries (in addition to any other legal obligations regarding quality of care); or (3) indicates evidence of a systemic failure to comply with applicable laws, rules or program instructions or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

[180] The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude a health care provider from program participation pursuant to 42 U.S.C. 1320a–7(b)(7) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997).

[181] *See* note 177.

3. Corrective Actions

As previously stated, the DMEPOS supplier should take appropriate corrective action, including prompt identification of any overpayment to the affected payor and the imposition of proper disciplinary action. If potential fraud or violations of the False Claims Act are involved, any repayment of the overpayment should be made as part of the discussion with the Government following a report of the matter to law enforcement authorities. Otherwise, the overpayment should be promptly refunded to the affected payor. The OIG recommends that the overpayment refund include the information as outlined in section II.E. Failure to disclose overpayments within a reasonable period of time could be interpreted as an intentional or knowing attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal or civil violation with respect to the DMEPOS supplier, as well as any individuals who may have been involved. For this reason, DMEPOS supplier compliance programs should emphasize that overpayments obtained from Medicare or other Federal health care programs should be promptly disclosed and returned to the payor that made the erroneous payment.

The OIG believes all DMEPOS suppliers, regardless of size, should take appropriate corrective action to remedy the identified deficiency.

III. Conclusion

Through this document, the OIG has attempted to provide a foundation to the process necessary to develop an effective and cost-efficient DMEPOS supplier compliance program. As previously stated, however, each program must be tailored to fit the needs and resources of an individual DMEPOS supplier, depending upon its size; number of locations; type of equipment provided; or corporate structure. The Federal and State health care statutes, rules, and regulations and Federal, State and private payor health care program requirements, should be integrated into every DMEPOS supplier's compliance program.

The OIG recognizes that the health care industry in this country, which reaches millions of beneficiaries and expends about a trillion dollars annually, is constantly evolving. In particular, legislation has been passed that creates additional Medicare program participation requirements, such as requiring DMEPOS suppliers to purchase surety bonds and expanding the Medicare supplier standards.[182] As stated throughout this guidance, compliance is a dynamic process that helps to ensure that DMEPOS suppliers and other health care providers are better able to fulfill their commitment to ethical behavior, as well as meet the changes and challenges being imposed upon them by Congress and private insurers. Ultimately, it is OIG's hope that a voluntarily created compliance program will enable DMEPOS suppliers to meet their goals, improve the quality of service to patients, and substantially reduce fraud, waste, and abuse, as well as the cost of health care, to Federal State and private health insurers.

Dated: June 29, 1999.

June Gibbs Brown,

Inspector General.

[FR Doc. 99–16945 Filed 7–2–99; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4401–N–02]

Change in Effective Date in 1999 Notice for Designation of Difficult Development Areas Under Section 42 of the Internal Revenue Code of 1986

AGENCY: Office of the Secretary, HUD.

ACTION: Notice.

SUMMARY: This document amends the Notice for the Designation of Difficult Development Areas, published December 9, 1998 (the 1999 Notice,) by extending 1998 eligibility for areas that were designated as 1998 Difficult Development Areas in the Notice published October 21, 1997 (the 1998 Notice) but were not designated as difficult development areas in the 1999 Notice. This amendment is limited to buildings described in section 42(h)(4)(B) of the Internal Revenue Code of 1986 (the Code) and located in a 1998 Difficult Development Area. The amendment is necessary because publication of the 1999 Notice three weeks prior to the effective date of the 1999 Notice did not provide adequate notice to affected entities. This Notice does not change the effective date in the 1999 Notice for (1) areas designated as Difficult Development Areas in the 1999 Notice that were not Difficult Development Areas in the 1998 Notice, or (2) that were Difficult Development Areas in both the 1998 Notice and the 1999 Notice.

FOR FURTHER INFORMATION CONTACT: With questions related narrowly to the issue of the effective date for areas that lost 1998 Difficult Development Area designations, Frederick J. Eggers, Deputy Assistant Secretary for Economic Affairs, Office of Policy Development and Research, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–3080, e-mail Frederick J.__Eggers@hud.gov. With questions on how areas are designated and on geographic definitions, Kurt G. Usowski, Economist, Division of Economic Development and Public Finance, Office of Policy Development and Research, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–0426, e-mail Kurt G.__Usowski@hud.gov. A text telephone is available for persons with hearing or speech impairments at (202) 708–9300. (These are not toll-free telephone numbers.) Additional copies of this notice are available through HUDUSER at (800) 245–2691 for a small fee to cover duplication and mailing costs.

Copies Available Electronically: This notice is available electronically on the Internet (World Wide Web) at http://www.huduser.org/ under the heading "Data Available from HUDUser."

SUPPLEMENTARY INFORMATION:

Background

On October 21, 1997 (62 FR 54732), HUD published in the **Federal Register** a Notice Designating Difficult Development Areas for calendar year 1998 (the 1998 Notice). The 1998 Notice provided that, in the case of a building described in section 42(h)(4)(B) of the Code, the list (of Difficult Development Areas) is effective if the bonds are issued and the building is placed in service after December 31, 1997.

On December 9, 1998 (64 FR 68116), HUD published in the **Federal Register** the Notice Designating Difficult Development Areas for calendar year 1999 (the 1999 Notice). The 1999 Notice provided that, in the case of a building described in section 42(h)(4)(B) of the Code, the list (of Difficult Development Areas) is effective if the bonds are issued and the building is placed in service after December 31, 1998.

Section 42(d)(5)(C) of the Code defines a Difficult Development Area as any area designated by the Secretary of HUD as an area that has high construction, land, and utility costs relative to the area gross median income. All designated Difficult Development Areas in metropolitan statistical areas or primary metropolitan statistical areas (MSAs/PMSAs) may not contain more than 20 percent of the aggregate population of all MSAs/PMSAs, and all designated areas not in

[182] *See* 63 FR 2926 (January 20, 1998).

metropolitan areas may not contain more than 20 percent of the aggregate population of all nonmetropolitan counties. In the case of buildings located in designated Difficult Development Areas, eligible basis can be increased by up to 130 percent of what it would otherwise be. This means that the available Low-Income Housing Tax Credit also can be increased by up to 30 percent.

HUD typically issues a Notice in the **Federal Register** early in the last quarter of a calendar year designating Difficult Development Areas for the forthcoming calendar year. HUD uses a ranking procedure to select Difficult Development Areas subject to the 20 percent population cap. Because income and housing cost conditions change, new areas are added to the list of designated Difficult Development Areas each year and some old areas are dropped from the list. The list published on December 9, 1998, dropped 9 metropolitan areas and 35 nonmetropolitan counties from the list of Difficult Development Areas and added 3 metropolitan areas and 40 nonmetropolitan counties to the list of Difficult Development Areas.

Determination

HUD recognizes that, with every new designation of Difficult Development Areas, some metropolitan areas and nonmetropolitan counties lose their designation and rental projects planned in these areas lose their eligibility for the extra credit. State agencies and rental project developers have adjusted to a system in which the future availability of the extra credits is uncertain. HUD attempts to publish the designation Notice early enough to allow State agencies and developers to make informed decisions for the forthcoming year. HUD did not publish the 1999 Notice until December 9, 1998, because the Department had to revise the list after section 508 of the Quality Housing and Work Responsibility Act of 1998 (Pub. L. 105–276, approved October 21, 1998), changed the rules for designating Difficult Development Areas as the rules apply to two counties. The late publication of the 1999 Notice impeded the effectiveness of the Difficult Development Area feature of the Low-Income Housing Tax Credit. Accordingly, HUD has decided to amend the effective date published in the 1999 Notice.

This amendment extends Difficult Development Area designations in the 1998 Notice through August 20, 1999 for any building described in section 42(h)(4)(B) of the Code that was located in a Difficult Development Area in the 1998 Notice, but not in the 1999 Notice if the bonds are issued or the building is placed in service before August 20, 1999. Therefore, for example, a building described in section 42(h)(4)(B) of the Code that was located in a Difficult Development Area designated in the 1998 Notice, but not located in a Difficult Development Area designated in the 1999 Notice, would be deemed to be located in a Difficult Development Area if either the bonds are issued or the building is placed in service from January 1, 1998 through August 20, 1999.

This Notice is consistent with section 42(d)(5)(C)(iii)(II) of the Code, which limits the cumulative population of metropolitan Difficult Development Areas to 20 percent of the cumulative population of all metropolitan areas and the cumulative population of nonmetropolitan Difficult Development Areas to 20 percent of the cumulative population of all nonmetropolitan counties. The 20 percent cap applies only to Difficult Development Area designations made by HUD for a particular year. The extension of time for the 1998 Difficult Development Areas does not reflect a determination by HUD that an aggregate population substantially in excess of 20 percent of the metropolitan or nonmetropolitan population should be treated as Difficult Development Areas for 1998. The notice is a ministerial administrative accommodation which may, for a limited period of time, result in an aggregate population slightly exceeding 20 percent of either the metropolitan or nonmetropolitan population being designated for that limited period of time. This temporary de minimis overlap of two separate Difficult Development Area designations, each of which complied with the 20 percent cap for the respective years in which those designations were made, is consistent with the statutory intent of the 20 percent limitation.

Moreover, HUD has consistently interpreted the 20 percent caps as permitting minimal overruns because it is impossible to determine whether the 20 percent cap has been exceeded, so long as the apparent excess is small, due to measurement error. *See* 62 FR 203. Despite the care and effort involved in a decennial census, the Census Bureau and users of census data recognize that the population counts for a given area are not precise. The actual extent of the measurement error is unknown. Thus, there can be errors in both the numerator and the denominator of the ratio of populations used in applying a 20 percent cap. In circumstances where a strict application of a 20 percent cap results in an anomalous situation, recognition of the unavoidable imprecision in the census data justifies accepting small variations above the 20 percent limit. Here, similarly, a strict application of the 20 percent cap would prevent the proposed accommodation and prevent the efficient administration of the statute.

Effective Date

This amendment is effective immediately.

A governmental unit continues to be obligated under § 42(m)(2) of the Code to ensure that the amount of credit attributable to a project affected by this Notice does not exceed the amount necessary for the financial feasibility of the project and its viability as a qualified low-income housing project throughout the credit period.

Other Matters

Environmental Impact

In accordance with 40 CFR 1508.4 of the CEQ regulations and 24 CFR 50.19(c)(6) of the HUD regulations, the policies and procedures contained in this notice provide for the establishment of fiscal requirements or procedures which do not constitute a development decision that affects the physical condition of specific project areas or building sites and therefore, are categorically excluded from the requirements of the National Environmental Policy Act, except for extraordinary circumstances, and a Finding of No Significant is not required.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this notice does not have a significant economic impact on a substantial number of small entities. The notice involves the designation of Difficult Development Areas as required by section 42 of the Code, as amended, for use by political subdivisions of the States in allocating the Low-Income Housing Tax Credit. This notice places no new requirements on the States, their political subdivisions, or the applicants for the credit.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism,* has determined that the policies contained in this notice will not have any substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the

distribution of power and responsibilities among the various levels of government. As a result, the notice is not subject to review under the order. The notice merely designates Difficult Development Areas as required under section 42 of the Code, as amended, for the use by political subdivisions of the States in allocating the Low-Income Housing Tax Credit. The notice also details the technical methodology used in making such designations.

Dated: July 1, 1999.

Andrew M. Cuomo,

Secretary.

[FR Doc. 99–17180 Filed 7–1–99; 2:55 pm]

BILLING CODE 4210–32–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Acceptance of Contribution for Geologic Mapping

AGENCY: United States Geological Survey, Interior.

ACTION: Notice of acceptance of contributed funds.

SUMMARY: The U.S. Geological Survey (USGS) announces that it has accepted a contribution of $18,500 from the Yosemite Association towards the publication of a geologic map of the Tower Peak Quadrangle in Yosemite National Park. The USGS would be pleased to consider contributions from other sources for similar purposes.

FOR FURTHER INFORMATION CONTACT: Mr. Donald Gautier, Chief Scientist, USGS Western Geologic Mapping Team, 345 Middlefield Road, Mail Stop 975, Menlo Park, CA 94023, Phone (650) 329–4909.

SUPPLEMENTARY INFORMATION: None.

Dated: May 27, 1999.

P. Patrick Leahy,

Chief Geologist, U.S. Geological Survey.

[FR Doc. 99–17042 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–Y7–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Approval of Petition for Reassumption of Exclusive Jurisdiction by the Chevak Traditional Council of Chevak, Alaska Over Indian Child Custody Proceedings Involving Indian Children Who Are Enrolled or Eligible for Enrollment With the Chevak Traditional Council of Chevak, Alaska and Who Reside or are Domiciled within the Native Village of Chevak, State of Alaska

AGENCY: Bureau of Indian Affairs, Interior, DOI.

ACTION: Notice.

SUMMARY: The Chevak Traditional Council of Chevak, Alaska has filed a petition with the Department of the Interior to reassume exclusive jurisdiction over Indian child custody proceedings involving Indian children who are enrolled or eligible for enrollment with the the Chevak Traditional Council of Chevak, Alaska and who reside or are domiciled within the Native Village of Chevak, Alaska.

The Assistant Secretary—Indian Affairs has reviewed the petition and determined that tribal exercise of jurisdiction is feasible and that the tribe has a suitable plan for exercising such jurisdiction. This notice constitutes the official approval of the Chevak Traditional Council of Chevak's petition by the Department of the Interior.

EFFECTIVE DATE: The Chevak Traditional Council of Chevak reassumes exclusive jurisdiction September 7, 1999.

FOR FURTHER INFORMATION CONTACT: The principal author of this document is Larry Blair, Bureau of Indian Affairs, Division of Social Services, 1849 C Street, NW, room 4603 MIB, Washington, DC 20240, (202) 208–2479.

SUPPLEMENTARY INFORMATION: The authority for the Assistant Secretary—Indian Affairs to publish this notice is contained in 25 CFR 13.14 and 209 DM 8. Section 108 of the Indian Child Welfare Act of 1978, Pub. L. 95–608, 92 Stat. 3074, 25 U.S.C. 1918, authorizes Indian tribes that occupy a reservation as defined in 25 U.S.C. 1903(10) over which a state asserts jurisdiction over Indian child custody proceedings, pursuant to Federal statute, to reassume jurisdiction over such proceedings.

To reassume such jurisdiction, a tribe must first file a petition in the manner prescribed in 25 CFR Part 13. Notice of receipt of this petition was published in the **Federal Register**, Vol 62, No. 71, page 1478, on January 10, 1997. The petition is then reviewed by the Department of the Interior using criteria set out in 25 CFR 13.12. If the Department finds that the tribe has submitted a suitable plan and that tribal exercise of jurisdiction is feasible, the petition is approved by publication in the **Federal Register**.

The geographic area subject to the reassumption of exclusive jurisdiction by the Chevak Traditional Council of Chevak, Alaska is the Native Village of Chevak.

Dated: June 28, 1999.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 99–16994 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Approval of Petition for Reassumption of Exclusive Jurisdiction by the Native Village of Barrow Over Indian Child Custody Proceedings Involving Indian Children who are Enrolled or Eligible for Enrollment With the Native Village of Barrow and who Reside or are Domiciled Within the Native Village of Barrow in the State of Alaska

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Native Village of Barrow, Alaska has filed a petition with the Department of the Interior to reassume exclusive jurisdiction over Indian child custody proceedings involving Indian children who are enrolled or eligible for enrollment with the Native Village of Barrow and who reside or are domiciled within the Native Village of Barrow in the State of Alaska.

The Assistant Secretary—Indian Affairs has reviewed the petition and determined that tribal exercise of jurisdiction is feasible and that the tribe has a suitable plan for exercising such jurisdiction. This notice constitutes the official approval of the Native Village of Barrow's petition by the Department of the Interior.

EFFECTIVE DATE: The Native Village of Barrow reassumes exclusive jurisdiction September 7, 1999.

FOR FURTHER INFORMATION CONTACT: The principal author of this document is Larry Blair, Bureau of Indian Affairs, Division of Social Services, 1849 C Street, N.W., room 4603 MIB, Washington, D.C. 20240. (202) 208–2479.

SUPPLEMENTARY INFORMATION: The authority for the Assistant Secretary—

Indian Affairs to publish this notice is contained in 25 CFR 13.14 and 209 DM 8. Section 108 of the Indian Child Welfare Act of 1978, Pub. L. 95–608, 92 Stat. 3074, 25 U.S.C. 1918, authorizes Indian tribes that occupy a reservation as defined in 25 U.S.C. 1903(10) over which a state asserts jurisdiction over Indian child custody proceedings, pursuant to Federal statute, to reassume jurisdiction over such proceedings.

To reassume such jurisdiction, a tribe must first file a petition in the manner prescribed in 25 CFR Part 13. Notice of receipt of this petition was published in the **Federal Register**, Vol 63, No. 213, page 59574, on November 4, 1998. The petition is then reviewed by the Department of the Interior using criteria set out in 25 CFR 13.12. If the Department finds that the tribe has submitted a suitable plan and that tribal exercise of jurisdiction is feasible, the petition is approved by publication in the **Federal Register.**

The geographic area subject to the reassumption of exclusive jurisdiction by the Native Village of Barrow is the Native Village of Barrow in the State of Alaska.

Dated: June 28, 1999.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 99–16995 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–030–1310–00]

Continental Divide/Wamsutter II Natural Gas Project

AGENCY: Bureau of Land Management, Interior.

ACTION: Extension of comment period for Draft Environmental Impact Statement.

SUMMARY: On April 30, 1999, the Bureau of Land Management (BLM) published a notice in the **Federal Register (Federal Register**, Vol. 64, No. 83, page 23349, April 30, 1999) announcing the availability of the Continental Divide/ Wamsutter II Natural Gas Project Draft Environmental Impact Statement (DEIS) and providing 60 days for review and comment by the public.

The U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the Wyoming Outdoor Council, the Wyoming Wildlife Federation, and Biodiversity Associates all have requested extension of the comment period. BLM has considered those requests and decided to extend that comment period for two weeks.

DATES: Written comments on the DEIS will be accepted until July 15, 1999.

ADDRESSES: Send written comments to: Clare Miller, Team Leader, Rawlins Field Office, Bureau of Land Management, 1300 N. Third Street, P.O. Box 2407, Rawlins, Wyoming 82301.

FOR FURTHER INFORMATION CONTACT: Clare Miller, phone 307–328–4245, or Teresa Deakins, phone 307–352–0211.

Dated: June 29, 1999.

Bill G. Daniels,

Acting,State Director.

[FR Doc. 99–16987 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–930–1430–01; COC–28673]

Public Land Order No. 7397; Opening of Land Under Section 24 of the Federal Power Act; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order opens, subject to the provisions of Section 24 of the Federal Power Act, 90 acres of National Forest System land withdrawn by a Geological Survey Order which established the Bureau of Land Management's Power Site Classification No. 441. This action will permit consummation of a pending Forest Service land exchange and retain the waterpower rights to the United States. The land has been and will continue to be open to mineral leasing and, under the provisions of the Mining Claims Rights Restoration Act of 1955, to mining.

EFFECTIVE DATE: August 5, 1999.

FOR FURTHER INFORMATION CONTACT: Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215–7076.

By virtue of the authority vested in the Secretary of the Interior of the Interior by the act of June 20, 1920, Section 24, as amended,16 U.S.C. 818 (1994), and pursuant to the determination of the Federal Regulatory Commission in DVCO–550–000, it is ordered as follows:

1. At 9 a.m. on August 5, 1999, the following described National Forest System land withdrawn by Geological Survey Order dated January 23, 1958, which established Power Site Classification No. 441, will be opened to disposal subject to the provisions of Section 24 of the Federal Power Act as specified by the Federal Energy Regulatory Commission determination DVCO–550–000, and subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law:

New Mexico Principal Meridian

Rio Grande National Forest

T. 40 N., R. 1 W.,
Sec. 19, NE¼NE¼, NE¼SW¼NE¼, N½ NW¼SW¼NE¼, N½SE¼NW¼, SW¼SE¼NW¼ and W½SE¼SE¼NW¼.

The area described contains approximately 90 acres in Mineral County.

Dated: June 8, 1999.

John Berry,

Assistant Secretary of the Interior.

[FR Doc. 99–17043 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–924–1430–01; SDM 42963 and SDM 43040]

Public Land Order No. 7398; Partial Revocation of Secretarial Orders Dated March 4, 1904 and April 9, 1914; South Dakota

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order partially revokes two Secretarial orders insofar as they affect 51.62 acres of public lands withdrawn for the Bureau of Reclamation's Belle Fourche Reclamation Project. The lands are no longer needed for this purpose and the revocation is needed to permit disposal of the lands through exchange. This action will open 11.52 acres to surface entry and 40 acres to surface entry and mining, subject to temporary segregations of record. The lands have been and will remain open to mineral leasing.

EFFECTIVE DATE: August 5, 1999.

FOR FURTHER INFORMATION CONTACT: Sandra Ward, BLM Montana State Office, P.O. Box 36800, Billings, Montana 59107, 406–255–2949.

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 (1994), it is ordered as follows:

1. The Secretarial Orders dated March 4, 1904 and April 9, 1914, which withdrew public lands for the Bureau of

Reclamation's Belle Fourche Reclamation Project, are hereby revoked insofar as they affect the following described lands:

Black Hills Meridian, South Dakota

(a) T. 7 N., R. 8 E.,
Sec. 7, lot 6.
(b) T. 8 N., R. 6 E.,
Sec. 20, NE¼SE¼.

The areas described aggregate 51.62 acres in Butte and Meade Counties.

2. At 9 a.m. on August 5, 1999, the lands described in paragraph 1(a) and 1(b) will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. on August 5, 1999, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

3. At 9 a.m. on August 5, 1999, the lands described in paragraph 1(a) will be opened to location and entry under the United States mining laws, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of any land described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1994), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: June 8, 1999.

John Berry,

Assistant Secretary of the Interior.

[FR Doc. 99–17044 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–921–1430–01; WYW 71437; WYW 71438; WYW 71439; WYW 71440; WYW 72565; WYW 72569; WYW 72573; WYW 72580; WYW 72587; WYW 72590; WYW 72591; WYW 72592; WYW 72593; WYW 72599; WYW 72600]

Public Land Order No. 7396; Partial Revocation of Secretarial Orders dated August 1, 1905, October 21, 1913, February 19, 1916, May 2, 1919, April 20, 1928, April 2, 1929, and August 30, 1956, and Revocation of Secretarial Orders dated May 18, 1923, December 30, 1926, October 25, 1930, December 20, 1946, September 19, 1947, June 14, 1951, and Public Land Order Nos. 3061, 3160, and 3292; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order revokes 7 Secretarial orders partially, and 6 Secretarial orders and 3 public land orders in their entirety, insofar as they affect 132,051.32 acres of public lands withdrawn for the Bureau of Reclamation's Shoshone Reclamation Project. The lands are no longer needed for reclamation purposes. Of the lands included in the revocation, 556.10 acres are within other overlapping withdrawals and will remain closed to surface entry and mining, and 128,155.68 acres will not be opened to surface entry and mining until the Bureau of Land Management completes a planning review. The lands have been and will remain open to mineral leasing. The remaining 3,339.54 acres have been conveyed out of Federal ownership.

EFFECTIVE DATE: July 6, 1999.

FOR FURTHER INFORMATION CONTACT: Janet Booth, BLM Wyoming State Office (WY 921), P.O. Box 1828, Cheyenne, WY 82003–1828, 307–775–6124.

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 (1994), it is ordered as follows:

1. The Secretarial Orders dated August 1, 1905, October 21, 1913, February 19, 1916, May 2, 1919, May 18, 1923, December 30, 1926, April 20, 1928, April 2, 1929, October 25, 1930, December 20, 1946, September 19, 1947, June 14, 1951, and August 30, 1956, and Public Land Order Nos. 3061, 3292, and 3160, which withdrew public lands for the Bureau of Reclamation's Shoshone Reclamation Project, are hereby revoked insofar as they affect the following described lands:

(a) Sixth Principal Meridian

T. 52 N., R. 96 W.,
Tracts 40N and 40P;
Tracts 41N, 41P, 41R, and 41T;
Tracts 42O, 42Q, 42S, and 42U;
Tracts 105O, 105P, and Tracts 105U to 105Z, inclusive;
Tract 106;
Tracts 107A to 107H, inclusive;
T. 53 N., R. 96 W.,
Sec. 34, lots 1 and 2;
Sec. 35, lots 1 to 4, inclusive, NE¼NW¼, NW¼NE¼, E½NW¼NW¼, and W½NE¼NE¼;
Sec. 36, lots 1 to 4, inclusive;
Tracts 40A to 40M, inclusive, and Tract 40O;
Tracts 41A to 41M, inclusive, Tracts 41O, 41Q, and 41S;
Tracts 42A to 42M, inclusive, Tracts 42P, 42R, and 42T;
Tracts 43A to 43D, inclusive, Tracts 43G to 43N, inclusive, Tracts 43R, 43S, 43U, and 43W.
T. 51 N., R. 97 W.,
Sec. 5, lots 7 to 12, inclusive, and lot 19;
Sec. 6, lots 14, 24, 25, and lots 34 to 37, inclusive;
Sec. 7, lots 10, 11, 41, and 42;
Tracts 75E to 75G, inclusive, and Tracts 75J to 75P, inclusive;
T. 52 N., R. 97 W.,
Sec. 1, lots 12 to 17, inclusive, lots 22 to 24, inclusive, lots 40 to 42, inclusive, and S½;
Sec. 2, lots 12 to 17, inclusive, lots 22 to 24, inclusive, lots 40 to 42, inclusive, and S½;
Sec. 3, lots 13 to 19, inclusive, lots 22 to 25, inclusive, lots 39, 41, 42, SE¼, and E½SW¼;
Sec. 4, lots 5 to 8, inclusive;
Sec. 5, lots 6, 8, 11, 12, 13, and 16;
Sec. 6, lots 8 to 15, inclusive;
Sec. 9, lot 9 and lots 21 to 23, inclusive;
Sec. 10, lots 16, 25, 26, 27, 28, E½, E½W½, and SW¼NW¼;
Sec. 11;
Sec. 12, lots 11, 12, 26, 27, N½, and NW¼SW¼;
Sec. 13, lots 26 to 29, inclusive, NW¼NW¼, S½NW¼, and SW¼;
secs. 14 and 15;
Sec. 16, lots 13 to 16, inclusive, and S½S½;
Sec. 17, lots 6 to 9, inclusive, lots 11 and 30, SW¼NE¼, S½NW¼, SW¼, NW¼SE¼, and S½SE¼;
Sec. 18, lots 10 to 14, inclusive, lots 24 and 35, SE¼NW¼, S½NE¼, SE¼, and E½SW¼;
Sec. 19, lots 9, 10, and lots 18 to 22, inclusive, NE¼, E½NW¼, NE¼SW¼, and N½SE¼;
Sec. 20, lots 14, 18, 25, 30, and 31, N½, and E½SE¼;
Sec. 21, lots 10, 11, 12, 23, 26, and 27, and N½;
Sec. 22, E½;
sec 23;
Sec. 24, lots 31 to 34, inclusive, NW¼NW¼, and NW¼SW¼;
Sec. 26, lot 34 and N½NW¼;
Sec. 27, lots 13, 14, lots 27 to 29, inclusive, and NE¼;
Sec. 28, lots 22, 32, and 33;

Sec. 29, lots 4 and 33;
Sec. 31, lot 31;
Sec. 32, lots 24 to 27, inclusive, lots 30 to 34, inclusive, SW¼, and NW¼SE¼;
Sec. 33, lots 1, 4, 10, 11, 12, and 28, and S½N½;
Tracts 38K to 38M, inclusive;
Tract 42N;
Tracts 43Q, 43T, 43V, and 43X;
Tracts 64A to 64C, inclusive;
Tracts 65A to 65J, inclusive;
Tracts 66A to 66D, inclusive, Tracts 66G to 66N, inclusive, and Tracts 66Q to 66T, inclusive;
Tracts 73A to 73D, inclusive;
Tracts 74A to 74L, inclusive;
Tracts 75B to 75D, inclusive;
Tracts 84A to 84H, inclusive;
Tracts 85A to 85D, inclusive, and Tracts 85G to 85J, inclusive;
Tracts 86A to 86D, inclusive, Tracts 86G to 86N, inclusive, and Tracts 86Q to 86T, inclusive;
Tracts 87A to 87P, inclusive;
Tracts 88A to 88L, inclusive;
Tracts 95A to 95P, inclusive;
Tracts 96A to 96J, inclusive;
Tracts 97A to 97D, inclusive, and Tracts 97G to 97J, inclusive;
Tracts 99A to 99D, inclusive, Tracts 99G to 99N, inclusive, and Tracts 99Q to 99T, inclusive;
Tracts 103A to 103H, inclusive;
Tracts 106A and 106B.

T. 53 N., R. 97 W.,
Sec. 33, E½;
Sec. 34;
Sec. 35, lots 2 and 3;
Tracts 38A to 38J, inclusive;
Tracts 43E, 43F, 43O, and 43P.

T. 50 N., R. 98 W.,
Sec. 6, lots 9, 10, and lots 14 to 16, inclusive;
Tracts 85S, 85U, and 85W.

T. 51 N., R. 98 W.,
Sec. 1, lots 15, 16, and 25;
Sec. 12, lots 1, 14, and 27;
Sec. 20, lots 12, 21, and 22;
Sec. 21, lot 16;
Sec. 31, lots 28 and 30;
Sec. 32, lot 31;
Tracts 62A to 62K, inclusive;
Tracts 63B, 63D, 63F, 63H, and Tracts 63I to 63T, inclusive;
Tracts 64B, 64D, 64F, 64H, and Tracts 64I to 64T, inclusive;
Tracts 65A to 65H, inclusive, and Tracts 65J to 65N, inclusive;
Tracts 66B to 66D, inclusive;
Tracts 67A to 67H, inclusive, and Tracts 67K to 67M, inclusive;
Tract 69;
Tracts 70B, 70D, 70F, and Tracts 70H to 70T, inclusive;
Tracts 71B, 71D, 71F, and Tracts 71H to 71T, inclusive;
Tract 72;
Tracts 75H and 75I;
Tract 76;
Tract 77;
Tract 78;
Tracts 79B, 79D, 79F, and Tracts 79H to 79T, inclusive;
Tracts 80B, 80D, 80F, 80H, Tracts 80L to 80S, inclusive, and Tracts 80V to 80Y, inclusive;
Tracts 81A to 81D, inclusive, Tracts 81G to 81N, inclusive, and Tracts 81Q to 81T, inclusive;
Tracts 82A to 82D, inclusive, Tracts 82G to 82N, inclusive, and Tracts 82Q to 82T, inclusive;
Tracts 83A to 83D, inclusive, Tracts 83G to 83N, inclusive, and Tracts 83Q to 83T, inclusive;
Tracts 84A to 84D, inclusive, Tracts 84G to 84N, inclusive, and Tracts 84Q to 84T, inclusive;
Tracts 85A to 85D, inclusive, Tracts 85G to 85N, inclusive, Tracts 85R, 85T, and 85V;
Tracts 91B and 91C.

T. 52 N., R. 98 W.,

T. 50 N., R. 99 W.,
Tracts 72A, 72B, 72G, and 72H;
Tract 73;
Tract 75;
Tract 76 (including those lots of Tract in T. 51 N., R. 99 W.);
Tracts 77M and 77N;
Tracts 87N, 87P, 87R, and 87T;
Tracts 88P and 88R.

T. 51 N., R. 99 W.,
Sec. 2, lots 17, 18, 25, and 26;
Sec. 7, lots 6, 7, 14, 15, 29, and 30;
Sec. 10, lots 16 and 27;
Sec. 11, lots 8 to 10, inclusive, lots 13, 16, 17, 21, 22, 25, 26, and 30, SW¼SE¼, and S½SW¼;
Sec. 14, lots 1 to 5, inclusive;
Tracts 38B, 38D, 38F, 38H, and Tracts 38I to 38S, inclusive;
Tracts 39B, 39D, 39F, and Tracts 39H to 39T, inclusive;
Tracts 40B, 40D, 40F, and Tracts 40H to 40T, inclusive;
Tracts 41B, 41D, 41F, and Tracts 41H to 41T, inclusive;
Tracts 42A to 42P, inclusive;
Tracts 43A to 43P, inclusive;
Tracts 44A to 44P, inclusive;
Tracts 45A to 45F, inclusive;
Tracts 46A to 46H, inclusive, and Tract 46P;
Tracts 47A, 47E, 47H, 47I, and Tracts 47L to 47P, inclusive;
Tracts 48A to 48J, inclusive, Tracts 48O and 48P;
Tracts 49A to 49P, inclusive;
Tracts 51A to 51P, inclusive;
Tracts 53A to 53C, inclusive,
Tracts 53F to 53L, inclusive, and Tracts 53O to 53R, inclusive;
Tracts 54A to 54D, inclusive, Tracts 54G to 54N, inclusive, and Tracts 54Q to 54T, inclusive;
Tracts 55A to 55D, inclusive, Tracts 55G to 55N, inclusive, and Tracts 55Q to 55T, inclusive;
Tracts 56A to 56P, inclusive;
Tracts 57A to 57P, inclusive;
Tracts 58A to 58I, inclusive, and Tracts 58O to 58P, inclusive;
Tracts 59A to 59P, inclusive;
Tracts 60A to 60P, inclusive;
Tracts 61A to 61P, inclusive;
Tracts 62A to 62P, inclusive;
Tracts 63A, 63B, Tracts 63G to 63I, inclusive, and Tract 63P;
Tracts 64A to 64H, inclusive;
Tracts 65A to 65H, inclusive;
Tracts 66A to 66D, inclusive, and Tracts 66G to 66J, inclusive;
Tracts 69B, 69D, 69F, and Tracts 69H to 69T, inclusive;
Tracts 70B, 70D, 70F, 70I, Tracts 70M to 70T, inclusive, and Tracts 70W to 70Z, inclusive;
Tracts 80J and 80K;
Tracts 81O and 81P;
Tracts 82E, 82F, 82O and 82P;
Tracts 83E, 83F, 83O and 83P;
Tracts 84E, 84F, 84O and 84P;
Tracts 85E, 85F, and Tracts 85O to 85Q, inclusive;
Tracts 87A to 87M, inclusive, Tracts 87O, 87Q, and 87S;
Tract 88A, Tracts 88H to 88J, inclusive, Tracts 88O and 88Q.

T. 52 N., R. 99 W.,
Sec. 1, lots 5 to 13, inclusive, lot 16, lots 19 to 21, inclusive, lots 34 and 36, and NW¼SW¼;
Sec. 2, lots 5, 8, and 9, lots 12 to 20, inclusive, and S½;
Sec. 3, S½S½;
Sec. 4, S½S½;
Sec. 8, lot 1, N½SE¼, and SW¼SE¼;
Sec. 9, lots 1 to 3, inclusive, lots 12 to 14, inclusive, N½N½, SW¼NW¼, and NW¼SW¼;
Sec. 10, lots 1 to 4, inclusive, and N½N½;
Sec. 11, lots 1 to 4, inclusive, and N½N½;
Sec. 12, lots 6 and 7;
Sec. 17, lots 2, 3, 6, 8, 9, and 12, NW¼, W½NE¼, N½SW¼, and W½SE¼;
Sec. 18, lots 5 to 9, inclusive, lot 12, E½W½, NE¼, and N½SE¼;
Sec. 19, lots 8 to 12, inclusive, lots 14, 22, and 24;
Sec. 20, lots 1, 5, and 6;
Sec. 21, lots 5, 6, 25, and 26;
Tracts 38A, 38C, 38E, and 38G;
Tracts 39A, 39C, 39E, and 39G;
Tracts 40A, 40C, 40E, and 40G;
Tracts 41A, 41C, 41E, and 41G;
Tracts 43A to 43P, inclusive; Tracts 44A to 44P, inclusive;
Tracts 45A to 45P, inclusive; Tracts 46A to 46P, inclusive;
Tracts 48A to 48C, inclusive, Tracts 48H to 48M, inclusive, and Tracts 48R to 48T, inclusive;
Tracts 49B to 49D, inclusive,
Tracts 49G to 49N, inclusive, Tract 49Q, and Tracts 49S to 49U, inclusive;
Tracts 50E, 50F, and Tracts 50I to 50P, inclusive;
Tracts 51E, 51F, 51O, and 51P;
Tracts 52E, 52F, 52O, and 52P;
Tracts 53A to 53P, inclusive;
Tracts 54A to 54P, inclusive;
Tracts 55A to 55P, inclusive;
Tracts 56A to 56P, inclusive;
Tracts 57A to 57P, inclusive;
Tracts 58A to 58P, inclusive;
Tracts 59A to 59P, inclusive;
Tracts 60A to 60N, inclusive;
Tracts 61A to 61F, inclusive;
Tracts 62A to 62F, inclusive;
Tracts 64A to 64P, inclusive;
Tracts 65A to 65P, inclusive;
Tracts 66A to 66P, inclusive;
Tracts 67E, 67F, 67O, and 67P,
Tracts 68E, 68F, 68O, and 68P;
Tracts 69A, 69C, 69E, and 69G;
Tracts 70A, 70C, 70E, and 70H;
Tracts 71A to 71N, inclusive;
Tracts 72A to 72H, inclusive;

Tracts 73A to 73H, inclusive;
Tracts 74A to 74D, inclusive;
Tracts 75A to 75D, inclusive;
Tract 80, lot 1;
Tracts 82E, and 82F;
Tracts 92E, 92F, 92O, and 92P.
T. 51 N., R. 100 W.,
Sec. 1, lots 2 to 11, inclusive, SW¼NE¼, SE¼NW¼, NE¼SW¼, NW¼SE¼, and SW¼SE¼;
Sec. 2, lots 1 to 6, inclusive;
Sec. 12, lots 1, 2, 5, 6, NW¼NE¼, and SW¼NE¼;
Tracts 40A to 40D, inclusive;
Tracts 41A to 41D, inclusive;
Tracts 42A to 42D, inclusive;
Tracts 43A to 43D, inclusive;
Tracts 44A to 44D, inclusive;
Tracts 45A to 45D, inclusive;
Tracts 53D, 53E, 53M and 53N;
Tracts 54E, 54F, 54O and 54P;
Tracts 55E, 55F, 55O and 55P;
Tracts 66E and 66F;
Tracts 70K, 70L, 70U, and 70V.
T. 52 N., R. 100 W.,
Sec. 5, lots 8 to 11, inclusive;
Sec. 6, lots 1 to 3, inclusive;
Sec. 7, lots 1 to 5, inclusive, and E½NE¼;
Sec. 8, N½;
Sec. 9, lots 1 to 4, inclusive, N½, and NE¼SE¼;
Secs. 10, 11, 13, 14, 15;
Sec. 16, lots 1 to 7, inclusive;
Sec. 17, lots 3 and 4, S½SW¼, SW¼SE¼, and N½SW¼;
Sec. 18, lots 3, 4, N½SE¼, N½NE¼SW¼, S½NE¼SW¼, SE¼SW¼, and S½SE¼;
Sec. 19, lots 1 to 4, inclusive, E½, and E½W½;
Secs. 20, 21, and 22;
Sec. 23, NW¼, and N½NE¼;
Sec. 24, lots 1, and 3, N½NW¼, NE¼, SW¼, and W½SE¼;
Sec. 25, lots 2 to 7, inclusive, NW¼, and W½NE¼;
Sec. 26, lot 1, E½NE¼, and NW¼NE¼;
Secs. 27, 28, and 29;
Sec. 30, lots 1 to 4, inclusive, E½W½, and E½;
Sec. 31, lots 1 to 4, inclusive, E½, E½NW¼, and E½SW¼;
Sec. 32;
Sec. 33, N½, N½S½, and S½S½;
Sec. 34, NW¼, E½, N½SW¼, and S½SW¼;
Sec. 35, lots 3 and 4, SW¼NW¼, SW¼, and SW¼SE¼;
Sec. 36, lots 5 to 8, inclusive;
Tract 39;
Tracts 40Q to 40T, inclusive;
Tract 41Q;
Tract 43C;
Tracts 44A to 44P, inclusive;
Tracts 48D to 48G, inclusive, and Tracts 48N to 48Q, inclusive;
Tracts 49E, 49F, 49O, and 49P;
Tract 70J.
T. 53 N., R. 100 W.,
Sec. 7, lots 8, 12, 13, and 14, and E½SW¼ (formerly lots 4, 6, 7, 52, and SE¼SW¼);
Sec. 19, lots 7 and 8;
Sec. 30, lots 5 to 8, inclusive;
Sec. 31, lots 5 to 8, inclusive;
Sec. 33, lots 1 to 4, inclusive;
Tracts 40A to 40P, inclusive;
Tracts 41A, 41E, 41F, 41H, 41I, 41K to 41N, inclusive, and Tracts 41P;
Tracts 44A to 44L, inclusive, and Tracts 44N to 44P, inclusive;
Tracts 45A to 45P, inclusive;
Tracts 46A to 46P, inclusive;
Tracts 47A to 47P, inclusive.
T. 54 N., R. 100 W.,
Sec. 31, lots 6, 10, 11, and 37A;
Tracts 39A, 39D, 39E, and 39H;
Tracts 41A, 41G, 41H, and 41L;
Tracts 43B and 43E;
Tracts 58A to 58C, inclusive.
T. 52 N., R. 101 W.,
Sec. 1, lot 1;
Sec. 6, lots 2 to 4, inclusive;
Sec. 7, lots 1 to 3, inclusive, E½NW¼, W½NE¼, and SE¼NE¼;
Sec. 9, lots 2 to 4, inclusive;
Sec. 11, lots 1 to 6, inclusive;
Sec. 12, lots 1 to 4, inclusive, E½NE¼, and S½;
Sec. 13, SE¼;
Sec. 14, lots 1, 2, E½NW¼, NE¼, and S½;
Sec. 15, lots 1 to 6, inclusive;
Sec. 16, lots 1 to 6, inclusive, and E½SE¼;
Sec. 17, lots 1 to 5, inclusive, W½W½, and SE¼SW¼;
Sec. 20, E½;
Sec. 21, lots 1 to 4, inclusive, NW¼SW¼, NW¼, and NW¼NE¼;
Sec. 22, lots 1 to 7, inclusive, lot 65, and E½E½;
Sec. 23;
Sec. 24, E½NE¼, E½SW¼NE¼, E½SE¼, E½W½SE¼, NW¼NE¼, W½SW¼NE¼, and W½W½SE¼;
Sec. 25, E½;
Sec. 26;
Sec. 27, lots 1 to 7, inclusive, E½E½, and SW¼SE¼;
Sec. 28, lots 1 to 3, inclusive, NW¼NW¼, S½N½, and S½;
Sec. 29, NW¼NE¼, E½NE¼, and E½SE¼;
Sec. 32, E½NE¼ and NE¼SE¼;
Sec. 33, lot 3 and W½W½;
Sec. 36, lots 1 to 5, inclusive;
Tracts 46E and 46F;
Tract 55J.
T. 53 N., R. 101 W.,
Sec. 12, lot 6, and lots 36 to 38, inclusive, (formerly lots 6, 7, 13);
Sec. 36, lots 1 to 6, inclusive, and E½NE¼.
T. 52 N., R. 102 W.,
Sec. 1, SE¼SE¼ and S½NE¼SE¼;
Sec. 11, lots 1 and 2;
Sec. 12, E½NE¼;
Sec. 27, lot 2, S½, S½NW¼, and SW¼NE¼;
Sec. 28, lot 5, N½SE¼, S½NE¼, and SE¼SE¼.

The areas described aggregate 128,711.78 acres in Park and Big Horn Counties.

(b) Sixth Principal Meridian

T. 52 N., R. 96 W.,
Tracts 105K to 105N, inclusive, and Tracts 105Q to 105T, inclusive;
Tract 107I to 107N, inclusive;
Tract 108A and 108B.
T. 53 N., R. 96 W.,
Tract 37;
Tract 38A to 38E, inclusive, Tracts 38H, 38I, and 38L;
Tract 39A and Tracts 39D to 39F, inclusive.
T. 51 N., R. 97 W.,
Sec. 7, lots 9, 13, and 14.
T. 52 N., R. 97 W.,
Sec. 27, lot 26 and E½NW¼;
Tract 83.
T. 53 N., R. 97 W.,
Tract 37.
T. 51 N., R. 98 W.,
Tract 46, lots 2, 23, and 26;
T. 52 N., R. 101 W.,
Sec. 6, lot 1;
Sec. 9, lot 1.

The areas described aggregate 3,339.54 acres in Park and Big Horn Counties. The total areas described in 1(a) and 1(b) aggregate 132,051.32 acres in Park and Big Horn Counties.

2. Of the lands described in Paragraph 1(a), 556.10 acres are within overlapping withdrawals and will remain closed to surface entry and mining, and 128,155.68 acres will not be opened to surface entry and mining until a planning review and an analysis are completed to determine if any of the lands need special designation and protection or have exchange potential.

3. The lands described in Paragraph 1(b) have been conveyed out of Federal ownership and this is a record-clearing action only.

Dated: June 8, 1999.

John Berry,

Assistant Secretary of the Interior.

[FR Doc. 99–16946 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–930–1430–01; N–1017, N–65608]

Notice of Realty Action; Nevada

AGENCY: Bureau of Land Management, DOI.

ACTION: Direct sale of reversionary interest in previously patented public land in Nye County, Nevada.

SUMMARY: The following described land in Nye County, Nevada, patented to the Nye County under provisions of the Recreation and Public Purposes Act, as amended, has been examined and found suitable for elimination of the reversionary clause in the patent, under provisions of section 203 and section 209 of the Federal Land Policy and Management Act (FLPMA) of October 21, 1976 (43 U.S.C. 1713 and 1719).

Mount Diablo Meridian, Nevada

T. 2 N., R. 42 E.,
Tract 37;
Consisting of 11.71 acres, more or less.

The above-described interest in the land would be conveyed directly to the present owner of record, Nye County. This interest will not be conveyed until at least 60 days after the date of

publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Kathy Sladish, Land Law Examiner, Bureau of Land Management, Battle Mountain Field Office, 50 Bastian Road, Battle Mountain, NV, 89820, (775) 635–4029.

SUPPLEMENTARY INFORMATION: The land was patented in 1990 for use as a hospital, museum and senior garden. The patent (number 27–90–0147) includes a clause providing for title to the land to revert to the United States if the approved plan of development is not followed. The land has been substantially altered to the point where management by the Bureau of Land Management would not be feasible. The land is not needed for any resource program and is not suitable for management by another Federal department or agency. It would be difficult and uneconomic to manage, if title reverted to the United States.

Nye County has requested full title to the subject parcel. This application to purchase the reversionary interest of the United States also constitutes an application for conveyance of the mineral interests. The applicant will be required to submit a $50.00 nonrefundable filing fee for conveyance of the mineral interest. Payment by Nye County of other fees associated with this transaction will also be required.

Upon publication of this Notice of Realty Action in the **Federal Register**, the lands will be segregated from all forms of appropriation under the public land laws, including the mining laws, pursuant to sections 203 and 209 of FLPMA. The segregation shall terminate upon issuance of a supplemental patent or other document of conveyance, upon publication in the **Federal Register** of a termination of segregation, or 270 days from date of this publication, which ever occurs first.

Patent, when issued, will contain the following reservations to the United States:

1. A right-of-way for ditches and canals constructed by the authority of the United States, Act of August 30, 1890, (43 U.S.C. 945);

2. A right-of-way for sewer line purposes, NEV–059832, and all appurtenances thereto, constructed by the United States through, over, or upon the land so patented, and the right of the United States, its agents or employees, to maintain, operate, repair or improve the same so long as needed or used for or by the United States.

And will be subject to:

1. Those rights for highway purposes granted to the Nevada Highway Department, its successors or assigns, by right-of-way NEV–057876, pursuant to the Act of August 27, 1958 (23 U.S.C. 317).

2. Those rights for power line purposes which have been granted to Sierra Pacific Power Company, its successors or assigns, by right-of-way N–4879, pursuant to the Act of March 4, 1911, as amended (formerly U.S.C. 961).

3. Those rights for power line purposes which have been granted to Sierra Pacific Power Company, its successors or assigns, by right-of-way N–51997, pursuant to the Act of October 21, 1976. (43 U.S.C. 1761).

4. Those rights for power line purposes which have been granted to Tonopah Public Utilities, its successors or assigns, by right-of-way N–52046, pursuant to the Act of October 21, 1976, (43 U.S.C. 1761).

5. All other valid existing rights.

For a period of 45 days from the date of publication in the **Federal Register**, interested parties may submit comments to the Field Manager, Battle Mountain District, 50 Bastian Road, Battle Mountain, NV 89820. Any adverse comments will be evaluated by the State Director, who may sustain, vacate or modify this realty action and issue a final determination. In the absence of timely filed objections, this realty action will become a final determination of the Department of the Interior.

Dated: June 24, 1999.

M. Lee Douthit,

Associate Field Manager.

[FR Doc. 99–16947 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–330–7123–00–6067]

Samoa Dunes Recreation Area and Eureka Dunes Riding Area, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Establishment of supplementary rules.

SUMMARY: The primary purpose of these supplementary rules is the enhancement of public safety and the protection of natural resources within and around the public lands commonly known as the Samoa Dunes Recreation Area and Eureka Dunes Riding Area. Both areas have been designated for the primary use of off-highway vehicles. Potential safety hazards to pedestrians and off-highway vehicles were identified, mainly due to the poor visibility of off-highway vehicles utilizing the dunes, trails and roads of these areas. The use of whip masts and flags, to enhance off-highway vehicle visibility, would greatly reduce the potential for accidents involving off-highway vehicles. The supplementary rule requiring whip masts and flags has been worded to complement and be consistent with a similar Bureau of Land Management regulation being used at the Imperial Dunes Recreation Area, El Centro, California (**Federal Register**/Vol. 53, No. 192, page 38953, Tuesday, October 4, 1988) and a similar State regulation affecting the Pismo Dunes Recreation (14 CFR 4609.1(c)).

Also, off-highway vehicles have been willfully disregarding signs, fences and other similar interpretive/physical barriers erected to prevent off-highway vehicles from entering sensitive biological areas and adjacent areas of private property. The prohibition against vehicle barrier violations will serve to protect and preserve public and private property concerns.

In addition to the regulations contained in 43 CFR Part 8340, 8341, 8343, 8365 and 9268, the California Vehicle Code and additional supplementary rules established by the Arcata Field Office, the following supplementary rules shall apply to the Samoa Dunes Recreation Area and Eureka Dunes Riding Area:

1. *Safety flags, whips and masts:* All off-highway motor vehicles registered under California Vehicle Code Section 38010 or other off-road vehicles, as defined in 43 CFR 8340.0–5(a) shall be equipped with a whip, which is any pole, rod, mast or antenna, that is securely mounted on the vehicle and which extends at least eight (8) feet from the surface of the ground when the vehicle is stopped. When the vehicle is stopped, the whip shall be capable of standing upright when supporting the weight of any attached flags. At least one whip attached to each vehicle shall have a solid red or orange colored safety flag with a minimum size of six (6) inches by twelve (12) inches and be attached within ten (10) inches to the top of the whip. Flags may be of pennant, triangle, square or rectangular shape. Club or other flags may be mounted below the safety flag or on a separate whip.

2. *Vehicle Barriers:* Taking any vehicle through, around, or beyond any structure, restrictive sign, recognizable barricade, fence, gate or traffic control barrier is prohibited. These actions affect approximately 412 acres of public land located in the Samoa Dunes Recreation Area and Eureka Dunes

Riding Area (T.5N., R.1W., Section 31 and T.5N., R.1W., Section 30/31, Humboldt Meridian).

EFFECTIVE DATE: July 1, 1999.

FOR FURTHER INFORMATION CONTACT: Bruce Cann, Outdoor Recreation Planner, or Michael Dodson, Law Enforcement Ranger, Bureau of Land Management, Arcata Field Office, 1695 Heindon Road, Arcata, California 95521, (707) 825–2300.

SUPPLEMENTARY INFORMATION: The authority for establishing supplementary rules is contained in 43 CFR 8365.1–6. Copies of these rules will be available in the Arcata Field Office. These rules will also be posted near and/or within the lands, sites or facilities affected in the Samoa Dunes Recreation Area and Eureka Dunes Riding Area. Violations of supplementary rules established under authority of 43 CFR 8365.1–6 are punishable by a fine not to exceed $10,000 and/or imprisonment not to exceed 12 months, under authority of 43 CFR 8360.7.

Daniel Averill,

Acting Arcata Field Manager.

[FR Doc. 99–16988 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

$670,000 in Funding Assistance for Non-Federal Acquisition of Civil War Battlefield Land

AGENCY: National Park Service, Interior.

ACTION: Availability of funding for acquisition of Civil War battlefield land.

SUMMARY: The National Park Service (NPS) announces the availability of $670,000 to assist States and local communities in acquiring for permanent protection lands, or interests in lands, at significant Civil War battlefield sites.

ADDRESSES: Funding proposals should be mailed to: Hampton Tucker, National Park Service, American Battlefield Protection Program, 1849 C Street, NW, NC–330, Washington, DC 20240, telephone (202) 343–3580.

FOR FURTHER INFORMATION: Hampton Tucker, National Park Service, American Battlefield Protection Program, 1849 C Street, NW, NC–330, Washington, DC 20240, telephone (202) 343–3580.

SUPPLEMENTARY INFORMATION: Under the 1999 Interior Appropriations Act (Public Law 105–83), Congress appropriated $8 million from the Land & Water Conservation Fund to assist non-Federal efforts to acquire and preserve Civil War battlefield lands. The Congress has assigned most of these funds to specific projects. It reserved $670,000 of the total and has asked the National Park Service to assign those funds. NPS seeks proposals from State and local governments—or from qualified non-profit historic preservation organizations acting through an agency of State or local government—for the non-federal acquisition of significant Civil War battlefield land. Project proposals are subject to the following requirements.

1. The 1999 Appropriations Act requires that these funds be matched on a two-for-one basis with non-federal dollars. That is, the federal dollars can pay for no more than one-third of the acquisition cost.

2. The purchase price must be supported by a qualified appraisal that has been approved by NPS as meeting the Uniform Appraisal Standards for Federal Land Acquisitions.

3. The battlefield land acquired with the assistance of these funds must be permanently protected from inappropriate development.

NPS will give priority to acquisition of land, or interests in land, within the "core" areas of Priority I and Priority II battlefields, as identified by the Congressionally-chartered Civil War Sites Advisory Commission (see list below). Among potential projects NPS will give highest priority to acquisition projects that can be completed within the immediate future.

Proposals should be submitted by August 20,1999, and must include:

1. A carefully drawn map (preferably on a U.S.G.S. Quadrangle Map) that sets out the boundaries of the battlefield and identifies within those boundaries the specific lands to be acquired.

2. The number of acres of land to be acquired.

3. A description of the battle-related events that occurred on the land.

4. A statement of whether the owner of the land to be acquired has indicated a willingness to sell the land.

5. A statement of the owner's asking price and/or the estimated fair market value of the land to be acquired.

6. A statement of how much federal assistance from this program the applicant is requesting.

7. A statement of how much matching share is already on hand or firmly pledged.

Priority I Civil War Battlefields

ALABAMA

Mobile Bay (Ft Morgan & Blakeley)

ARKANSAS

Prairie Grove

GEORGIA

Allatoona, Chickamauga Kennesaw Mountain, Ringgold Gap

KENTUCKY

Mill Springs, Perryville

LOUISIANA

Port Hudson

MARYLAND

Antietam, Monocacy, South Mountain

MISSISSIPPI

Brices Cross Roads, Chickasaw Bayou, Corinth, Port Gibson, Raymond, Vicksburg

MISSOURI

Byram's Ford, Fort Davidson, Newtonia

NEW MEXICO

Glorieta Pass

NORTH CAROLINA

Bentonville, Fort Fisher

OKLAHOMA

Honey Springs

PENNSYLVANIA

Gettysburg

SOUTH CAROLINA

Secessionville

TENNESSEE

Chattanooga, Fort Donelson, Spring Hill

VIRGINIA

Boydton Plank Road, Brandy Station, Bristoe Station, Cedar Creek, Chaffin's Farm/New Market Heights, Chancellorsville, Cold Harbor, Deep Bottom II, Fisher's Hill, Gaines' Mill, Glendale, Kernstown I, Malvern Hill, Manassas, Second Mine Run, North Anna, Petersburg, Richmond, Spotsylvania Court House, White Oak Road, Wilderness

WEST VIRGINIA

Harpers Ferry, Rich Mountain

Priority II Civil War Battlefields

ARKANSAS

Chalk Bluff, Devil's Backbone, Elkin's Ferry, Marks' Mills, Prairie D'an

COLORADO

Sand Creek

GEORGIA

Dalton I, Davis' Cross Road, Griswoldville, Kolb's Farm, Lovejoy's Station, New Hope Church, Resaca, Rocky Face Ridge

KENTUCKY

Cynthiana, Munfordville, Richmond

LOUISIANA

Fort De Russy, Irish Bend, LaFourche Crossing, Mansfield, Mansura

MARYLAND

Boonsborough

MISSISSIPPI

Big Black River Bridge, Champion Hill, Grand Gulf, Okolona, Snyder's Bluff

MISSOURI

Carthage, Fredericktown, Lexington, Lone Jack, Newtonia

NEW MEXICO

Valverde

NORTH CAROLINA

Monroe's Cross Roads, Roanoke Island, Wyse Fork

OKLAHOMA

Chustenahlah

SOUTH CAROLINA

Grimball's Landing, Honey Hill

TENNESSEE

Brentwood, Fair Garden, Murfreesborough, Parker's Cross Roads, Thompson's Station

TEXAS

Sabine Pass II

VIRGINIA

Aquia Creek, Berryville, Buckland Mills, Cedar Mountain, Cool Springs, Cross Keys, Cumberland Church, Dinwiddie Courthouse, 1st Deep Bottom, Hampton Roads, Hatcher's Run, Haw's Shop, Lewis' Farm, Peebles' Farm, Piedmont, Port Republic, Port Walthall Junction, Ream's Station, Rice's Station, Sailor's Creek, Saltville, Suffolk (Hill's Point), Sutherland's Station, Swift Creek, Tom's Brook, Trevilian Station, Ware Bottom Church, White Oak Swamp

WEST VIRGINIA

Hoke's Run, Smithfield Crossing, Summit Point

Dated: June 30, 1999.

H. Bryan Mitchell,

Chief, American Battlefield Protection Program.

[FR Doc. 99–17041 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Capital Region; National Capital Memorial Commission; Notice of Public Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the national Capital Memorial Commission (the Commission) will be held at 2:00 p.m., on Thursday, July 22, at the National Building Museum, Room 312, 5th and F Streets, NW, Washington, DC.

The purpose of the meeting will be to discuss currently authorized and proposed memorials in the District of Columbia and environs.

In addition to discussing general matters and routine business, the agenda is expected to include the following:

I. Consultation: Memorial proponents will consult with the Commission on aspects of one authorized memorial:

(a) Site selection alternatives for the Benjamin Banneker Memorial along the L'Enfant Promenade.

II. The Commission will conclude preparation of a draft report on its review of the Commemorative Works Act of 1986. This report was required by the Subcommittee on National Parks, Historic Preservation, and Recreation, United States Senate Committee on Energy and Natural Resources. The Commission will review recommendations offered by the National Capital Planning Commission/ National Capital Memorial Commission/ Commission of Fine Arts Joint Task Force on Memorials which convened, in part, to assist in an evaluation of that Act.

The Commission was established by Public Law 99–652, the Commemorative Works Act, to advise the Secretary and the Administrator, General Services Administration, (the Administrator) on policy and procedures for establishment of (and proposals to establish) commemorative works in the District of Columbia and its environs, as well as such other matters as it may deem appropriate concerning commemorative works.

The Commission examines each memorial proposal for conformance to the Commemorative Works Act, and makes recommendations to the Secretary and the Administrator and to Members and Committees of Congress. The Commission also serves as a source of information for persons seeking to establish memorials in Washington, DC, and it environs.

The members of the Commission are as follows:

Director, National Park Service
Chairman, National Capital Planning Commission
Architect of the Capitol
Chairman, American Battle Monuments Commission
Chairman, Commission of Fine Arts
Mayor of the District of Columbia
Administrator, General Services Administration
Secretary of Defense

The meeting will be open to the public. Any person may file with the Commission a written statement concerning the matters to be discussed. Persons who wish to file a written statement or testify at the meeting or who want further information concerning the meeting may contact Ms. Nancy Young, Executive Secretary to the Commission, at (202) 619–7097.

Dated: June 28, 1999.

Joseph M. Lawler,

Acting Regional Director, National Capital Region.

[FR Doc. 99–16984 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before June 26, 1999. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, 1849 C St. NW, NC400, Washington, DC 20240. Written comments should be submitted by July 21, 1999.

Beth Boland,

Acting Keeper of the National Register.

ALABAMA

Marshall County

Julia Street Memorial United Methodist Church, 302 Thomas Ave., Boaz, 99000855

ARIZONA

Yavapai County

Wingfield, Hank and Myrtle, Homestead, 806 E. Quaterhorse Ln., Camp Verde, 99000857

ARKANSAS

Pulaski County

Tuf Nut Historic Commericial District, 300–312 S. Rock St. and 423 E. Third St, Little Rock vicinity, 99000856

CONNECTICUT

Litchfield County

Plymouth Center Historic District, Roughly along Main, North, and South Sts., Cater, Hillside Ave., Ives Crossing, and Maple St., Plymouth, 99000858

New Haven County

Naugatuck Center Historic District, Roughly bounded by Fairview Ave., Hillside Ave., Terrace Ave., Water St. and Pleasant View St., Naugatuck, 99000859

FLORIDA

Hillsborough County

Old Tampa Children's Home, 3302 N. Tampa Ave., Tampa, 99000863

Palm Beach County

Ferndix Building,
401 Fern St., West Palm Beach, 99000861
Van Valkenburg, Grant House,
213 Rosemary Ave., West Palm Beach, 99000860

Polk County

Central Avenue School, 604 S. Central Ave., Lakeland, 99000865
Cleveland Court School, 328 E. Edgewood Dr., Lakeland, 99000862
Cox, John F., Grammar School, 1005 N. Massachusetts Ave., Lakeland, 99000864

MASSACHUSETTS

Berkshire County

Farnams Village Historic District, Farnams Rd., Lanesborough Rd., and Cheshire Rd., Cheshire, 99000866

NEW YORK

Columbia County

Peck House, NY 203, Chatham, 99000869

Dutchess County

Graham—Brush Log House, Church St., Pine Plains, 99000870

Nassau County

Clifton, (Roslyn Harbor, New York MPS) 355 Bryant Ave., Roslyn Harbor, 99000874
Greenridge—Arthur Williams House, (Roslyn Harbor, New York MPS) 875 Bryant Ave., Roslyn Harbor, 99000875
Mudge Farmhouse, (Roslyn Harbor, New York MPS) 535 Motts Cove Rd. S, Roslyn Harbor, 99000876
Smith, Stephen and Charles, House, (Roslyn Harbor, New York MPS) 450 Bryant Ave., Roslyn Harbor, 99000873
Willowmere, (Roslyn Harbor, New York MPS) 435 Bryant Ave., Roslyn Harbor, 99000872

NORTH CAROLINA

Onslow County

Yopps Meeting House, (Onslow County MPS) NC 172, jct. with Sneads Ferry Rd., Sneads Ferry vicinity, 99000868

Orange County

Carolina Inn, 211 Pittsboro St., Chapel Hill, 99000867

PENNSYLVANIA

Allegheny County

Whitehill— Gleason Motors, 5815 Baum Blvd., Pittsburgh, 99000878

Centre County

Philipsburg Historic District, Roughly bounded by East Presqueisle St., Hillcrest Dr., Oak, Railroad, Spruce and Laurel Sts., Philipsburg, 99000881

Franklin County

Rock Hill Farm, 12995 and 12755 Bain Rd., Mercersburg, 99000880

Northampton County

Weona Park Carousel, PA 512, Pen Argyl, 99000879

Warren County

Warren Historic District, Oil Industry Resources in Western Pennsylvania MPS) Roughly bounded by Comewango Cr., the Allegheny R., 7th Ave. and Laurel St., Warren, 99000877

TEXAS

Tarrant County

Our Mother of Mercy Catholic Church and Parsonage, 1100 and 1104 Evans Ave., Fort Worth, 99000882
Saint James Second Street Baptist Church, 210 Harding St., Fort Worth, 99000883

[FR Doc. 99–17040 Filed 7–2–99; 8:45 am]
BILLING CODE 4310–70–U

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of Director's Order Concerning the Establishment of a National Tourism Policy; Correction

June 4, 1999.

In FR doc. 99–13061 published in the **Federal Register** on May 24, 1999, on page 28009 under **FOR FURTHER INFORMATION CONTACT** the telephone number is corrected to read "202/208–6057."

Georgette Tolbert,

Director of Tourism, National Park Service.

[FR Doc. 99–16983 Filed 7–2–99; 8:45 am]
BILLING CODE 4310–70–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decrees Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with Departmental policy, the Department of Justice gives notice that four proposed consent decrees in the consolidated cases captioned *United States* v. *Cantrell, et. al.,* Civil Action No. C–1–97–981 (S.D. Ohio) and *United States* v. *Ohio Power Co., et al.,* Civil Action No. C–1–98–247 (S.D. Ohio), were lodged with the United States District Court for the Southern District of Ohio, Western Division, on June 21, 1999, pertaining to the Automatic Containers Superfund Site (the "Site"), located near Ironton, in Lawrence County, Ohio. The proposed consent decrees would resolve certain civil claims of the United States for recovery of more than $1.3 million in unreimbursed past response costs under Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended ("CERCLA"), 42 U.S.C. 9607, against two defendants and 28 third-party defendants in the consolidated cases.

The first proposed consent decree, captioned "Partial Consent Decree with Settling Defendant Mansbach Realty Co. (d/b/a Mansbach Metal Co.) and Certain Third-Party Settling Defendants" would require Defendant Mansbach's payment of $585,000 (on its own behalf and on behalf of 24 so-called "Mansbach Supplier" Third-Party Defendants) in reimbursement of past CERCLA response costs the United States incurred in connection with the Site. (The following Mansbach Supplier Third-Party Defendants are Settling Defendants under that proposed consent decree: American Commercial Barge Line LLC (and its related corporate entity American Commercial Lines LLC); American Electric Power Service Corporation (and its related corporate entities Ohio Power Company and Indiana Michigan Power Company); Ashland Oil, Inc. (now known as Ashland Inc.); Baker Iron & Metal Co., Inc.; Merdie Boggs & Sons; Crounse Corporation; CSX Transportation, Inc. (in its own name and as successor by merger to Louisville and Nashville Railroad Company); E.I. du Pont Nemours and Company; General American Transportation Corporation; Helm Financial Corporation (and its related entities Helm-Atlantic Associates Limited Partnership, Helm-Pacific leasing, and HM Joint Venture); Ingram Industries, Inc.; The David J. Joseph Company; The Valley Line Company (formerly known as Mississippi Valley Barge Line Company); Norfolk Southern Railway Company; Nugent Sand Company; The Ohio River Company (and its related corporate entity Midland Enterprises Inc.); Progress Rail Services Corporation; Kentucky Electric Steel, Inc.; Ross Brothers Construction Co.; Sears, Roebuck and Co.; Superior Marine Ways, Inc.; and Union Tank Car Company.) The second proposed consent decree, captioned "Partial Consent Decree with Settling Defendant Oak Hill Foundry & Machine Works, Inc.," would provide for payment of an additional $91,000 by Defendant Oak Hill. The third proposed consent decree, captioned "Partial Consent Decree with Certain Third-Party Settling Defendants," would provide for payment of an additional $13,000 by Third-Party Defendants Muth Lumber Co., Crace Construction Co., and Lawrence County Medical Center. The fourth proposed consent decree, captioned "Partial Consent Decree with Setting Defendant City of Ironton, Ohio," would provide for payment of an additional $26,000 by the City. Taken together, the four proposed consent decrees would resolve claims against 30 parties in exchange for payment of $715,000, as provided by the proposed consent decrees.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decrees. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resource Division, United States Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Cantrell, et al.*, Civil Action No. C–1–97–981 (S.D. Ohio) and *United States* v. *Ohio Power Co., et al.*, Civil Action No. C–1–98–247 (S.D. Ohio), and DOJ Reference Nos. 90–11–3–1756 and 90–11–3–1756/1, and the proposed consent decree(s) which the comments address.

The proposed consent decrees may be examined at: (1) The Office of the Untied States Attorney for the Southern District of Ohio, 220 U.S. Courthouse, 100 East Fifth street, Cincinnati, Ohio 45202 (contact Gerald Kaminski (513–684–3711)); (2) the United States Environmental Protection Agency (Region 5), 77 West Jackson Boulevard, Chicago, Illinois 60604–3590 (contact Mony Chabria (312–886–6842)); and (3) the U.S. Department of Justice, Environment and Natural Resources Division Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005 (202–624–0892). Copies of the proposed consent decrees may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005. In requesting copies, please refer to the referenced case and DOJ Reference Number, the proposed consents decree(s) requested, and enclose a check for the amount(s) described below, made payable to the Consent Decree Library. The cost for a copy of the "Partial Consent Decree with Settling Defendant Mansbach Realty Co. (d/b/a Mansbach Metal Co.) and Certain Third-Party Settling Defendants" and all appendices is $13.50 (54 pages at 25 cents per page reproduction costs). The cost for a copy of the "Partial Consent Decree with Settling Defendant Oak Hill Foundry & Machine Works, Inc." and all appendices is $6.25 (25 pages at 25 cents per page reproduction costs). The cost for a copy of the "Partial Consent Decree with certain Third-Party Settling Defendants" and all appendices is $6.75 (27 pages at 25 cents per page reproduction costs). The cost for a copy of the "Partial Consent Decree with Settling Defendant City or Ironton, Ohio" and all appendices is $6.25 (25 pages at 25 cents per page reproduction costs).

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 99–16942 Filed 7–2–99; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Antitrust Division

U.S. v. Signature Flight Support Corporation, et al.; Public Comments and Plaintiff's Response

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that the Public Comment and Plaintiff's Response have been filed with the United States District Court of the District of Columbia in United States v. Signature Flight Support Corporation, Civ. Action No. 9900537 (RCL).

On March 1, 1999, the United States filed a civil antitrust Complaint alleging that Signature Flight Support Corporation's ("Signature") proposed acquisition of AMR Combs, Inc., ("Combs") would violate section 7 of the Clayton Act, 15 U.S.C. 18. The Complaint alleged that Signature and Combs are fixed based operators (FBOs) located at various airports throughout the United States. Signature's acquisition of Combs would have eliminated its only FBO competitor at Bradley International Airport and at Palm Springs Regional Airport. The acquisition would have also significantly reduced the likelihood of entry of a third, independent FBO competitor at Denver Centennial Airport. As a result, the proposed acquisition would substantially lessen competition for FBO services at those airports in violation of section 7 of the Clayton Act.

Public comment was invited within the statutory 60-day comment period. The one comment received, and the response thereto, is hereby published in the **Federal Register** and filed with the Court. Copies of these materials may be obtained on request and payment of a copying fee.

Constance K. Robinson,

Director of Operations and Merger Enforcement, Antitrust Division.

Plaintiff's Response to Public Comment

Pursuant to the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h) ("Tunney Act"), the United States hereby responds to the single public comment received regarding the proposed Final Judgment in this case.

I. Background

On March 1, 1999, the United States Department of Justice ("the Department") filed the Complaint in this matter. The Complaint alleges that Signature Flight Support Corporation's ("Signature") proposed acquisition of AMR Combs, Inc. ("Combs"), a wholly owned, indirect subsidiary of AMR Corporation, would violate section 7 of the Clayton Act, 15 U.S.C. § 18. The Complaint alleges that Signature and Combs are fixed base operators (FBOs) located primarily at various airports throughout the United States. FBOs provide flight support services to general aviation customers. By acquiring the Combs FBO facilities, Signature would eliminate its sole FBO competitor at Bradley International Airport ("BDL") and at Palm Springs Regional Airport ("PSP"). In addition, Signature's proposed acquisition would significantly reduce the likelihood of entry by a third, independent FBO competitor at Denver Centennial Airport ("APA"). As a result, the Complaint alleges, the proposed acquisition would substantially lessen competition for FBO services at APA, BDL and PSP in violation of section 7 of the Clayton Act. 15 U.S.C. § 18.

Simultaneously with the filing of the Complaint, the Department filed the proposed Final Judgment and Stipulation signed by all the parties that allows for entry of the proposed Final Judgment following compliance with the Tunney Act. The Department also filed a Competitive Impact Statement ("CIS") on March 15, 1999, that was subsequently published in the **Federal Register** on March 26, 1999. The CIS explains in detail the provisions of the proposed Final Judgment, the nature and purposes of these proceedings, and the transaction giving rise to the alleged violation.

As the Complaint and the CIS explain, the merger as originally proposed was likely to reduce or eliminate competition in three specific markets for flight support services—the APA, BDL and PSP markets. The proposed Final Judgment is intended to prevent the expected lessening of competition the merger would cause in those markets.

As a remedy to competitive harm in the BDL and PSP markets for flight support services, the Department and Signature, Combs, and AMR agreed to divestiture of one of the FBO businesses at each airport. In addition, the parties agreed to remedy the competitive harm in the APA market for flight support services by transferring Signature's

interest in a new FBO facility at APA to another FBO or by divesting the existing Combs FBO business to an independent and financially viable competitior. These remedies are intended to protect consumers by ensuring continued vigorous competition in each market.

The 60-day comment period for public comments expired on May 25, 1999. The Department had received only one comment, from Robert A. Wilson, President of Wilson Air Center, an FBO located at the Memphis International Airport in Memphis, Tennessee.[1]

II. Response to the Public Comment

Wilson opposes the Department's decision to permit Signature's acquisition of Combs subject to the divestiture of FBO facilities or interests in FBO facilities at APA, BDL and PSP. Wilson claims that the Department should have challenged the acquisition in another market that consists of the Memphis International Airport. The Wilson comment indicates that the Memphis International Airport market has only two FBO competitors: Combs and Wilson Air Center. According to Wilson, shortly before the announcement of the transaction between Signature and Combs, Combs had negotiated various agreements with the Memphis and Shelby County Airport Authority that he believes place Wilson Air Center at a competitive disadvantage. In Wilson's view, Signature's purchase of Combs is objectionable because it perpetuates what he considers to be anticompetitive agreements at the Memphis International Airport.

The Clayton and Sherman Acts, judicial precedent, and the Horizontal Merger Guidelines[2] govern the Department's review of mergers. The first step in the review is defining relevant product and geographic markets where the merging firms are actual or potential competitors. Once the relevant markets are identified, the analysis turns to the competitive implications of the proposed transaction's elimination of one of the firms. Signature and Combs did not compete with one another at the Memphis International Airport, and there was no indication that Signature planned to become an independent competitor at the airport. Since there was no actual or potential competition and thus, no substantial lessening of competition, that market would not be—and, in fact, was not—one that merited review. Instead, the Department identified three geographic markets were Signature and Combs were actual or potential competitors, and determined that, as a result of the acquisition, competition in those markets would be substantially lessened. Accordingly, the Department brought its case on the basis of those three markets, and obtained as relief divestitures designed to ensure continued competition in each market. In sum, the Wilson comment does not raise competition issues caused by the proposed acquisition.

III. The Legal Standard Governing the Court's Public Interest Determination

Once the Department moves for entry of the proposed Final Judgment, the Tunney Act directs the Court to determine whether entry of the proposed Final Judgment "is in the public interest." 15 U.S.C. § 16(e). In making that determination, the "court's function is not to determine whether the resulting array of rights and liabilities 'is one that will best serve society,' but only to confirm that the resulting 'settlement is within the reaches of the public interest.'" *United States* v. *Western Elec. Co.*, 993 F.2d 1572, 1576 (D.C. Cir. 1993) (citation omitted).[3] The Court should evaluate the relief set forth in the proposed Final Judgment and should enter the proposed Final Judgment if it falls within the government's "rather broad discretion to settle with defendant within the reaches of the public interest." *United States* v. *Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *accord United States* v. *Associated Milk Producers*, 534 F.2d 113, 117–18 (8th Cir. 1976).

Because Wilson argues for a different case than the one that the Department brought, and does not address the relief ordered by the proposed Final Judgment, the comment raises no issues relevant to this Tunney Act proceeding. The Tunney Act does not contemplate a judicial reevaluation of the government's determination of which violations to allege in the Complaint. The government's decision not to bring a particular case based on the facts and law before it at a particular time, like any other decision not to prosecute, "involves a complicated balancing of a number of factors which are peculiarly within [the government's] expertise." *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985). Thus, the Court may not look beyond the Complaint "to evaluate claims that the government did not make and to inquire as to why they were not made." *Microsoft*, 56 F.3d at 1459; *see also Associated Mild Producers*, 534 F.2d at 117–18.

Similarly, the government has wide discretion within the reaches of the public interest to resolve potential litigation. *See, e.g., Western Elect.*, 993 F.2d at 1577; *United States* v. *American Tel. & Tel. Co.*, 552 F. Supp. 131, 151–52 (D.D.C. 1982). The Supreme Court has recognized that a government antitrust consent decree is a contract between the parties to settle their disputes and differences, *United States* v. *ITT Continental Baking Co.*, 420 U.S. 223, 235–38 (1975); *United States* v. *Armour & Co.*, 402 U.S. 673, 681–82 (1971), and "normally embodies a compromise; in exchange for the saving of cost and elimination of risk, the parties each give up something they might have won had they proceeded with the litigation." *Armour*, 402 U.S. at 681. This proposed Final Judgment has the virtue of bringing the public certain benefits and protection without the uncertainty and expense of protracted litigation. *Id.; Microsoft*, 56 F.3d at 1459.

Finally, the entry of a governmental antitrust decree forecloses no private party from seeking and obtaining appropriate antitrust remedies. Thus, defendants will remain liable for any illegal acts, and any private party may challenge such conduct if and when appropriate. If the commenting party has a basis for suing the defendants, it may do so. The legal precedent discussed above holds that the scope of a Tunney Act proceeding is limited to whether entry of this particular proposed Final Judgment, agreed to by the parties as settlement of this case, is in the public interest.

IV. Conclusion

After careful consideration of the comment, the Department concludes that entry of the proposed Final Judgment will provide an effective and appropriate remedy for the antitrust violation alleged in the Complaint and is in the public interest. The Department will move the Court to enter the proposed Final Judgment after the public comment and this Response have been published in the **Federal Register**, as 15 U.S.C. § 16(d) requires.

Dated this 21st day of June, 1999.

[1] The comment is attached. The Department plans to public promptly the comment and this response in the Federal Register. The Department will provide the Court with a certificate of compliance with the requirements of the Tunney Act and file a motion for entry of final judgment once publication takes place.

[2] Federal Trade Commission and United States Department of Justice, Horizontal Merger Guidelines (1992, rev. 1997).

[3] The *Western Electric* decision concerned a consensual modification of an existing antitrust decree. The Court of Appeals assumed that the Tunney Act was applicable.

Respectfully submitted.

Nina B. Hale,

Salvatore Mass,

U.S. Department of Justice, Antitrust Division, 325 7th Street, NW, Suite 500, Washington, D.C. 20530, (202) 307–6351.

Certificate of Service

I, Marian Honus, hereby certify that, on June 21, 1999, I caused the foregoing document to be served on defendants Signature Flight Support Corporation, AMR Combs, Inc., and AMR Corporation by having a copy mailed, first-class, postage prepaid, to:

William Norfolk, Esq.,

Sullivan & Cromwell, 125 Broad Street, New York, NY 1004.

Eugene A. Burrus, Esq.,

AMR Corporation, P.O. Box 619616, MD 5675, Dallas Fort Worth Airport, TX 75261.

Marian Honus

May 21, 1999.

Mr. Roger W. Fones,

Chief, Transportation, Energy and Agriculture Section, Department of Justice, Antitrust Division, 325 Seventh St., NW, Suite 500, Washington, DC 20530

RE: Comments of Wilson Air Center, LLC in Response to **Federal Register** Notice Regarding Proposed Final Judgment and Competitive Impact Statement: *United States of America* v. *Signature Flight Support Corporation, et al.*, **Federal Register** 58 (March 26, 1999)

Dear Mr. Fones: Wilson Air Center, LLC ("Wilson Air") is an independently owned Fixed Base Operation ("FBO") and is the only FBO other than AMR Combs, Inc. ("AMR") located at the Memphis International Airport, Memphis, Tennessee (the "Memphis Airport"). Wilson Air comments on the proposed acquisition insofar as it will impact FBO competition at the Memphis Airport as follows:

Wilson Air is opposed to the acquisition of AMR by Signature Flight Support Corporation ("Signature") because it will perpetuate agreements between AMR and the Memphis and Shelby County Airport Authority (the "Authority") which will give Signature an illegal competitive advantage for FBO customers at the Memphis Airport. The timing and substance of the recently executed anti-competitive agreements suggests that they were negotiated in anticipation of the instant sale to improperly increase the value of AMR's Memphis operation. If the proposed sale is implemented at the Memphis Airport such that Signature assumes the anti-competitive agreements that are in place, FBO competition at the Memphis Airport will be stifled and Wilson Air will be irreparably harmed.

The Anti-Competitive Agreements

The new lease between the Airport Authority and AMR was executed in late July or early August of 1998 but was made effective as of June 1, 1998 (the "Lease"). A copy of the AMR Lease is at EXHIBIT A. In the Lease, AMR procured terms which make it impossible for Wilson Air to fairly compete for customers. The Lease also directly violates the Federal Grant Assurances [1] which, as a contractual obligation for the receipt of Federal funding, mandate fair and equitable treatment of FBOs so that competition can be preserved at airports supported with Federal funds.

Disparate Lease Rates

The terms of the Lease which violate the Federal Grant Assurances create the anti-competitive environment which the Grant Assurances sought to prevent. The Lease includes disparate pricing terms.[2] At Paragraph 4 and in its Exhibit C, the Lease in 1998 granted to AMR property at rates far below the then existing market and far below rates which had been set for Wilson Air more than four (4) years earlier. More precisely, effective June 30, 1998, the Lease requires AMR to pay between $.0759 per square foot for "unimproved land" and $.0949 per square foot for "improved land." In the lease, AMR's base lease rental schedule increases incrementally through 2010. Even so, rates for "unimproved land" remain well below the rates paid by Wilson Air until after June 30, 1005. The rates charged to AMR are shown on Exhibit C to the Lease (EXHIBIT A). Moreover, it appears that AMR is paying nothing for the 13,500 square feet occupied by the General Aviation Building. In stark contrast Wilson Air, in a lease of more unimproved land negotiated in 1994 which extends through 2005, must pay $.12 per square foot. Wilson Air at that higher rate was required to build its entire facility from the ground up. A copy of Wilson Air's lease is at EXHIBIT B.

The disparate rates included in the Lease make it impossible for Wilson Air profitably to offer its current and prospective FBO tenants lease rates which are competitive with the lease rates offered by AMR. AMR has already used the disparate lease rates to procure for itself customers. As shown in Paragraph 8a of the sublease at EXHIBIT C, AMR as of July 17, 1998, subleased to Richard's Aviation, Inc. at the rate of $.0759 per square foot—four and one-half cents less than the Authority had leased unimproved land to Wilson Air. The inability of Wilson Air to enter match such a rate is obvious. And, as Paragraph IIB of the Notice states "(t)he largest source of revenues for an FBO is its fuel sales" and (g)eneral aviation customers generally buy fuel from the same FBO from which they obtain those other services (hangar rental, office space rental, etc.)". Thus, the reduced lease rates given to AMR preclude Wilson Air from competing for hangar tenants and for fuel customers. This Lease term restrains trade and commerce at the Memphis Airport as it relates to the two FBOs and appears to violate both Section 7 of the Clayton Act and Section 1 of the Sherman Act.

Disparity in Land Under Lease

Wilson Air currently has approximately 16 acres of land under lease. Through the Lease, AMR has increased the acreage held by it and has obtained an option for even more land.[3] At this same time, Wilson Air has repeatedly requested from the Authority and has been denied additional land on which to expand its operations. AMR's Lease grants AMR an option on three separate parcels totaling 13.53 acres (identified in the Lease as N, O and P). In the new Lease, as amended, the Authority grants AMR an option to these parcels for $.02 to $.03 per square foot. In addition, 15.45 more acres of new land were added to the new AMR lease.

These terms of the Lease are anti-competitive in that they give AMR approximately 3 times Wilson Air's acreage with which it can entice customers away from Wilson Air at rates well below what Wilson Air must pay the Airport Authority without worrying about running out of space to grow. Since AMR has more land than it can use, it can grant a sublease like the one at EXHIBIT C "at cost" knowing that it will get the customer's business for fuel.[4]

Additionally, the location of the land covered by the Lease also precludes Wilson Air access to valuable military fueling contracts. Due to space limitation, Wilson Air cannot bid on and receive military fueling contracts because Wilson Air does not have the available land to handle the type and size of military aircraft for fueling purposes. As with the rental rates, these lease terms appear to violate Section 7 of the Clayton Act and Section 1 of the Sherman Act.

From the documents produced to Wilson Act, it appears that AMR has been responsible for the maintenance and repair of the General Aviation Building ("GAB") for more than 15 years, but has evidently failed

[1] The Grant Assurances set out fully at Section 47107 of 49 United State Code under the heading Economic Nondiscrimination provide that "(e)ach fixed-base operator shall be subject to the same rates, fees, rentals, and other charges as are uniformly applicable to all other fixed-base operators making the same or similar use of such airport * * *" Id. At Para. 22(c). Paragraph 23 of the Grant Assurances, entitled Exclusive Rights, goes on to state that an airport authority sponsor"* * * will permit no exclusive right for the use of the airport by any person providing * * * aeronautical services to the public." The Memphis Airport between 1994 and 2008 has and is scheduled to receive $119,380,000 in federal grant funds from the Federal Aviation Administration. As such, Memphis Airport is a federally assisted airport operation and must comply with the Federal Grant Assurances which are incorporated into the Authority's grant funding contracts with the FAA

[2] The Authority has asserted that the Lease is merely an extension of AMR's 1979 Lease and an accommodation for giving up other land. The many substantial discrepancies between the Lease and AMR's 1979 lease show that it is indeed a new document and not an extension of the old lease. Other documents exchanged between AMR and the Authority further rebut this claim.

[3] AMR had approximately 20 acres under its 1979 lease of the south complex. A copy of that lease is at EXHIBIT D.

[4] Paragraph 37 of the sublease at EXHIBIT C tied that sublease to a "fuel agreement." Wilson Air, despite request, has never seen that "fuel agreement." After voicing its concerns, Wilson Air was advised that Paragraph 37 of the Lease was amended to prohibit exclusive fueling agreement being entered into by AMR and its subtenants and customers.

to meet those obligations. Rather than force AMR to comply with its maintenance and repair obligations, however, the Lease grants AMR rent incentives and abatements on the GAB property. Those Lease terms are far more favorable to AMR than the rent terms offered to Wilson Air for another building on the Memphis Airport even though the two buildings will be subject to the same type of FBO usage. Wilson Air has asked the Authority to lease to it a building known as the Northwest AirLink building (the "NWA"). The Authority ordered a 1995 appraisal which compared the NWA to more expensive off-airport commercial buildings and indicated an adjusted appraisal rental rate of $5.50 per square foot.

Instead of offering any incentives like those given to AMR, the Authority has demanded a $6.50 per square foot rental rate from Wilson Air. The NWA previously has not been used for general aviation tenants, but if Wilson Air rented the building, it would be used for general aviation tenants and general aviation related services. Again by contrast, the Authority in the Lease has abated rent through 2010 on the GAB to AMR while simultaneously demanding that Wilson Air pay $6.50 per square foot for use of the NWA property.[5] Both buildings require the expenditure of substantial funds for improvements and will experience the same or similar uses.

This unequal treatment as to office square precludes Wilson Air from effectively competing for tenants which would require use of such facilities.

In addition to the Lease, AMR and the Authority negotiated two separate "letter agreements" which granted AMR month-to-month leases on 3.21 acres and 6.09 acres of improved (closed) runway and taxilane property respectively. The December 16, 1997 letter agreement and the July 27, 1998, letter agreement are at EXHIBITS E and F. The Authority has now acknowledged that while Wilson Air was being told that no additional land was available to Wilson Air, the Authority was giving AMR the free use of this valuable acreage. Thus, the Authority allowed AMR to use land at no cost, while denying land to Wilson Air and requiring it to pay full rent for all land used.[6]

A portion of this land now lies within one of the option parcels granted to AMR and as recently as May 11, 1999, AMR (already operating at the Memphis Airport under the "Signature" name) has used the land without paving rental fees. This is another indicia of the manner in which Wilson Air has been hurt by the anti-competitive agreements between the Authority and AMR. These anti-competitive agreements will persist unless Signature is precluded from assuring these agreements at the Memphis Airport.

Wilson Air submits that permitting Signature to move forward with the acquisition of AMR's rights at the Memphis Airport will violate the Competitive Impact Statement and the spirit of the Proposed Final Judgment in the subject suit. Wilson Air further asserts that the Authority's pending assignment of the AMR lease terms to Signature as required by the AMR Lease will perpetuate the anti-competitive environment between FBO's at the Memphis Airport.

Accordingly, Wilson Air requests that the Department of Justice consider the above in determining whether to support the entry of the Final Judgment in the above-cited suit. Alternatively, Wilson Air requests that Department of Justice expand its investigation into the anti-competitive aspects of the sale of AMR to Signature Flight Support Corporation to include consideration of the AMR Lease at the Memphis Airport.

Very truly yours,

Wilson Air Center, LLC

Robert A. Wilson,

President.

RAW/kaw

Enclosures

Exhibits A, B, C, D, & E can be obtained from the Document Office, U.S. Department of Justice, 325 7th Street, N.W., Room 215, Washington, D.C. 20530, or (202) 514–2481.

[FR Doc. 99–16943 Filed 7–2–99; 8:45 am]

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[5] A 1997 airport appraisal of the GAB indicated a minimum $.75 per square foot rental on the building prior to renovation.

[6] Apparently, AMR is still using the old AMR north complex, an additional approximate 12 acre site at a different location on the airport, to service tenants, even though Wilson Air Center has been advised that this site has been designated for use for FedEx Corporation expansion.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Request OMB Emergency Approval; Immigration Bond.

On June 29, 1999, the Department of Justice, Immigration and Naturalization Service (INS) published a notice in the **Federal Register** at 64 FR 34862, notifying the public that it had submitted a reinstatement with change of a previously approved information collection using emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance with section 1320.13(a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The notice failed to specify the requested date of OMB approval. Therefore, the INS requests OMB approval by July 9, 1999. If granted, the emergency approval is only valid for 180 days. All comments and/or questions pertaining to this pending request for emergency approval should be received prior to July 9,1999 and must be directed to OMB, Office of Information and Regulatory Affairs, Attention: Mr. Stuart Shapiro, 202–395–7316, Department of Justice Desk Officer, Washington, DC 20503.

Comments regarding the emergency submission of this information collection may also be submitted via facsimile to Mr. Shapiro at 202–395–6974.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the INS requests written comments and suggestions from the public and affected agencies concerning this information collection. Comments are encouraged and will be accepted for "sixty days" from September 7, 1999. During the 60-day regular review, all comments and suggestions or questions regarding additional information, to include instructions, should be directed to Mr. Richard A. Sloan, 202–514–3291, Director, Policy Directives and Instructions Branch. Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement with change of a previously approved collection.

(2) *Title of the Form/Collection:* Immigration Bond.

(3) *Agency form number, if any, and the applicable component sponsoring the collection:* Form I–352. Detention and Deportation Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This information will be

used by the Service to determine eligibility release of a detained alien on bond, and will collect information of the obligor of the bond who is taking the responsibility of the released alien.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 25,000 responses at 30 minutes or (.5) hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 12,500 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW., Washington, DC 20530.

Dated: July 1, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalizatian Service.

[FR Doc. 99–17146 Filed 7–1–99; 12:37 pm]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

[INS No. 1997–99]

Announcement of a Change of Address for the Houston Asylum Office

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice of a change of address for the Houston Asylum Office.

SUMMARY: This notice announces a change of address for the Houston Asylum Office. On March 1, 1999, both the physical office location and mailing address for correspondence and delivery of packages changed. The public telephone and facsimile (FAX) numbers have also changed. The new addresses and telephone and Fax numbers are listed in the supplementary information section of this notice. Asylum applicants are to continue to appear for interviews at the address shown on their interview appointment notice. This notice is necessary to ensure that correspondence and packages are properly routed to the correct address and that individuals can contact the office telephonically. Since Match 1, 1999, the Immigration and Naturalization Service has continued to accept correspondence sent to the former address and will continue to accept and forward correspondence to the correct address until November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Christine Davidson, Supervisory Asylum Officer, or Marta Rothwarf, Asylum Officer, Office of International Affairs, Immigration and Naturalization Service, 425 I Street, NW, ULLICO Bldg., Third Floor, Washington, DC 20536, telephone (202) 305–2663.

SUPPLEMENTARY INFORMATION: On March 1, 1999, the Houston Asylum Office moved to a new location. All parties are to use the following addresses and telephone numbers when sending correspondence or packages, or to contact the asylum office. Asylum applicants are to continue to appear for interviews at the address shown on their interview appointment notice.

What Is the New Mailing Address for the Houston Asylum Office?

Correspondence must be mailed to the Houston Asylum Office at the following address: U.S. Immigration and Naturalization Service, Houston Asylum Office, P.O. Box 670626, Houston, TX 77267–0626.

What Is the Actual Physical Address for the Houston Asylum Office?

Federal Express, United Parcel Service, or Express Mail packages must be delivered to the following address: U.S. Immigration and Naturalization Service, Houston Asylum Office, 16630 Imperial Valley Drive, Suite 200, Houston, TX 77060.

What Are the New Telephone and FAX Numbers for the Houston Asylum Office?

Telephone: (281) 774–5992.

FAX: (281) 774–4830.

What Are the Hours of Operation for the Houston Asylum Office?

The office is open Monday through Friday, from 7 a.m. to 4 p.m.

What Happens if Correspondence Is Sent to the Former Address?

Correspondence that is sent to the former address will be accepted and forwarded to the correct address by the Service until November 3, 1999. After November 3, 1999, correspondence will be returned to the sender as undeliverable.

Dated: June 18, 1999.

Doris Meissner,

Cammissianer, Immigratian and Naturalizatian Service.

[FR Doc. 99–16958 Filed 7–2–99; 8:45 am]

BILLING CODE 4410–10–M

PAROLE COMMISSION

Sunshine Act Meeting

Record of Vote of Meeting Closure (Public Law 94–409) (5 U.S.C. Sec. 552b)

I, Michael J. Gaines, Chairman of the United States Parole Commission, was present at a meeting of said Commission which started at approximately nine-thirty a.m. on Tuesday, June 29, 1999, at the U.S. Parole Commission, 5550 Friendship Boulevard, 4th Floor, Chevy Chase, Maryland 20815. The purpose of the meeting was to decide three appeals from the National Commissioners' decisions pursuant to 28 C.F.R. Section 2.27. Three Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the meeting and certifications of General Counsel that this meeting may be closed by vote of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Michael J. Gaines, Edward F. Reilly, Jr., and John R. Simpson.

IN WITNESS WHEREOF, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: June 30, 1999.

Michael J. Gaines,

Chairman, U.S. Parale Commissian.

[FR Doc. 99–17147 Filed 7–1–99; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A). This program helps to ensure that: requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized;

collection instruments are clearly understood; and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed new collection of administrative and survey data on Unemployment Insurance (UI) exhaustees.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before September 7, 1999.

ADDRESSES: Anissa Holm, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–4231, Washington, DC 20210, phone: (202) 208–5915 x201 (this is not a toll-free number), fax (202) 219–8506 (this is not a toll-free number), e-mail aholm@doleta.gov.

FOR FURTHER INFORMATION CONTACT: Anissa Holm, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–4231, Washington, DC 20210, phone: (202) 208–5918 x201 (this is not a toll-free number), fax (202) 219–8506 (this is not a toll-free number), e-mail aholm@doleta.gov.

SUPPLEMENTARY INFORMATION:

I. Background

As part of its mandate under Section 906 of the Social Security Act to establish a continuing and comprehensive program of research to evaluate the unemployment compensation system, the U.S. Department of Labor, Employment and Training Administration (ETA), is conducting a study of Unemployment Insurance (UI) exhaustees. This study is intended to examine the extent to which recent changes in the U.S. labor market have affected the composition of UI recipients who exhaust benefits and have influenced their postexhaustion labor market experiences. A further objective of the study is to explore recipients' experiences with the delivery of reemployment services and examine whether changes in the workforce development system have affected these experiences.

To meet these objectives, the study will: (1) Identify the factors that explain why recipients exhaust their UI benefit entitlements; (2) examine the labor market experiences of exhaustees and nonexhaustees; (3) assess the extent of recipients' participation in education, training, and reemployment services; (4) determine how patterns in recipient characteristics, labor market experiences, and participation in reemployment services have changed over time, especially over the past decade, and (5) consider the implications of the findings for UI benefit and reemployment services policies.

II. Current Actions

To examine these issues, ETA is planning to collect administrative records on UI and reemployment service receipt for random samples of UI recipients drawn from 25 States. ETA is also planning to collect survey data from a subsample of UI exhaustees and, for comparison purposes, a subsample of nonexhaustees. The survey will collect data items unavailable from administrative records. These data include detailed information on background characteristics of sample members, including the characteristics of their pre-UI jobs; information on their employment and earnings and job characteristics following receipt of UI; and information on their use of education, training, and reemployment services.

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Type of Review: New.

Agency: United States Department of Labor, Employment and Training Administration.

Title: Study of Unemployment Insurance Exhaustees.

Agency Number: 1205.

Affected Public: Individuals, State governments.

Cite/reference	Total respondents	Frequency	Total responses	Average time per response	Burden (hours)
State administrative data request	25	One time	25	80 hours	2,000
UI recipient survey	4,000	One time	4,000	35 minutes	2,333
Totals			4,025		4,333

Total Burden Cost: $580,089.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information request; they will also become a matter of public record.

Dated: June 29, 1999.

Grace A. Kilbane,

Director, Unemployment Insurance Service.

[FR Doc. 99–17008 Filed 7–2–99; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

NASA's Procurement Policies, Practices, and Initiatives; Notice of Mmeeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: NASA will conduct an open forum meeting to solicit questions, views and opinions of interested persons or firms concerning NASA's procurement policies, practices, and initiatives. The purpose of the meeting is to have an open discussion between NASA's Associate Administrator for Procurement, industry, and the public.

DATES: August 12, 1999, from 9:00 to 11:00AM

ADDRESSES: The meeting will be held at the NASA—Ames Research Center, Space Science Auditorium, Bldg. 245, 2nd Floor, North Warehouse Road, Moffett Field, CA 94035.

FOR FURTHER INFORMATION CONTACT: Michael R. Basta, NASA—Ames Research

Center, P.O. Box 1000, Mail Stop 241–1, Code JAB, Moffett Field, CA 94035–1000, (650) 604–4010.

SUPPLEMENTARY INFORMATION: Format: There will be a presentation by the Associate Administrator for Procurement, followed by a question and answer period. Procurement issues will be discussed, including NASA policies used in the award and administration of contracts; this forum will be similar to one held recently at Kennedy Space Center in Florida.

Admittance: Doors will open at a half-hour prior to the presentation. Admittance will be on a first-come, first-served basis. Auditorium capacity is limited to approximately 90 persons; therefore, a maximum of two representatives per firm is requested. No reservations will be accepted. Questions for the open forum should be presented at the meeting and should not be submitted in advance. Position papers are not being solicited.

Initiatives: In addition to the general discussion mentioned above, NASA invites comments or questions relative to its ongoing Procurement Initiatives, some of which include but are not limited to the following:

Risk-Based Acquisition Management

This initiative seeks to integrate the principles of risk management throughout the acquisition process by purposefully considering the various aspects of risk when developing the acquisition strategy, selecting sources, choosing contract type, structuring fee incentives, and conducting contractor surveillance.

Consolidated Contracting Initiative.

The CCI initiative emphasizes developing, using, and sharing contracts to meet Agency objectives.

Performance Based Contracting

This initiative is focused on structuring an acquisition around the purpose of the work to be performed rather than using broad, imprecise statements or prescribing of how the work is to be performed.

Profit/Fee Initiative

This initiative will assess the effectiveness of the Agency's profit/fee practices as a means for motivating and rewarding contractor performance.

In addition, it will investigate other, non-traditional ways to motivate contractor performance.

Tom Luedtke,

Associate Administrator for Procurement.

[FR Doc. 99–17037 Filed 7–2–99; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Council on the Humanities; Meeting

June 30, 1999.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended) notice is hereby given the National Council on the Humanities will meet in Washington, DC on March 22–23, 1999.

The purpose of the meeting is to advise the Chairman of the National Endowment for the Humanities with respect to policies, programs, and procedures for carrying out his functions, and to review applications for financial support and gifts offered to the Endowment and to make recommendations thereon to the Chairman.

The meeting will be held in the Old Post Office Building, 1100 Pennsylvania Avenue, NW, Washington, DC. A portion of the morning and afternoon sessions on July 15–16, 1999, will not be open to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code because the Council will consider information that may disclose: Trade secrets and commercial or financial information obtained from a person and privileged or confidential; information of a personal nature the disclosure of which will constitute a clearly unwarranted invasion of personal privacy; and information the disclosure of which would significantly frustrate implementation of proposed agency action. I have made this determination under the authority granted me by the Chairman's Delegation of Authority dated July 19, 1993.

The agenda for the session on July 15, 1999 will be as follows:

Committee Meetings

(Open to the Public)

Policy Discussion

9:00–10:30 a.m.
- Preservation and Access/Challenge Grants—Room 415
- Public Programs—Room 420
- Federal/State Partnership—Room 507

11:30 a.m until Adjourned
- Research Programs—Room M07
- Education Programs—Room M07

(Closed to the Public)

Discussion of Specific Grant Applications and Programs before the Council

9:00–11:30 a.m.
- Research Programs—Room M07
- Education Programs—Room M07

10:30 a.m. until Adjourned
- Preservation and Access/Challenge Grants—Room 415
- Public Programs—Room 420
- Federal/State Partnership—Room 507

1:30–2:30 p.m.
- National Humanities Medals Meeting—Room 430

The morning session on July 16, 1999 will convene at 9:00 a.m., in the 1st Floor Council Room, M–09, and will be open to the public, as set forth below. The agenda for the morning session will be as follows:

Minutes of the Previous Meeting

Reports

A. Opening Remarks and Presentations
B. Staff Report
C. Reports on Policy & General Matters
1. Overview
2. Research Programs
3. Education Programs
3. Preservation and Access and Challenge Grants
4. Public Programs
5. Federal/State Partnership
6. National Humanities Medals

The remainder of the proposed meeting will be given to the consideration of specific applications and closed to the public for the reasons stated above.

Further information about this meeting can be obtained from Ms. Nancy E. Weiss, Advisory Committee Management Officer, Washington, DC 20506, or call area code (202) 606–8322, TDD (202) 606–8282. Advance notice of any special needs or accommodations is appreciated.

Nancy E. Weiss,

Advisory Committee Management Officer.

[FR Doc. 99–16960 Filed 7–2–99; 8:45 am]

BILLING CODE 7536–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Advanced Computational Infrastructure and Research; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Advanced Computational Infrastructure & Research (#1185).

Date and Time: September 9–10, 1999, 8:30 am to 5:00 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Suite 320, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Charles H. Koelbel, Program Director, Advanced Computational

Research Program, Suite 1122, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 306–1962.

Purpose of Meeting: To provide recommendations and advice concerning Software proposals submitted to NSF for financial support.

Agenda: To review and evaluate Proposals in the Advanced Computational Research Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: June 30, 1999.

Karen J. York,

Committee Management Officer.

[FR Doc. 99–17006 Filed 7–2–99; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Polar Programs; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Polar Programs (1209).

Date and Time: July 15–16, 1999, 8:30 a.m. to 5 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Room 1295, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Mr. Guy Guthridge, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1033.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Antarctic Artist & Writers proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c)(4) and (6) of the Government in the Sunshine Act.

Dated: June 30, 1999.

Karen J. York,

Committee Management Officer.

[FR Doc. 99–17007 Filed 7–2–99; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: U. S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. *Type of submission, new, revision, or extension:* Revision.

2. *The title of the information collection:* Changes, Tests and Experiments, and Updating of Final Safety Analysis Reports (10 CFR Parts 50 and 72).

3. *The form number if applicable:* Not applicable.

4. *How often the collection is required:* Information is required to be collected when changes, tests or experiments are made by the licensee; reporting of these changes is required every two years. Updating the final safety analysis report (FSAR) is required every two years for independent spent fuel storage installations (ISFSIs) and for power reactor facilities.

5. *Who will be required or asked to report:* Reports are submitted by licensees of production or utilization facilities licensed under 10 CFR Part 50 and by licensees and certificate holders for ISFSIs and spent fuel storage casks, pursuant to 10 CFR Part 72.

6. *An estimate of the number of responses:* The annual number of responses is estimated as 112 reports.

7. *The estimated number of annual respondents:* The total number of respondents under Part 50 is 175 reactor licensees. In addition, there are 18 respondents subject to Part 72. Since the reporting for these respondents is on a two-year cycle, the annual number of respondents is 112.

8. *An estimate of the total number of hours needed annually to complete the requirement or request:* The total number of hours annually is estimated at 377,160 hours (an increase of 37,300 hours)—54,770 hours (a decrease of 180 hours) for reporting; 269,316 hours (a decrease of 15,594 hours) for recordkeeping. This total estimate also includes an annualized one-time burden of 53,069 hours for implementation of the revisions to the rule through procedures and training of personnel. The hours needed depend upon the number and complexity of changes that a licensee chooses to make. The hours needed for a power reactor respondent are estimated to be significantly greater than those for a spent fuel storage cask certificate holder or ISFSI licensee.

9. *An indication of whether Section 3507(d), Pub. L. 104–13 applies:* Applicable.

10. *Abstract:* The NRC is revising requirements pertaining to changes, tests, and experiments, and for updating of final safety analysis reports. The purpose of the rulemaking is to clarify requirements and to allow more flexibility for certain changes that a licensee can make without receiving prior NRC approval.

Submit, by August 5, 1999, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (lower level), Washington, DC. OMB clearance packages are available at the NRC worldwide web site (http://www.nrc.gov/NRC/PUBLIC/OMB/index.html). The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer by August 5, 1999: Erik Godwin, Office of Information and Regulatory Affairs (3150–0011 and 3150–0132), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3087.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 25th day of May, 1999.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 99–17018 Filed 7–2–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–286]

Power Authority of the State of New York; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DRP–64 issued to the Power Authority of the State of New York (the licensee) for operation of the Indian Point Nuclear Generating Unit No. 3 (IP3) located in Westchester County, New York.

The proposed amendment would extend the allowed outage time (AOT) for the 32 Emergency Diesel Generator (EDG) and its Fuel Oil Storage Tank (FOST) from 72 hours to 7 days on a one-time basis.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Does the proposed License amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed License amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated. The EDGs and their associated fuel oil systems are not part of any accident initiation; therefore, there is no increase in the probability of an accident. At a minimum, two EDGs are still available with sufficient fuel oil supply to mitigate IP3 design basis accidents. The minimum safeguards equipment can still be powered even if the 32 EDG is assumed to be lost due to single failure. This has been verified by EDG loading calculation, IP3–CALC–ED–00207, "480V Bus 2A, 3A, 5A & 6A and EDGs 31,32 and 33 Accident Loading." With the 32 EDG available and aligned for automatic start capability (although declared inoperable) during this 32-FOST outage, further backup to the 31 and 33 EDGs is provided. By the design of the overall EDG fuel oil system, the 32 EDG fuel oil day tank is able to be supplied with sufficient fuel oil supply from either the 31 or 33 FOSTs in order to support operation of the 32 EDG, if necessary.

To support fuel oil needs of all three EDGs, if necessary, the FSAR [final safety analysis report] describes that additional fuel oil supplies are available on the Indian Point site and locally near the site. Further EDG fuel oil supplies are maintained in the New Rochelle-Mount Vernon, NY area, about 40 miles from IP3. Overall, the EDGs are designed as backup AC power sources in the event of a Loss of Offsite Power (LOOP). The proposed AOT does not change the conditions or minimum amount of safeguards equipment assumed in the safety analysis for design basis accident mitigation, since a minimum of 2 EDGs is assumed. No changes are proposed as to how the EDGs provide plant protection. Additionally, no new modes of overall plant operation are proposed as a result of this change. A PRA [probabilistic risk assessment] evaluation determined that the conditional core damage probability (CCDP) for this scenario will be less than the threshold value of 1 E–6. Therefore, the proposed one-time license amendment to TS [Technical Specification] 3.7.B.1 does not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Does the proposed License amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed TS change does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change does not introduce any new overall modes of plant operation or make any permanent physical changes to plant systems necessary for effective accident mitigation. The minimum required EDG operation remains unchanged by removal of this single FOST [Fuel Oil Storage Tank] for repair. Additionally, added requirements to minimize risk associated with loss of offsite power also support this one-time extended AOT. Also, as previously stated, the EDGs and FOSTs are not part of any accident initiation. Therefore, the proposed one-time license amendment to TS 3.7.B.1 does not create the possibility of a new or different kind of accident from any previously evaluated.

(3) Does the proposed License amendment involve a significant reduction in a margin of safety?

No. The proposed License amendment does not involve a significant reduction in a margin of safety. The minimum safeguards loads can be maintained available if needed for design basis accident mitigation with 2 EDGs operable combined with their respective FOSTs. The 32 EDG will be available and aligned for automatic start capability (though declared inoperable) during this outage. The additional fuel oil needed to support 3 EDGs in this condition is available as indicated in the present design and licensing basis. The FSAR describes that this fuel can be provided from the Indian Point site, local sources and from a source about 40 miles away to support the additional 30,026 gallons TS required fuel oil already existing at the Buchanan substation. Therefore, sufficient fuel oil will be available for potential events that could occur during this 7-day AOT. The PRA evaluation for the case of maintaining the 32 EDG available (though declared inoperable) with its FOST out for repair indicates an acceptable safety margin below the risk-informed threshold of 1E–6.

The 480VAC electrical distribution system can be fed from a number of TS independent 13.8kV and 138kV offsite power sources to minimize reliance of IP3 on EDG power sources during the extended AOT requested. Additional requirements to minimize risk associated with the potential for loss of offsite power sources within this TS change also ensure that this extended AOT does not involve a significant reduction in safety margin. On this basis, the proposed one-time license amendment to TS 3.7.B.1 does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and

Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received maybe examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By August 5, 1999, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the White Plains Public Library, 100 Martine Avenue, White Plains, New York, 10601. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one ccontention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Mr. David E. Blabey, 10 Colombus Circle, New York, New York, 10019, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated June 4, 1999, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Whiite Plains Public Library, 100 Martine Avenue, White Plains, New York, 10601.

Dated at Rockville, Maryland, this 29th day of June 1999.

For the Nuclear Regulatory Commission.

George F. Wunder,

Project Manager, Section 1, Project Directorate I, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 99–17017 Filed 7–2–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. STN 50–528, STN 50–529, and STN 50–530]

Arizona Public Service Company, Palo Verde Nuclear Generating Station, Units 1, 2, and 3; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from certain requirements of its regulations for Facility Operating License Nos. NPF–41, NPF–51, and NPF–74, for operation of the Palo Verde Nuclear Generating Station (Palo Verde, or the licensee), Units 1, 2, and 3, located in Maricopa County, Arizona.

Environmental Assessment

Identification of the Proposed Action

The proposed action would exempt the licensee from the requirements of 10 CFR 50.71(e)(4) regarding submission of revisions to the Updated Final Safety Analysis Report (UFSAR). Under the proposed exemption, the licensee would submit revisions to the UFSAR, common to all three units, to the NRC no later than 24 calendar months from the previous revision. The licensee also requested that the exemption apply to (1) revisions made to the quality assurance program (which has been incorporated into the UFSAR) pursuant to 10 CFR 50.54(a)(3), (2) the safety evaluation summary reports for facility changes made under 10 CFR 50.59 pursuant to 10 CFR 50.59(b)(2), and (3) the reports of changes to the Technical Specification (TS) Bases.

The proposed action is in accordance with the licensee's application for exemption dated June 9, 1998, as supplemented by letter dated December 21, 1998.

The Need for the Proposed Action

The proposed action is needed to reduce undue regulatory burden for units that share a common UFSAR regarding the requirements of Section 50.71(e)(4). Section 50.71(e)(4) requires licensees to submit updates to their UFSAR annually or within 6 months after each refueling outage provided that the interval between successive updates does not exceed 24 months. Since all three Palo Verde units share a common UFSAR, the licensee must update the same document annually or within 6 months after a refueling outage for each unit. The underlying purpose of the rule was to relieve licensees of the burden of filing annual FSAR revisions while assuring that such revisions are made at least every 24 months.

The Commission reduced the burden, in part, by permitting a licensee to submit its FSAR revisions 6 months after refueling outages for its facility, but did not provide in the rule for multiple unit facilities sharing a common FSAR. Rather, the Commission stated, "With respect to the concern about multiple facilities sharing a common FSAR, licensees will have maximum flexibility for scheduling updates on a case-by-case basis" (57 FR 39355) . Allowing the exemption would maintain the UFSAR current within 24 months of the last revision. Submission of the quality assurance program changes and the 10 CFR 50.59 design change report with the UFSAR revision, as permitted by 10 CFR 50.54(a)(3) and 10 CFR 50.59(b)(2), respectively, also would not exceed a 24-month interval. In addition, submission of the TS Bases changes made in accordance with TS 5.5.14 would not exceed a 24-month interval.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action and concludes that the proposed action is administrative in nature and unrelated to plant operations.

The proposed action will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action does not involve any historic sites. It does not affect nonradiological plant effluents and has no other environmental impacts. Therefore, there are no significant nonradiological environmental impacts associated with this action.

Accordingly, the Commission concludes that there are no significant environmental impacts associated with this action.

Alternative to the Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed action (i.e., the "no-action" alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

The proposed action does not involve the use of any resources not previously considered in the Final Environmental Statement Related to the Operation of Palo Verde Nuclear Generating Station, Units 1, 2, and 3, dated February 1982 (NUREG–0841).

Agencies and Persons Contacted

In accordance with its stated policy, on May 13, 1999, the staff consulted with the Arizona State official, Mr. Audbry Godwin of the Arizona Radiation Protection Agency, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated June 9, 1998, as supplemented by letter dated December 21, 1998, which are available for public inspection at the Commission's Public Document Room, Gelman Building, 2120 L Street, NW., Washington DC, and at the local public document room located at the Phoenix Public Library, 1221 N. Central Avenue, Phoenix, Arizona 85004.

Dated at Rockville. Maryland this 25th day of June 1999.

For the Nuclear Regulatory Commission.

Mel B. Fields,

Project Manager, Section 2, Project Directorate IV & Decommissioning Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 99–17016 Filed 7–2–99; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection; Comment Request for Clearance of a Revised Information Collection: RI 30–2 and RI 30–44

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget a

request for clearance of a revised information collection. RI 30–2, Annuitant's Report of Earned Income, is used annually to determine if disability retirees under age 60 have earned income which will result in the termination of their annuity benefits. RI 30–44, Annuitant's Report of Income—Followup, is sent to annuitants whose returned RI 30–2 forms are unusable or damaged.

Comments are particularly invited on:

—Whether this collection of information is necessary for the proper performance of functions of the Office of Personnel Management, and whether it will have practical utility;

—Whether our estimate of the public burden of this collection is accurate, and based on valid assumptions and methodology; and

—Ways in which we can minimize the burden of the collection of information on those who are to respond, through use of the appropriate technological collection techniques or other forms of information technology.

We estimate 21,000 RI 30–2 forms and 260 RI 30–44 forms are completed annually. The RI 30–2 takes approximately 35 minutes to complete for an estimated annual burden of 12,250 hours. The RI 30–44 takes approximately 5 minutes to complete for an estimated annual burden of 22 hours. The total annual estimate burden is 12,272.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, or E-mail to mbtoomey@opm.gov.

DATES: Comments on this proposal should be received on or before September 7, 1999.

ADDRESSES: Send or deliver comments to—Dennis A. Matteotti, Acting Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349, Washington, DC 20415.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Cyrus S. Benson, Budget & Administrative Services Division, (202) 606–0623.

Office of Personnel Management.

Janice R. Lachance,

Director.

[FR Doc. 99–16989 Filed 7–2–99; 8:45 am]

BILLING CODE 6325–01–P

OFFICE OF PERSONNEL MANAGEMENT

[RI 20–63]

Submission for OMB Review; Comment Request for Review of a Revised Information Collection

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget a request for review of a revised information collection. RI 20–63, Survivor Annuity Election for a Spouse, is used by the Civil Service Retirement System (CSRS) to provide information about the amount of annuity payable after a survivor reduction and to obtain a survivor benefits election from annuitants who are eligible to elect to provide survivor benefits for a spouse. Using RI 20–63 the annuitant may elect the survivor benefit, decline to make the election, or ask for information about electing less than the maximum survivor benefit.

Comments are particularly invited on: whether this information is necessary for the proper performance of functions of the Office of Personnel Management, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Approximately 2,400 RI 20–63 forms and 200 cover letters are completed per year. It is estimated to take approximately 45 minutes to complete the form with a burden of 1,800 hours and 10 minutes to complete the letter, which gives a burden of 34 hours. The total burden for RI 20–63 is 1,834 hours.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, or E-mail to mbtoomey@opm.gov.

DATES: Comments on this proposal should be received on or before September 7, 1999.

ADDRESSES: Send or deliver comments to—Ronald W. Melton, Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349, Washington, DC 20415.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Phyllis R. Pinkney, Management Analyst, Budget & Administrative Services Division, (202) 606–0623.

Office of Personnel Management.

Janice R. Lachance,

Director.

[FR Doc. 99–16991 Filed 7–2–99; 8:45 am]

BILLING CODE 6325–01–U

OFFICE OF PERSONNEL MANAGEMENT

[RI 25–49]

Submission for OMB Review; Comment Request for Review of a Revised Information Collection

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) has submitted to the Office of Management and Budget a request for review of a revised information collection. To verify that adult student annuitants are entitled to payments, OPM needs to know that a full-time enrollment has been maintained. RI 25–49, Verification of Full-Time School Attendance, is used for this purpose.

Approximately 10,000 RI 25–49 forms are completed annually. Each form takes approximately 60 minutes to complete. The annual estimated burden is 10,000 hours.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, or E-mail to mbtoomey@opm.gov

DATES: Comments on this proposal should be received on or before August 5, 1999.

ADDRESSES: Send or deliver comments to—

Dennis A. Matteotti, Acting Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349, Washington, DC 20415

and

Joseph Lackey, OPM Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW, Room 10235, Washington, DC 20503

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Phyllis R. Pinkney,

Management Analyst, Budget and Administrative Services Division, (202) 606–0623.

Office of Personnel Management.

Janice R. Lachance,

Director.

[FR Doc. 99–16990 Filed 7–2–99; 8:45 am]

BILLING CODE 6325–01–U

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–41572; File No. SR–CTA/CA–99–01]

Consolidated Tape Association; Notice of Filing of Fourth Charges Amendment to the Second Restatement of the Consolidated Tape Association Plan and the Third Charges Amendment to the Restated Consolidated Quotation Plan

June 28, 1999.

Pursuant to Rule 11Aa3–2 [1] of the Securities Exchange Act of 1934 ("Act"),[2] notice is hereby given that on June 14, 1999, the Consolidated Tape Association ("CTA") and the Consolidated Quotation ("CQ") Plan Participants ("Participants") [3] filed with the Securities and Exchange Commission ("Commission") or "SEC") amendments to the Restated CTA Plan and CQ Plan. The amendments propose (1) to modify the fees payable by vendors of the Network A market information in respect of nonprofessional subscriber services, (2) to introduce pay-for-use rates into the Network A rate schedules following a pilot test that commenced in November 1997, (3) to grant each vendor of a pay-for-use service the ability to limit its monthly pay-for-use obligation for each of its customers that qualifies as a nonprofessional subscriber, and (4) to establish an enterprise arrangement pursuant to which broker-dealers would enjoy a maximum monthly obligation of $500,000 for aggregate monthly Network A market data fees incurred for interrogation services (both display-device and pay-per-use) that it provides to its officers, partners and employees and to its nonprofessional, brokerage-account customers.

Pursuant to Rule 11Aa3–2(c)(1), the CTA and CQ Participants submitted this notice of proposed amendments to two effective national market system plans.[4] The Commission is publishing this notice to solicit comments from interested persons on the amendments.

I. Description and Purpose of the Amendments

A. Rule 11Aa3–2

1. Nonprofessional Subscriber Service Rates

The participants under the Plans that make Network A last sale information and Network A quotation information available (the "Network A Participants") impose on vendors a monthly fee of $5.25 for each nonprofessional subscriber to whom the vendor provides a Network A market data display service. These amendments proposed to reduce that monthly fee from $5.25 for each nonprofessional subscriber to (i) $1.00 for each of the first 250,000 nonprofessional subscribers to whom a vendor provides a Network A display service during the month and (ii) $.50 for each additional nonprofessional subscriber.

The objective of the proposed plan amendments is to encourage the proliferation of those services and the widespread dissemination of Network A market data. The Network A Participants also believe that reductions in the nonprofessional subscriber rates respond to the growing number of broker-dealers and vendors that wish to provide on-line services to their customers, which services may, for example, enable their customers to price portfolios with real-time information and to receive "dynamically updated" services, such as real-time ticker displays.

For the nonprofessional subscriber rates (rather than the much higher professional subscriber rates) to apply to any of its subscribers, a vendor must make certain that the subscriber qualifies as a nonprofessional subscriber,[5] subject to the same criteria that have applied since 1983, when the Network A Participants first established a reduced rate for nonprofessional subscribers.

Only those nonprofessional subscribers that actually gain access to at least one real-time Network A quote or price during the month will be charged the proposed fees by the Network A Participants.

2. Pay-for-Use Rates

Since November 1997, the Network A Participants have conducted a pilot program [6] pursuant to which vendors provide services that account for the use of market data on the basis of one cent per quote packet.[7] Vendors that have contracted to provide a usage-based service are required to pay one-cent for every quote packet that they make available, whether to professional or nonprofessional subscribers. The fee is an alternative to the other fee that the Network A Participants have historically charged professional and nonprofessional subscribers.

Based on their experience with the one-cent-per-quote fee and their extensive consultation with vendors and member organizations, the Network A Participants are proposing to modify the one-cent fee and to make the modified fee part of the Network A rate schedule.

Under the modified rates, each vendor would pay:

i. Three-quarters of one cent ($0.0075) for the first 20 million quote packets that it distributes during a month;

ii. One-half of one cent ($0.005) for the next 20 million quote packets that it distributes during that month (*i.e.*, quote packets 20,000,001 through 40,000,000 million); and

iii. One-quarter of one cent ($0.0025) for every quote packet in excess of 40 million that it distributes during that month.

The Network A Participants believe that the proposed pay-for-use fees may motivate additional market data vendors and broker-dealers to provide pay-for-use services, thereby making real-time market data even more readily available to investors through those channels.

3. Interplay of Nonprofessional-Subscriber and Pay-for-Use Rates

The Network A Participants further propose to reduce the cost exposure of vendors and broker-dealers by permitting them to limit the amount due from each nonprofessional subscriber

[1] 17 CFR 240.11Aa3–2.

[2] 15 U.S.C. 78s(b)(1).

[3] The amendments were executed by each Participant in each of the Plans. The Participants include American Stock Exchange LLC, Boston Stock Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., Cincinnati Stock Exchange, Inc., National Association of Securities Dealers, Inc., New York Stock Exchange, Inc., Pacific Exchange, Inc., and Philadelphia Stock Exchange, Inc.

[4] The CTA and CQ Plans have been designated as effective transaction reporting plans pursuant to Exchange Act Rule 11Aa3–1(b).

[5] A "nonprofessional subscriber" shall receive the information solely for his personal, non-business use. The subscriber shall not furnish the information to any other person. *See* NYSE and ASE Application and Agreement for the Privilege of Receiving Last Sale Information & Bond Last Sale Information as a Nonprofessional Subscriber, for the qualifications necessary to be classified as a nonprofessional subscriber.

[6] *See* Securities Exchange Act Rel. No. 39370 (November 26, 1997), 62 FR 64414 (December 5, 1997).

[7] A "quote packet" refers to any data element, or all data elements, relating to a single issue. Last sale price, opening price, high price, low price, volume, net change, bid, offer, size, best bid and best offer all exemplify data elements. "IBM" exemplifies a single issue. An index value constitutes a single issue data element.

each month. The vendors and broker-dealers would be eligible to pay the lower of either the aggregate pay-per-use fees that would apply to the subscriber's usage during the month or the monthly $1.00 first-tier nonprofessional subscriber fee. The Network A Participants propose to offer this flexibility to each subscriber that qualifies as a nonprofessional subscriber and that has agreed to the terms and conditions that apply to the receipt of market information as a nonprofessional subscriber.

For ease of administration, the Network A Participants propose to allow each vendor and broker-dealer to apply the $1.00 fee for any month in which each nonprofessional subscriber retrieves 134 or more quote packets during the month, without regard to the marginal per-quote rate that the vendor or broker-dealer pays that month (*i.e.*, three-quarters, one-half or one-quarter cent per quote packet). In addition, each vendor may reassess each month to determine which fee is more economical, the per-quote fee or the nonprofessional subscriber fee.

4. Enterprise Arrangement

In response to input from the brokerage community, the Network A Participants propose to introduce an enterprise arrangement and to make it available to United States-registered broker-dealers. The concept would apply to the devices that those broker-dealers use internally and to those broker-dealers' distribution of market data to their securities-trading customers. It would not apply to broker-dealers that make market data available to non-brokerage customers.

The enterprise arrangement would limit the aggregate amount that United States-registered broker-dealers would be required to pay in any month to (i) the receipt and use of market data by its officers, partners and employees and those of its affiliates, and to (ii) the pay-for-use and monthly display-device interrogation services that it or its United States-registered broker-dealer affiliates provide to their nonprofessional, brokerage-account customers (*i.e.*, customers that qualify as nonprofessional subscribers and that have opened a trading account pursuant to an applicable brokerage account agreement). Fees not eligible for inclusion in the enterprise arrangement's monthly payment limitation are (i) pay-for-use and display device fees payable by (A) professional subscribers and (B) nonprofessional subscribers that do not have brokerage accounts with the broker-dealer or its United States-registered broker-dealer affiliates, (ii) access fees, and (iii) program classification charges.

The enterprise arrangement's maximum monthly payment through the end of calendar year 2000 shall be $500,000. Thereafter, the Network A Participants propose to increase that maximum on an annual basis in an amount equal to the percentage increase in the annual composite share volume for the preceding calendar year, subject to a maximum annual increase of five percent.

The proposal responds to broker-dealer input suggesting that CTA develop an enterprise-wide approach to pricing. CTA anticipates that like other proposals, this one will encourage new and additional uses of real time data by making the cost less expensive and more predictable.

In addition, the Network A Participants propose to make some minor, non-substantive changes to the form of Schedules A–1 and A–2 of Exhibit E to both the CTA Plan and the CQ Plan.

* * * * *

This amendment furthers the objectives of the national market system regarding the dissemination of last sale information delineated in Sections 11A(a)(1)(C), 11A(a)(1)(D) and 11A(a)(3)(B) of the Act.

B. Governing or Constituent Documents

Not applicable.

C. Implementation of Amendment

The Participants have manifested their approval of the proposed amendments to the CTA and CQ Network A rate schedules by means of their execution of the amendments. The rate changes would become effective on the first day of the month that follows the month in which the Commission approves the proposed plan amendments.

D. Development and Implementation Phases

See Item I(C).

E. Analysis of Impact on Competition

The proposed amendments do not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Network A Participants do not believe that the proposed plan amendments introduce terms that are unreasonably discriminatory for the purposes of Section 11A(c)(1)(D) of the Act.

F. Written Understanding or Agreements Relating to Interpretation of, or Participation in, Plan

Not applicable.

G. Approval by Sponsors in Accordance With Plans

In accordance with Section XII(b)(iii) of the CTA Plan and Section IX(b)(iii) of the CQ Plan, each of the Participants has approved the fee reductions.

H. Description of Operation of Facility Contemplated by the Proposed Amendment

Not applicable.

I. Terms and Conditions of Access

See Item I(A) above.

J. Method of Determination and Imposition, and Amount of, Fees and Charges

See Item I(A) and the text of the amendments.

K. Method and Frequency of Processor Evaluation

Not applicable.

L. Dispute Resolution

Not applicable.

II. Rule 11Aa3–1 (Solely in its Application to the Amendments to the CTA Plan)

A. Reporting Requirements

Not applicable.

B. Manner of Collecting, Processing, Sequencing, Making Available and Disseminating Last Sale Information

Not applicable.

C. Manner of Consolidation

Not applicable.

D. Standards and Methods Ensuring Promptness, Accuracy and Completeness of Transaction Reports

Not applicable.

E. Rules and Procedures Addressed to Fraudulent or Manipulative Dissemination

Not applicable.

F. Terms of Access to Transaction Reports

See Item I(A).

G. Identification of Marketplace of Execution

Not applicable.

III. Solicitation of Comments

Section 11A of the Act requires that the Commission assure fair competition among brokers and dealers and assure

the availability to brokers, dealers and investors of information with respect to quotations for and transactions in securities.[8] Another provision in this section authorizes the Commission to prescribe rules to assure that all persons may obtain this market data on terms that are "not unreasonably discriminatory."

Based on these standards, the Commission requests comment on whether the tiered fee structure applicable to users is unreasonably discriminatory.

1. The usage-based fee is structured as a fee per user with decreases for larger numbers of users. Will this tiered fee structure have an effect on competition among broker-dealers?

2. Will these volume discounts inure to the benefit of retail investors equally regardless of the broker-dealer they choose?

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the CTA. All submissions should refer to the file number in the caption above and should be submitted by July 27, 1999.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–16953 Filed 7–2–99; 8:45 am]

BILLING CODE 8010–01–M

[8] 15 U.S.C. 78k–1(a)(1)(C)(i) and (ii).

[9] 17 CFR 200.30–3(a)(27).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–41558; File No. SR–CBOE–99–21]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to Changes to the Firm Quote Rule

June 24, 1999.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 27, 1999, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. 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

CBOE proposes to amend Rule 8.51, Trading Crowd Firm Disseminated Market Quotes, to expand the categories of orders entitled to firm quote treatment and to specify to what extent multiple orders entered by the same beneficial owner at the same time will be entitled to firm quote treatment. The text of the proposed rule change is available at the Office of the Secretary, 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 Exchange 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 Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 8.51 to expand the categories of orders entitled to firm quote protection and to specify to what extent multiple orders entered by the same beneficial owner and represented at a trading station at approximately the same time will be entitled to firm quote protection.

Currently, Rule 8.51(a) states that "non-broker-dealer customer" orders up to the specified size (currently 10 contracts) are entitled to be executed at the offer (bid) which is displayed when a buy (sell) customer reaches the trading station where the particular option class is located for trading.[3] The Exchange is proposing to expand the category of orders entitled to this protection such that, with one exception, all orders would be entitled to the firm quote treatment under Rule 8.51(a). The firm quote requirement would not apply to orders of individuals who trade in the account of a market-maker or specialist on the Exchange or on another exchange, which account is exempt from the provisions of Regulation T of the Board of Governors of the Federal Reserve System pursuant to Section 7(c)(2) of the Act.[4] This exception would exclude not only market-maker accounts but also customer accounts of market-makers or specialists. In other words, the proposal would apply to orders of broker-dealers (other than those acting as market-makers) regardless of whether they are agency or proprietary orders. The appropriate Floor Procedure Committee would have the authority to determine not to extend firm quote treatment to broker-dealer orders in a particular class of options under its jurisdiction.

In proposing this change, the Exchange believes that extending the firm quote treatment to broker-dealer orders will provide an incentive to broker-dealers to send their orders to the Exchange because they will be assured that their order will be executed at the

[3] *But see* Securities Exchange Act Release No. 40957 (January 20, 1999), 64 FR 4485 (January 28, 1999) (File No. SR–CBOE–98–53, proposing to raise the number of contracts guaranteed under the firm quote rule to the RAES contract limit).

[4] Section 7(c)(2) of the Act specifies those categories of persons that are exempt from the requirements of Regulation T with respect to the arrangement, extension or maintenance of credit to finance securities transactions. Among those persons exempted are members of national securities exchanges or registered broker-dealers who arrange or maintain credit to finance their activities as market makers.

displayed bid or offer, as appropriate. Currently, CBOE trading crowds and specialists or crowds on other exchanges have the option to trade a broker-dealer order at the displayed quote or to change the displayed bid (offer) to reflect that the previously displayed bid (offer) is no longer available. This "trade or fade" policy is codified in paragraph (b) of Rule 8.51.

The Exchange is also proposing to amend Rule 8.51 to deny the firm quote protection to those orders or portions of orders for the same class of options (whether for the same or different series) that are entered by the same beneficial owner and that are represented at the trading station at approximately the same time and that cumulatively exceed the firm quote requirement for that particular class of options. For example, assume the firm quote requirement in option ABC is ten contracts and that a broker-dealer simultaneously sends orders to the floor broker in a crowd to by ten at-the-money call options in each of three different series for that class ABC. The floor broker will likely represent each of these three orders one after another. Under the proposed new paragraph (a)(3) of Rule 8.51, only the first of these three orders would be entitled to firm quote protection. The crowd would be required to trade the other two ten lot orders at the displayed market or to change that market pursuant to the terms of the "trade or fade" policy set forth in paragraph (b) of the Rule.

The Exchange believes that customers or broker-dealers can attempt to circumvent the limits of the firm quote protection by submitting orders at the same time that are in many respects economically very similar. If the market-makers in a crowd were required to fill each of these orders at the displayed quotes without the possibility of refreshing those quotes they would essentially be responsible for honoring the displayed quotes in the crowd at a level beyond the intended protection and would be subjected to undue risk. The potential risk will be even greater than it is today with the expansion in the category of orders that will be entitled to firm quote protection. In addition, the potential risk will be increased if the firm quote limit were to be raised. The Exchange recently submitted a filing with the Commission proposing to expand the allowable firm quote limit up to 50 contracts. The Exchange believes that providing for limits on the extension of the firm quote protection in cases where multiple orders for the same class of options are submitted at approximately the same time is the best way to ensure the viability of the expansion of the firm quote protection that the Exchange has proposed in both this filing (with respect to an expansion in the category of orders entitled to the firm quote guarantee) and in SR–CBOE–98–53 (with respect to an expansion in the allowable firm quote contract limit).

The Exchange also proposes to amend paragraph (b) of Rule 8.51 and Interpretation .06 to make them consistent with the change in the categories of orders now subject to the firm quote guarantee.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with and furthers the objectives of Section 6(b)(5) of the Act[5] in that it is designed to remove impediments to a free and open market and protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any 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 the 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, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–CBOE–99–21 and should be submitted by July 27, 1999.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–16949 Filed 7–2–99; 8:45 am]

BILLING CODE 8010–01–M

[5] 15 U.S.C. 78f(b)(5).

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

(Release No. 34–41571; File No. SR–NASD–99–22)

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change Relating to Limited Usage Service Fees

June 28, 1999.

On April 28, 1999, the National Association of Securities Dealers, Inc. ("NASD" or "Association"), through its wholly owned subsidiary, the Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NASD Rule 7010 to eliminate its Limited Usage Service Fee.

The proposed rule change was published for comment in the **Federal Register** on May 28, 1999.[3] The Commission did not receive any comments on the proposed rule change. This order approves the proposed rule change.

Nasdaq is proposing to amend NASD Rule 7010 to eliminate its Limited Usage

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 41432 (May 20, 1999), 64 FR 29075.

Service Fee.[4] Currently, professional market participants may obtain, through an approved portable quotation device, Nasdaq Level I and Last Sale Information on up to 250 Nasdaq securities for a monthly fee of $6.00. The fee currently has approximately 95 subscribers and has never exceeded 200 users during its existence. In light of this low participant usage and the burdens associated with administering the Limited Usage Service, Nasdaq has determined to discontinue this service and its related fee. Nasdaq notes that the information provided through the Limited Usage Service will still be widely available to professionals through numerous other mediums and vendors.

The Commission finds that the proposed rule change is consistent with the requirements of the Act[5] and the rules and regulations thereunder applicable to a national securities association. In particular, the Commission finds the proposal is consistent with the requirements of sections 15A(b)(5)[6] and (6)[7] because the proposed rule change is designed to provide for the equitable allocation of reasonable fees among those using the NASD's facilities or systems and is not designed to permit unfair discrimination between customers, issuers, brokers or dealers.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[8] that the proposed rule change (SR–NASD–99–22) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority,[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–16951 Filed 7–2–99; 8:45 am]

BILLING CODE 8010–01–M

[4] This fee was established on a pilot basis on January 3, 1984. *See* Securities Exchange Act Release No. 20522 (January 3, 1984), 49 FR 1440 (January 11, 1984).

[5] The Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. The Commission finds that the proposed rule change increases efficiency by refining the fee structure and lessening confusion about available services. The Commission also finds that the proposed rule change is not discriminatory and does not impinge on competition because the information provided through the Limited Usage Service is still widely available through other mediums. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78*o*–3(b)(5).

[7] 15 U.S.C. 78*o*–3(b)(6).

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–41568; File No. SR–NASD–98–26]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval to Amendment No.7 to a Proposed Rule Change by the National Association of Securities Dealers, Inc. To Institute, on a Pilot Basis, New Primary Nasdaq Market Maker Standards for Nasdaq National Market Securities

June 28, 1999.

I. Introduction

On March 19, 1998, the National Association of Securities Dealers, Inc. ("NASD" or "Association"), through its wholly-owned subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to: (a) Implement, on a pilot basis, new Primary Nasdaq Market Maker ("PMM") standards for all Nasdaq National Market ("NNM") securities; (b) extend the NASD's Short Sale Rule pilot until November 1, 1998; and (c) extend the suspension of existing PMM standards until May 1, 1998. On March 30, 1998, the Commission issued notice of the filing and approved, on an accelerated basis, the portions of the filing extending the NASD's Short Sale Rule pilot and the suspension of existing PMM standards.[3] The Short Sale Rule pilot and the suspension of existing PMM standards was subsequently extended until June 30, 1999.[4]

On June 22, 1999, Nasdaq proposed to (1) continue to suspend the current PMM standards until December 31, 1999, and (2) extend the NASD's Short Sale Rule pilot (including extending the amendment to the definition of "legal" short sale) until December 31, 1999.[5]

Background

Presently, NASD Rule 4612 provides that a member registered as a Nasdaq market maker pursuant to NASD Rule 4611 may be deemed a PMM if that member meets certain threshold standards. The implementation of the SEC Order Handling Rules and what some perceive as a concurrent move toward a more order-driven, rather than a quote-driven, market raised questions about the continued relevance of those PMM standards. As a result, such standards were suspended beginning in early 1997.[6] Currently, all market makers are designated as PMMs.

Since February 1997, Nasdaq has worked to develop PMM standards that are more meaningful in what may be an increasingly order-driven environment and that better identify firms engaged in responsible market making activities deserving of the benefits associated with being a PMM, such as being exempt from NASD Rule 3350, the NASD's Short Sale Rule. The NASD now proposes to extend the current suspension of the existing PMM standards.

In light of a substantial number of comments on the proposed new PMM standards, Nasdaq staff in August 1998 convened a subcommittee to develop new standards. Nasdaq expects that it will file an amendment to SR–NASD–98–26 to incorporate the new PMM standards that currently are being developed by the subcommittee, or in the alternative, that it will withdraw SR–NASD–98–26 and will submit the new PMM standards as a new filing.

For the reasons discussed below, the Commission has determined to grant accelerated approval to Nasdaq's request, in Amendment No. 7, to continue to suspend the current PMM standards and to extend the NASA's Short Sale Rule Pilot until December 31, 1999.

II. Proposed Rule Change

In the current amendment, Nasdaq is proposing to extend the Short Sale Rule pilot (including extending the amendment to the definition of "legal" short sale) and the suspension of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Exchange Act Release No. 39819 (March 30, 1998) 63 FR 16841 (April 6, 1998).

[4] *See* Exchange Act Release No. 41195 (March 19, 1999) 64 FR 14778 (March 26, 1999).

[5] *See* letter from Robert E. Aber, Senior Vice President and General Counsel, Nasdaq, to Richard Strasser, Assistant Director, Division of Market Regulation, SEC, dated June 21, 1999.

[6] *See* Exchange Act Release No. 38294 (February 14, 1997) 62 FR 8289 (February 24, 1997) (approving temporary suspension of PMM standards); Exchange Act Release No. 39198 (October 3, 1997) 62 FR 53365 (October 14, 1997) (extending suspension through April 1, 1998); Exchange Act Release No. 39818 (March 30, 1998) 63 FR 16841 (April 6, 1998) (extending suspension through May 1, 1998); Exchange Act Release No. 39936 (April 30, 1998); 63 FR 25253 (May 7, 1998) (extending suspension through July 1, 1998); Exchange Act Release No. 40140 (June 26, 1998) 63 FR 36464 (July 6, 1998) (extending suspension through October 1, 1998); Exchange Act Release No. 40485 (September 24, 1998) 63 FR 52780 (October 1, 1998) (extending suspension through March 31, 1999); Exchange Act Release No. 41195 (March 19, 1999) 64 FR 14778 (March 26, 1999) (extending suspension through June 30, 1999).

existing PMM standards to allow more time to refine the PMM standards.

The proposed rule language, as amended, follows. Additions are italicized; deletions are bracketed.

NASD Rule 3350

(a)–(k) No Changes.

(l) This Rule shall be in effect until [June 30, 1999] *December 31, 1999.*

III. Discussion

After careful consideration, the Commission has found, for the reasons set forth below, that the extension of the Short Sale Rule pilot and the suspension of the existing PMM standards until December 31, 1999, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder. In particular, the extension is consistent with Section 15A(b)(6)[7] of the Exchange Act. Section 15A(b)(6) requires that the NASD's rules be designed, among other things, to remove impediments to and perfect the mechanism of a free and open market and a national market system and to promote just and equitable principles of trade. The Commission finds that continuation of the Short Sale Rule pilot and the continued suspension of the current PMM standards will maintain the status quo while the Commission and the NASD review the operation of revised PMM standards. Because the Commission's ultimate stance on the Short Sale Rule may be affected, in part, by the operation of revised PMM standards, it is reasonable to keep the Short Sale Rule pilot in place while work continues on the PMM standards. Furthermore, it is judicious, in the short term, to avoid reintroducing the previous PMM standards prior to the implementation of a new PMM pilot.

In finding that the suspension of the existing PMM standards is consistent with the Exchange Act, the Commission reserves judgment on the merits of the NASD's Short Sale Rule, any market maker exemptions to that rule, and the proposed new PMM standards. The Commission recognizes that the Short Rule already has generated significant public comment. Such commentary, along with any further comment on the interaction of the Short Sale Rule with the proposed new PMM standards, will help guide the Commission's evaluation of the Short Sale Rule and new PMM standards. During the PMM pilot period, the Commission anticipates that the NASD will continue to address the Commission's questions and concerns and provide the Commission staff with any relevant information about the practical effects and the operation of the revised PMM standards and possible interaction between those standards and the NASD's Short Sale Rule.

The Commission finds good cause for approving the extension of the Short Sale Rule pilot (including extending the amendment to the definition of "legal" short sale) and the suspension of existing PMM standards prior to the 30th day after the date of publication of notice of the filing in the **Federal Register**. It could be disruptive to the Nasdaq market and confusing to market participants to reintroduce the previous PMM standards for a brief period prior to implementing a new PMM pilot.

IV. Solicitation of Comments

Inerested persons are invited to submit written data, views, and arguments concerning Amendment No. 7, including whether the proposed Amendment is consistent with the Exchange Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASD–98–26 and should be submitted by July 27, 1999.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Exchange Act,[8] that Amendment No. 7 to the proposed rule change, SR–NASD–98–26, which extends the NASD Short Sale Rule pilot and the suspension of the current PMM standards to December 31, 1999, be and hereby is approved on an accelerated basis.[9]

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–16952 Filed 7–2–99; 8:45 am]

BILLING CODE 8010–01–M

[7] 15 U.S.C. 78o–3(b)(6).

[8] 15 U.S.C. 78s(b)(2).

[9] In approving Amendment No. 7, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(F).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–41567; File No. SR–PCX–99–19]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Stock Exchange, Inc. Relating to Fines for Damage of Exchange Property

June 28, 1999.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 4, 1999, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On June 21, 1999, the Exchange filed Amendment No. 1. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PCX proposes to amend PCX Rule 10.13 to include fines for the intentional or reckless use and/or damage of Exchange equipment. The text of the proposed rule change is available at the Office of the Secretary, PCX 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 PCX 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 PCX has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 10.13, governing Minor Rule Plan violations, to include fines for the intentional or reckless use and/or damage of Exchange equipment. First, if there is abuse of property but no property damage is involved, the Exchange proposes fines of $100, $250, and $500 for the first, second, and third violations respectively.

Second, for abuse of equipment where property damage is involved, the Exchange proposes fines of $500, $750, and $1,000 for the first, second, and third violations respectively, plus the cost to repair or replace the equipment. The Exchange proposes these fines to cover costs of repairing or replacing equipment resulting from intentional or reckless use by Members. In addition, the Exchange proposes these fines to deter intentional or reckless use and subsequent damage of equipment.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with section 6(b)[3] of the Act in general and furthers the objectives of section 6(b)(4)[4] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other person using its facilities.[5]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[6] and subparagraph (f)(6) of Rule 19b–4 thereunder[7] because the proposed rule change (1) does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; (3) does not become operative for 30 days from the date of filing, or such shorter time that the Commission may designate if consistent with the protection of investors and the public interest; and (4) the PCX provided the Commission with written notice of its intent to file the proposed rule change at least five business days prior to the filing date. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. 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 at the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the PCX. All submissions should refer to File No. SR–PCX–99–19 and should be submitted by July 27, 1999.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–16950 Filed 7–2–99; 8:45 am]

BILLING CODE 8010–01–M

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4).

[5] In reviewing the proposed rule change, the Commission considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6).

[8] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before August 5, 1999. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Jacqueline White, Small Business Administration, 409 3rd Street, SW, 5th Floor, Washington, DC 20416; and *OMB Reviewer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7040.

SUPPLEMENTARY INFORMATION:

Title: Secondary Market Assignment and Disclosure.

Form No: 1088.

Frequency: On Occasion.

Description of Respondents: Secondary Market Participants.

Annual Responses: 5,000.

Annual Burden: 7,500.

Dated: June 18, 1999.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 99–17000 Filed 7–2–99; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0317]

BCC Capital Corp.; Notice of License Surrender

Notice is hereby given that BCC Capital Corporation ("BCC"), 280 Park Avenue, New York, New York 10017, has surrendered its license to operate as

a small business investment company under the Small Business Investment Act of 1958, as amended ("the Act"). EDCLP was licensed by the U.S. Small Business Administration on September 24, 1976.

Under the authority vested by the Act and pursuant to the regulations promulgated thereunder, the surrender of the license was accepted on May 6, 1999, and accordingly, all rights, privileges, and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

United States Small Business Administration.

Dated: June 28, 1999.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 99–17002 Filed 7–2–99; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0355]

European Development Capital Limited Partnership; Notice of License Surrender

Notice is hereby given that European Development Capital Limited Partnership ("EDCLP"), 280 Park Avenue, New York, New York 10017, has surrendered its license to operate as a small business investment company under the Small Business Investment Act of 1958, as amended ("the Act"). EDCLP was licensed by the U.S. Small Business Administration on May 3, 1979.

Under the authority vested by the Act and pursuant to the regulations promulgated thereunder, the surrender of the license was accepted on May 6, 1999, and accordingly, all rights, privileges, and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Small Business Administration.

Dated: June 28, 1999.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 99–17001 Filed 7–2–99; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application (99–04–C–00–BLI) To Impose Only, Impose and Use and Use Only the Revenue From a Passenger Facility Charge (PFC) at Bellingham International Airport, Submitted by the Port of Bellingham, Bellingham International Airport, Bellingham, WA

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 only, impose and use and use only PFC revenue at Bellingham International Airport under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before August 5, 1999.

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. John Sibold, Director of Aviation, at the following address: Port Of Bellingham, 4201 Mitchell Way, Bellingham, WA 98226.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Bellingham International Airport, under section 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Ms. Mary E. Vargas, (425) 227–2660; 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 (99–04–C–00–BLI) to impose only, impose and use and use only PFC revenue at Bellingham International Airport, under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On June 24, 1999, the FAA determined that the application to impose and use the revenue from a PFC submitted by the Port of Bellingham, Bellingham International Airport, Bellingham, Washington, was substantially complete within the requirements of section 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than September 23, 1999.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: January 1, 2000.

Proposed charge expiration date: March 1, 2004.

Total requested for use approval: $1,445,000.

Brief description of proposed project: Impose Only: Terminal rehabilitation and expansion; Impose and Use: Terminal design; Use only: Alpha taxiway pullout on north.

Class or classes of air carriers, which the public agency has requested not be required to collect PFC's: Air taxi/commercial operators.

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 315, 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 Bellingham International Airport.

Issued in Renton, Washington on June 24, 1999.

David A. Field,

Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 99–16957 Filed 7–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 99–5604 Notice 1]

Orion Bus Industries Inc.; Receipt of Application for Determination of Inconsequential Noncompliance

Orion Bus Industries, Inc. (Orion) of Oriskany, New York, has applied to be exempted from the notification and remedy requirements of the 49 U.S.C. Chapter 301 "Motor Vehicle Safety because of a noncompliance with Federal Motor Vehicle Safety Standard

(FMVSS) No. 205 Glazing Materials." The basis of the application is that the noncompliance is inconsequential to motor vehicle safety. Orion has filed an appropriate report pursuant to 49 CFR Part 573 "Defect and Noncompliance Information Reports."

This notice of receipt of an application is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgement concerning the merits of the application.

Orion submitted the following information in accordance with the requirements of 49 CFR Part 556, "Exemption for Inconsequential Defect or Noncompliance."

Vehicles Involved

Orion II, Orion V and Orion VI transit buses manufactured between January 17, 1996, and November 30, 1998, equipped with non-opening fixed glass windows. The serial numbers of the affected vehicles fall within the range: Orion II—005917 through 6058, Orion V—32516 through 34054 and Orion VI—40006 through 40315.

Description of the Noncompliance

Certain Orion II, Orion V, and Orion VI transit buses were equipped with fixed glass non-sliding windows which were not marked as required by S6 of FMVSS No. 205, specifically Section 6 of ANSI Z26 as incorporated by reference. They also were not marked with the symbol "DOT" or the manufacturer's code mark as required by S6.2 of FMVSS No. 205. The window glazing is marked with architectural code numbers by mistake. The windows meet the performance requirements of FMVSS No. 205.

Number of Vehicles

Five hundred and ten (510) vehicles as of November 30, 1998 potentially contain the noncompliance.

Supporting Information

Although the glazing does not meet the requirements of Section S6, FMVSS No. 205, the glazing has been tested and complies to AS–3, AS–2 and AS–1 of ANSI Z26.1 as required for the application. The window supplier has three different plant locations, two of which specialize in building-type windows and the third one in vehicle windows. Whenever the plant specializing in vehicle windows gets backed up with orders, the window supplier sends its excess orders, to one of the other plants for completion. The employee sandblasting the logos at one of the building glass plants did not realize this was motor vehicle glass and put architectural codes on all windows.

There are a total of eighteen different parts numbers affected. The windows in question are used on both the curb side and road side of the bus as well as at the rear of the vehicle. On the curb side the windows are used in the front and rear doors as well as passenger windows. The door glass ranges in size from 6″ x 32″ to 18″ x 34″ and the side and rear passenger windows range from 18″ x 34″ to 34″ x 34″. The only front facing glass is used for destination signs and is a separate piece mounted above the front windshield. All windows in this application were purchased from Barber Glass Industries Inc., 485 Southgate Drive, Guelph, Ontario, Canada N1G 3W6, Phone 519–824–2399 and Fax 519–824–1493. (DOT 522 is its Manufacturer Identification Number).

Orion argues that:

Barber Glass has stated that if a person used the architectural codes sandblasted on the bus windows in error to go to a glass shop to replace a broken bus window the glass they would get would meet the required ANSI A26.1 safety glass requirements listed in FMVSS 205. They would not however, be able to match the window tint as vehicle windows use different vinyls for their tinting purposes and would have to specify automotive glass to get the matching window tints.

Orion Bus Industries, Inc. believes that, based upon the above information, the noncompliance described above is inconsequential as it relates to motor vehicle safety.

Interested persons are invited to submit written data, views and arguments on the petition of Orion, described above. Comments should refer to the Docket Number and be submitted to: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. It is requested that two copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date will also be filed and will be considered to the extent practicable. When the application is granted or denied, the Notice will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: August 5, 1999.

(49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.50 and 49 CFR 501.8)

Issued on: June 28, 1999.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

[FR Doc. 99–16956 Filed 7–2–99; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33774]

Chicago SouthShore & South Bend Railroad—Trackage Rights Exemption—CSX Transportation, Inc.

CSX Transportation, Inc. (CSXT) has agreed to grant overhead trackage rights to Chicago SouthShore & South Bend Railroad (CSS) over CSXT's Barr Subdivision between the connection with CSS at milepost BI241.4, at Miller, IN, and CSXT's connection with Baltimore and Ohio Chicago Terminal Railroad Company (B&OCT) at milepost BI248.8, at Pine Junction, IN, a distance of approximately 7.4 miles.

The transaction is scheduled to be consummated on or shortly after June 30, 1999.

The purpose of the trackage rights is to permit CSS to interchange certain traffic with B&OCT at Barr Yard, thereby promoting operating efficiencies.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33774, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on (1) Rose-Michele Weinryb, Esq., Chicago SouthShore & South Bend Railroad, 1350 New York Ave., NW., Suite 800, Washington, DC 20005–4797, and (2) Charles M. Rosenberger, CSX Transportation, Inc., 500 Water Street, Jacksonville, FL 32202.

Board decisions and notices are available on our website at "WWW.STB.DOT.GOV."

Decided: June 28, 1999.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 99–16897 Filed 7–2–99; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Termination; Alliance Assurance Company of America, American Mercury Insurance Company, Boston Old Colony Insurance Company, GIGNA Indemnity Insurance Company, CIGNA Insurance Company of the Midwest, Continental Reinsurance Corporation, European Reinsurance Corporation of America, Illinois National Insurance Co., Insurance Company of North America, Kansas City Fire and Marine Insurance Company, London Assurance of America, Inc. (The), Mid-Century Insurance Company, Phoenix Assurance Company of New York, Providence Washington Insurance Company, Sea Insurance Company of America (The), Sun Insurance Office of America Inc., Toklo Marine and Fire Insurance Company, Limited (The), U.S. Branch, Transcontinental Insurance Company, Transportation Insurance Company and Valley Forge Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 16 to the Treasury Department Circular 570; 1998 Revision, published July 1, 1998, at 63 FR 36080.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificate of Authority issued by the Treasury to the above named Companies, under the United States Code, Title 31, Sections 9304–9308, to qualify as an acceptable surety and/or reinsurer on Federal bonds is terminated effective June 30, 1999.

The Companies were last listed as an acceptable sureties and/or reinsurers on Federal bonds at 63 FR 36080, July 1, 1998.

With respect to any bonds currently in force with above listed Companies, bond-approving officers may let such bonds run to expiration and need not secure new bonds. However, no new bonds should be accepted from the Company. In addition, bonds that are continuous in nature should not be renewed.

The Circular may be viewed and downloaded through the Internet at http://www.fms.treas.gov/c570/index.html. A hard copy may be purchased from the Government Printing Office (GPO), Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 048000–00516–1.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6A04, Hyattsville, MD 20782.

Dated: June 28, 1999.

Michael C. Salapka,

Acting Director, Financial Accounting and Services Division, Financial Management Service.

[FR Doc. 99–17012 Filed 7–2–99; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Termination—Glens Falls Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 15 to the Treasury Department Circular 570; 1998 Revision, published July 1, 1998, at 63 FR 36080.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–7116.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificate of Authority issued by the Treasury to Glens Falls Insurance Company, of Wilmington, Delaware, under the United States Code, Title 31, Sections 9304–9308, to qualify as an acceptable surety on Federal bonds is terminated effective today.

The Company was last listed as an acceptable surety on Federal bonds at 63 FR 36093, July 1, 1998.

With respect to any bonds currently in force with Glens Falls Insurance Company, bond-approving officers should secure new bonds with acceptable sureties in those instances where a significant amount of liability remains outstanding. In addition, bonds that are continuous in nature should not be renewed.

The Treasury Department Circular 570 may be viewed and downloaded through the Internet (http://www.fms.treas.gov/c570/index.html). A hard copy may be purchased from the Government Printing Office (GPO), Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 048000–00516–1.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6A04, Hyattsville, MD 20782.

Dated: June 28, 1999.

Judith R. Tillman,

Acting Assistant Commissioner, Financial Operations, Financial Management Service.

[FR Doc. 99–17015 Filed 7–2–99; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Termination—Nobel Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 14 to the Treasury Department Circular 570; 1998 Revision, published July 1, 1998, at 63 FR 36080.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–7102.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificate of Authority issued by the Treasury to Nobel Insurance Company of Dallas, TX, under the United States Code, Title 31, Sections 9304–9308, to qualify as an acceptable surety on Federal bonds is terminated effective June 30, 1999.

The Company was last listed as an acceptable surety on Federal bonds at 63 FR 36101, July 1, 1998.

With respect to any bonds currently in force with Nobel Insurance Company bond-approving officers should secure new bonds with acceptable sureties in those instances where a significant amount of liability remains outstanding. In addition, bond that are continuous in nature should not be renewed.

The Treasury Department Circular 570 may be viewed and downloaded through the Internet (http://

www.fms.treas.gov/c570/index.html) A hard copy may be purchased from the Government Printing Office (GPO), Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 048–000–00516–1.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch 3700 East-West Highway, Room 6A04, Hyattsville, MD 20782.

Dated: June 28, 1999.

Judith R. Tillman,

Acting Assistant Commissioner, Financial Operations, Financial Management Service.

[FR Doc. 99–17014 Filed 7–2–99; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF VETERANS AFFAIRS

Enhanced-Use Development at the James H. Quillen Veterans Affairs Medical Center, Mountain Home, TN

AGENCY: Department of Veterans Affairs.

ACTION: Notice of intent to award.

SUMMARY: The Secretary of the Department of Veterans Affairs has designated the Department of Veterans Affairs James H. Quillen Veterans Affairs Medical Center in Mountain Home, Tennessee, as a site for an Enhanced-Use lease development for a co-generation energy center. The Department intends to award an Enhanced-Use lease of real property for a term not-to-exceed 35 years to Energy Systems Group, Inc., a developer/operator.

FOR FURTHER INFORMATION CONTACT: Robert B. Eidson, Capital Assets Manager, Office of the Director (00B), James H. Quillen VA Medical Center, Mountain Home (Johnson City), TN 37684, (423)–926–1171, extension 7112.

SUPPLEMENTARY INFORMATION: 38 U.S.C. 8161, *et seq.*, specifically provides that the Secretary may enter into an Enhanced-Use lease, if the Secretary determines that at least part of the use of the property under the lease will be to provide appropriate space for an activity contributing to the mission of the Department; the lease will not be inconsistent with and will not adversely affect the mission of the Department; and the lease will enhance the property. This project meets these requirements.

Approved: June 24, 1999.

Togo D. West, Jr.,

Secretary of Veterans Affairs.

[FR Doc. 99–16982 Filed 7–2–99; 8:45 am]

BILLING CODE 8320–01–M

Corrections

Federal Register
Vol. 64, No. 128
Tuesday, July 6, 1999

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Municipal Interest Rates for the Third Quarter of 1999

Correction

In notice document 99–16388, beginning on page 34630 in the issue of Monday, June 28, 1999, make the following correction:

On page 34631, in the first column, in the table under the heading "RUS rate (0.000)" for the year 2013, "5.875" should read "4.875".

[FR Doc. C9–16388 Filed 7–2–99; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 90

[FRL 6308-6]

RIN 2060-AE29

Phase 2 Emission Standards for New Nonroad Spark-Ignition Nonhandheld Engines At or Below 19 Kilowatts

Correction

In the issue of Wednesday, June 30, 1999, on page 35256, in the first column, in the correction of rule document 99-6175, in the second line, § 90.706, "(b)(7)" should read § 90.706 "(b)(1)".

[FR Doc. C9–6175 Filed 7–2–99; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 214

[INS 1992-99]

RIN 1115-AF47

Extending the Period of Duration of Status for Certain F and J Nonimmigrant Aliens

Correction

In the issue of Tuesday, June 22, 1999, on page 33346, in the second column, in the correction of rule document 99-15032, in the second line, The correction should read by removing "§ 214.2(j)(1(iv)" and adding "§ 214.2(j(1)(vi)".

[FR Doc. C9–15032 Filed 7–2–99; 8:45 am]

BILLING CODE 1505–01–D

federal register

Tuesday
July 6, 1999

Part II

Environmental Protection Agency

40 CFR Part 62

Federal Plan Requirements for Hospital/ Medical/Infectious Waste Incinerators Constructed on or Before June 20, 1996; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[AD–FRL–6365–8]

RIN 2060–AI25

Federal Plan Requirements for Hospital/Medical/Infectious Waste Incinerators Constructed On or Before June 20, 1996

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On September 15, 1997, EPA adopted emission guidelines for existing hospital/medical/infectious waste incinerator(s) (HMIWI). Sections 111 and 129 of the Clean Air Act (Act or CAA) require States with existing HMIWI subject to the emission guidelines to submit plans to EPA that implement and enforce the emission guidelines. Indian tribes may submit, but are not required to submit, Tribal plans to implement and enforce the emission guidelines in Indian country. State plans were due from States with HMIWI subject to the emission guidelines on September 15, 1998. If a State or Tribe with existing HMIWI does not submit an approvable plan within 2 years after promulgation of the emission guidelines (September 15, 1999), sections 111(d) and 129 of the Act require EPA to develop, implement, and enforce a Federal plan for HMIWI in that State/Tribal area. In this action the EPA proposes a Federal plan to implement emission guidelines for HMIWI located in States and Indian country without effective State or Tribal plans. This Federal plan will most likely be an interim action for many of these areas because when a State/Tribal plan becomes effective, the Federal plan will no longer apply to HMIWI covered by such plan.

DATES: *Comments.* You must submit comments on this proposal on or before September 7, 1999.

Public Hearings. The EPA will hold public hearings, if requested. Requests must be received by August 5, 1999. See the ADDRESSES section of this preamble for information on requesting a public hearing. You can obtain the date and location of the public hearing(s) by calling (919) 541–5420 or by E-mailing to banker.lalit@epa.gov after August 5, 1999.

ADDRESSES: *Comments.* Send your comments on this proposal (in duplicate, if possible) to: Air and Radiation Docket and Information Center (MC–6102), Attention docket number A–98–24, U. S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. You may also submit your comments electronically by following the instructions in the **SUPPLEMENTARY INFORMATION** section of this preamble.

Docket. Docket numbers A–98–24 and A–91–61 contain the supporting information for this proposed rule and the supporting information for EPA's promulgation of emission guidelines for existing HMIWI, respectively. These dockets are available for public inspection and copying between 8:00 a.m. and 5:30 p.m., Monday through Friday, at EPA's Air and Radiation Docket and Information Center (Mail Code 6102), 401 M Street, SW., Washington, D.C. 20460, or by calling (202) 260–7548. The docket is located in Room M–1500, Waterside Mall (ground floor, central mall). The fax number for the Center is (202) 260–4000 and the E-mail address is A-and-R-Docket@epa.gov. A reasonable fee may be charged for copying. In addition to the docket, you can find an electronic copy of this document at the EPA/STAPPA/ALAPCO Unified Air Toxics Website (http://www.epa.gov/ttn/uatw/129/hmiwi/rihmiwi.html).

Public Hearings. The public hearing(s) will be held in the respective EPA Regional Office covering the State from which a request was received. If you wish to speak at a public hearing you should notify Mr. Lalit Banker, Program Implementation and Review Group, Information Transfer and Program Integration Division (MD–12), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541–5420.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposal, contact Mr. Lalit Banker at (919) 541–5420, Program Implementation and Review Group, Information Transfer and Program Integration Division (MD–12), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (banker.lalit@epa.gov). If you have technical questions, contact Mr. Rick Copland at (919) 541–5265, Combustion Group, Emission Standards Division (MD–13), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (copland.rick@epa.gov). If you have questions regarding the implementation of this Federal plan, contact your EPA Regional Office. Regional Office contacts are provided in **SUPPLEMENTARY INFORMATION.**

SUPPLEMENTARY INFORMATION: *Regulated Entities.* If you own or operate an existing HMIWI and are not already subject to an EPA-approved and effective State or Tribal plan, you may be covered by this proposed action. Existing HMIWI are those that commenced construction, modification, or reconstruction on or before June 20, 1996. Regulated categories and entities include those listed in Table 1.

TABLE 1.—REGULATED ENTITIES [a]

Category	Examples of regulated entities
Industry	Hospitals, nursing homes, research laboratories, other health care facilities, commercial waste disposal companies.
Federal Government	Armed services, public health service, Federal hospitals, other Federal health care facilities.
State/local/Tribal Government	State/county/city hospitals and other health care facilities.

[a] This table is not intended to be exhaustive, but rather, provides a guide for the public regarding entities likely to be regulated by this proposed Federal plan. This table lists the types of entities that EPA is aware of that could potentially be regulated. Other types of entities not listed in the table could also be affected. Other types of entities not listed in the table could also be affected. To determine whether your facility is regulated by the standards or emission guidelines for HMIWI, you should carefully examine the applicability criteria in subpart HHH.

Electronic submittal of comments. You may submit comments and data on this proposed rule via E-mail. Send E-mail submittals to A-and-R-Docket@epa.gov. You may file E-mail comments at most Federal Depository Libraries. Do not submit confidential business information through E-mail. You may also submit comments and data on diskettes in WordPerfect 5.1 or 6.1 file format or ASCII file format. Electronic comments must avoid the use of special characters or any form of encryption. Identify all comments and data for this proposal, whether in paper form or electronic form, by docket number A–98–24.

EPA Regional Office Contacts. Table 2 is a listing of EPA Regional Office contacts who can answer questions regarding implementation of this Federal plan.

TABLE 2.—EPA REGIONAL CONTACTS FOR HMIWI

Region	Regional contact	Phone/Fax	States and protectorates
I	John Courcier, courcier.john@ epa.gov	617–918–1659; 617–918–1505 (fax)	CT, ME, MA, NH, RI, VT.
II	Christine DeRosa, derosa.christine@ epa.gov.	212–637–4022; 212–637–3901 (fax)	NJ, NY, Puerto Rico, Virgin Islands.
	Ted Gardella, gardella.anthony@epa.gov	212–637–3892; 212–637–3901 (fax).	
III	James B. Topsale, topsale.jim@epa.gov	215–814–2190; 215–814–2114 (fax)	DE, DC, MD, PA, VA, WV.
IV	Scott Davis, davis.scottr@epa.gov	404–562–9127; 404–562–9095 (fax)	AL, FL, GA, KY, MS, NC, SC, TN.
V	Ryan Bahr, bahr.ryan@epa.gov	312–353–4366; 312–886–5824 (fax)	IN.
	Charles Hatten, hatten.charles@epa.gov	312–886–6031; 312–886–5824 (fax)	WI.
	Mark Palermo, palermo.mark@ epa.gov	312–886–6082; 312–886–5824 (fax)	IL, OH.
	Victoria Hayden, hayden.victoria@ epa.gov.	312–886–4023; 312–886–5824 (fax)	WI.
	Doug Aburano, aburano.douglas@ epa.gov.	312–353–6960; 312–886–5824 (fax)	MN.
VI	Mick Cote, cote.mick@epa.gov	214–665–7219; 214–665–7263 (fax)	AR, LA, NM, OK, TX.
VII	Wayne Kaiser, kaiser.wayne@epa.gov	913–551–7603; 913–551–7844 (fax)	IA, KS, MO, NE.
	Ward Burns, burns.ward@epa.gov	913–551–7960; 913–551–7844 (fax)	
VIII	Meredith Bond, bond.meredith@epa.gov	303–312–6438; 303–312–6064 (fax)	CO, MT, ND, SD, UT, WY.
IX	Patricia Bowlin, bowlin.patricia@epa.gov	415–744–1188; 415–744–1076 (fax)	AZ, CA, HI, NV, American Samoa, Guam.
X	Catherine Woo, woo.catherine@epa.gov	206–553–1814; 206–553–0110 (fax)	AK, ID, OR, WA.

Preamble Outline

I. Background

A. HMIWI Regulations

On September 15, 1997, EPA promulgated emission guidelines for existing HMIWI under authority of sections 111 and 129 of the Act. *See* 62 FR 48348 (to be codified at 40 CFR part 60, subpart Ce, §§ 60.30e through 60.39e). To make these emission guidelines enforceable, States with existing HMIWI were required to submit to EPA within 1 year following promulgation of the emission guidelines a State plan that implements and enforces the emission guidelines. States without any existing HMIWI were required to submit to the Administrator a letter of negative declaration certifying that there are no HMIWI in the State. No plan is required for States that do not have any HMIWI.

As discussed in section I.D. of this preamble, Indian Tribes may, but are not required to, submit Tribal plans to cover HMIWI in Indian country. A Tribe may submit to the Administrator a letter of negative declaration certifying that no HMIWI are located in the Tribal area. No plan is required for Tribes that do not have any HMIWI.

Sections 111 and 129 of the Act and 40 CFR 60.27(c) and (d) require EPA to develop, implement, and enforce a Federal plan to cover existing HMIWI located in States that do not have an approved plan. Furthermore, EPA plans to develop, implement, and enforce a Federal plan for Indian country until Tribes receive approval to administer their own programs. Hospital/medical/infectious waste incinerators located in States or Tribal areas that mistakenly submit a letter of negative declaration would be subject to the Federal plan until a State or Tribal plan that includes these HMIWI is approved and effective. Today's action proposes the HMIWI Federal plan.

B. Who This HMIWI Federal Plan Affects

This proposed HMIWI Federal plan would affect existing HMIWI for which construction commenced on or before June 20, 1996. HMIWIs would be subject to this Federal plan if any of the following is true on the effective date of the Federal plan:

(1) The State or Tribal plan has not become effective;[a]

(2) The State or Tribal plan was in effect but was subsequently vacated in whole or in part; or

(3) The State or Tribal plan was in effect but was subsequently revised such that it is no longer as protective as the emission guidelines.

The specific applicability of this plan is described in proposed §§ 62.14400 through 62.14403 of subpart HHH.

The Federal plan would become effective 30 days after final promulgation. Once an approved State or Tribal plan is in effect, the Federal plan would no longer apply to HMIWI covered by such plan.

C. Implementing Authority

The EPA Regional Administrators will be the delegated authority for implementing the HMIWI Federal plan. All reports required by this Federal plan should be submitted to the appropriate Regional Office Administrator. Table 2 under **SUPPLEMENTARY INFORMATION** lists the names and addresses of the EPA Regional Office contacts and the States that they cover.

D. HMIWI Federal Plan and Indian Country

The term "Indian country," as used in this preamble, means (1) all land within the limits of any Indian reservation under the jurisdiction of the United States government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation; (2) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State; and (3) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

The HMIWI Federal plan would apply throughout Indian country to ensure that there is not a regulatory gap for existing HMIWI in Indian country. However, Indian tribes now have the authority under the Act to develop Tribal plans in the same manner that States develop State plans. On February 12, 1998, EPA promulgated regulations that outline provisions of the Act for which EPA is authorized to treat Tribes in the same manner as States. *See* 63 FR 7254 (Final Rule for Indian Tribes: Air Quality Planning and Management, (Tribal Authority Rule)) (codified at 40 CFR part 49). As of March 16, 1998, the effective date of the Tribal Authority Rule, EPA has had authority under the Act to approve Tribal programs such as Tribal plans to implement and enforce HMIWI emission guidelines.

1. Tribal Implementation

Section 301(d) of the Act authorizes the Administrator to treat an Indian tribe as a State under certain circumstances. The Tribal Authority Rule, which implements section 301(d) of the Act, identifies provisions of the Act for which a Tribe should be treated as a State. *See* 40 CFR 49.3 and 49.4. Under the Tribal Authority Rule, a Tribe is treated as a State for purposes of this Federal plan. If a Tribe meets the criteria below, EPA can delegate to an Indian tribe authority to implement the Federal plan in the same way it can delegate authority to a State:

(1) The applicant is an Indian tribe recognized by the Secretary of the Interior;

(2) The Indian tribe has a governing body carrying out substantial governmental duties and functions;

(3) The functions to be exercised by the Indian tribe pertain to the management and protection of air resources within the exterior boundaries of the reservation or other areas within the tribe's jurisdiction; and

(4) The Indian tribe is reasonably expected to be capable, in the EPA Regional Administrator's judgement, of carrying out the functions to be exercised in a manner consistent with the terms and purposes of the Act and all applicable regulations. *See* 40 CFR 49.6.

2. EPA Implementation

The Act also provides EPA with the authority to administer Federal programs in Indian country. This authority is based in part on the general purpose of the Act, which is national in scope. Section 301(a) of the Act provides EPA broad authority to issue regulations that are necessary to carry out the functions of the Act. The EPA believes that Congress intended for EPA to have the authority to operate a Federal program when Tribes choose not to develop a program, do not adopt an approvable program, or fail to adequately implement an air program authorized under section 301(d) of the Act.

Section 301(d)(4) of the Act authorizes the Administrator to directly administer provisions of the Act to achieve the appropriate purpose where Tribal implementation is not appropriate or administratively not feasible. The Agency's interpretation of its authority to directly implement Clean Air Act programs in Indian country is discussed in more detail in the proposed Federal Operating Permits Rule, *see* 62 FR 13747 (March 21, 1997), and in the Tribal Authority Rule. *See* 63 FR at 7262–7263.

Many Tribes may have delayed development of air quality regulations and programs pending promulgation of the Tribal Authority Rule. As mentioned previously, Tribes may, but are not required to, submit an HMIWI plan under section 111(d) of the Act.

3. Applicability in Indian Country

The Federal plan would apply throughout Indian country except where a State or Tribal plan has been explicitly approved by EPA to cover an area of Indian country. This approach is consistent with that in the proposed Federal Operating Permits Rule cited above where the rationale is discussed in detail. The EPA requests comments on applying the HMIWI Federal plan in Indian country as described here.

E. HMIWI Federal Plan and Compliance Schedules

The emission guidelines require the HMIWI owner or operator to come into compliance with the State or Tribal plan within 1 year after approval of such plan, or within 1 year after promulgation of the Federal plan (whichever applies). *See* 40 CFR 60.39e(b). However, if the State or Tribal plan contains measurable and enforceable increments of progress, the HMIWI may be allowed up to 3 years after approval of the plan (but in no case later than September 15, 2002) to come into compliance. *See* 40 CFR 60.39e(c).

This proposed Federal plan contains measurable and enforceable increments of progress that allow sources up to 3 years after promulgation of the Federal plan to comply (but in no case later than September 15, 2002.) The increments of progress are discussed in section II.E of this preamble.

1. Due Within 1 Year of Promulgation

Except under the special circumstances that are discussed below, HMIWI that are planning to shut down rather than comply with the requirements of the Federal plan must do so by the date 1 year after the Federal plan is promulgated. In addition, according to § 60.39e(e) of subpart Ce, all HMIWI that continue to operate 1 year after the Federal plan promulgation date must comply with the operator

[a] The effective date of a State or Tribal plan from EPA's perspective (a State and Tribe may have an earlier effective date) is 30 days after the State or Tribal plan approval is published in the **Federal Register** if the approval is via the regular regulatory procedure of proposal with opportunity for comment followed by promulgation. If the approval is by direct final rule making, the effective date of the State/Tribal plan is 60 days after the approval is published in the **Federal Register** if no adverse comments are received.

training and qualification requirements and the inspection requirements of the plan within 1 year. This includes HMIWI that comply within 1 year, as well as those that have been granted an extension beyond the 1 year compliance date (i.e., HMIWI with extended retrofit schedules and HMIWI granted an extension pursuant to § 60.39e(d) of subpart Ce).

2. Special Provisions of § 60.39e(d)

The Federal plan may contain provisions allowing HMIWI that are planning to shut down the opportunity to petition the State, Tribe, or EPA for an extension beyond the 1-year compliance date. *See* 40 CFR 60.39e(d). This proposed Federal plan contains provisions for granting and denying petitions for an extension beyond the 1-year compliance deadline (but no later than September 15, 2002). An example of a facility that might petition the enforcement authority for such an extension is a facility installing an onsite alternative waste treatment technology. It is possible that installation cannot be completed within 1 year, and the facility has no feasible waste disposal options other than onsite incineration while the alternative technology is being installed.

The requirements for a petition under the Federal plan, which are set forth at proposed § 62.14471 of subpart HHH, are the same as the requirements listed at § 60.39e(d) of subpart Ce, except that EPA proposes a specific date of 90 days following promulgation of the Federal plan by which petitions must be submitted to EPA under the Federal plan. This time frame, which is more than 2 years after promulgation of the emission guidelines and more than 9 months from today's proposal, should give sources sufficient time to examine their waste disposal options and to prepare the necessary documentation to justify their need for an extension. This time frame also gives EPA sufficient time to grant or deny the petition before the 1-year compliance deadline arrives.

F. Status of State Plan Submittals

Sections 111(d) and 129(b)(2) of the Act, as amended, 42 U.S.C. 7411(d) and 7429(b)(2), authorize EPA to develop and implement a Federal plan for HMIWI located in States with no approved and effective State plan. The EPA has received final State plans from New York, Delaware, Louisiana, Georgia, Alabama, North Dakota, Montana, and Colorado. The EPA has received draft State plans from Puerto Rico, Maryland, West Virginia, Pennsylvania, Iowa, Ohio, Indiana, Minnesota, Illinois, Michigan, South Dakota, Utah, Washington, and Wyoming. Other States are making significant progress on their State plans and EPA expects many State plans to be approved before this Federal plan is final.

The EPA anticipates letters of negative declaration from New Mexico and Oregon. The EPA is not aware of any Indian tribes that are developing Tribal plans.

The preamble of the final Federal plan will list States and Tribes that have an EPA-approved plan in effect on the date the final Federal plan is signed by the EPA Administrator. As Regional Offices approve State plans, they will also, in the same action, amend the appropriate subpart of 40 CFR part 62 to codify their approvals.

The EPA will maintain a list of State plan submittals and approvals on the Unified Air Toxics Website at http://www.epa.gov/ttn/uatw/129/hmiwi/rihmiwi.html. The list will help HMIWI owners or operators determine whether their HMIWI is affected by a State plan, a Tribal plan, or the Federal plan. Hospital/medical/infectious waste incinerator owners and operators can also contact the EPA Regional Office for the State in which their HMIWI is located to determine whether there is an approved and effective State plan in place.

II. Required Elements of the HMIWI Federal Plan

Because the EPA is proposing a Federal plan to cover HMIWI located in States or Tribes where plans are not in effect, this proposal includes the same elements as are required for State plans: (1) Identification of legal authority and mechanisms for implementation; (2) inventory of HMIWI; (3) emissions inventory; (4) emission limits; (5) compliance schedules; (6) public hearing; (7) testing, monitoring, inspection, reporting, and recordkeeping; (8) waste management plan; (9) operator training and qualification; and (10) progress reporting. See 40 CFR part 60 subparts B and C and sections 111 and 129 of the Act. Docket item II–B–3 in docket A–98–24 identifies each element and indicates where it is addressed. Each element is described below as it relates to the proposed HMIWI Federal plan.

A. Legal Authority and Enforcement Mechanism

A State or Tribal plan must demonstrate that the State or Tribe has the legal authority to adopt and implement the emission guidelines. 40 CFR 60.26. In its plan, the State or Tribe must identify the enforcement mechanism for implementing the emission guidelines, such as a State or Tribal rule.

1. EPA's Legal Authority in States

Section 301(a) of the Act provides the EPA with broad authority to write regulations that carry out the functions of the Act. Sections 111(d) and 129(b)(3) of the Act authorize the EPA to develop a Federal plan for States that do not submit approvable State plans.

2. EPA's Legal Authority in Indian Country

Section 301(a) provides EPA with the authority to administer Federal programs in Indian country. Section 301(d)(4) of the Act authorizes the Administrator to directly administer provisions of the Act where Tribal implementation of those provisions is not appropriate or administratively not feasible. See section I.D. of this preamble for a more detailed discussion of EPA's authority to administer the HMIWI Federal plan in Indian country.

The EPA is proposing this Federal regulation under the legal authority of the Act to implement the emission guidelines in those States and areas of Indian country not covered by an approved plan. As discussed in section IV of this document, implementation and enforcement of the Federal plan may be delegated to Tribal, State, or local agencies when requested by a State, Tribal, or local agency, and when EPA determines that such delegation is appropriate.

B. Inventory of Affected HMIWI

A State or Tribal plan must include an inventory of HMIWI affected by the emission guidelines. 40 CFR 60.25(a). Consistent with this requirement, docket number A–98–24, item II–B–1 contains an inventory of all the HMIWI EPA is aware of that will be covered by this proposed Federal plan.

This inventory was initially created in 1995 in connection with development of the HMIWI emission guidelines. In late 1998, EPA gave States an opportunity to submit updates to the 1995 list. Many States responded and in most cases, EPA was able to incorporate these updates. However, EPA recognizes that this list may not be complete. Therefore, sources subject to this Federal plan would include, but would not be limited to, the HMIWI listed in docket A–98–24, item II–B–1. States, Tribes, or individuals with corrections to the Federal plan inventory are invited to submit their corrections during the comment period for this proposal.

Hospital/medical/infectious waste incinerators that are located in a State

or Tribal area with an approved and effective plan, but that are not covered by such plan (for example, because they were inadvertently omitted from the coverage of the plan and the plan fails to contain language that would include inadvertently omitted HMIWI), would automatically be covered by the Federal plan. There will be no need to reopen the Federal plan to add such HMIWI.

C. Inventory of Emissions

A State plan must include an emissions estimate for HMIWI subject to the emission guidelines. 40 CFR 60.25(a). The pollutants to be inventoried are dioxins/furans, cadmium (Cd), lead (Pb), mercury (Hg), particulate matter (PM), hydrogen chloride (HCl), nitrogen oxides (NO_X), carbon monoxide (CO), and sulfur dioxide (SO_2). For this proposal, EPA has estimated the emissions from each HMIWI that would be covered by the Federal plan for the nine pollutants regulated by the Federal plan. This emissions inventory is included in item II–B–1 in docket A–98–24.

Pollutant emissions are expressed in kilograms per year (kg/yr) for most pollutants and grams per year (g/yr) for dioxins/furans. The emissions inventory is based on available information about the HMIWI and emission factors developed for purposes of calculating nationwide air impacts of the emission guidelines. Refer to the emissions estimates memorandum in docket A–98–24 (item II–B–1) for the complete emissions inventory and details on the calculations.

D. Emission Limits

A State plan must include emission limits. 40 CFR 60.24(a). Section 129(b)(2) of the Act requires these emission limits to be "at least as protective as" those in the emission guidelines. The emission limits in this proposed HMIWI Federal plan are the same as those contained in the emission guidelines.

The HMIWI source category is divided into three subcategories based on waste burning capacity: Small (≤200 pounds per hour [lb/hr]), medium (>200 to 500 lb/hr), and large (>500 lb/hr). Separate emission limits apply to each subcategory of existing HMIWI. Small HMIWI that meet certain "rural criteria" are allowed to meet less stringent emission limits. The numerical emission limits and additional requirements are summarized in section VI of this preamble.

E. Increments of Progress

Increments of progress are required for HMIWI that need more than 1 year from State plan approval to comply, or in the case of the Federal plan, more than 1 year after promulgation of the final Federal plan. 40 CFR 60.24(e)(1). Increments of progress are necessary in order to ensure that HMIWI needing more time to comply are making progress toward meeting the emission limits. This proposed HMIWI Federal plan includes as its compliance schedule the same five increments of progress from 40 CFR 60.21(h), as required by 40 CFR 60.24(e)(1), along with defined and enforceable dates for completion of each increment.

1. How EPA Determined the Compliance Schedule

The increments of progress and the time proposed for their completion are based on case studies conducted by EPA of eight HMIWI that completed retrofits of the types of controls needed to meet the subpart Ce emission limits. These case studies are documented in docket A–98–24, item II–A–1. Based on these case studies, it appears that some HMIWI may need more than 1 year to retrofit with controls. Using the schedules from the case studies as a basis, the EPA determined the proper intervals for each of the subpart B increments.

To ensure compliance, the five increments of progress proposed for the Federal plan are the minimum increments of progress allowed by subpart B, *see* 40 CFR 60.21(h), and are found at proposed § 62.14470(b) of subpart HHH. The following increments would apply to all HMIWI, regardless of category or size, that require longer than 1 year after the promulgation date of this Federal plan to comply:

(1) Submit final control plan;

(2) Award contracts for control systems or process modifications or orders for purchase of components;

(3) Begin onsite construction or installation of the air pollution control device(s) or process changes;

(4) Complete onsite construction or installation of the air pollution control device(s) or process changes; and

(5) Final compliance.

Subpart Ce suggests additional increments of progress, however, the EPA is proposing not to include additional increments of progress. By not imposing additional increments of progress, EPA hopes to minimize burden on the industry that could result with more increments. EPA, however, solicits comment on whether additional increments are warranted.

2. Owner/Operator Responsibilities

The HMIWI owner or operator is responsible for meeting each of the five increments of progress for each HMIWI unit no later than the applicable compliance date. The owner or operator must notify EPA as each increment of progress is achieved, as well as when any is missed. The notification must identify the increment and the date the increment is achieved (or missed). If an owner or operator misses an increment deadline, the owner or operator must also notify EPA when the increment is finally achieved. The owner or operator must mail the notification to the applicable EPA Regional Office within 10 business days after the increment date defined in the Federal plan. (See Table 1 under the **FOR FURTHER INFORMATION CONTACT** section of this document for a list of Regional Offices.)

The definition of each increment of progress, along with its proposed completion date, follows.

Submit Final Control Plan. To meet this increment, the owner or operator of each HMIWI must submit a plan that describes, at a minimum, the air pollution control devices and/or process changes that will be employed so that each HMIWI complies with the emission limits and other requirements. A final control plan is not required for units that will be shut down.

Completion date: September 15, 2000.

Award Contract. To award a contract means the HMIWI owner or operator enters into legally binding agreements or contractual obligations that cannot be canceled or modified without substantial financial loss to the owner or operator. The EPA anticipates that the owner or operator may award a number of contracts to complete the retrofit. To meet this increment of progress, the HMIWI owner or operator must award a contract or contracts to initiate onsite construction, to initiate onsite installation of air pollution control devices, and/or to incorporate process changes. The owner or operator must mail a copy of the signed contract(s) to EPA within 10 business days of entering the contract(s).

Completion date: April 15, 2001.

Begin Onsite Construction. To begin onsite construction, installation of air pollution control devices, or process change means to begin any of the following:

(1) Installation of an air pollution control device in order to comply with the final emission limits as outlined in the final control plan;

(2) Physical preparation necessary for the installation of an air pollution control device in order to comply with the final emission limits as outlined in the final control plan;

(3) Alteration of an existing air pollution control device in order to comply with the final emission limits as outlined in the final control plan;

(4) Alteration of the waste combustion process to accommodate installation of an air pollution control device in order to comply with the final emission limits as outlined in the final control plan; or

(5) Process changes identified in the final control plan in order to meet the emission standards.

Completion date: December 15, 2001.

Complete Onsite Construction. To complete onsite construction means that all necessary air pollution control devices or process changes identified in the final control plan are in place, onsite, and ready for operation on the HMIWI.

Completion date: July 15, 2002.

Final Compliance. To be in final compliance means to incorporate all process changes or complete retrofit construction in accordance with the final control plan and to connect the air pollution control equipment or process changes such that if the HMIWI is brought on line all necessary process changes or air pollution control equipment will operate as designed.

Completion date: September 15, 2002.

The EPA believes this compliance schedule is achievable and necessary based on the following:

(1) When determining completion dates for the increments of progress, EPA applied the maximum amount of time that most HMIWI in the case study needed in order to comply;

(2) Since September 15, 1997 when the emission guidelines were promulgated, HMIWI owners and operators have known that they would need to make process changes or install controls by September 15, 2002; and

(3) The EPA believes that a compliance schedule with enforceable increments of progress is necessary to ensure final compliance by September 15, 2002.

3. Failure to Comply

If an HMIWI does not achieve final compliance by September 15, 2002, this proposed Federal plan would require the HMIWI to shut down by September 15, 2002, complete the retrofit while not operating, and be in compliance upon restarting. Shut down is necessary in order to avoid being out of compliance and subject to possible enforcement action.

F. Waste Management Plan Requirements

Under the emission guidelines, State plans must require owners and operators of HMIWI to develop waste management plans in compliance with 40 CFR 60.55c. *See* 40 CFR 60.35e. The proposed HMIWI Federal plan includes the same requirement (see proposed 40 CFR 62.14430 and 62.14431 of subpart HHH).

G. Testing, Monitoring, Inspection, Recordkeeping, and Reporting Requirements

Under the emission guidelines, State plans must include the testing, monitoring, recordkeeping, and reporting requirements set forth at 40 CFR 60.37e and 60.38e of subpart Ce. The proposed HMIWI Federal plan includes virtually the same requirements (see proposed 40 CFR 62.14450 through 62.14455 and §§ 62.14460 through 62.14465 of subpart HHH).

Minor changes are proposed to the testing and monitoring requirements to clarify the meaning of those requirements and to insert some text that was inadvertently omitted from the emission guidelines. Subpart Ce specifies a 3-hour rolling average when monitoring maximum charge rate. While this is correct for continuous and intermittent HMIWI, it is not correct for batch HMIWI. For batch HMIWI, the requirement is proposed to be a daily average, consistent with the definition of maximum charge rate for batch units.

H. Operator Training and Qualification Requirements

Under the emission guidelines, State plans must include the operator training and qualification requirements set forth at 40 CFR 60.53c. *See* 40 CFR 60.34e. The proposed HMIWI Federal plan includes these requirements as well (see proposed 40 CFR 62.14420 through 62.14425 of subpart HHH).

I. Record of Public Hearings

A State must provide opportunity for public participation in adopting the State plan. *See* 40 CFR 60.23(c). In adopting any HMIWI Federal plan, the EPA will hold public hearing(s) at appropriate Regional Offices, if requested. A record of the public hearing(s), if any, will appear in the docket.

J. Progress Reports

Under the emission guidelines, States or Tribes with approved and effective plans must send annual progress reports to the appropriate Regional Office to show their progress toward implementation of the emission guidelines. 40 CFR 60.25(e). Under the Federal plan, the EPA Regional Offices will prepare these progress reports. States or Tribes that have been delegated the authority to implement and enforce this Federal plan would also be required to submit annual progress reports to the appropriate EPA Regional Office.

Appendix D of 40 CFR part 60 requires reporting of emissions data to the Aerometric Emissions Information Retrieval System Facility Subsystem (AIRS). These reports can be combined with the State implementation plan report required by 40 CFR 51.321 in order to avoid double reporting. Under the proposed Federal plan, EPA Regional Offices would report AIRS emissions data. If a State or Tribe has been delegated the authority to implement and enforce the Federal plan, the State or Tribe would report emissions data to AIRS.

Each progress report must include the following items: (1) Status of enforcement actions; (2) status of increments of progress; (3) identification of sources that have shut down or started operation; (4) emission inventory data for sources that were not in operation at the time of plan development, but that began operation during the reporting period; (5) additional data as necessary to update previously submitted source and emission information; and (6) copies of technical reports on any performance testing and monitoring.

III. HMIWI That Have or Will Shut Down

A. Inoperable Units

In cases where an HMIWI has shut down and does not intend to restart, the HMIWI may be left off the source inventory in a State, Tribal, or this Federal plan if it is rendered inoperable. The HMIWI owner/operator may do the following to render an HMIWI inoperable: (1) Weld the waste charge door shut, (2) remove stack (and by-pass stack, if applicable), (3) remove combustion air blowers, and/or (4) remove burners or fuel supply.

B. HMIWI That Have Shut Down

Hospital/medical/infectious waste incinerators that are known to have already shut down (but are not known to be inoperable) are included in the source inventory of this proposed Federal plan. Such units must also be identified in any State or Tribal plan submitted to EPA.

1. Restarting Before September 15, 2002

If the owner or operator of an inactive HMIWI plans to restart before September 15, 2002, the owner or operator would be required to submit a control plan for the HMIWI and bring the HMIWI into compliance with the applicable compliance schedule. Final compliance is required for all pollutants and all HMIWI no later than September 15, 2002. (See section II.E for the discussion on compliance schedules and increments of progress.)

2. Restarting After September 15, 2002

Under this proposed Federal plan, a control plan would not be needed for inactive HMIWI that restart after September 15, 2002. However, before restarting, such HMIWI would have to complete the operator training and qualification requirements and inspection requirements (if applicable) and complete retrofit or process modifications upon restarting. Performance testing to demonstrate compliance would be required within 180 days after restarting. There would be no need to show that the increments of progress have been met since these steps would have occurred before restart while the HMIWI was shut down and not generating emissions. An HMIWI that operates out of compliance after September 15, 2002 would be in violation of the Federal plan and subject to enforcement action.

IV. Implementation of the Federal Plan and Delegation

A. Background of Authority

Under sections 111(d) and 129(b) of the Act, EPA is required to adopt emission guidelines that are applicable to existing solid waste incineration sources. These emission guidelines are not enforceable until EPA approves a State or Tribal plan or adopts a Federal plan that implements and enforces them, and the State, Tribal, or Federal plan has become effective. As discussed above, the Federal plan regulates HMIWI in States or Tribal areas that do not have approved plans in effect.

Congress has determined that the primary responsibility for air pollution prevention and control rests with State and local agencies. *See* section 101(a)(3) of the Act. Consistent with that overall determination, Congress established sections 111 and 129 of the Act with the intent that the States and local agencies take the primary responsibility for ensuring that the emission limitations and other requirements in the emission guidelines are achieved. Also, in section 111(d) of the Act, Congress explicitly required that EPA establish procedures that are similar to those under section 110(c) for State Implementation Plans. Although Congress required EPA to propose and promulgate a Federal plan for States that fail to submit approvable State plans on time, EPA strongly encourages States to submit approvable plans. The EPA strongly encourages States that are unable to submit approvable plans to request delegation of the Federal plan so that they can have primary responsibility for implementing the emission guidelines, consistent with Congress' intent.

Approved and effective State plans or delegation of the Federal plan is EPA's preferred outcome since EPA believes that State and local agencies not only have the responsibility to carry out the emission guidelines, but also have the "insider" knowledge and enforcement resources critical to achieving the highest rate of compliance. For these reasons, EPA will do all that it can to expedite delegation of the Federal plan to State and local agencies, whenever possible.

The EPA also believes that Indian tribes are the primary parties responsible for regulating air quality within Indian country. See EPA's Indian Policy ("Policy for Administration of Environmental Programs on Indian Reservations," signed by William D. Ruckelshaus, Administrator of EPA, dated November 4, 1984, reaffirmed in 1994 in a memorandum entitled "EPA Indian Policy," signed by Carol M. Browner, Administrator of EPA, dated March 14, 1994).

B. Delegation of the Federal Plan and Retained Authorities

If a State or Indian tribe intends to take delegation of the Federal plan, the State or Indian tribe must submit to the appropriate EPA Regional Office a written request for delegation of authority. The State or Indian tribe must explain how it meets the criteria for delegation. *See generally* "Good Practices Manual for Delegation of NSPS and NESHAP" (EPA, February 1983). In order to obtain delegation, an Indian tribe must also establish its eligibility to be treated in the same manner as a State (section I.D. of the preamble). The letter requesting delegation of authority to implement the Federal plan must demonstrate that the State or Tribe has adequate resources, as well as the legal and enforcement authority to administer and enforce the program. A Memorandum of Agreement (MOA) between the State or Tribe and the EPA would set forth the terms and conditions of the delegation, the effective date of the agreement, and would also serve as the mechanism to transfer authority. Upon signature of the agreement, the appropriate EPA Regional Office would publish an approval notice in the **Federal Register**, thereby incorporating the delegation authority into the appropriate subpart of 40 CFR part 62.

If authority is not delegated to a State or Indian tribe, EPA will implement the Federal plan. Also, if a State or Tribe fails to properly implement a delegated portion of the Federal plan, EPA will assume direct implementation and enforcement of that portion. The EPA will continue to hold enforcement authority along with the State or Tribe even when a State or Tribe has received delegation of the Federal plan. In all cases where the Federal plan is delegated, the EPA will retain and will not transfer authority to a State or Tribe to approve the following items:

(1) Alternative site-specific operating parameters established by facilities using HMIWI controls other than a wet scrubber or dry scrubber followed by a fabric filter; and

(2) Alternative methods of demonstrating compliance.

Hospital/medical/infectious waste incinerator owners or operators who wish to establish alternative operating parameters or alternative methods of demonstrating compliance should submit a request to the Regional Office Administrator with a copy to the appropriate State or Tribe.

C. Mechanisms for Transferring Authority

There are two mechanisms for transferring implementation authority to States, Tribes, and local agencies: (1) EPA approval of a State or Tribal plan after the Federal plan is in effect; and (2) if a State or Tribe does not submit or obtain approval of its own plan, EPA delegation to a State or Tribe of the authority to implement certain portions of this Federal plan to the extent appropriate and if allowed by State or Tribal law. Both of these options are described in more detail below.

1. State or Tribe Submits a Plan After HMIWI Located in the Area Are Subject to the Federal Plan

After HMIWI in a State or Tribal area become subject to the Federal plan, the State, Tribal, or local agency may still adopt and submit a plan to EPA. If EPA determines that the State or Tribal plan is as protective as the emission guidelines, EPA will approve the State or Tribal plan. If EPA determines that the plan is not as protective as the emission guidelines, EPA will disapprove the plan and the HMIWI covered in the State or Tribal plan would remain subject to the Federal plan until a State or Tribal plan covering those HMIWI is approved and effective.

Upon the effective date of a State or Tribal plan, the Federal plan would no longer apply to HMIWI covered by such plan and the State, Tribal, or local agency would implement and enforce the State or Tribal plan in lieu of the Federal plan. When an EPA Regional Office approves a State or Tribal plan, it will amend the appropriate subpart of 40 CFR part 62 to indicate such approval.

2. State Takes Delegation of the Federal Plan

State, Tribal, or local agencies may assume implementation of this Federal plan. As discussed above, EPA believes that it is advantageous and the best use of resources for State, Tribal, or local agencies to agree to undertake, on EPA's behalf, administrative and substantive roles in implementing the Federal plan to the extent appropriate and where authorized by State or Tribal law. These functions could include administration and oversight of compliance reporting and recordkeeping requirements, HMIWI inspections, and preparation of draft notices of violation. The EPA would retain responsibility for bringing enforcement actions against sources violating Federal plan provisions.

V. Title V Operating Permits

Section 502(a) of the Act requires sources "subject to standards or regulations under section 111" to obtain title V operating permits. *See also* 40 CFR 70.3(a)(2) and 71.3(a)(2). Because EPA is proposing this Federal plan under sections 111 and 129 of the Act, sources subject to this Federal plan must obtain title V permits. Those title V permits must assure compliance with all applicable requirements for the source, including all applicable requirements of this Federal plan. *See* 40 CFR 70.6(a)(1), 70.2, 71.6(a)(1) and 71.2.

Under section 129(e) of the Act, owners or operators of HMIWI subject to this Federal plan must operate pursuant to a title V permit no later than 36 months after promulgation of the HMIWI emission guidelines (i.e., by September 15, 2000), or by the effective date of the State, Tribal, or Federal title V permit program that covers the area in which the unit is located, whichever is later. If an owner or operator is required to obtain a title V permit for the first time by virtue of being subject to the Federal plan, the owner or operator must submit a complete title V permit application by the applicable permit deadline (i.e., by September 15, 2000) or the effective date of the State, Tribal, or Federal operating permits program, whichever is later.[b]

An earlier permit deadline may apply if an HMIWI is subject to title V for another reason. For example, an HMIWI might already be subject to title V as a result of being a major source under one or more of three major source definitions in title V—section 112, section 302, or part D of title I of the Act. *See* 40 CFR 70.3(a)(1) and 71.3(a)(1) (subjecting major sources to title V permitting) and §§ 70.2 and 71.2 (defining major source for purposes of title V). An HMIWI might also already be subject to title V if it is subject to some other earlier promulgated standard under section 111 or 112 of the Act. *See* 40 CFR 70.3(a)(2) and (3), 71.3(a)(2) and (3). If an owner or operator is already subject to title V by virtue of some other requirement and has submitted a timely and complete permit application but the title V permit has not yet been released by the permitting authority, then the owner or operator should supplement its title V application by including the applicable requirements of the Federal plan in accordance with 40 CFR 70.5(b) or 71.5(b).

If an owner or operator of an HMIWI is already subject to title V by virtue of some other requirement on the effective date of this Federal plan and already possesses a title V permit with a remaining term of 3 or more years, then the owner or operator will receive from its permitting authority a notice of intent to reopen the title V permit to include the requirements of the Federal plan in accordance with the procedures established in 40 CFR 70.7(f) or 71.7(f). An owner or operator of an HMIWI with a title V permit having a remaining term of less than 3 years on the effective date of this Federal plan need not modify its title V permit, as a matter of Federal law, to include the Federal plan requirements until that permit is renewed.[c] However, the owner or operator remains subject to, and must act in compliance with, the Federal plan requirements.

Owners or operators of combustors that burn only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste and co-fired combustors, as defined in this proposed Federal plan, must comply only with certain recordkeeping and reporting requirements set forth in the proposed Federal plan. *See* proposed § 62.14400. They are not subject to the other substantive emissions control-related requirements of the Federal plan as long as they comply with the recordkeeping and reporting requirements set forth as conditions for their exemption. Owners and operators of these sources are not required to obtain title V operating permits as a matter of Federal law if the only reason they would potentially be subject to title V is these nonemissions control-related recordkeeping and reporting requirements. *See* proposed § 62.14480. The EPA interprets the CAA and the regulations at parts 70 and 71 to mean that these sources are "not subject to standards or regulations under section 111" for purposes of title V permitting. *See* CAA section 502(a) and 40 CFR 70.3(a)(2) and 71.3(a)(2). Therefore, these sources would not be required to apply for title V permits on the basis of the applicability of recordkeeping and reporting requirements necessary to qualify for exemption from the substantive emissions control-related requirements of this proposed Federal plan. However, owners and operators of sources that burn only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste, and co-fired combustors, that do not comply with the recordkeeping and reporting requirements necessary to qualify for exemption from the other requirements of the Federal plan would become subject to those other requirements and would have to obtain title V permits. Moreover, if, in the future, EPA promulgates regulations subjecting any of these sources to substantive requirements other than these recordkeeping and reporting requirements, these sources could become subject to title V at that time.

Section 502(a) of the Act requires title V permits of listed sources, including any source "subject to standards or regulations under section 111 * * *." *See also* 40 CFR 70.3(a)(2) and 71.3(a)(2). The EPA reads the recordkeeping and reporting requirements of this proposed Federal plan, which are simply conditions for exemption from the other substantive emissions control-related requirements of the Federal plan, not to be requirements that would make a source "subject to" a section 111 standard (here the HMIWI Federal plan) within the

[b] Section 503(d) of the Act and 40 CFR 70.7(b) and 71.7(b) allow a source to operate without being in violation of title V once the source has submitted a timely and complete permit application, even if the source has not yet received a final title V operating permit from the permitting authority. To this end, the application should be submitted early enough for the permitting authority to find the application either complete or incomplete before the application deadline. In the event the application is found incomplete by the permitting authority, the source must submit the information needed to make the application complete by the application deadline in order to obtain the application shield. *See* proposed 40 CFR 62.14481 and 40 CFR 70.5(a)(2) and 71.5(a)(2).

[c] *See* CAA section 502(b)(6); 40 CFR 70.7(f)(1)(i) and 71.7(f)(1)(i). The CAA authorizes State, Tribal and Federal operating permit programs to require permits to be reopened and modified to incorporate the requirements of the Federal plan when fewer than 3 years remaining on a source's permit, however, so permitting authorities could reopen permits sooner than required by Federal law. Such reopenings should be completed no later than 18 months after promulgation of the applicable requirement. Any sources in this situation may wish to consult their operating permit program regulations or permitting authorities to determine whether revisions to their permits are necessary to incorporate the Federal plan requirements.

meaning of these statutory and regulatory provisions. Accordingly, HMIWI that comply with the recordkeeping and reporting requirements necessary for their exemption from the other substantive emissions control-related requirements of the Federal plan are not "subject to" the Federal plan solely for purposes of being required to obtain a title V permit. Hospital/medical/ infectious waste incinerators that are subject to Federal plan requirements other than these recordkeeping or reporting conditions as well as HMIWI that fail to comply with any of the conditions for exemption from these other substantive emissions control-related Federal plan requirements are subject to title V permitting under section 502(a).

It is worth noting that section 502(a) of the Act also provides a mechanism for the Administrator to "promulgate regulations to exempt" one or more source categories from title V permitting requirements, if EPA finds that compliance with such requirements is "impracticable, infeasible, or unnecessarily burdensome on such categories, except that the Administrator may not exempt any major source from such regulations." The EPA is *not* invoking this mechanism to justify its conclusion that the HMIWI discussed above are not required to obtain title V permits. These HMIWI have not been "exempted" from title V within the meaning of the last sentence of section 502(a), and the Agency does not purport to have made the statutory showing of impracticability, infeasibility or unnecessary burden for these sources. Rather, the Agency believes that the recordkeeping and reporting requirements with which these HMIWI must comply are not the type of requirements that make them "subject to" a standard or regulation under section 111 within the meaning of the first sentence of section 502(a). In EPA's view, HMIWI in this unique position do not even meet the threshold criteria for sources required to obtain title V permits under section 502(a) of the Act.

In addition to being consistent with the governing statutory provisions, EPA believes this approach is sound and environmentally protective. Where HMIWI have only recordkeeping and/or reporting obligations designed to show they are not subject to the other requirements of the Federal plan, EPA does not believe that it makes sense to compel them to obtain title V permits based upon a possible technical argument that in that minimal sense they are subject to the subpart for purposes of section 502(a) of the Act. Moreover, because these HMIWI may well not currently be covered by applicable Federal requirements other than this Federal plan's recordkeeping and reporting requirements, a contrary approach would lead to the paradoxical and unreasonable result that these HMIWI would be obtaining title V permits whose sole requirements were conditions demonstrating their exemption from the other substantive requirements of the Federal standard that triggered the need to obtain a permit.

In addition to the likely bareness of these HMIWI title V permits, the applicability and compliance provisions these HMIWI must meet are simpler than the usual applicable requirements in a title V permit. Therefore, the multiple, sometimes complex applicability determinations so integral to the title V permit issuance process are accomplished here through simple notifications to EPA (or delegated EPA Regional Office, State, or Tribe). While title V permits are important in helping States and Tribes, EPA, sources, and the public assure compliance with a source's Clean Air Act obligations, the Agency does not believe this objective would be significantly advanced by these sources obtaining title V permits, particularly not to a degree that would outweigh the time, resources, expense and permit fees associated with the permit process in this instance. The EPA believes the approach described herein comports with the Act and Federal regulations, represents a sensible solution to these uniquely situated sources, and affords the environmental protection demanded by the law.

VI. Owner/Operator Responsibilities

The proposed HMIWI Federal rule (40 CFR part 62, subpart HHH) which will implement this Federal plan includes emission limits, monitoring and performance testing requirements, inspection requirements (for small rural HMIWI only), waste management plan requirements, operator training and qualification requirements, and recordkeeping and reporting requirements. These emission standards and requirements are the same as those in the emission guidelines (40 CFR part 60, subpart Ce). The requirements are summarized in this section.

A. Applicability

The HMIWI Federal plan would apply to existing HMIWI that are not covered by an approved and effective State or Tribal plan or are located in a State or Tribal area that has incorrectly submitted a negative declaration. An existing HMIWI is an HMIWI for which construction commenced on or before June 20, 1996. Hospital/medical/ infectious waste incinerators for which construction commenced after June 20, 1996 or modification commenced after March 16, 1998 are not subject to the Federal plan; they are new sources and are subject to the 40 CFR part 60 subpart Ec New Source Performance Standards (NSPS). An HMIWI is defined as any device that combusts any amount of medical/infectious waste or hospital waste. The terms "medical/infectious waste" and "hospital waste" are defined in proposed § 62.14490 of subpart HHH.

Incinerators that burn only pathological, low-level radioactive, or chemotherapeutic waste (all defined in proposed § 62.14490 of subpart HHH) are required to notify EPA of an exemption claim and keep records of the periods of time when only pathological, low-level radioactive, or chemotherapeutic waste is burned. However, these HMIWI are not subject to the other substantive requirements of the Federal plan during periods when they burn such wastes provided that they comply with the applicable notification and recordkeeping requirements. Existing incinerators, processing operations, or boilers that cofire hospital waste and/or medical/ infectious waste with other fuels or wastes and combust 10 percent or less combined medical/infectious and hospital waste by weight (on a calendar quarter basis) are also not subject to the other substantive requirements of the Federal plan provided they file an exemption claim and keep records of the amounts of each fuel and waste burned. Any unit required to have a permit under section 3005 of the Solid Waste Disposal Act is exempt from the Federal plan, as are municipal waste combustors subject to 40 CFR part 60 subparts Cb, Ea, or Eb. Finally, pyrolysis units (as defined at 40 CFR 62.14490 of subpart HHH) and cement kilns firing hospital waste and/or medical/ infectious waste are also not subject to this Federal plan.

The HMIWI source category is divided into small (≤200 lb/hr), medium (>200 to 500 lb/hr), and large (>500 lb/hr) subcategories based on waste burning capacity. Waste burning capacity is determined either by the maximum design capacity or by the "maximum charge rate" established during the most recent performance test. In other words, a source may change its size designation by establishing an enforceable "maximum charge rate" lower than its design capacity. For example, a "medium" unit with a design capacity of 250 lb/hr may establish a maximum charge rate of 200

lb/hr and be considered a "small" unit for purposes of the Federal plan. Separate requirements apply to each subcategory of existing HMIWI.

B. Emission Limits

Table 1 of subpart HHH provides the emission limits for existing HMIWI covered by the proposed Federal plan. In addition to the emission limits presented in Table 1, all HMIWI are subject to a 10 percent stack opacity limitation. Stack opacity will be determined using EPA Reference Method 9.

The Federal plan contains alternative emission limits for small HMIWI that meet the following "rural criteria": (1) The small HMIWI is located at least 50 miles from the nearest Standard Metropolitan Statistical Area (SMSA) boundary; and (2) the small HMIWI burns no more than 2,000 pounds of hospital waste and medical/infectious waste per week. For this Federal plan, the list of areas comprising each SMSA as of June 30, 1993 (defined by the Office of Management and Budget (OMB)) will be used to determine whether a small HMIWI meets the "rural criteria." The list of areas comprising each SMSA is presented in OMB Bulletin No. 93–17 entitled "Revised Statistical Definitions for Metropolitan Areas." This document is available for public inspection and copying at EPA's Air and Radiation Docket and Information Center (docket A–91–61, item IV–J–125). See the **ADDRESSES** section at the beginning of this preamble for the telephone number and location of the docket. In addition, OMB Bulletin No. 93–17 is available at: http://www.census.gov/population/estimates/metro-city/93mfips.txt, or from National Technical Information Services, 5285 Port Royal Road, Springfield, Virginia 22161, (703) 487–4650 (document number PB 93–192–664). The alternative emission limits for small HMIWI that meet the rural criteria are provided in Table 1 of subpart HHH.

C. Additional Requirements

This section presents the other major provisions of the Federal plan for HMIWI. With the exception of the emission limits referenced above and the compliance and performance testing requirements and the inspection requirements described in this section, HMIWI that meet the small rural criteria are to comply with the same additional requirements as all other existing HMIWI. This section does not attempt to show all requirements of the Federal plan. The regulatory text of subpart HHH contains a full and comprehensive statement of the requirements of the proposed Federal plan.

The proposed Federal plan contains operator training and qualification requirements for all HMIWI. Each facility would be required to have at least one trained and qualified operator on duty or on-call. The trained and qualified operator must pass an HMIWI operator training course and meet qualification requirements. Also, each facility would be required to develop site-specific HMIWI operating procedures. Employees involved with HMIWI operation must review the site-specific operating information annually.

The proposed Federal plan would require all facilities to develop a waste management plan that identifies the feasibility and approach of separating certain components of the healthcare waste stream in order to reduce the amount of toxic emissions from incinerated waste.

The compliance and performance testing requirements in the proposed Federal plan differ for small rural HMIWI and for all other HMIWI. Small rural HMIWI would be required to conduct an initial performance test to determine compliance with the PM, CO, CDD/CDF, and Hg emission limits and opacity limit, and establish operating parameters. In addition, small rural HMIWI would be required to conduct annual tests to determine compliance with the opacity limit.

The compliance and performance testing requirements in the proposed Federal plan would require facilities with small non-rural, medium, and large HMIWI to conduct an initial performance test to determine compliance with the PM, CO, CDD/CDF, HCl, Pb, Cd, and Hg emission limits and opacity limit, and establish operating parameters. These HMIWI would also be required to conduct annual performance tests to determine compliance with the PM, CO, and HCl emission limits and opacity limit. The proposed Federal plan would allow facilities to conduct performance tests for PM, CO, and HCl every third year if the previous three performance tests demonstrate that the facility is in compliance with the emission limits for PM, CO, and HCl.

The proposed Federal plan contains monitoring requirements for all HMIWI. Each facility would be required to install and maintain equipment to continuously monitor operating parameters including secondary chamber temperature, waste feed rate, bypass stack, and air pollution control device (APCD) operating parameters as appropriate. The proposed Federal plan would require facilities to obtain monitoring data at all times during HMIWI operation.

In addition, the proposed Federal plan contains reporting and recordkeeping requirements for all HMIWI. Facilities would be required to maintain records for 5 years of results from the initial performance test and all subsequent performance tests, operating parameters, inspections (small rural HMIWI only), and operator training and qualification. Facilities would be required to submit the results of the initial performance test and all subsequent performance tests, and to submit reports on emission rates or operating parameters that have not been recorded or which exceeded applicable limits.

A summary of dates for compliance with the Federal plan for HMIWI is presented in Table 3.

TABLE 3.—COMPLIANCE TIMES UNDER THE FEDERAL PLAN FOR ALL HMIWI

Requirement	Compliance time
Operator training and qualification	Within 1 year after promulgation of the Federal plan (for HMIWI that continue to operate beyond 1 year after promulgation).
Waste management plan	Within 60 days after initial performance test.
Final compliance with emission limits	Within 1 year after promulgation of the Federal plan or by September 15, 2002 if the source is granted an extension.
Initial performance test	Within 180 days after achieving final compliance.
Repeat performance test	Within 12 months following initial performance test and annually thereafter.[a]
Parameter monitoring	Continuously, upon completion of initial performance test.
Inspection (small rural HMIWI only)	Within 1 year after promulgation of the Federal plan (for HMIWI that continue to operate beyond 1 year after promulgation.
Recordkeeping	Continuously, upon completion of initial performance test.

TABLE 3.—COMPLIANCE TIMES UNDER THE FEDERAL PLAN FOR ALL HMIWI—Continued

Requirement	Compliance time
Reporting	Within 60 days after initial performance test; annually for subsequent reporting requirements; semiannually, if noncompliance.

[a] Facilities may conduct performance tests for PM, CO, and HC1 every third year if the previous three performance tests demonstrate that the facility is in compliance with the emission limits for PM, CO, and HC1.

VII. Administrative Requirements

This section addresses the following administrative requirements: Docket, Paperwork Reduction Act, Executive Orders 12866, 12875, 13045, and 13084, Unfunded Mandates Reform Act, Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act, and the National Technology Transfer and Advancement Act. Since today's proposed rule merely implements the emission guidelines promulgated on September 15, 1997 (codified at 40 CFR part 60, subpart Ce) as they apply to HMIWI and does not impose any new requirements, much of the following discussion of administrative requirements refers to the documentation of applicable administrative requirements in the preamble to the 1997 rule promulgating the emission guidelines (62 FR 48347–48379, September 15, 1997).

A. Docket

The docket is intended to be an organized and complete file of the administrative records compiled by EPA. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so they can effectively participate in the rulemaking process. Along with proposed and promulgated standards and their preambles, the contents of the docket (with limited exceptions) will serve as the record in the case of judicial review. See section 307(d)(7)(A) of the Act.

As discussed above, a docket has been prepared for this action pursuant to the procedural requirements of section 307(d) of the Act, 42 U.S.C. 7607(d). Docket number A–91–61 contains the technical support for the September 15, 1997 emission guidelines. Docket number A–98–24 contains additional supporting information for this proposed rule.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An information collection request (ICR) document has been prepared by EPA (ICR No. 1899.01) and a copy may be obtained from Ms. Sandy Farmer by mail at OP Regulatory Information Division, U. S. Environmental Protection Agency (2137), 401 M Street, SW., Washington, DC 20460; by E-mail at farmer.sandy@epa.gov; or by calling (202) 260–2740. A copy may also be downloaded off the Internet at http://www.epa.gov/icr.

This ICR reflects the burden estimate for the emission guidelines which were promulgated in the **Federal Register** on September 15, 1997.[d] The burden estimate includes the burden associated with State/Tribal plans as well as the burden associated with today's proposed Federal plan. Consequently, the burden estimates described below overstate the information collection burden associated with the Federal plan. However, upon approval by EPA, a State/Tribal plan becomes Federally enforceable. Therefore, it is important to estimate the full burden associated with the State/Tribal plans and the Federal plan. As State/Tribal plans are approved, the Federal plan burden will decrease, but the overall burden of the State/Tribal plans and the Federal plan will remain the same.

The information collected would be used by EPA to ensure that the HMIWI regulatory requirements are implemented and are complied with on a continuous basis. Records and reports would be necessary to enable EPA to identify existing HMIWI that may not be in compliance with the HMIWI regulatory requirements. Based on reported information, EPA would decide which units should be inspected and what records or processes should be inspected. The records that owners and operators of existing HMIWI maintain would indicate to EPA whether personnel are operating and maintaining control equipment properly.

Based on the inventory of HMIWI used to develop the emission guidelines, the HMIWI regulatory requirements (i.e., the State/Tribal plans and Federal plan) are projected to affect approximately 2,373 existing HMIWI in the United States or protectorates. A number of State plans are expected to be approved within the year following Federal plan promulgation. When a State plan is approved, the Federal plan will no longer apply to HMIWI covered in that State plan.

The estimated average annual burden for industry for the first 3 years after the promulgation of the emission guidelines would be 133,404 hours annually at a cost of $5,858,292 per year to meet the monitoring, recordkeeping, and reporting requirements. The estimated average annual burden, over the first 3 years, for the regulatory agencies (State and Federal) would be 10,984 hours at a cost of $438,736 (including travel expenses) per year.

Burden means total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a regulatory agency. This includes the time needed to do the following: review instructions; develop, acquire, install, and use technology and systems for the purposes of collecting and validating information; process, maintain, and disclose information; amend previously applicable instructions and requirements to reflect new HMIWI State or Federal plan requirements; train personnel to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR part 15.

Send comments on the Agency's need for this information, the accuracy of the burden estimates provided, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques to the Director, OP Regulatory Information Division, U. S. Environmental Protection Agency (2137), 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW.,

[d] In promulgating the September 15, 1997 rule setting the NSPS and emission guidelines, EPA assessed only the ICR requirements associated with the NSPS. *See* 62 FR at 48373–74.

Washington, DC 20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence. Because OMB is required to make a decision on the ICR between 30 and 60 days after today's request for comment, a comment to OMB is best assured of having its full effect if OMB receives it by August 5, 1999. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Executive Order 12866

Under Executive Order 12866, 58 FR 51735, (October 4, 1993), EPA must determine whether the regulatory action is "significant" and, therefore, subject to OMB review and the requirements of the Executive Order. The EPA considered the 1997 emission guidelines to be significant and the rules were reviewed by OMB in 1997. *See* 62 FR 48374. The Federal plan proposed today would simply implement the 1997 emission guidelines and does not result in any additional control requirements or impose any additional costs above those previously considered during promulgation of the 1997 emission guidelines. Therefore, this regulatory action is considered "not significant" under Executive Order 12866.

D. Executive Order 12875

Under Executive Order 12875, 58 FR 58093 (October 26, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or Tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and Tribal governments, the nature of their concerns, any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and Tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create a mandate on State, local, or Tribal governments. The rule does not impose any enforceable duties on these entities. Moreover, this Federal plan simply implements the 1997 emission guidelines and does not result in any additional control requirements or impose any additional costs above those previously considered during promulgation of the 1997 emission guidelines. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

E. Executive Order 13045

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," 62 FR 19885 (April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate affect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This proposed rule is not subject to Executive Order 13045 because (1) it is not an economically significant regulatory action as defined by Executive Order 12866, and (2) it is based on technology performance and not on health or safety risks.

F. Executive Order 13084

Under Executive Order 13084. 63 FR 27655 (May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian Tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

The Federal plan proposed today does not significantly or uniquely affect communities of Indian Tribal governments. The proposed Federal plan would not impose any enforceable duties on those governments. Moreover, this Federal plan simply implements the 1997 emission guidelines and does not result in any additional control requirements or impose any additional costs above those previously considered during promulgation of the 1997 emission guidelines. Thus, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

G. Unfunded Mandates Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and

timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

An unfunded mandates statement was prepared and published in the preamble to the September 15, 1997 NSPS and emission guidelines. See 62 FR at 48374–78. The EPA has determined that the proposed HMIWI Federal plan does not include any new Federal mandates or additional requirements above those previously considered during promulgation of the 1997 emission guidelines. Therefore, the requirements of the UMRA do not apply to this proposed rule.

H. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act

The Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. 601 *et seq.*, requires Federal agencies to give special consideration to the impacts of regulations on small entities, which are defined as small businesses, small organizations, and small governments. During the 1997 HMIWI emission guidelines rulemaking, EPA estimated that small entities would not be affected by the promulgated emission guidelines and standards, and therefore, a regulatory flexibility analysis was not required. *See* 62 FR at 48378–79. This proposed Federal plan would not establish any new requirements. Therefore, pursuant to the provisions of 5 U.S.C. 605(b), EPA certifies that this Federal plan will not have a significant impact on a substantial number of small entities, and thus a regulatory flexibility analysis is not required.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Pub L. 104–113, section 12(d), 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The NTTAA does not apply because the proposed Federal plan would implement an existing rule to which NTTAA did not apply. In addition, the emission guidelines, which the Federal plan is based on, does not require new technology or impose new technical standards.

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 17, 1999.

Carol M. Browner,

Administrator.

40 CFR part 62 is proposed to be amended as follows:

PART 62—[AMENDED]

1. The Authority citation for part 62 continues to read as follows:

Authority: 42 U.S.A. 7401–7642.

2. Amend § 62.13 by adding paragraph (c) to read as follows:

§ 62.13 Federal Plans

* * * * *

(c) The substantive requirements of the hospital/ medical/infectious waste incinerator Federal plan are contained in subpart HHH of this part. These requirements include emission limits, compliance schedules, testing, monitoring and reporting and recordkeeping requirements.

* * * * *

3. Amend part 62 by adding subpart HHH consisting of §§ 62.14400 through § 62.14499 as follows:

Subpart HHH—Federal Plan Requirements for Hospital/Medical/Infectious Waste Incinerators Constructed on or before June 20, 1996

Sec.

Applicability

Emission Limits

Operator Training and Qualification 62.14420

Waste Management Plan

Inspection Requirements

Compliance, Performance Testing, and Monitoring Requirements

Reporting and Recordkeeping Requirements

Compliance Schedule

Permitting Obligation

Subpart HHH—Federal Plan Requirements for Hospital/ Medical/ Infectious Waste Incinerators Constructed On or Before June 20, 1996

Applicability

§ 62.14400 Am I subject to this subpart?

(a) You are subject to this subpart if paragraphs (a) (1), (2), and (3) of this section are all true:

(1) You own or operate an HMIWI that is not covered by an EPA approved and effective State or Tribal plan;

(2) Construction of the HMIWI commenced on or before June 20, 1996; and

(3) You do not meet any of the exemptions in paragraph (b) of this section:

(b) The following exemptions apply:

If you...	And you...	And you...	Then you...
(1) Own or operate an HMIWI that combusts only pathological waste, low-level radioactive waste, and/or chemothera-peutic waste (all defined in 40 CFR 62.14490).	Notify the EPA Administrator (or delegated enforcement authority) of an exemption claim.	Keep records on a calendar quarter basis of the periods of time when only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste is combusted.	Are not subject to the other requirements of this subpart during periods when only pathological, low-level radioactive, and/or chemotherapeutic wastes are combusted.
(2) Own or operate a co-fired combustor (defined in 40 CFR 62.14490).	Notify the EPA Administrator (or delegated enforcement authority) of an exemption claim and you provide an estimate of the relative weight of hospital waste, medical/infectious waste, and other fuels and/or wastes to be combusted.	Keep records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted, and the weight of all other fuels and wastes combusted at the co-fired combustor.	Are not subject to the other requirements of this subpart.
(3) Own or operate a combustor that must have a permit under Section 3005 of the Solid Waste Disposal Act.	.....	.....	Are not subject to this subpart.
(4) Own or operate a combustor which meets the applicability requirements of 40 CFR part 60 subpart Cb, Ea, or Eb (standards or guidelines for certain municipal waste combustors).	.....	.....	Are not subject to this subpart.
(5) Own or operate a pyrolysis unit (defined in 40 CFR 62.14490) processing hospital waste and/or medical/infectious waste.	.....	.....	Are not subject to this subpart.
(6) Own or operate a cement kiln firing hospital waste and/or medical/ infectious waste.	.....	.....	Are not subject to this subpart.

§ 62.14401 How do I determine if my HMIWI is covered by an approved and effective State or Tribal plan?

This part (40 CFR part 62) contains a list of all States and Tribal areas with approved Clean Air Act section 111(d)/ 129 plans in effect. However, this part is only updated once a year. Thus, if this part does not indicate that your State or Tribal area has an approved and effective plan, you should contact your State environmental agency's air director or your EPA Regional Office to determine if approval occurred since publication of the most recent version of this part.

§ 62.14402 If my HMIWI is not listed on the Federal plan inventory, am I exempt from this subpart?

Not necessarily. Sources subject to this subpart include, but are not limited to, the inventory of sources listed in docket A–98–24 for the Federal plan.

§ 62.14403 What happens if I modify an existing HMIWI?

(a) If you commenced modification (defined in § 62.14490) of an existing HMIWI after March 16, 1998, you are subject to 40 CFR part 60, subpart Ec (40 CFR 60.50c through 60.58c) and you are not subject to this subpart, except as provided in paragraph (b) of this section.

(b) If you made physical or operational changes to your existing HMIWI solely for the purpose of complying with this subpart, these changes are not considered a modification, and you are not subject to 40 CFR part 60, subpart Ec (40 CFR 60.50c through 60.58c). You remain subject to this subpart.

Emission Limits

§ 62.14410 Are there different emission limits for different locations and sizes of HMIWI?

Yes, there are different emission limits for small rural, small, medium, and large HMIWI. To determine the size category of your HMIWI, consult the definitions in § 62.14490.

§ 62.14411 What emission limits apply to my HMIWI?

You must operate your HMIWI in compliance with the emission limit requirements for your HMIWI size category listed in Table 1 of this subpart.

§ 62.14412 What stack opacity requirements apply?

Your HMIWI (regardless of size category) must not discharge into the atmosphere from the stack any gases that exhibit greater than 10 percent opacity (6-minute block average).

§ 62.14413 When do the emission limits and stack opacity requirements apply?

The emission limits and stack opacity requirements of this subpart apply at all times except during periods of startup, shutdown, or malfunction, provided that no hospital waste or medical/infectious waste is charged to your HMIWI during periods of startup, shutdown, or malfunction.

Operator Training and Qualification

§ 62.14420 Am I required to have a trained and qualified operator?

You must have a fully trained and qualified HMIWI operator, either at your facility or able to be at your facility within 1 hour. The trained and qualified HMIWI operator may operate the HMIWI directly or be the direct supervisor of one or more HMIWI operators.

§ 62.14421 How does an operator become trained and qualified?

(a) The HMIWI operator can obtain training and qualification through a State-approved program or as provided in paragraph (b) of this section.

(b) If there are no State-approved training and qualification programs available or if your operator does not want to participate in a State-approved program, then your operator must complete a training course that includes the requirements in § 62.14422 and satisfy the qualification requirements in § 62.14423.

§ 62.14422 What are the requirements for a training course that is not part of a State-approved program?

A training course must include:

(a) Twenty-four hours of training that includes all of the following subjects:

(1) Environmental concerns, including pathogen destruction and types of emissions;

(2) Basic combustion principles, including products of combustion;

(3) Operation of the type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures;

(4) Combustion controls and monitoring;

(5) Operation of air pollution control equipment and factors affecting performance (if applicable);

(6) Methods to monitor pollutants (continuous emission monitoring systems and monitoring of HMIWI and air pollution control device operating parameters) and equipment calibration procedures (where applicable);

(7) Inspection and maintenance of the HMIWI, air pollution control devices, and continuous emission monitoring systems;

(8) Actions to correct malfunctions and conditions that may lead to malfunction;

(9) Bottom and fly ash characteristics and handling procedures;

(10) Applicable Federal, State, and local regulations;

(11) Work safety procedures;

(12) Prestartup inspections; and

(13) Recordkeeping requirements.

(b) An examination designed and administered by the instructor; and (c) Reference material distributed to the attendees covering the course topics.

§ 62.14423 What are the qualification requirements for operators who do not participate in a State-approved program?

(a) Operators who do not participate in a State-approved program must satisfy paragraphs (a)(1) and (2) of this section:

(1) The operator must complete a training course that satisfies the requirements in § 62.14422; and

(2) The operator must have either 6 months experience as an HMIWI operator, 6 months experience as a direct supervisor of an HMIWI operator, or completion of at least two burn cycles under the observation and supervision of two qualified HMIWI operators.

(b) The operator's qualification is valid after paragraphs (a)(1) and (2) of this section are completed.

(c) To remain qualified, the operator must complete and pass an annual review or refresher course of at least 4 hours covering, at a minimum, the following:

(1) Update of regulations;

(2) Incinerator operation, including startup and shutdown procedures;

(3) Inspection and maintenance;

(4) Responses to malfunctions or conditions that may lead to malfunction; and

(5) Discussion of operating problems encountered by attendees.

(d) If the operator's qualification lapses, he or she must renew it by one of the following methods:

(1) For a lapse of less than 3 years, complete and pass a standard annual refresher course described in paragraph (c) of this section;

(2) For a lapse of 3 years or more, complete and pass a training course with the minimum criteria described in § 62.14422.

§ 62.14424 What documentation must I maintain onsite?

(a) You must maintain the following at the facility:

(1) Summary of the applicable standards under this subpart;

(2) Description of basic combustion theory applicable to an HMIWI;

(3) Procedures for receiving, handling, and charging waste;

(4) Procedures for startup, shutdown, and malfunction;

(5) Procedures for maintaining proper combustion air supply levels;

(6) Procedures for operating the HMIWI and associated air pollution control systems within the standards established under this subpart;

(7) Procedures for responding to malfunction or conditions that may lead to malfunction;

(8) Procedures for monitoring HMIWI emissions;

(9) Reporting and recordkeeping procedures; and

(10) Procedures for handling ash.

(b) You must keep the information listed in paragraph (a) of this section in a readily accessible location for all HMIWI operators. This information, along with records of training, must be available for inspection by the EPA or its delegated enforcement agent upon request.

§ 62.14425 When must I review the documentation?

(a) You must establish a program for reviewing the information listed in § 62.14424 annually with each HMIWI operator (defined in § 62.14490).

(b) You must conduct your initial review of the information listed in § 62.14424 within [date 6 months after publication of the final rule] or prior to assumption of responsibilities affecting HMIWI operation, whichever date is later.

(c) You must conduct subsequent reviews of the information listed in § 62.14424 annually.

Waste Management Plan

§ 62.14430 Must I prepare a waste management plan?

Yes. All HMIWI owners or operators must have a waste management plan.

§ 62.14431 What must my waste management plan include?

Your waste management plan must identify both the feasibility of, and the approach for, separating certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from incinerated waste. The waste management plan you develop may address, but is not limited to, paper,

cardboard, plastics, glass, battery, or metal recycling, or purchasing recycled or recyclable products. Your waste management plan may include different goals or approaches for different areas or departments of the facility and need not include new waste management goals for every waste stream. When you develop your waste management plan it should identify. where possible, reasonably available additional waste management measures, taking into account the effectiveness of waste management measures already in place, the costs of additional measures, the emission reductions expected to be achieved, and any other potential environmental or energy impacts they might have. In developing your waste management plan, you must consider the American Hospital Association publication entitled "An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities." This publication (AHA Catalog No. 057007) is available for purchase from the American Hospital Association (AHA) Service, Inc., Post Office Box 92683, Chicago, Illinois 60675–2683.

§ 62.14432 When must my waste management plan be completed?

As specified in § 62.14463 and § 62.14464, you must submit your waste management plan with your initial report, which is due 60 days after your initial performance test.

Inspection Requirements

§ 62.14440 Which HMIWI are subject to inspection requirements?

Only small rural HMIWI (defined in § 62.14490) are subject to inspection requirements.

§ 62.14441 When must I inspect my small rural HMIWI?

(a) You must inspect your small rural HMIWI by [date 1 year after publication of final rule].

(b) You must conduct inspections as outlined in § 62.14442 annually (no more than 12 months following the previous annual equipment inspection).

§ 62.14442 What must my inspection include?

At a minimum, you must do the following during your inspection:

(a) Inspect all burners, pilot assemblies, and pilot sensing devices for proper operation, and clean pilot flame sensor as necessary;

(b) Check for proper adjustment of primary and secondary chamber combustion air, and adjust as necessary;

(c) Inspect hinges and door latches, and lubricate as necessary;

(d) Inspect dampers, fans, and blowers for proper operation;

(e) Inspect HMIWI door and door gaskets for proper sealing;

(f) Inspect motors for proper operation;

(g) Inspect primary chamber refractory lining, and clean and repair/replace lining as necessary;

(h) Inspect incinerator shell for corrosion and/or hot spots;

(i) Inspect secondary/tertiary chamber and stack, and clean as necessary;

(j) Inspect mechanical loader, including limit switches, for proper operation, if applicable;

(k) Visually inspect waste bed (grates), and repair/seal, as necessary;

(l) For the burn cycle that follows the inspection, document that the incinerator is operating properly and make any necessary adjustments;

(m) Inspect air pollution control device(s) for proper operation, if applicable;

(n) Inspect waste heat boiler systems to ensure proper operation, if applicable;

(o) Inspect bypass stack components;

(p) Ensure proper calibration of thermocouples, sorbent feed systems and any other monitoring equipment; and

(q) Generally observe that the equipment is maintained in good operating condition.

§ 62.14443 When must I do repairs?

You must complete any necessary repairs within 10 operating days of the inspection unless you obtain written approval from the EPA Administrator (or delegated enforcement authority) establishing a different date when all necessary repairs of your HMIWI must be completed.

Compliance, Performance Testing, and Monitoring Requirements

§ 62.14450 What are the testing requirements for small rural HMIWI?

(a) If you operate a small rural HMIWI (defined in § 62.14490), you must conduct an initial performance test for PM, opacity, CO, dioxin/furan, and Hg using the test methods and procedures outlined in § 62.14452.

(b) After the initial performance test is completed or is required to be completed under § 62.14470. whichever date comes first, if you operate a small rural HMIWI you must determine compliance with the opacity limit by conducting an annual performance test (no more than 12 months following the previous performance test) using the applicable procedures and test methods listed in § 62.14452.

(c) The 2,000 lb/wk limitation for small rural HMIWI does not apply during performance tests.

(d) The EPA Administrator may request a repeat performance test at any time.

§ 62.14451 What are the testing requirements for HMIWI that are not small rural?

(a) If you operate an HMIWI that is not a small rural HMIWI, you must conduct an initial performance test for PM, opacity, CO, dioxin/furan, HCl, Pb, Cd, and Hg using the test methods and procedures outlined in § 62.14452.

(b) After the initial performance test is completed or is required to be completed under § 62.14470, whichever date comes first, you must:

(1) Determine compliance with the opacity limit by conducting an annual performance test (no more than 12 months following the previous performance test) using the applicable procedures and test methods listed in § 62.14452.

(2) Determine compliance with the PM, CO, and HCl emission limits by conducting an annual performance test (no more than 12 months following the previous performance test) using the applicable procedures and test methods listed in § 62.14452. If all three performance tests over a 3-year period indicate compliance with the emission limit for a pollutant (PM, CO, or HCl), you may forego a performance test for that pollutant for the next 2 years. At a minimum, you must conduct a performance test for PM, CO, and HCl every third year (no more than 36 months following the previous performance test). If a performance test conducted every third year indicates compliance with the emission limit for a pollutant (PM, CO, or HCl), you may forego a performance test for that pollutant for an additional 2 years. If any performance test indicates noncompliance with the respective emission limit, you must conduct a performance test for that pollutant annually until all annual performance tests over a 3-year period indicate compliance with the emission limit.

(c) The EPA Administrator may request a repeat performance test at any time.

§ 62.14452 What test methods and procedures must I use?

You must use the following test methods and procedures to conduct performance tests to determine compliance with the emission limits:

(a) All performance tests must consist of a minimum of three test runs conducted under representative operating conditions;

(b) The minimum sample time must be 1 hour per test run unless otherwise indicated in this section;

(c) You must use EPA Reference Method 1 of 40 CFR part 60, appendix A to select the sampling location and number of traverse points;

(d) You must use EPA Reference Method 3, 3A, or 3B of 40 CFR part 60, appendix A for gas composition analysis, including measurement of oxygen concentration. You must use EPA Reference Method 3, 3A, or 3B of 40 CFR part 60, appendix A simultaneously with each reference method;

(e) You must adjust pollutant concentrations to 7 percent oxygen using the following equation:

$C_{adj} = C_{meas} (20.9–7)/(20.9–\%O_2)$

Where:

C_{adj} = pollutant concentration adjusted to 7 percent oxygen;

C_{meas} = pollutant concentration measured on a dry basis at standard conditions

(20.9–7) = 20.9 percent oxygen—7 percent oxygen (defined oxygen correction basis);

20.9 = oxygen concentration in air, percent; and

$\%O_2$ = oxygen concentration measured on a dry basis at standard conditions, percent.

(f) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 5 or 29 of 40 CFR part 60, appendix A to measure particulate matter emissions;

(g) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 9 of 40 CFR part 60, appendix A to measure stack opacity;

(h) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 10 or 10B of 40 CFR part 60, appendix A to measure the CO emissions;

(i) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 23 of 40 CFR part 60, appendix A to measure total dioxin/furan emissions. The minimum sample time must be 4 hours per test run. If you have selected the toxic equivalency standards for dioxin/furans under § 62.14411, you must use the following procedures to determine compliance:

(1) Measure the concentration of each dioxin/ furan tetra- through octa-congener emitted using EPA Reference Method 23;

(2) For each dioxin/furan congener measured in accordance with paragraph (i)(1) of this section, multiply the congener concentration by its corresponding toxic equivalency factor specified in Table 2 of this subpart;

(3) Sum the products calculated in accordance with paragraph (i)(2) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(j) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 26 of 40 CFR part 60, appendix A to measure HCl emissions. If you have selected the percentage reduction standards for HCl under § 62.14411, compute the percentage reduction in HCl emissions ($\%R_{HCl}$) using the following formula:

$$(\%R_{HCl}) = \left(\frac{E_i - E_o}{E_i}\right) \times 100$$

Where:

$\%R_{HCl}$ = percentage reduction of HCl emissions achieved;

E_i = HCl emission concentration measured at the control device inlet, corrected to 7 percent oxygen (dry basis at standard conditions); and

E_o = HCl emission concentration measured at the control device outlet, corrected to 7 percent oxygen (dry basis at standard conditions).

(k) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 29 of 40 CFR part 60, appendix A to measure Pb, Cd, and Hg emissions. If you have selected the percentage reduction standards for metals under § 62.14411, compute the percentage reduction in emissions ($\%R_{metal}$) using the following formula:

$$(\%R_{metal}) = \left(\frac{E_i - E_o}{E_i}\right) \times 100$$

Where:

$\%R_{metal}$ = percentage reduction of metal emission (Pb, Cd, or Hg) achieved;

E_i = metal emission concentration (Pb, Cd, or Hg) measured at the control device inlet, corrected to 7 percent oxygen (dry basis at standard conditions); and

E_o = metal emission concentration (Pb, Cd, or Hg) measured at the control device outlet, corrected to 7 percent oxygen (dry basis at standard conditions).

(l) If you are using a continuous emission monitoring system (CEMS) to demonstrate compliance with any of the emission limits under § 62.14411 or § 62.14412, you must:

(1) Determine compliance with the appropriate emission limit(s) using a 12-hour rolling average, calculated each hour as the average of the previous 12 operating hours (not including startup, shutdown, or malfunction). Performance tests using EPA Reference Methods are not required for pollutants monitored with CEMS.

(2) Operate a CEMS to measure oxygen concentration, adjusting pollutant concentrations to 7 percent oxygen as specified in paragraph (e) of this section.

(3) Operate all CEMS in accordance with the applicable procedures under appendices B and F of 40 CFR part 60.

(m) Use of the bypass stack during a performance test will invalidate the performance test.

§ 62.14453 What must I monitor?

(a) If your HMIWI is a small rural HMIWI, or your HMIWI is equipped with a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and wet scrubber:

(1) You must establish the appropriate maximum and minimum operating parameters, indicated in Table 3, as site-specific operating parameters during the initial performance test to determine compliance with the emission limits; and

(2) After the date on which the initial performance test is completed or is required to be completed under § 62.14470, whichever comes first, your HMIWI must not operate above any of the applicable maximum operating parameters or below any of the applicable minimum operating parameters listed in Table 3 and measured as 3-hour rolling averages (calculated each hour as the average of the previous 3 operating hours), at all times except during startup, shutdown, malfunction, and performance tests.

(b) If your HMIWI is not a small rural HMIWI, and you are using an air pollution control device other than a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and a wet scrubber to comply with the emission limits under § 62.14411, you must petition the EPA Administrator for site-specific operating parameters to be established during the initial performance test and you must continuously monitor those parameters thereafter. You may not conduct the initial performance test until the EPA Administrator has approved the petition.

§ 62.14454 How must I monitor the required parameters?

(a) You must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the applicable maximum and minimum operating parameters listed in Table 3 of this subpart such that these devices (or methods) measure and record values for the operating parameters at the

frequencies indicated in Table 3 of this subpart at all times except during periods of startup and shutdown. For charge rate, the device must measure and record the date, time, and weight of each charge fed to the HMIWI. This must be done automatically, meaning that the only intervention from an operator during the process would be to load the charge onto the weighing device. For batch HMIWI, the maximum charge rate is measured on a daily basis (the amount of waste charged to the unit each day).

(b) For all HMIWI except small rural HMIWI, you must install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of the bypass stack, including the date, time, and duration of such use.

(c) For all HMIWI except small rural HMIWI, if you are using controls other than a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and a wet scrubber to comply with the emission limits under § 62.14411, you must install, calibrate (to manufacturers' specifications), maintain, and operate the equipment necessary to monitor the site-specific operating parameters developed pursuant to § 62.14453(b).

(d) You must obtain monitoring data at all times during HMIWI operation except during periods of monitoring equipment malfunction, calibration, or repair. At a minimum, valid monitoring data must be obtained for 75 percent of the operating hours per day for 90 percent of the operating days per calendar quarter that your HMIWI is combusting hospital waste and/or medical/infectious waste.

§ 62.14455 What if my HMIWI goes outside of a parameter limit?

(a) Operation above the established maximum or below the established minimum operating parameter(s) constitutes a violation of established operating parameter(s). Operating parameter limits do not apply during startup, shutdown, malfunction, and performance tests.

(b) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is a small rural HMIWI,

And your HMIWI	Then you are in violation of
Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The PM, CO, and dioxin/furan emission limits.

(c) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is equipped with a dry scrubber followed by a fabric filter:

And your HMIWI	Then you are in violation of
(1) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The CO emission limit.
(2) Operates above the maximum fabric filter inlet temperature (3-hour rolling average), above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI), and below the minimum dioxin/furan sorbent flow rate (3-hour rolling average) simultaneously.	The dioxin/furan emission limit.
(3) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum HCl sorbent flow rate (3-hour rolling average) simultaneously.	The HCl emission limit.
(4) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum Hg sorbent flow rate (3-hour rolling average) simultaneously.	The Hg emission limit.
(5) Uses the bypass stack (except during startup, shutdown, or malfunction)	The PM, dioxin/furan, HCl, Pb, Cd, and Hg emission limits.

(d) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is equipped with a wet scrubber:

And your HMIWI	Then you are in violation of
(1) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The CO emission limit.
(2) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum pressure drop across the wet scrubber (3-hour rolling average) or below the minimum horsepower or amperage to the system (3-hour rolling average) simultaneously.	The PM emission limit.
(3) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI), below the minimum secondary chamber temperature (3-hour rolling average), and below the minimum scrubber liquor flow rate (3-hour rolling average) simultaneously.	The dioxin/furan emission limit.
(4) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum scrubber liquor pH (3-hour rolling average) simultaneously.	The HCl emission limit.
(5) Operates above the maximum flue gas temperature (3-hour rolling average) and above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) simultaneously.	The Hg emission limit.
(6) Uses the bypass stack (except during startup, shutdown, or malfunction)	The PM, dioxin/furan, HCl, Pb, Cd, and Hg emission limits.

(e) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is equipped with a dry scrubber followed by a fabric filter and a wet scrubber:

And your HMIWI	Then you are in violation of
(1) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The CO emission limit.
(2) Operates above the maximum fabric filter inlet temperature (3-hour rolling average), above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI), and below the minimum dioxin/furan sorbent flow rate (3-hour rolling average) simultaneously.	The dioxin/furan emission limit.
(3) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum scrubber liquor pH (3-hour rolling average) simultaneously.	The HCl emission limit.
(4) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum Hg sorbent flow rate (3-hour rolling average) simultaneously.	The Hg emission limit.
(5) Uses the bypass stack (except during startup, shutdown, or malfunction)	The PM, dioxin/furan, HCl, Pb, Cd, and Hg emission limits.

(f) You may conduct a repeat performance test within 30 days of violation of applicable operating parameter(s) to demonstrate that your HMIWI is not in violation of the applicable emission limit(s). You must conduct repeat performance tests pursuant to this paragraph using the identical operating parameters that indicated a violation under paragraph (b), (c), (d) or (e) of this section.

(g) If you are using a CEMS to demonstrate compliance with any of the emission limits in Table 1 of this subpart or § 62.14412, and your CEMS indicates compliance with an emission limit during periods when operating parameters indicate a violation of an emission limit under paragraphs (b), (c), (d), or (e) of this section, then you are considered to be in compliance with the emission limit. You need not conduct a repeat performance test to demonstrate compliance.

(h) You may conduct a repeat performance test in accordance with § 62.14452 at any time to establish new values for the operating parameters.

Reporting and Recordkeeping Requirements

§ 62.14460 What records must I maintain?

You must maintain the following:

(a) Calendar date of each record;

(b) Records of the following data:

(1) Concentrations of any pollutant listed in Table 1 and/or measurements of opacity;

(2) The HMIWI charge dates, times, and weights and hourly charge rates;

(3) Fabric filter inlet temperatures during each minute of operation, as applicable;

(4) Amount and type of dioxin/furan sorbent used during each hour of operation, as applicable;

(5) Amount and type of Hg sorbent used during each hour of operation, as applicable;

(6) Amount and type of HCl sorbent used during each hour of operation, as applicable;

(7) Secondary chamber temperatures recorded during each minute of operation;

(8) Liquor flow rate to the wet scrubber inlet during each minute of operation, as applicable,

(9) Horsepower or amperage to the wet scrubber during each minute of operation, as applicable;

(10) Pressure drop across the wet scrubber system during each minute of operation, as applicable;

(11) Temperature at the outlet from the wet scrubber during each minute of operation, as applicable;

(12) The pH at the inlet to the wet scrubber during each minute of operation, as applicable;

(13) Records of the annual equipment inspections, any required maintenance, and any repairs not completed within 10 days of an inspection or the time frame established by the EPA Administrator or delegated enforcement authority, as applicable;

(14) Records indicating use of the bypass stack, including dates, times, and durations; and

(15) If you are complying by monitoring site-specific operating parameters under § 62.14453(b), you must monitor all operating data collected.

(c) Identification of calendar days for which data on emission rates or operating parameters specified under paragraphs (b)(1) through (15) of this section were not obtained, with an identification of the emission rates or operating parameters not measured, reasons for not obtaining the data, and a description of corrective actions taken;

(d) Identification of calendar days, times and durations of malfunctions, and a description of the malfunction and the corrective action taken.

(e) Identification of calendar days for which data on emission rates or operating parameters specified under paragraphs (b)(1) through (15) of this section exceeded the applicable limits, with a description of the exceedances, reasons for such exceedances, and a description of corrective actions taken.

(f) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating parameters, as applicable.

(g) Records showing the names of HMIWI operators who have completed review of the documentation in § 62.14424 as required by § 62.14425, including the date of the initial review and all subsequent annual reviews;

(h) Records showing the names of the HMIWI operators who have completed the operator training requirements, including documentation of training and the dates of the training;

(i) Records showing the names of the HMIWI operators who have met the criteria for qualification under § 62.14423 and the dates of their qualification; and

(j) Records of calibration of any monitoring devices as required under § 62.14454.

§ 62.14461 For how long must I maintain records?

You must maintain the records specified under § 62.14460 for a period of at least 5 years.

§ 62.14462 Where must I keep the records?

You must maintain all records specified under § 62.14460 onsite in either paper copy or computer-readable

format, unless an alternative format is approved by the EPA Administrator.

§ 62.14463 What reporting requirements must I satisfy?

You must report the following to the EPA Administrator (or delegated enforcement authority):

(a) The initial performance test data as recorded under § 62.14450(a) or § 62.14451(a) (whichever applies);

(b) The values for the site-specific operating parameters established pursuant to § 62.14453, as applicable;

(c) The waste management plan as specified in § 62.14431;

(d) The highest maximum operating parameter and the lowest minimum operating parameter for each operating parameter recorded for the calendar year being reported, pursuant to § 62.14453, as applicable;

(e) The highest maximum operating parameter and the lowest minimum operating parameter, as applicable, for each operating parameter recorded pursuant to § 62.14453 for the calendar year preceding the year being reported, in order to provide a summary of the performance of the HMIWI over a 2-year period;

(f) Any information recorded under § 62.14460(c) through (e) for the calendar year being reported;

(g) Any information recorded under § 62.14460(c) through (e) for the calendar year preceding the year being reported, in order to provide a summary of the performance of the HMIWI over a 2-year period;

(h) The results of any performance test conducted during the reporting period;

(i) If no exceedances or malfunctions occurred during the calendar year being reported, a statement that no exceedances occurred during the reporting period;

(j) Any use of the bypass stack, duration of such use, reason for malfunction, and corrective action taken; and

(k) Records of the annual equipment inspections, any required maintenance, and any repairs not completed within 10 days of an inspection or the time frame established by the EPA Administrator (or delegated enforcement authority).

§ 62.14464 When must I submit reports?

(a) You must submit the information specified in § 62.14463(a) through (c) no later than 60 days following the initial performance test.

(b) You must submit an annual report to the EPA Administrator (or delegated enforcement authority) no more than 1 year following the submission of the information in paragraph (a) of this section and you must submit subsequent reports no more than 1 year following the previous report (once the unit is subject to permitting requirements under title V of the Clean Air Act, you must submit these reports semiannually). The annual report must include the information specified in § 62.14463(d) through (k), as applicable.

(c) You must submit semiannual reports containing any information recorded under § 62.14460(c) through (e) no later than 60 days following the end of the semiannual reporting period. The first semiannual reporting period ends 6 months following the submission of information in paragraph (a) of this section. Subsequent reports must be submitted no later than 6 calendar months following the previous report.

§ 62.14465 Who must sign all submitted reports?

All reports must be signed by the facilities manager (defined in § 62.14490).

Compliance Schedule

§ 62.14470 When must I comply with this subpart if I plan to continue operation of my HMIWI?

If you plan to continue operation of your HMIWI, then you must follow the requirements in paragraph (a) or (b) of this section depending on when you plan to come into compliance with the requirements of this subpart.

(a) If you plan to continue operation and come into compliance with the requirements of this subpart by [date 1 year after publication of final rule], then you must complete the requirements of paragraphs (a)(1) through (a)(4) of this section.

(1) You must comply with the operator training and qualification requirements and inspection requirements (if applicable) of this subpart by [date 1 year after publication of final rule].

(2) You must achieve final compliance by [date 1 year after publication of final rule]. This includes incorporating all process changes and/or completing retrofit construction. connecting the air pollution control equipment or process changes such that the HMIWI is brought on line, and ensuring that all necessary process changes and air pollution control equipment are operating properly.

(3) You must conduct the initial performance test required by § 62.14450(a) (for small rural HMIWI) or § 62.14451(a) (for HMIWI that are not small rural HMIWI) within 180 days after the date when you are required to achieve final compliance under paragraph (a)(2) of this section.

(4) You must submit an initial report including the results of the initial performance test and the waste management plan no later than 60 days following the initial performance test (see § 62.14463 and § 62.14464 for complete reporting and recordkeeping requirements).

(b) If you plan to continue operation and come into compliance with the requirements of this subpart after [date 1 year after publication of final rule], but before September 15, 2002, then you must complete the requirements of paragraphs (b)(1) through (b)(4) of this section.

(1) You must comply with the operator training and qualification requirements and inspection requirements (if applicable) of this subpart by [date 1 year after publication of final rule].

(2) You must demonstrate that you are taking steps towards compliance with the emission limits in the subpart by completing the increments of progress in paragraphs (b)(2)(i) through (b)(2)(v) of this section. You must submit notification to the EPA Administrator (or delegated enforcement authority) within 10 business days of completing (or failing to complete by the applicable date) each of the increments of progress listed in paragraphs (b)(2)(i) through (b)(2)(v) of this section. Your notification must be signed by your facilities manager (defined in § 62.14490).

(i) You must submit a final control plan by September 15, 2000. Your final control plan must, at a minimum, include a description of the air pollution control device(s) or process changes that will be employed for each unit to comply with the emission limits and other requirements of this subpart.

(ii) You must award contract(s) for onsite construction, onsite installation of emission control equipment, or incorporation of process changes by April 15, 2001. You must submit a signed copy of the contract(s) awarded.

(iii) You must begin onsite construction, begin onsite installation of emission control equipment, or begin process changes needed to meet the emission limits as outlined in the final control plan by December 15, 2001.

(iv) You must complete onsite construction, installation of emission control equipment, or process changes by July 15, 2002.

(v) You must achieve final compliance by September 15, 2002. This includes incorporating all process changes and/or completing retrofit construction as described in the final

control plan, connecting the air pollution control equipment or process changes such that the HMIWI is brought on line, and ensuring that all necessary process changes and air pollution control equipment are operating properly.

(3) You must conduct the initial performance test required by § 62.14450(a) (for small rural HMIWI) or § 62.14451(a) (for HMIWI that are not small rural HMIWI) within 180 days after the date when you are required to achieve final compliance under paragraph (b)(2)(v) of this section.

(4) You must submit an initial report including the result of the initial performance test and the waste management plan no later than 60 days following the initial performance test (see § 62.14463 and § 62.14464 for complete reporting and recordkeeping requirements).

§ 62.14471 When must I comply with this subpart if I plan to shut down?

If you plan to shut down, then you must follow the requirements in either paragraph (a) or (b) of this section depending on when you plan to shut down.

(a) If you plan to shut down by [date 1 year after publication of final rule] rather that come into compliance with the requirements of this subpart, then you must shut down by [date 1 year after publication of final rule] to avoid coverage under any of the requirements of this subpart.

(b) If you plan to shut down rather than come into compliance with the requirements of this subpart, but are unable to shut down by [date 1 year after publication of final rule], then you may petition EPA for an extension by following the procedures outlined in paragraphs (b)(1) through (b)(3) of this section.

(1) You must submit your request for an extension to the EPA Administrator (or delegated enforcement authority) by [date 90 days after publication of final rule]. Your request must include:

(i) Documentation of the analyses undertaken to support your need for an extension, including an explanation of why your requested extension date is sufficient time for you to shut down while [date 1 year after publication of final rule] does not provide sufficient time for shut down. Your documentation must include an evaluation of the option to transport your waste offsite to a commercial medical waste treatment and disposal facility on a temporary or permanent basis; and

(ii) Documentation of incremental steps of progress, including dates for completing the increments of progress, that you will take towards shutting down. Some suggested incremental steps of progress towards shut down are provided as follows:

If you. . .	Then your increments of progress could be. . .
Need an extension so you can install an onsite alternative waste treatment technology before you shut down your HMIWI.	—Date when you will enter into a contract with an alternative treatment technology vendor, —Date for initiating onsite construction or installation of the alternative technology, —Date for completing onsite construction or installation of the alternative technology, and —Date for shutting down the HMIWI.
Need an extension so you can acquire the services of a commercial medical/infectious waste disposal company before you shut down your HMIWI.	—Date when price quotes will be obtained from commercial disposal companies, —Date when you will enter into a contract with a commercial disposal company, and —Date for shutting down the HMIWI.

(2) You must shut down no later than September 15, 2002.

(3) You must comply with the operator training and qualification requirements and inspection requirements (if applicable) of this subpart by [date 1 year after publication of the final rule].

§ 62.14472 When must I comply with this subpart if I plan to shut down and later restart?

If you wish to shut down and later restart, then you must follow the compliance times in paragraph (a) or (b) of this section depending on when you restart.

(a) If you plan to shut down and restart prior to September 15, 2002, then you must:

(1) Meet the compliance schedule outlined in § 63.14470(a) if you restart prior to [date 1 year after publication of the final rule]; or

(2) Meet the compliance schedule outlined in § 62.14470(b) if you restart after [date 1 year after publication of the final rule]. Any missed increments of progress need to be completed prior to or upon the date of restart.

(b) If you plan to shut down and restart after September 15, 2002, then you must complete the requirements of paragraphs (b)(1) through (b)(4) of this section.

(1) You must comply with the operator training and qualification requirements and inspection requirements (if applicable) of this subpart before restarting your HMIWI.

(2) You must achieve final compliance upon restarting your HMIWI. This includes incorporating all process changes and/or completing retrofit construction, connecting the air pollution control equipment or process changes such that the HMIWI is brought on line, and ensuring that all necessary process changes and air pollution control equipment are operating properly.

(3) You must conduct the initial performance test required by § 62.14450(a) (for small rural HMIWI) or § 62.14451(a) (for HMIWI that are not small rural HMIWI) within 180 days after the date when you restart.

(4) You must submit an initial report including the results of the initial performance test and the waste management plan no later than 60 days following the initial performance test (see § 62.14463 and § 62.14464 for complete reporting and recordkeeping requirements).

Permitting Obligation

§ 62.14480 Does this subpart require me to obtain an operating permit under title V of the Clean Air Act and implementing regulations?

This subpart requires you to obtain an operating permit under title V of the Clean Air Act and implementing regulations ("title V permit") unless you are only subject to the recordkeeping and reporting requirements listed at §§ 62.14400(b)(1) or (b)(2). Also, if you own or operate a unit described in §§ 62.14400(b)(3), (b)(4), (b)(5) or (b)(6), you are not subject to any requirements

of this subpart; therefore, this subpart does not require you to obtain a title V permit.

§ 62.14481 When must I submit a title V permit application for my HMIWI?

You must submit a title V permit application in time for it to be determined or deemed complete by no later than September 15, 2000 or by the effective date of a title V permit program in the State or Tribal area in which the unit is located, whichever is later. (An earlier deadline may apply if your HMIWI is also subject to title V's permitting requirements because of some other triggering requirement.) A "complete" title V permit application is one that has been approved by the appropriate permitting authority as complete under section 503 of the Clean Air Act and 40 CFR parts 70 and 71. It is not enough to have submitted a title V permit application by September 15, 2000 because the application must be determined or deemed complete by the permitting authority by that date for your HMIWI to operate after that date in compliance with Federal law.

Definitions

§ 62.14490 Definitions.

Batch HMIWI means an HMIWI that is designed such that neither waste charging nor ash removal can occur during combustion.

Biologicals means preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing, or treating humans or animals or in research pertaining thereto.

Blood products means any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon, etc.

Body fluids means liquid emanating or derived from humans and limited to blood; dialysate; amniotic, cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; and semen and vaginal secretions.

Bypass stack means a device used for discharging combustion gases to avoid severe damage to the air pollution control device or other equipment.

Chemotherapeutic waste means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Co-fired combustor means a unit combusting hospital waste and/or medical/infectious waste with other fuels or wastes (e.g., coal, municipal solid waste) and subject to an enforceable requirement limiting the unit to combusting a fuel feed stream, 10 percent or less of the weight of which is comprised, in aggregate. of hospital waste and medical/infectious waste as measured on a calendar quarter basis. For purposes of this definition, pathological waste, chemotherapeutic waste, and low-level radioactive waste are considered "other" wastes when calculating the percentage of hospital waste and medical/infectious waste combusted.

Continuous emission monitoring system or *CEMS* means a monitoring system for continuously measuring and recording the emissions of a pollutant.

Continuous HMIWI means an HMIWI that is designed to allow waste charging and ash removal during combustion.

Dioxins/furans means the combined emissions of tetra- through octa-chlorinated dibenzo-para-dioxins and dibenzofurans, as measured by EPA Reference Method 23.

Dry scrubber means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gases in the HMIWI exhaust stream forming a dry powder material.

Fabric filter or *baghouse* means an add-on air pollution control system that removes particulate matter (PM) and nonvaporous metals emissions by passing flue gas through filter bags.

Facilities manager means the individual in charge of purchasing, maintaining, and operating the HMIWI or the owner's or operator's representative responsible for the management of the HMIWI. Alternative titles may include director of facilities or vice president of support services.

High-air phase means the stage of the batch operating cycle when the primary chamber reaches and maintains maximum operating temperatures.

Hospital means any facility which has an organized medical staff, maintains at least six inpatient beds, and where the primary function of the institution is to provide diagnostic and therapeutic patient services and continuous nursing care primarily to human inpatients who are not related and who stay on average in excess of 24 hours per admission. This definition does not include facilities maintained for the sole purpose of providing nursing or convalescent care to human patients who generally are not acutely ill but who require continuing medical supervision.

Hospital/medical/infectious waste incinerator or HMIWI or HMIWI unit means any device that combusts any amount of hospital waste and/or medical/infectious waste.

Hospital/medical/infectious waste incinerator operator or *HMIWI operator* means any person who operates, controls or supervises the day-to-day operation of an HMIWI.

Hospital waste means discards generated at a hospital, except unused items returned to the manufacturer. The definition of hospital waste does not include human corpses, remains, and anatomical parts that are intended for interment or cremation.

Infectious agent means any organism (such as a virus or bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

Intermittent HMIWI means an HMIWI that is designed to allow waste charging, but not ash removal, during combustion.

Large HMIWI means:

(1) Except as provided in paragraph (2) of this definition;

(i) An HMIWI whose maximum design waste burning capacity is more than 500 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 500 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds per day.

(2) The following are not large HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 500 pounds per hour; or

(ii) A batch HMIWI whose maximum charge rate is less than or equal to 4,000 pounds per day.

Low-level radioactive waste means waste material which contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable federal or State standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or by-product material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions. During periods of malfunction the operator must operate within established parameters as much as possible, and monitoring of all applicable operating parameters must continue until all

waste has been combusted or until the malfunction ceases, whichever comes first.

Maximum charge rate means:

(1) For continuous and intermittent HMIWI, 110 percent of the lowest 3-hour average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limits.

(2) For batch HMIWI, 110 percent of the lowest daily charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limits.

Maximum design waste burning capacity means:

(1) For intermittent and continuous HMIWI;

$C = P_V \times 15{,}000/8{,}500$

Where:

C = HMIWI capacity, lb/hr
P_V = primary chamber volume, ft^3
15,000 = primary chamber heat release rate factor, Btu/ft^3 /hr
8,500 = standard waste heating value, Btu/lb;

(2) For batch HMIWI;

$C = P_V \times 4.5/8$

Where:

C = HMIWI capacity, lb/hr
P_V = primary chamber volume, ft^3
4.5 = waste density, lb/ft^3
8 = typical hours of operation of a batch HMIWI, hours.

Maximum fabric filter inlet temperature means 110 percent of the lowest 3-hour average temperature at the inlet to the fabric filter (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the dioxin/furan emission limit.

Maximum flue gas temperature means 110 percent of the lowest 3-hour average temperature at the outlet from the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the mercury (Hg) emission limit.

Medical/infectious waste means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals that is listed in paragraphs (1) through (7) of this definition. The definition of medical/infectious waste does not include hazardous waste identified or listed under the regulations in part 261 of this chapter; household waste, as defined in § 261.4(b)(1) of this chapter; ash from incineration of medical/infectious waste, once the incineration process has been completed; human corpses, remains, and anatomical parts that are intended for interment or cremation; and domestic sewage materials identified in § 261.4(a)(1) of this chapter.

(1) Cultures and stocks of infectious agents and associated biologicals, including:Cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

(2) Human pathological waste, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.

(3) Human blood and blood products including:

(i) Liquid waste human blood;

(ii) Products of blood;

(iii) Items saturated and/or dripping with human blood; or

(iv) Items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also included in this category.

(4) Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

(5) Animal waste including contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals or testing of pharmaceuticals.

(6) Isolation wastes including biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

(7) Unused sharps including the following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

Medium HMIWI means:

(1) Except as provided in paragraph (2) of this definition;

(i) An HMIWI whose maximum design waste burning capacity is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is more than 1,600 pounds per day but less than or equal to 4,000 pounds per day.

(2) The following are not medium HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 200 pounds per hour or more than 500 pounds per hour; or

(ii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds per day or less than or equal to 1,600 pounds per day.

Minimum dioxin/furan sorbent flow rate means 90 percent of the highest 3-hour average dioxin/furan sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the dioxin/furan emission limit.

Minimum Hg sorbent flow rate means 90 percent of the highest 3-hour average Hg sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the Hg emission limit.

Minimum hydrogen chloride (HCl) sorbent flow rate means 90 percent of the highest 3-hour average HCl sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the HCl emission limit.

Minimum horsepower or amperage means 90 percent of the highest 3-hour average horsepower or amperage to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the applicable emission limits.

Minimum pressure drop across the wet scrubber means 90 percent of the highest 3-hour average pressure drop across the wet scrubber PM control device (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the PM emission limit.

Minimum scrubber liquor flow rate means 90 percent of the highest 3-hour

average liquor flow rate at the inlet to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with all applicable emission limits.

Minimum scrubber liquor pH means 90 percent of the highest 3-hour average liquor pH at the inlet to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the HCl emission limit.

Minimum secondary chamber temperature means 90 percent of the highest 3-hour average secondary chamber temperature (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the PM, CO, or dioxin/furan emission limits.

Modification or *Modified HMIWI* means any change to an HMIWI unit after March 16, 1998, such that:

(1) The cumulative costs of the modifications, over the life of the unit, exceed 50 per centum of the original cost of the construction and installation of the unit (not including the cost of any land purchased in connection with such construction or installation) updated to current costs, or

(2) The change involves a physical change in or change in the method of operation of the unit which increases the amount of any air pollutant emitted by the unit for which standards have been established under section 129 or section 111.

Operating day means a 24-hour period between 12:00 midnight and the following midnight during which any amount of hospital waste or medical/infectious waste is combusted at any time in the HMIWI.

Operation means the period during which waste is combusted in the incinerator excluding periods of startup or shutdown.

Particulate matter or PM means the total particulate matter emitted from an HMIWI as measured by EPA Reference Method 5 or EPA Reference Method 29.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Primary chamber means the chamber in an HMIWI that receives waste material, in which the waste is ignited, and from which ash is removed.

Pyrolysis means the endothermic gasification of hospital waste and/or medical/infectious waste using external energy.

Secondary chamber means a component of the HMIWI that receives combustion gases from the primary chamber and in which the combustion process is completed.

Shutdown means the period of time after all waste has been combusted in the primary chamber. For continuous HMIWI, shutdown must commence no less than 2 hours after the last charge to the incinerator. For intermittent HMIWI, shutdown must commence no less than 4 hours after the last charge to the incinerator. For batch HMIWI, shutdown must commence no less than 5 hours after the high-air phase of combustion has been completed.

Small HMIWI means:

(1) Except as provided in paragraph (2) of this definition;

(i) An HMIWI whose maximum design waste burning capacity is less than or equal to 200 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 200 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is less than or equal to 1,600 pounds per day.

(2) The following are not small HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is more than 200 pounds per hour;

(ii) A batch HMIWI whose maximum charge rate is more than 1,600 pounds per day.

Small rural HMIWI means a small HMIWI which is located more than 50 miles from the boundary of the nearest Standard Metropolitan Statistical Area and which burns less than 2,000 pounds per week of hospital waste and medical/infectious waste.

Standard conditions means a temperature of 20°C and a pressure of 101.3 kilopascals.

Standard Metropolitan Statistical Area or *SMSA* means any areas listed in OMB Bulletin No. 93–17 entitled "Revised Statistical Definitions for Metropolitan Areas" dated June 30, 1993. This information can also be obtained from the nearest Metropolitan Planning Organization.

Startup means the period of time between the activation of the system and the first charge to the unit. For batch HMIWI, startup means the period of time between activation of the system and ignition of the waste.

Wet scrubber means an add-on air pollution control device that utilizes an alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Delegation of Authority

§ 62.14495 What authorities will be retained by the EPA Administrator?

The following authorities will be retained by the EPA Administrator and not transferred to the State or Tribe:

(a) The requirements of § 62.14453(b) establishing operating parameters when using controls other than a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and a wet scrubber.

(b) Alternative methods of demonstrating compliance under 40 CFR 60.8.

TABLE 1 OF SUBPART HHH OF PART 62.—EMISSION LIMITS FOR SMALL RURAL, SMALL, MEDIUM, AND LARGE HMIWI

Pollutant	Units (7 percent oxygen, dry basis at standard conditions)	Emission limits			
		HMIWI size			
		Small rural	Small	Medium	Large
Particulate matter.	Milligrams per dry standard cubic meter (grains per dry standard cubic foot).	197 (0.086)	115 (0.05)	69 (0.03)	34 (0.015)
Carbon monoxide.	Parts per million by volume	40	40	40	40

TABLE 1 OF SUBPART HHH OF PART 62.—EMISSION LIMITS FOR SMALL RURAL, SMALL, MEDIUM, AND LARGE HMIWI—Continued

Pollutant	Units (7 percent oxygen, dry basis at standard conditions)	Emission limits			
		HMIWI size			
		Small rural	Small	Medium	Large
Dioxins/furans	Nanograms per dry standard cubic meter total dioxins/furans (grains per billion dry standard cubic feet) or nanograms per dry standard cubic meter TEQ (grains per billion dry standard cubic feet).	800 (350) or 15 (6.6)	125 (55) or 2.3 (1.0)	125 (55) or 2.3 (1.0)	125 (55) or 2.3 (1.0)
Hydrogen chloride.	Parts per million by volume or percent reduction.	3,100	100 or 93%	100 or 93%	100 or 93%
Sulfur dioxide	Parts per million by volume	55	55	55	55
Nitrogen oxides	Parts per million by volume	250	250	250	250
Lead	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	10 (4.4)	1.2 (0.52) or 70%	1.2 (0.52) or 70%	1.2 (0.52) or 70%
Cadmium	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	4 (1.7)	0.16 (0.07) or 65%	0.16 (0.07) or 65%	0.16 (0.07) or 65%
Mercury	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	7.5 (3.3)	0.55 (0.24) or 85%	0.55 (0.24) or 85%	0.55 (0.24) or 85%

TABLE 2 OF SUBPART HHH OF PART 62.—TOXIC EQUIVALENCY FACTORS

Dioxin/furan congener	Toxic equivalency factor
2,3,7,8-tetrachlorinated dibenzo-p-dioxin	1
1,2,3,7,8-pentachlorinated dibenzo-p-dioxin	0.5
1,2,3,4,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,7,8,9-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,6,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzo-p-dioxin	0.01
octachlorinated dibenzo-p-dioxin	0.001
2,3,7,8-tetrachlorinated dibenzofuran	0.1
2,3,4,7,8-pentachlorinated dibenzofuran	0.5
1,2,3,7,8-pentachlorinated dibenzofuran	0.05
1,2,3,4,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,7,8,9-hexachlorinated dibenzofuran	0.1
2,3,4,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzofuran	0.01
1,2,3,4,7,8,9-heptachlorinated dibenzofuran	0.01
octachlorinated dibenzofuran	0.001

TABLE 3 OF SUBPART HHH OF PART 62.—OPERATING PARAMETERS TO BE MONITORED AND MINIMUM MEASUREMENT AND RECORDING FREQUENCIES

Operating parameters to be monitored	Minimum frequency		HMIWI			
	Data measurement	Data recording	Small rural HMIWI	HMIWI [1] with dry scrubber followed by fabric filter	HMIWI [1] with wet scrubber	HMIWI [1] with dry scrubber followed by fabric filter and wet scrubber
Maximum operating parameters: Maximum charge rate	Once per charge	Once per charge	✔	✔	✔	✔

TABLE 3 OF SUBPART HHH OF PART 62.—OPERATING PARAMETERS TO BE MONITORED AND MINIMUM MEASUREMENT AND RECORDING FREQUENCIES—Continued

Operating parameters to be monitored	Minimum frequency		HMIWI			
	Data measurement	Data recording	Small rural HMIWI	HMIWI [1] with dry scrubber followed by fabric filter	HMIWI [1] with wet scrubber	HMIWI [1] with dry scrubber followed by fabric filter and wet scrubber
Maximum fabric filter inlet temperature.	Continuous	Once per minute		✔		✔
Maximum flue gas temperature	Continuous	Once per minute			✔	✔
Minimum operating parameters:						
Minimum secondary chamber temperature.	Continuous	Once per minute	✔	✔	✔	✔
Minimum dioxin/furan sorbent flow rate.	Hourly	Once per hour		✔		✔
Minimum HCl sorbent flow rate	Hourly	Once per hour		✔		✔
Minimum mercury (Hg) sorbent flow rate.	Hourly	Once per hour		✔		✔
Minimum pressure drop across the wet scrubber or minimum horsepower or amperage to wet scrubber.	Continuous	Once per minute			✔	✔
Minimum scrubber liquor flow rate	Continuous	Once per minute			✔	✔
Minimum scrubber liquor pH	Continuous	Once per minute			✔	✔

[1] Does not include small rural HMIWI.

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July 6, 1999

Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Proposed Rule To Remove the Bald Eagle in the Lower 48 States From the List of Endangered and Threatened Wildlife; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AF21

Endangered and Threatened Wildlife and Plants; Proposed Rule To Remove the Bald Eagle in the Lower 48 States From the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the Fish and Wildlife Service (the Service), propose to remove the bald eagle (*Haliaeetus leucocephalus*), from the List of Endangered and Threatened Wildlife in the lower 48 States of the United States. We propose this action because the available data indicate that this species has recovered. The recovery is due in part to habitat protection and management actions initiated under the Endangered Species Act. It is also due to reduction in levels of persistent organochlorine pesticides such as DDT occurring in the environment. Section 4(g) of the Act requires the Service to monitor recovered species for at least 5 years following delisting. This rule describes our proposed post-delisting monitoring plan for bald eagles. Removal of the bald eagle as a threatened species under the Act will not affect the protection provided under the Bald and Golden Eagle Protection Act, the Migratory Bird Treaty Act, and many other state laws.

DATES: Comments from all interested parties concerning the proposal to delist the bald eagle in the lower 48 States must be received by October 5, 1999. Public hearing requests must be received by August 20, 1999.

Comments from all interested parties on the collection of information from the public during the 5-year monitoring period will be considered if received on or before September 7, 1999. The Office of Management and Budget (OMB) has up to 60 days to approve or disapprove information collection but may respond after 30 days. Therefore, to ensure maximum consideration, your comments should be received by OMB by August 5, 1999.

ADDRESSES: Send your comments and other information concerning the proposal to delist the bald eagle in the lower 48 States to: Jody Gustitus Millar, Bald Eagle Recovery Coordinator, U.S. Fish and Wildlife Service, 4469–48th Avenue Court, Rock Island, IL 61201 or comments may be sent through our web site at www.fws.gov/r3pao/eagle.

Also send your comments and suggestions on specific information collection requirements to Rebecca Mullin, Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 224 ARLSQ, 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Jody Gustitus Millar, Bald Eagle Recovery Coordinator at the above address, telephone 309/793–5800 ext. 524, or refer to our website at www.fws.gov/r3pao/eagle.

SUPPLEMENTARY INFORMATION:

Background

The bald eagle, *Haliaeetus leucocephalus,* is well known as our Nation's symbol. Its large and powerful appearance is distinguished by its white head and tail contrasting against its dark brown body. Though once endangered, the bald eagle population in the lower 48 States has increased considerably in recent years. Regional bald eagle populations in the northwest, Great Lakes, Chesapeake Bay, and Florida have increased 5-fold in the past 20 years. Bald eagles are now repopulating areas throughout much of the species' historic range that were unoccupied only a few years ago.

Note: Unless otherwise noted with specific citations, the following life history information is derived from our 5 recovery plans for the bald eagle and from Gerrard and Bortolotti (1988), see References.

The bald eagle ranges throughout much of North America, nesting on both coasts from Florida to Baja California, Mexico in the south, and from Labrador to the western Aleutian Islands, Alaska in the north. The earliest known record of a bald eagle comes from a cave in Colorado. Deposits from that cave are dated at 670,000 to 780,000 years old (Dr. Steve Emslie, University of North Carolina, pers. comm. 1998). An estimated quarter to a half million bald eagles lived on the North American continent before the first Europeans arrived.

Haliaeetus leucocephalus (literally, sea eagle with a white head) is the only species of sea eagle native to North America. It was first described in 1766 as *Falco leucocephalus* by Linnaeus. This South Carolina specimen was later renamed as the southern bald eagle, subspecies *Haliaeetus leucocephalus leucocephalus* (Linnaeus) when Townsend identified the northern bald eagle as *Haliaeetus leucocephalus alascanus* in 1897 (Peters 1979). By the time the bald eagle was listed throughout the lower 48 States under the Endangered Species Act in 1978, the subspecies were no longer recognized by ornithologists (American Ornithologists Union 1983).

The bald eagle is a bird of aquatic ecosystems. It frequents estuaries, large lakes, reservoirs, major rivers, and some seacoast habitats. Fish is the major component of its diet, but waterfowl, seagulls, and carrion are also eaten. The species may also use prairies if adequate food is available. Bald eagle habitats encompass both public and private lands.

Bald eagles usually nest in trees near water, but are known to nest on cliffs and (rarely) on the ground. Nest sites are usually in large trees along shorelines in relatively remote areas that are free of disturbance. The trees must be sturdy and open to support a nest that is often 5 feet wide and 3 feet deep. Adults tend to use the same breeding areas year after year, and often the same nest, though a breeding area may include one or more alternate nests. A 35-year old nest at Vermilion, Ohio, measured 8½ feet across at the top and 12 feet deep before it blew down in 1925 (Herrick 1932). In winter, bald eagles often congregate at specific wintering sites that are generally close to open water and offer good perch trees and night roosts.

Bald eagles are long-lived. The longest living bald eagle known in the wild was reported near Haines, Alaska as 28 years old (Schempf 1997). Bald eagles from Arizona are known to have exceeded 12 years of age (Hunt et al. 1992). In captivity, bald eagles may live 40 or more years.

It is presumed that once they mate, the bond is long-term, though documentation is limited. Variations in pair bonding are known to occur. If one mate dies or disappears, the other will accept a new partner. The female bald eagle usually weighs 10 to 14 pounds in the northern sections of the continent and is larger than the male, which weighs 8 to 10 pounds. The wings span 6 to 7 feet. The northern birds are larger and heavier than southern birds, with the largest birds in Alaska and Canada, and the smallest in Arizona or Florida.

Bald eagle pairs begin courtship about a month before egg-laying. In the south, courtship occurs as early as September, and in the north, as late as May. The nesting season lasts about 6 months. Incubation lasts approximately 35 days and fledging takes place at 11 to 12 weeks of age. Parental care may extend 4 to 11 weeks after fledging (Wood, Collopy, and Sekerak 1998). The fledgling bald eagle is generally dark brown except the underwing linings which are primarily white. Between fledging and adulthood, the bald eagle's

appearance changes with feather replacement each summer. Young dark bald eagles may be confused with the golden eagle, *Aquila chrysaetos*. The bald eagle's distinctive white head and tail are not apparent until the bird fully matures, at 4 to 5 years of age.

As they leave their breeding areas, some bald eagles stay in the general vicinity while most migrate for several months and hundreds of miles to their wintering grounds. Young eagles may wander randomly for years before returning to nest in natal areas.

Northern bald eagles winter in areas such as the Upper Mississippi River, Great Lakes shorelines and river mouths in the Great Lakes area. For mid-continent bald eagles, wintering grounds may be the southern States, and for southern bald eagles, whose nesting occurs during the winter months, the non-breeding season foraging areas may be Chesapeake Bay or Yellowstone National Park during the summer. Eagles seek wintering (non-nesting) areas offering an abundant and readily available food supply with suitable night roosts. Night roosts typically offer isolation and thermal protection from winds. Carrion and easily scavenged prey provide important sources of winter food in terrestrial habitats far from open water.

The first major decline in the bald eagle population probably began in the mid to late 1800s. Widespread shooting for feathers and trophies led to extirpation of eagles in some areas. Shooting also reduced part of the bald eagle's prey base. Big game animals like bison, which were seasonally important to eagles as carrion, were decimated. Waterfowl, shorebirds and small mammals were also reduced in numbers. Carrion treated with strychnine, thallium sulfate and other poisons were used as bait to kill livestock predators and ultimately killed many eagles as well. These were the major factors, in addition to loss of nesting habitat from forest clearing and development, that contributed to a reduction in bald eagle numbers through the 1940s.

In 1940, the Bald Eagle Protection Act (16 U.S.C. 668–668d) was passed. This law prohibits the take, possession, sale, purchase, barter, or offer to sell, purchase or barter, transport, export or import, of any bald eagle, alive or dead, including any part, nest, or egg, unless allowed by permit (16 U.S.C. 668(a)). "Take" includes pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb (16 U.S.C. 668c; 50 CFR 22.3). The Bald Eagle Protection Act and increased public awareness of the bald eagle's status resulted in partial recovery or at least a slower rate of decline of the species in most areas of the country.

In the late 1940s, shortly after World War II, the use of dichloro-diphenyl-trichloroethane (DDT) and other organochlorine compounds became widespread. Initially, DDT was sprayed extensively along coastal and other wetland areas to control mosquitos (Carson 1962). Later it was used as a general crop insecticide. As DDT accumulated in individual bald eagles from ingesting prey containing DDT and its metabolites, reproductive success plummeted. In the late 1960s and early 1970s, it was determined that dichlorophenyl-dichloroethylene (DDE), the principal breakdown product of DDT, accumulated in the fatty tissues of the adult female bald eagles. DDE impaired calcium release necessary for normal egg shell formation, resulting in thin shells and reproductive failure.

In response to this decline, the Secretary of the Interior, on March 11, 1967 (32 FR 4001), listed bald eagles south of the 40th parallel as endangered under the Endangered Species Preservation Act of 1966 (16 U.S.C. 668aa–668cc). Bald eagles north of this line were not included in that action primarily because the Alaskan and Canadian populations were not considered endangered in 1967. On December 31, 1972, DDT was banned from use in the United States by the Environmental Protection Agency. The following year, the Endangered Species Act of 1973 (the Act) (16 U.S.C. 1531–1544) was passed.

Nationwide bald eagle surveys, conducted in 1973 and 1974 by us, other cooperating agencies, and conservation organizations, revealed that the eagle population throughout the lower 48 States was declining. We responded in 1978 by listing the bald eagle, *Haliaeetus leucocephalus,* throughout the lower 48 States as endangered except in Michigan, Minnesota, Wisconsin, Washington, and Oregon, where it was designated as threatened (43 FR 6233, February 14, 1978). Sub-specific designations for northern and southern eagles were dropped.

The Act contains provisions for listing, protection, and recovery of imperiled species. An endangered species is defined under the Act as a species that is in danger of extinction throughout all or a significant portion of its range. A threatened species is defined as any species that is likely to become endangered within the foreseeable future throughout all or a significant portion of its range. The Act and its implementing regulations prohibit the take of any listed species. Take is defined as harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt any of these acts. It also prohibits shipment in interstate commerce in the course of commercial activity, or sale or offer for sale in interstate or foreign commerce. The Act requires review of all activities funded, permitted or conducted by Federal agencies to consider impacts to endangered and or threatened species. The purpose of the Act is to restore endangered and threatened animals and plants to the point where they are again viable, self-sustaining components of their ecosystems.

To facilitate the recovery of the bald eagle and the ecosystems upon which it depends, we divided the lower 48 States into 5 recovery regions. Separate recovery teams composed of experts in each geographic area prepared recovery plans for their region. The teams established goals for recovery and identified tasks to achieve those goals. Coordination meetings were held regularly among the 5 teams to exchange data and other information.

What Are the Five Recovery Regions Established for the Bald Eagle and the Dates of Their Approved Recovery Plans?

Recovery region	Date of recovery plan	States
Chesapeake Bay	1982, rev. 1990	Virginia east of the Blue Ridge Mountains, Delaware, Maryland, the eastern half of Pennsylvania, the "panhandle" of West Virginia, and the southern two-thirds of New Jersey.
Pacific	1986	Idaho, Nevada, California, Oregon, Washington, Montana, and Wyoming.
Southeastern	1984, rev. 1989	Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and eastern Texas.

Recovery region	Date of recovery plan	States
Southwestern	1982	Oklahoma and Texas west of the 100th meridian, New Mexico, Arizona, and that area of California bordering the Lower Colorado River.
Northern States	1983	All remaining 25 States and parts thereof.

Recovery Accomplishments

The Service and other Federal, State, tribal, and local cooperators from across the Nation have funded and carried out many of the tasks described within the recovery plans. Annual expenditures for the recovery and protection of the bald eagle by public and private agencies have exceeded $1 million each year for the past decade (Service records). State fish and wildlife agencies have played a vital role in restoring eagles to areas from which they were extirpated or in which their numbers were greatly reduced. These activities include conducting annual surveys of breeding and productivity, purchasing lands for the protection of bald eagle habitat, reintroduction and habitat management programs, and public outreach.

A partial survey conducted by the National Audubon Society in 1963 reported on 417 active nests in the lower 48 States, with an average of 0.59 young produced per nest. Surveys we coordinated in 1974 resulted in a population estimate of 791 occupied breeding areas for the lower 48 States.

Breeding and productivity surveys have been conducted annually on a State-by-State basis since the early 1980s. Data collection methods vary somewhat from State to State but generally include surveys by aircraft or visits to the site each year during the breeding season to determine the number of occupied breeding areas, and a second survey just before fledging to count the number of young produced at the site. Some States conduct the surveys themselves with agency personnel, others collate data from partners (including cooperating agencies), while some data is collected by personal interviews with reliable sources. Though the data collection methods may vary, most States agree that the data provided to us is a minimum number.

Since the development and implementation of the recovery plans, the bald eagle's population growth has exceeded most of the goals established in the various plans. In 1994, our cooperators reported about 4,450 occupied breeding areas with an estimated average young per occupied territory of 1.16. Compared to surveys conducted in 1974, the number of occupied breeding areas in 1994 in the lower 48 States had increased by 462 percent (Figure 1). Between 1990 and 1994, there was a 47 percent increase.

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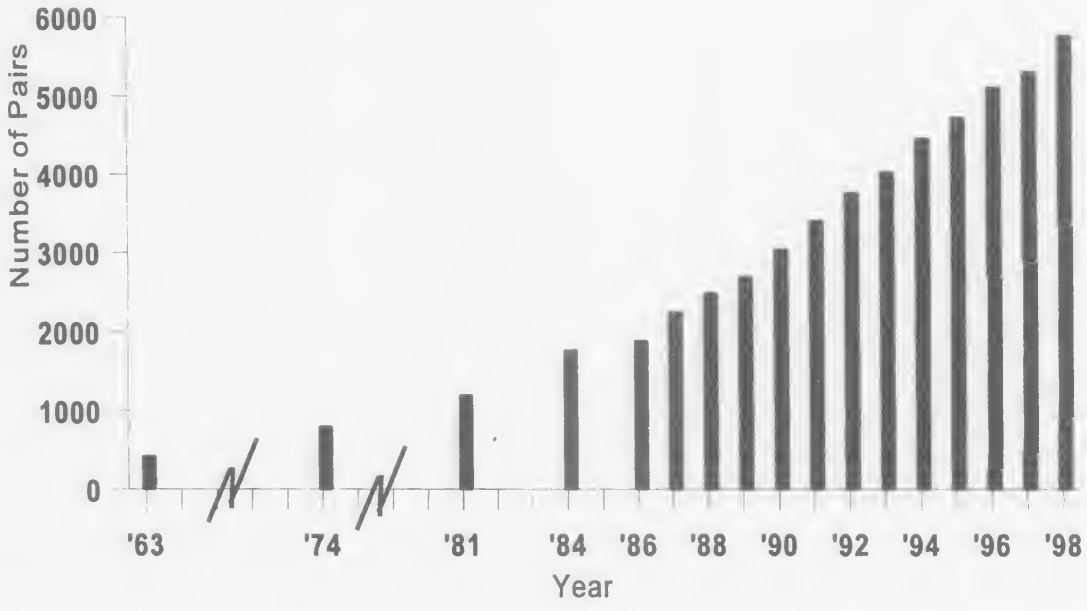

Figure 1. Number of bald eagle pairs in lower 48 states from 1963 through 1998.

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The bald eagle was reclassified in 1995 from endangered to threatened as a result of the significant increase in numbers of nesting pairs, increased productivity and expanded distribution (60 FR 36000, July 12, 1995).

Recovery continues to progress at an impressive rate. In the past 10 years, the bald eagle's nesting population has increased at an average rate of about 8

percent per year (Figure 1). The current nesting population in the lower 48 States constitutes more than a tenfold increase from the known population level in 1963. We estimate that the breeding population exceeded 5,748 occupied breeding areas in 1998. The bald eagle population has essentially doubled every 7 to 8 years during the past 30 years.

Recovery has been broadly distributed throughout the bald eagle's range. In 1984, 13 states had no nesting pairs of bald eagles. By 1998, all but 2 of the lower 48 States supported nesting pairs. In 1984, the 6 States of Florida, Wisconsin, Michigan, Minnesota, Washington and Oregon contained 73 percent of all nesting pairs in the lower 48 States. By 1998, these six States had a reduced share of 56 percent of all nesting pairs, due to increased nesting in other states. Much of the greater distribution of nesting sites is due to reoccupancy of vacant nesting habitat where competition for nest sites is minimal and an adequate prey base exists.

An expanding population requires the successful production of young. Reproduction has generally met or exceeded target values established by recovery teams nationally for the past 10 years. Certain geographically restricted areas still have contamination threats, such as southern California, the Columbia River, along the Great Lakes and parts of Maine (see *E.* under the Summary of Factors Affecting the Species section). Because the adults are long-lived, a minimum of 0.7 young per occupied breeding area is necessary to maintain a stable population (Sprunt, *et al.* 1973). With a national average of more than one fledgling per occupied breeding area since 1990, the eagle population continues to increase in overall size and maintain a healthy reproductive rate.

Recovery within recovery regions has also been successful. Recovery plans and objectives were designed to guide and measure recovery efforts. They are intended to be general goals rather than absolute numeric targets. We discuss recovery goals for the 5 regions and the bald eagle's attainment of those goals discussed below.

What Are the Goals for Bald Eagle Recovery in Each Recovery Region and What Has Been Achieved?

Chesapeake Recovery Region

Delisting Goals: Sustain 300–400 pairs with an average productivity of 1.1 young per active nest over 5 years with permanent protection of sufficient habitat to support this nesting population and enough roosting and foraging habitat to support population levels commensurate with increases throughout the Atlantic coastal area.

Achievements: Numeric delisting goals were met in 1996 with more than 300 occupied breeding areas estimated since 1992 and average productivity of 1.1 young per occupied breeding area. In 1998, 538 occupied breeding areas were estimated with an average productivity of 1.21. Habitat protection work continues.

Protecting bald eagle habitat remains a concern in the Chesapeake Recovery Region. The area contains large, expanding human population centers contributing to rapid development pressures and high land values that can conflict with bald eagle habitat needs. However, since 1990, occupied breeding areas for the bald eagle have doubled in the Chesapeake Recovery Region. This increase is greater than that found in any other recovery region. This indicates that adequate habitat is still available for an increasing population of bald eagles despite land development pressures. The Endangered Species Act has been a key factor in protecting eagle habitat in the Chesapeake area, particularly through the application of buffer zones around nest trees.

Northern States Recovery Region

Delisting Goals: 1,200 occupied breeding areas distributed over a minimum of 16 states with an average annual productivity of at least 1.0 young per occupied nest.

Since reclassification, the Northern States Recovery Team has reconvened to review the plan. The team supported the numerical goals established in 1983 but emphasized continued habitat protection concerns.

Achievements: Delisting goals were met in 1991 with 1,349 occupied breeding areas distributed over 20 States and an estimated average productivity since 1991 of greater than 1.0. In 1998 the estimated number of occupied breeding areas for the Northern States Recovery Region exceeded 2,204. Some of the most rapidly expanding areas of bald eagle nesting are in states with the majority of their lands held in private ownership. For example, between 1990 and 1998, the bald eagle population in Iowa increased from 8 to 83 occupied breeding areas. In this same period, Missouri has gone from 11 to 45 occupied breeding areas; Illinois increased from 8 to 43 occupied breeding areas; and Oklahoma has gone from 0 to 26 occupied breeding areas. The Northern States Recovery Region includes large tracts of federally owned land that is prime bald eagle habitat. The three States with the largest bald eagle populations in the Northern States Recovery Region (Minnesota, Wisconsin, and Michigan) contain large proportions of public land, and eagle numbers did not quite double during the same 8-year span. Thus, habitat on private property has proven to be very important for the continued expansion of the bald eagle population in this region.

Pacific Recovery Region

Delisting Goals: A minimum of 800 nesting pairs with an average reproductive rate of 1.0 fledged young per occupied breeding area, and an average success rate for occupied breeding areas of not less than 65% over a 5 year period are necessary for recovery. Attainment of breeding population goals should be met in at least 80% of management zones. Wintering populations should be stable or increasing.

Achievements: Numeric delisting goals have been met since 1995. Productivity has averaged about 1.0 young per occupied breeding area since 1990. The average success rate for occupied breeding areas has exceeded 65 percent for the past five years. For 1998, six of the seven Pacific region States reported an average success rate of 75 percent. However, the plan goal for distribution among management zones is not yet fully achieved for all areas. The number of occupied breeding areas exceeded 800 in 1990 and has continued to increase. In 1998, 1,480 occupied breeding areas were estimated. Twenty-eight of 37 (76%) management zone targets have been met. The zone targets were based on a best estimate for each area at the time, and several management zones that still lack nesting bald eagles may not contain preferred habitat. Of the 28 zones where target levels have been met, at least 11 have more than doubled the established goal. Wintering populations have been tracked in the Pacific and many other States using the mid-winter bald eagle surveys. However, wintering populations are difficult to assess because concentrations are dependent on weather and food supply and thus can be quite variable from year to year.

Southeastern Recovery Region

Delisting goals: Consider delisting if the recovery trend continues for 5 years after reclassification goals are met. Develop the criteria for delisting when the species is reclassified from endangered to threatened.

After the reclassification to threatened in 1995, the Southeastern States Bald Eagle Recovery Team reconvened to

consider criteria for delisting. The most recent recommendations of the recovery team are to achieve an average of 1,500 occupied breeding areas over the most recent 3-year period, with an average production of greater than 0.9 young per occupied breeding area over the same 3 year period, and 8 of 11 states meeting their nesting and productivity goals.

Achievements: Reclassification goals have been met and exceeded from 1991 through the most current data year of 1998. At the current rate of increase, the team expects the southeastern region to exceed 1,500 pairs in 1999 and meet the newly recommended delisting criteria by the year 2000. Production since 1991 averaged 1.17 young per occupied territory, exceeding the goal of greater than 0.9. In 1998, 1,485 occupied breeding areas were estimated with a productivity of 1.15 per occupied breeding area. Newly revised individual state goals are expected to be met by 6 of 11 States by the year 2000.

Southwestern Recovery Region

Delisting Goals: None given. Reclassification Goals: 10–12 young per year over a 5-year period; population range has to expand to include one or more river drainages in addition to the Salt and Verde Systems.

Achievements: 40 occupied breeding areas were reported for 1998 with 36 of those in Arizona and 4 in New Mexico. Productivity was estimated at 0.63 per occupied breeding area. Breeding has expanded beyond the Salt and Verde Systems into the Gila, Bill Williams, and San Carlos River systems in Arizona and the Rio Grande in New Mexico. The number of breeding pairs has more than doubled in the last 15 years.

Bald eagle recovery team members met in 1996 and discussed delisting criteria for the region. Potential reduction of support for the Arizona Nestwatch Program is a significant regional concern. Since the 1980's, the Nestwatch Program has rescued 48 eagles and eggs, and documented 52 cases of fishing line or tackle posing a threat to the nesting eagles and eaglets. At least 15 percent of the bald eagle production is due to the assistance provided by Nestwatch volunteers and staff. The State of Arizona is working with us and other partners to develop a Conservation Agreement which would insure the longevity of the Nestwatch Program.

Previous Federal Action

On July 12, 1995, we published the final rule to reclassify the bald eagle from threatened in 5 States and endangered in the remaining lower 48 States, to threatened throughout the lower 48 States (60 FR 36000). With that action, the Service recognized one population of bald eagles in the lower 48 States. Previous to that action, the proposed rule to reclassify the bald eagle was published on July 12, 1994, (59 FR 35584) and an advanced notice of a proposed rule was published on February 7, 1990 (55 FR 4209). Listing actions are discussed in the Background section.

Summary of Factors Affecting the Species

Section 4 of the Act and the regulations (50 CFR part 424) promulgated to implement its listing provisions, set forth the procedures for listing, reclassifying, and delisting species on the Federal lists. A species will be listed if the Secretary of the Interior determines that one or more of 5 factors listed in section 4(a)(1) of the Act threatens the continued existence of the species. A species may be delisted, according to 50 CFR 424.11(d), if the best scientific and commercial data available substantiate that the species is neither endangered nor threatened for one of the following reasons: (1) Extinction; (2) recovery; or (3) original data for classification of the species were in error.

The bald eagle is proposed for delisting due to recovery. Discussion of the 5 listing factors and their application to the recovery of the bald eagle are discussed below.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Nesting and wintering habitats are both critical to the continued survival of the bald eagle. Based on increasing population trends, neither nesting nor wintering habitats appear to be limiting, and there are no indications that availability of these habitats will limit the bald eagle population in the near future. Bald eagle habitat on Federal lands will remain protected under the regulatory mechanisms listed in factor D below, though to a lesser degree. Activities on private lands involving a Federal action will be subject to many of the laws listed in factor D. With the knowledge of habitat management gained through the recovery process, we expect that federal actions that result in a loss of habitat will be at an acceptable level and will not affect the population's stability.

B. Over-Utilization for Commercial, Recreational, Scientific, or Educational Purposes

There is no legal commercial or recreational use of bald eagles. We consider future legal and enforcement measures sufficient to protect the bald eagle from illegal activities, including trade. We exercise very strict control over the use of bald eagles or their parts for scientific, educational, and Native American religious activities. To respond to the religious needs of Native Americans, we have established the National Eagle and Wildlife Property Repository in Commerce City, Colorado, which serves as a collection point for dead eagles. As a matter of policy, all Service units transfer salvaged bald eagle parts and carcasses to this center. Members of Federally recognized tribes can obtain a permit from us authorizing them to receive and possess whole eagles, parts, or feathers from the repository for religious purposes. After removal from protection under the Endangered Species Act, we will still issue permits for limited exhibition and educational purposes, selected research work, and other special purposes consistent with the Bald and Golden Eagle Protection Act (16 U.S.C. 668–668d). We will not issue these permits if the status of the bald eagle will be adversely effected.

C. Disease or Predation

Predation is not a significant problem for bald eagle populations. Incidents of mortality due to territorial disputes have been reported by National Wildlife Health Research Center pathologists based on examination of carcasses.

Diseases such as avian cholera, avian pox, aspergillosis, tuberculosis, Mexican chicken bug, and botulism may affect individual eagles, but are not considered to be a significant threat to the population. According to the National Wildlife Health Research Center in Madison, Wisconsin, only 2.7 percent of bald eagles submitted to the Center between 1985 and 1990 died of infectious disease. Its widespread population distribution generally helps to protect the bald eagle from these catastrophic events.

From 1994–1999, 58 eagles died at man-made lakes in Arkansas from apparent avian brain lesion syndrome (also referred to as vacuolar myelinopathy), and more recently, the disease has been detected in eagles in North Carolina. At present, this is a poorly understood disease and is present in other avian species (primarily coots and recently found in several species of waterfowl) in the southeast. While a toxic agent is suspected in the deaths of the eagles and other avian species, cooperative efforts are underway to determine the prevalence of this disease and its origin. Although these mortalities can have a localized

impact on bald eagles, there is currently no evidence that the overall recovery of the population is affected.

D. The Inadequacy of Existing Regulatory Mechanisms

After removal from the list of species protected by the Act, the bald eagle remains fully protected by the following Federal wildlife laws in the United States. We believe these laws and related State statutes are adequate to protect and sustain a recovered bald eagle population.

The Bald and Golden Eagle Protection Act (16 U.S.C. 668–668d) prohibits without specific authorization take, possession, selling, purchase, barter, offer to sell, purchase, or barter, transport, export or import, of any bald or golden eagle, alive or dead or any part, nest or egg thereof. Use of bald eagles for falconry is prohibited. Take under this act is defined as "to pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb" (50 CFR 22.3).

The Migratory Bird Treaty Act (16 U.S.C. 703–711) prohibits, without specific authorization, the possession, transport, or take of any migratory bird (including bald eagles), their parts, nests or eggs. Take prohibitions under this statute includes actions to pursue, hunt, take, capture, kill, possess, sell, barter, purchase, ship, export or import protected species.

The Lacey Act (16 U.S.C. 3372 and 18 U.S.C. 42–44) among other provisions, makes it unlawful to export, import, transport, sell, receive, acquire, or purchase any bald eagle, (1) taken or possessed in violation of any law, treaty, or regulation of the United States or in violation of any Indian tribal law or (2) to be taken, sold, or transported in interstate or foreign commerce, in violation of any law or regulation of any State or in violation of any foreign law.

In addition to Federal laws governing the taking of bald eagles within the United States, international agreements govern the transport of bald eagles across international borders. International trade in bald eagles to and from the United States is strictly regulated. The Convention on International Trade in Endangered Species (CITES) is an international treaty for the regulation of trade in species threatened with extinction and those that may become threatened if trade is not regulated. The bald eagle is currently listed under Appendix I of CITES, and, as a result, international trade in bald eagles not otherwise prohibited is restricted by the United States and 145 other signatory nations.

Section 101 (a) of the Clean Water Act (33 U.S.C. 1251–13287) states that the objective of this law is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters and provides the means to assure the "protection and propagation of fish, shellfish, and wildlife" (section 101 (a)(2)). This statute contributes in a significant way to the protection of bald eagles and their food supply through provisions for water quality standards, protection from the discharge of harmful pollutants, contaminants (section 303(c), section 304(a), and section 402) and discharge of dredge or fill material into all waters, including wetlands (section 404).

Another important regulatory mechanism affecting bald eagles is the requirement that pesticides be registered with the Environmental Protection Agency. Under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136), the Environmental Protection Agency requires environmental testing of new pesticides. Testing the effects of pesticides on representative wildlife species before the pesticide is registered is specifically required. It is meant as a safeguard to avoid the type of environmental catastrophe that occurred from organochlorine pesticides which led to the listing of this species.

The Federal Land Policy and Management Act (43 U.S.C. 1701–1784) requires that public lands be managed to protect the quality of scientific, ecological, and environmental qualities and to preserve and protect certain lands in their natural condition to provide food and habitat for fish and wildlife.

The Fish and Wildlife Coordination Act (16 U.S.C. 661–666c) requires that Federal agencies sponsoring, funding, or permitting activities related to water resource development projects request review of these actions by us and the State natural resources management agency. These comments must be given equal consideration with other project purposes.

The National Environmental Policy Act (42 U.S.C. 4321–4370d) requires the Federal agencies to evaluate the potential effects of their proposed actions on the human environment and requires the preparation of an environmental impact statement whenever projects may result in significant impacts. Federal agencies must identify adverse environmental impacts of their proposed actions and develop alternatives that undergo the scrutiny of other public and private organizations as a part of their decision making process.

Recovery actions developed under the Endangered Species Act have provided the baseline of knowledge for management of bald eagles. Recommendations for management and protection of bald eagles will continue to be made in accordance with all applicable environmental laws.

Removal of the bald eagle from the Federal list of endangered and threatened species will not affect its status under State laws as a threatened or endangered species or suspend any other legal protections provided by State law. States may have more restrictive laws protecting wildlife, and these will not be affected by this Federal action. Also, some States may choose to remove the bald eagle from their list of threatened and endangered species.

Finally, the Endangered Species Act remains an important regulatory mechanism should an unexpected decline in bald eagle numbers occur. In the event that a significant decrease in the bald eagle population occurs, we could relist the species through normal or emergency procedures as a threatened or endangered species.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Bald eagles are subject to direct and indirect mortality from a variety of human related activities. Intentional shooting, poisoning, and smuggling still occur, as well as deaths due to electrocution and strikes by wind turbines. Death and reproductive failure resulting from exposure to pesticides and secondary lead poisoning are well documented.

In recent years, the use of harmful chemicals known to impair reproduction in bald eagles has declined throughout the United States. A few areas still exist where concentrations of these chemicals impair reproductive success. However, these areas are geographically restricted and have not prevented recovery of the population nationally. There is no evidence to indicate that the use of harmful organochlorines in Latin America impact the bald eagle since the eagle's southern range is not known to extend south of northern Mexico.

The pesticide DDT came into widespread use after World War II. DDT ingested through the eagle's diet of fish, waterfowl, gulls, and other prey resulted in egg shell thinning. As a result, many eggs broke when incubated by the parent, while others suffered embryonic mortality and failed to hatch. By the early 1960s, recruitment had dropped and population numbers plummeted. In response to human health risks associated with DDT it was banned from

use in 1972. Reductions in DDT levels in freshwater fish over time have coincided with a steady increase in bald eagle numbers (Figure 2).

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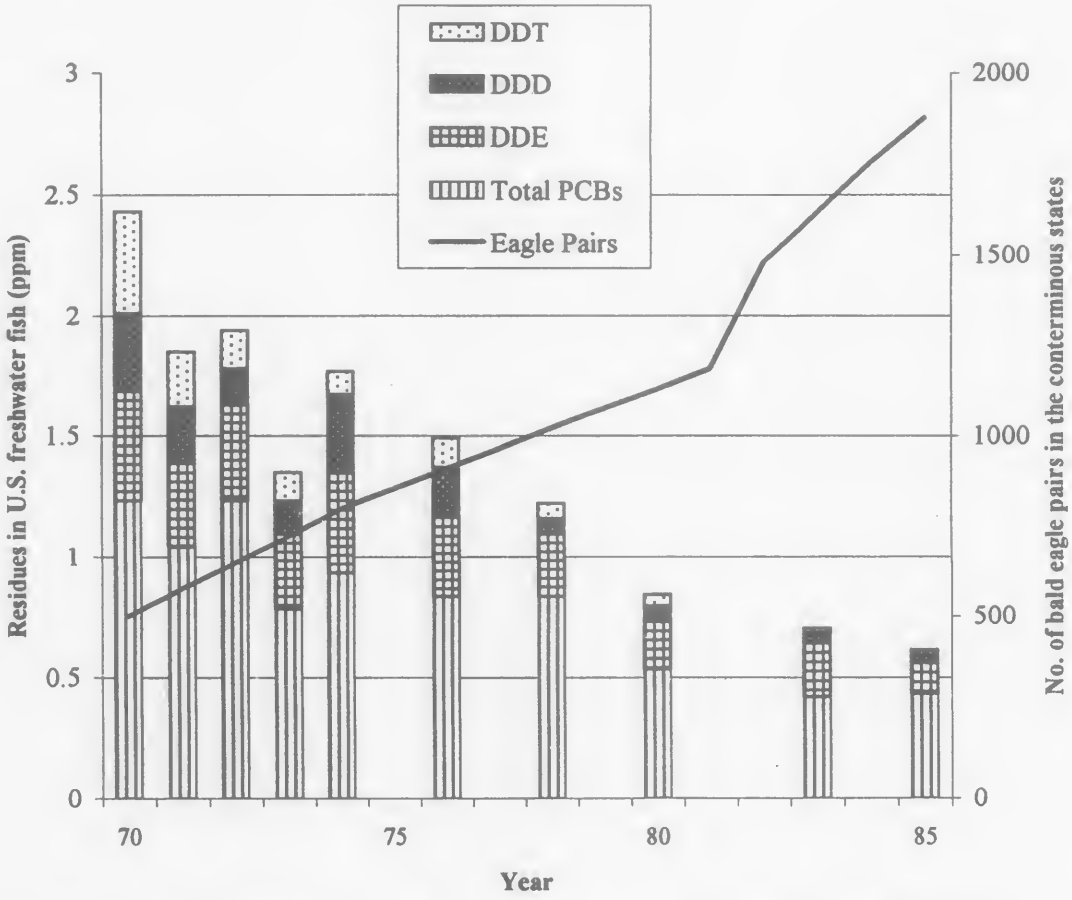

Figure 2. Mean concentrations of DDT and its primary metabolites, DDE and DDD, and of total polychlorinated biphenyls (PCBs) in fish, 1970-86. Also shown are the estimated number of bald eagle pairs in the conterminous United States during the same period. (From: Schmitt and Bunck 1995).

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By 1976, registrations of dieldrin, heptachlor, chlordane, and other toxic persistent pesticides, were canceled for all but the most restricted uses in the United States. Most uses of PCBs were restricted in 1977 and continued to be phased out during the 1980s (Schmitt and Bunck 1995).

During the 1970s, the Service implemented a monitoring program to examine the long-term trends in the presence of pesticides and other harmful chemicals in fish and wildlife (Schmitt and Bunck 1995). Fish, starlings and duck wings were collected nationwide between 1972 and 1985. The program tracked a downward trend of DDT concentrations in fish, starlings, and duck wings paralleled by declining DDE (a degradation product of DDT) concentrations in bald eagle eggs and increasing eagle eggshell thickness (Wiemeyer *et al.* 1993). Concentrations of other persistent insecticides such as heptachlor, dieldrin, endrin, and chlordane were also documented as declining nationally in fish, starlings and duck wings.

While there has been a national decline in concentrations of these harmful organochlorine compounds, some areas of the country still harbor high concentrations and reproduction of bald eagles in these areas is depressed. For instance, the Channel Islands area of southern coastal California continues to have severe problems related to DDE impacts to bald eagle productivity (Garcelon 1994, Sharpe and Garcelon 1999). The Palos Verdes Shelf is contaminated from historic releases from a nearby manufacturing plant. Bald eagles in the Channel Islands are present only through reintroduction efforts. Wiemeyer *et al.* (1993) found that addled bald eagle eggs collected from the Klamath Basin and Cascade Lakes region in Oregon ranked second (behind Maine) in DDE concentrations among the fifteen States sampled, indicating potential residual problems. Coastal areas which were sprayed for mosquitos and for cotton and orchard

pests still have higher concentrations of DDE than other lands (Schmitt and Bunck 1995). DDE concentrations along the Great Lakes remain a concern for that area.

Residues of PCBs, which are persistent and toxic much like DDT, have also declined throughout the United States (Figure 2). They remain a problem in some areas, most notably the Great Lakes. Atmospheric transport and the internal cycling of contaminants already present in these lakes will likely keep PCB concentrations elevated (Schmitt and Bunck 1995). Bowerman (1993) has documented lower reproduction among eagles nesting along the coasts of the Great Lakes in Michigan compared to those nesting further inland. The severity of the problem along the Great Lakes coast apparently is being compensated for by eagles produced from the interior of the State seeking territories along the Great Lakes coast. Michigan's bald eagle population has increased, though at a slower rate than other states with major bald eagle populations.

High concentrations of mercury cause a variety of neurological problems in bald eagles. Flight and other motor skills can be significantly altered. High mercury concentrations may also reduce the hatching rate of eggs. Concentrations of mercury in fish declined significantly from 1969 through 1974 as a result of restriction on its uses, but concentrations have not changed appreciably since 1974. Recent findings have highlighted the importance of atmospheric transport in the maintenance of elevated concentrations and the accumulation of mercury in certain areas, such as Lake Champlain and the Florida Everglades (Schmitt and Bunck 1995).

The most important source of lead affecting bald eagles is waterfowl wounded with lead shot. The requirement in 1991 to use non-toxic shot for waterfowl hunting has greatly reduced the threat of lead poisoning to bald eagles.

New chemicals are entering the environment and though they may not be as persistent as their predecessors, many are toxic and their breakdown products are poorly understood. Maintaining a contaminant profile of bald eagles nationwide will be an integral part of our monitoring program. It will serve as a safeguard to reduce the possibility of population level effects from harmful contaminants.

The shooting of bald eagles was prohibited in 1918 with the Migratory Bird Treaty Act, and again in 1940 with the Bald Eagle Protection Act (golden eagles were added in 1962). Large-scale mortality from unregulated shooting, like that which occurred early in this century, has been significantly reduced. Hunter education courses routinely include bald eagle identification material to educate hunters about bald eagles and the protections that the species is afforded. Although some illegal shooting of eagles is likely to occur, this is no longer considered a significant threat to the survival of species.

Other causes of mortality to individual eagles continue to occur. Many electrical power lines have been configured to reduce electrocution to raptors, though electrocutions still occur. Problem power lines still need to be identified and modified to prevent electrocutions. Areas where road-killed animals are left near the highway can result in car collisions with bald eagles, particularly in winter when eagles feed on carrion more frequently. Efforts to reduce these mortalities are being undertaken locally.

Human disturbance of bald eagles is a continuing threat which may increase as numbers of bald eagles increase and human development continues to expand into the rural areas. Numerous studies have documented that most bald eagles will flush from the nest site if disturbed by human presence. If the disturbance occurs frequently, nesting can fail, and the adults may or may not nest again. Through the Endangered Species Act recovery process, management guidelines have been developed for bald eagle nesting and wintering sites in various portions of the species' range. Specific conservation measures and recommendations have also been developed through the section 7 consultation process to reduce disturbance at feeding sites. In areas throughout the country, land management practices have been successfully modified to reduce human disturbance to bald eagles. We will make these guidelines readily available to agencies and the public to promote their widespread use.

Human-related impacts will continue after the bald eagle is removed from protection under the Endangered Species Act, and may increase locally with the continued growth of the eagle population and subsequent conflicts with expanding human activities. However, through remaining statutes, knowledge gained and partnerships developed in the recovery process, many of these conflicts can be avoided or minimized.

Conclusion of Recovery Analysis and Status Review

Due to the wide distribution of the bald eagle, we established five recovery regions to outline recovery planning goals and needs on a regional basis leading to the development of five separate recovery plans for the species. The five plans, originally developed in the 1980s, described a variety of numerical target levels for breeding pairs and productivity for different regions to measure recovery success and to set criteria for reclassification and/or delisting. In 1994, after the implementation of the five recovery plans and steady increases in the population, the status of the bald eagle was reviewed. The analysis included an assessment of known movement and migratory patterns among and between recovery regions, and concluded that a rangewide status of "threatened" for a single population of bald eagles throughout the lower 48 States was appropriate. The bald eagle was then formally reclassified as a threatened species on that basis in 1995. Treating the bald eagle as a single listed population is consistent with our 1996 "Policy Regarding the Recognition of Distinct Vertebrate Population Segments under the Endangered Species Act" (61 FR 4722).

This proposal is based on an internal status review of bald eagle recovery achievements conducted in 1998 and 1999, including an assessment of long-term nesting and productivity data (U.S. Fish and Wildlife Service, 1999, unpublished data), coordination with States and Tribes, an analysis of the five listing factors, and the definition of a "threatened" species under the Act. Decisions regarding the status of the overall bald eagle population as listed, take into consideration all of the regional recovery plan goals and established criteria, but ultimately address the status and the degree of remaining threats on a rangewide level.

Bald eagle recovery goals have generally been met or exceeded for the species on a rangewide basis. There is no sizeable area in the lower 48 states where we have not seen substantial increases in eagle numbers. Conversely, there is no sizeable area where eagle numbers continue to decline. We believe the surpassing of recovery targets over broad areas and on a regional basis, and the continued increase in eagle numbers since reclassification, effectively compensates for any local shortfall in meeting targets in a few recovery sub-areas or units.

Recovery planning for wide ranging species such as the eagle, involves

assumptions about habitat suitability and carrying capacity over large areas. In practice, the response of a species to management protections and subtle differences in habitat quality should be expected to vary across a large landscape, in this case involving many States and physiographic regions. Although we acknowledge that not every sub-area recovery target has been met for each plan, we conclude that recovery as outlined for the species as a whole, has been achieved.

We have reviewed the best available scientific and commercial data and conclude the following:

(1) A widespread reduction in use of persistent pesticides and their adverse effects on the bald eagle is evident.

(2) Other threats are not currently of sufficient magnitude, individually or collectively, to place the species at risk of extinction.

(3) Sufficient knowledge has been gained through the recovery process to properly manage the bald eagle in the future.

(4) Widespread trends in the population indicate that the bald eagle has recovered and no longer in danger of extinction nor is it likely to become in danger of extinction within the foreseeable future throughout all or a significant portion of its range.

For these reasons we propose to remove the bald eagle from the List of Endangered and Threatened Wildlife.

Effects of This Rule

This rule as proposed will remove the protection afforded the bald eagle under the Endangered Species Act. The provisions of the Bald and Golden Eagle Protection Act and the Migratory Bird Treaty Act including prohibitions on the taking of bald eagles will remain in place. Bald eagles are prohibited for use in falconry under provisions of the Bald and Golden Eagle Protection Act (50 CFR 22.24). These and other laws affecting bald eagles are discussed in factor D above. This rule will not affect the bald eagle's status as a threatened or endangered species under State laws or suspend any other legal protections provided by State law. States may have more restrictive laws protecting wildlife, and these will not be affected by this Federal action. However, this rule may prompt some States to remove protection for the bald eagle under their endangered species laws.

Future Conservation Measures

Section 4(g)(1) of the Act requires that the Secretary of the Interior, through the Service, monitor species for at least 5 years after removal from the list of endangered and threatened species. If evidence acquired during this monitoring period shows that the bald eagle should be relisted to prevent it from becoming threatened with extinction, we may use the normal or emergency listing authority, as appropriate, provided for by the Act. At the end of the 5-year monitoring period, we intend to coordinate with our partners regarding bald eagle monitoring and will review all available information to determine if relisting is appropriate.

Monitoring Plan

The bald eagle was listed under the Act in 1978. Since that time bald eagle nesting and productivity have been monitored throughout the lower 48 States. The monitoring has provided us with information regarding the status and health of the bald eagle population. At a minimum, monitoring included a census of the number of occupied breeding areas, defined as a pair defending a nesting territory in nesting season, and the number of young produced, which has been censused near the age of fledging. This effort has produced an excellent data set and forms the basis of this delisting proposal. If the historic population monitoring effort is continued following bald eagle delisting, we believe that monitoring for contaminants may be the only additional effort needed.

In preparation of this rule, we requested each State to indicate its intentions regarding post-delisting monitoring should this rule become final. More than 80 percent of all States in the lower 48 intend to continue the same monitoring effort for at least 5 years post-delisting. Many of our Federal partners have also indicated a willingness to continue bald eagle monitoring.

As a result of the strong support from our partners, we will work to ensure that nationwide monitoring of bald eagle nesting continue annually for the 5 years following delisting. The monitoring will be the same as it has been through the time the bald eagle has been listed following the guidelines set forth in the recovery plans. It includes the following:

(1) Number of Occupied Breeding Areas. We will work with partners to monitor numbers of occupied breeding areas in each state annually and collate the data. This will continue the extensive data set that has been developed over the past 20 years.

(2) Number of Young Produced. This requires a second visit to the nesting site near time of fledging. Number of young fledged is an important indicator of reproductive health and may act as an early warning for problems such as disease, contaminant effects, lack of adequate habitat, disturbance, etc.

(3) Contaminant Analysis and Archiving. We are proposing to examine contaminant effects on reproduction by collecting addled eggs from those areas having past problems and where present or suspected problems occur. The eggs would be taken every year for the first 5 years, and possibly a reduced number of collections would be made thereafter. Collections should be taken from the same immediate nest site area. We are also proposing to sample blood from a small subset of nesting pairs covering a broad geographic range and a broad range of human influences. All eggs and blood will be archived by freezing at −80°C. In the event contamination or poisoning is suspected, archived samples will be withdrawn and properly analyzed by Service-approved laboratories. In addition, a subset of the egg samples will be analyzed each year for organochlorines which are known to adversely impact bald eagle reproductive success. A subset of blood samples will be analyzed where contaminant exposure is suspected.

Five-Year Post-Delisting Assessment

(4) At the end of 5 years post-delisting, we will review the most current bald eagle data set for the lower 48 States, assess the results and make this information available to the public. We will also consult with States and other partners to determine the need for future monitoring efforts which may include consideration of national or regional monitoring protocols.

(5) At the end of 5 years post-delisting, we will also consider evidence of any factors significantly affecting the population which may indicate that a serious decline is occurring and that relisting should be considered. These factors include but are not limited to the following: a) contaminant-related concerns which result in mortality or effects on breeding activities; b) declining numbers of occupied breeding areas; c) declining reproduction; and d) significant changes in distribution.

Public Comments Solicited

We request comments on three aspects of this proposed rulemaking:

A. Proposed Delisting

We are soliciting comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. Send your comments to the Service's bald eagle recovery

coordinator (see **ADDRESSES** section). We are particularly seeking comments concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to this species;

(2) Additional information concerning the range, distribution, and population size of this species;

(3) Current or planned activities in the range of this species and their possible impacts on this species;

(4) Data on population trends;

(5) Information and comments pertaining to the proposed monitoring program contained in this proposal.

The final decision on this proposal for the bald eagle will take into consideration comments and additional information we receive during this comment period.

The Endangered Species Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days of the date of publication of this proposal. Such requests must be made in writing and sent to the Service's bald eagle recovery coordinator (see **ADDRESSES** section).

B. Executive Order 12866

Executive Order 12866 requires agencies to write regulations that are easy to understand. We invite your comments on how to make this proposal easier to understand including answers to questions such as the following.

(1) Is the discussion in the "Supplementary Information" section of the preamble helpful in understanding the proposal?

(2) Does the proposal contain technical language or jargon that interferes with its clarity?

(3) Does the format of the proposal (groupings and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? What else could the Service do to make the proposal easier to understand?

(See **ADDRESSES** section)

C. Paperwork Reduction Act

OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Public Law 104–13, 44 U.S.C. 3501 *et seq.*) require that interested members of the public and affected agencies have an opportunity to comment on agency information collection and record keeping activities (see 5 CFR 1320.8(d)). We intend to collect information from the public during the 5-year monitoring period following delisting of the bald eagle. A description of the information collection burden and the comments requested on this collection are included in the Paperwork Reduction Act section below.

Paperwork Reduction Act

Simultaneous with publication of this proposed delisting rule, we have submitted an application for information collection approval from OMB. We may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.

Section 4(g) of the Endangered Species Act requires that all species that are delisted due to recovery be monitored for a minimum of 5 years. A general description of the information that will be collected during the monitoring period was provided above in the Monitoring section of this proposal.

We intend to collect information from States, researchers and land managers associated with a variety of organizations and agencies. Some of the information gathered will be part of already ongoing State, Federal, or private monitoring programs. We will also use information from other study areas where appropriate data are available.

The information collected will allow us to detect any failure of the species to sustain itself following delisting. If during this monitoring period we determine that the species is not sufficiently maintaining its recovered status, we could relist the species as endangered or threatened under the Endangered Species Act.

We estimate approximately 60 respondents to requests for information on the status of the bald eagle per year. Different respondents may provide one or more types of information. A total of 125 burden hours per year is estimated for these 60 respondents.

OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act, require that interested members of the public and affected agencies have an opportunity to comment on information collection and record keeping activities (see 5 CFR 1320.8(d)). Comments are invited on (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical, or other technical collection techniques or other forms of information technology. Send comments on information collection to OMB and the Service's Information Collection Clearance Officer (see **ADDRESSES** section).

National Environmental Policy Act

We have determined that an Environmental Assessment or Environmental Impact Statement, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. We published a notice outlining the Service's reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

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Author. The primary author of this proposed rule is Jody Gustitus Millar, U.S. Fish and Wildlife Service, Rock Island Field Office (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, Title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201-4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

§ 17.11 [Amended]

2. Section 17.11(h) is amended by removing the entry for "Eagle, bald, *Haliaeetus leucocephalus*" under "BIRDS" from the List of Endangered and Threatened Wildlife.

§ 17.41 [Amended]

3. Section 17.41 is amended by removing and reserving paragraph (a).

Dated: June 21, 1999.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 99–16924 Filed 7–2–99; 8:45 am]

BILLING CODE 4310–55–P

federal register

Tuesday
July 6, 1999

Part IV

Environmental Protection Agency

40 CFR Parts 260, 261, 264, etc.
Hazardous Waste Management System; Modification of the Hazardous Waste Program; Hazardous Waste Lamps; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261 264, 265, 268, 270 and 273

[FRL–6371–3]

RIN 2050–AD93

Hazardous Waste Management System; Modification of the Hazardous Waste Program; Hazardous Waste Lamps

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Today's final rule adds hazardous waste lamps to the federal list of universal wastes regulated under the Resource Conservation and Recovery Act (RCRA). Handlers of universal wastes are subject to less stringent standards for storing, transporting, and collecting these wastes. The Agency has concluded that regulating spent hazardous waste lamps as a universal waste under 40 CFR Part 273 will lead to better management of these lamps and will facilitate compliance with hazardous waste requirements. Today's final rule, which streamlines the Subtitle C management requirements for hazardous waste lamps, also supports energy conservation efforts.

EFFECTIVE DATE: This final rule is effective on January 6, 2000.

ADDRESSES: The official record for this rulemaking is identified as Docket F–99–FLEF–FFFFF and is in the EPA RCRA docket, located in the RCRA Information Center (RIC) at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA 22202. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling (703) 603–9230. The public may copy a maximum of 100 pages from the regulatory docket at no charge. Additional copies cost $0.15/page.

FOR FURTHER INFORMATION CONTACT: The RCRA/Superfund/EPCRA/UST Hotline at (800) 424–9346 (toll free) or TDD (800) 553–7672 (hearing impaired). In the Washington, D.C. metropolitan area, call (703) 412–9810. For technical information about this rule, contact Marilyn Goode of the Office of Solid Waste (5304W), U.S. Environmental Protection Agency, 401 M St. SW., Washington DC 20460, phone 703–308–8800, or E-mail goode.marilyn@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Internet Availability

This rule is available on the Internet. Using a World Wide Web (WWW) browser, type http://www.epa.gov/epaoswer/osw/hazwaste.htm#id.

Official Record

The official record for this action is kept in a paper format. The official record is maintained at the address in the **ADDRESSES** section at the beginning of this document.

Outline of Today's Document

I. Background

Under Subtitle C of the Resource Conservation and Recovery Act (RCRA) the Environmental Protection Agency (EPA) has promulgated regulations governing the nation's hazardous waste management program. These regulations are found at parts 260 through 279 of title 40 of the Code of Federal Regulations. These regulations first define which materials are considered solid wastes and then identify wastes that are hazardous and thus subject to RCRA hazardous waste requirements. Requirements are then set forth for hazardous waste generators,

transporters, and owners and operators of treatment, storage, and disposal facilities (TSDs). On May 11, 1995, EPA finalized streamlined requirements for collecting certain widely dispersed hazardous wastes under the Universal Waste Rule, codified in 40 CFR part 273. Today's rule extends the scope of that rule by adding hazardous waste lamps.

A. Current Regulations

Any person who generates a solid waste, as defined in 40 CFR 261.2, must determine whether or not the solid waste is a hazardous waste, either because the waste is listed as a hazardous waste in subpart D of 40 CFR part 261 or because the waste exhibits one or more of the characteristics of hazardous waste, as provided in subpart C of 40 CFR part 261. Data available to EPA, including studies conducted by the Agency, indicate that many fluorescent and high intensity discharge (HID) lamps exhibit the toxicity characteristic (TC) for mercury because of the use of that compound in producing these lamps. Some HID and other types of lamps may also exhibit the toxicity characteristic for lead, principally because of the use of lead solder. Before today's rulemaking (except as explained in the next paragraph), generators of spent lamps that exhibited hazardous waste characteristics were subject to the RCRA Subtitle C hazardous waste management requirements. Generators were subject to all applicable requirements of 40 CFR parts 260 through 268, including the on-site management, pre-transport, and manifesting requirements of part 262.

Spent hazardous waste lamps sent for reclamation are considered spent materials (rather than sludges or by-products) and are therefore solid wastes. A spent material is "any material that has been used and as a result of contamination can no longer serve the purpose for which it was produced without processing" (40 CFR 261.1(c)(1)). Generators of solid wastes (including spent lamps) are thus responsible for determining whether the wastes are hazardous (through testing or through their knowledge of the material).

However, even though waste lamps are considered solid and hazardous wastes if they exhibit hazardous waste characteristics, not all generators of these spent lamps have had to manage the lamps as hazardous waste. Under RCRA Subtitle C, there are different requirements for generators of hazardous waste depending on the amount of hazardous waste generated in a calendar month. Conditionally-exempt small quantity generators (CESQGs) (i.e., generators of less than 100 kilograms of hazardous waste in a calendar month) are not subject to RCRA Subtitle C hazardous waste management standards and may choose to send their wastes to a municipal solid waste landfill or other facility approved by a state for the management of industrial or municipal non-hazardous wastes (40 CFR 261.5). Generators of more than 100 kilograms and less than 1,000 kilograms in a calendar month are subject to the RCRA hazardous waste management standards, but are allowed to comply with certain reduced regulatory requirements (40 CFR 262.34). Generators of more than 1,000 kilograms of hazardous waste in a calendar month are required to comply fully with federal hazardous waste regulations. Household generators of waste lamps may be exempt from hazardous waste management requirements under 40 CFR 261.4(b)(1). Also, several states already regulate waste lamps as universal wastes under their authorized state hazardous waste programs.

B. Proposed Rule

On July 27, 1994 (59 FR 38288), EPA proposed two approaches for controlling the management of spent lamps, specifically mercury-containing lamps. Mercury-containing lamps include fluorescent, high pressure sodium, mercury vapor, and metal halide lamps. In that notice, the Agency requested comment on whether either approach was appropriate for protecting human health and the environment from potential releases of mercury. The two management options proposed by EPA were less stringent than the existing federal regulations. Both regulatory alternatives provide streamlined requirements for certain waste management activities in lieu of regulating spent mercury-bearing lamps under the full RCRA Subtitle C management standards.

The first regulatory alternative proposed by EPA was a conditional exclusion from hazardous waste regulation for waste mercury-containing lamps. Under the proposed conditional exclusion, waste mercury-containing lamps could be disposed in a municipal landfill provided the landfill was permitted by a state with an EPA-approved municipal solid waste landfill permitting program or managed at a mercury reclamation facility permitted, licensed, or registered by a state. The second regulatory alternative included in the proposed rule was to add waste mercury-containing lamps to the universal waste program, which consists of streamlined regulations designed to address the management of certain widely generated hazardous wastes. EPA also solicited comment on whether to add other types of spent hazardous waste lamps (e.g., lamps that are hazardous waste because they fail the TC for other constituents, such as lead) to the universal waste program.

C. The Toxicity Characteristic

Under section 3001 of the Resource Conservation and Recovery Act (RCRA), EPA is charged with defining which solid wastes are hazardous by identifying characteristics that indicate hazardous waste and by listing particular solid wastes as hazardous wastes. On May 19, 1980, the Agency promulgated the Extraction Procedure Toxicity Characteristic (EPTC) to determine the toxicity of waste. The EPTC regulated eight metals, four insecticides, and two herbicides. On March 29, 1990, in response to section 3001(g) of RCRA, which was added by the Hazardous and Solid Waste Amendments (HSWA) of 1984, the Agency replaced the Extraction Procedure with the Toxicity Characteristic Leaching Procedure (TCLP). Like the EPTC, the TCLP is used to determine the toxicity of waste. Although regulatory levels for the metals (including mercury) remained the same as originally promulgated in 1980, the promulgation of the Toxicity Characteristic resulted in additional wastes becoming regulated as hazardous due to the new leaching procedure (the TCLP) and to the addition of regulatory levels for more waste constituents.

In the 1994 proposal on spent lamps, the Agency did not propose, or request comment on, regulatory language that would modify or amend the current hazardous waste toxicity characteristic provisions published in 40 CFR 261.24. However, EPA noted that the Agency was conducting long-term studies on the fate and transport of TC metals in ground water, and that the TC regulatory levels for mercury may be changed when that work is completed. The proposed rule also requested submission of any municipal solid waste leachate or groundwater data to support this separate effort. Because of the extreme complexity of mercury chemistry in the environment and because scientific knowledge about the environmental fate and transport of mercury continues to evolve, this work is still ongoing.

The most recent data available to the Agency demonstrate greater mobility than previously thought. These data include updated groundwater modeling, as well as field data collected by the Agency in reviewing the hazardous characteristics generally, the TCLP test,

and Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) Records of Decision (RODs) from municipal solid waste landfills. As explained in more detail in responses to comments and elsewhere in the record, these data expand upon and corroborate data cited in the proposal that mercury can migrate from municipal solid waste landfills in harmful concentrations and reach human drinking water sources located over a mile from the landfill in significant concentrations, i.e., concentrations exceeding allowable mercury in drinking water. Thus, actual site data from recent and on-going studies support the Agency's conclusion that mercury is present in significant concentrations in both leachate and groundwater at non-hazardous waste landfill sites, including municipal solid waste landfills, and has migrated off-site to drinking water sources (in some instances in concentrations exceeding Federal drinking water standards). This conclusion is sufficient to warrant continued regulation of spent lamps containing mercury as hazardous waste.

Even though EPA did not re-open issues related to the appropriateness of the TCLP for evaluating the toxicity of mercury-bearing waste in this proposal, the Agency is clarifying that the recent opinion of the D.C. Circuit in *Columbia Falls Aluminum Company* v. *EPA,* 139 F.3d 914 (D.C. Cir. 1998) ("*Columbia Falls*"), does not affect the use of the TCLP to determine whether spent waste lamps exhibit the toxicity characteristic and, therefore, should be regulated as hazardous wastes under RCRA Subtitle C.

Columbia Falls presented unique and limited circumstances which do not apply to the question of using the TCLP for determining whether spent lamps are hazardous wastes. In the context of *Columbia Falls,* EPA had established treatment standards for spent aluminum potliners (hazardous waste code K088), and the treatment standards used the TCLP to measure the performance of the treatment technology in mitigating the hazard presented by several hazardous constituents found in the waste, including arsenic and fluoride. In the case of *Columbia Falls,* all of the commercial treatment capacity for the waste (K088) was provided by a single facility, and all of the treatment residue from this single process was disposed at a single location in a dedicated monofill.[1] Notwithstanding that the treatment process was able to achieve the treatment standards for arsenic and fluoride as measured by the TCLP (i.e., the treatment residue, when tested with the TCLP, never exceeded the regulatory levels), actual *leachate* from the single disposal site contained significantly higher levels of these two constituents. EPA had not offered any substantive explanation for continued use of the TCLP to measure performance of the treatment process for these constituents after the disparities between the predicted leaching using the TCLP and the actual performance in the field became known. Under these circumstances, the court held that it was arbitrary and capricious to continue to use the TCLP to establish treatment standards for spent potliner wastes because it bore no rational relationship to what was actually occurring.

None of these circumstances applies to the question of using the TCLP to determine the toxicity of spent lamps and, therefore, whether such lamps are hazardous wastes in the first place. With respect to mercury, the TCLP has not been shown in this case to under predict mercury leachate concentrations for 100 percent of the wastes to which the test applies.

First, there is no question that it is reasonable to model a disposal environment where lamps are disposed with municipal solid waste, since most lamps are disposed in municipal solid waste landfills, or would be if they were not hazardous wastes. The grinding feature of the TCLP protocol is likewise reasonable, since there is no dispute that lamps will be crushed after they are landfilled. The dilution/attenuation feature of the TCLP is likewise a reasonable approximation of fate and transport of mercury which escapes from the lamp matrix. There is no chemical reason why such mercury would be immobile. The mercury itself is primarily the divalent form which can form mobile salts or soluble mercury acetate upon exposure to acidic municipal solid waste (a phenomenon modeled by the pH and acid of the simulated leachate in the TCLP test (see Memorandum To the Docket from Gregory Helms entitled "Solubility of Mercury Salts," dated June 18, 1999).

Second, as explained in more detail in responses to comments and other materials in the record, mercury has proven mobile in municipal solid waste landfill environments, migrating in leachate to contaminate ambient groundwater at concentrations exceeding the federal maximum contaminant levels (MCLs) used for drinking water (see EPA's "Summary of Mercury Damage Incidents from CERCLA Records of Decisions (RODs)," June 9, 1999, and chart entitled "Maximum Mercury Concentration Observed in Leachate from Landfill Cells," June 11, 1999.) Mercury contamination from municipal solid waste leachate exceeding MCLs has actually been found in groundwater drinking wells over a mile from the landfill (well past the 500 feet used in the TC for fate and transport assumptions). These concentrations are within an order of magnitude, or within the same order of magnitude, as predicted in the TC. *Id.* Thus, the reasonableness of using the TC to evaluate the hazardousness of these wastes is firmly supported by empirical data.

D. Universal Waste Rule

On February 11, 1993, EPA proposed streamlined hazardous waste management requirements for collecting and managing certain widely generated hazardous wastes (58 FR 8102). The Agency finalized the Universal Waste Rule on May 11, 1995 (60 FR 25492). The final rule promulgated streamlined hazardous waste management regulations for hazardous waste batteries, certain hazardous waste pesticides, and mercury-containing thermostats. Handlers of universal wastes are subject to less stringent standards for storing, transporting, and collecting these wastes. These standards serve to encourage environmentally sound collection and proper management of these hazardous wastes.

The universal waste regulations apply to handlers and transporters of universal wastes. Handlers include universal waste generators and collection facilities. The regulations distinguish between "large quantity handlers of universal waste" (those who handle more than 5,000 kilograms of total universal waste at one time) and "small quantity handlers of universal waste" (those who handle 5,000 kilograms or less of universal waste at one time). The 5,000 kilogram accumulation criterion applies to the quantity of all universal wastes accumulated.

Universal waste handlers who generate or manage items designated as universal waste are exempt from certain requirements routinely applied to hazardous waste management and instead are subject to the management standards under part 273. These include streamlined standards for storing universal waste, labeling and marking waste or containers, preparing and sending shipments of universal wastes off-site, employee training, and response to releases. Large quantity handlers of universal waste (LQHUW) also must provide notification of universal waste management to the appropriate EPA Region (or state director in authorized

[1] 62 FR 1993 (Jan. 14, 1997).

states), obtain an EPA identification number, and retain for three years records of off-site shipments of universal waste. Small quantity handlers of universal waste (SQHUW) are not required to manifest wastes, notify the EPA region, or keep records of universal waste shipments.

Transporters of universal waste also are subject to less stringent requirements than the full Subtitle C hazardous waste transportation regulations. Universal waste transporters must comply with all applicable Department of Transportation (DOT) regulations and ensure transportation of universal waste to a universal waste handler or a destination facility. Transporters may store universal waste at a transfer facility for ten days or less and must contain any releases of universal waste. Transporters of universal waste do not have to comply with RCRA hazardous waste manifest requirements.

Destination facilities are those facilities that treat, dispose, or recycle universal wastes. Universal waste destination facilities are subject to all currently applicable requirements for hazardous waste treatment, storage, and disposal facilities and must receive a RCRA permit for such activities. Hazardous waste recycling facilities that do not store hazardous wastes prior to recycling may be exempt from permitting under federal regulations (40 CFR 261.6(c)(2)).

In the universal waste proposal, the Agency did not propose to include spent fluorescent lamps in the universal waste regulations because further investigation into the issue was necessary. However, EPA requested comment on several questions related to fluorescent lamps (58 FR 8110). First, EPA requested comment on the risks posed by these lamps in landfills or municipal waste combustors. Second, EPA requested information on the risks of current or developing mercury recovery technologies. The Agency received a number of comments in response to these questions. Some commenters supported including waste lamps in the Universal Waste Rule, and other commenters suggested other regulatory alternatives for managing these lamps. The comments addressing the management of waste mercury-containing lamps that were received in response to the universal waste proposed rule are addressed in the background documents for today's rulemaking.

E. Energy Efficient Lighting Programs

Prior to publication of the proposed rule, the Agency initiated a review of the potential risks represented by waste mercury-containing lamps and began to analyze the contribution of such lamps to total mercury emissions to the environment. The Agency undertook this evaluation in part because of the importance of promoting energy efficiency. The use of energy-efficient lighting can reduce mercury emissions from coal-burning power plants as well as reduce emissions of carbon dioxide and sulfur oxide. Energy-efficient lighting in all U.S. commercial floor space currently illuminated by less efficient fluorescent lamps would save an estimated 35 to 40 billion kilowatt hours of electricity annually. This saving would result in reduced emissions of mercury, carbon dioxide, sulfur dioxide and nitrogen dioxide, some of which are projected to cause greenhouse effects.

Replacing energy inefficient lighting systems with energy efficient lighting systems requires the use and eventual disposal of spent mercury-containing lamps. It was suggested that requiring the management of spent lamps in accordance with the full Subtitle C hazardous waste management requirements could discourage participation in energy efficient lighting programs, since facilities might avoid or postpone replacement of lamps because of potential disposal costs. If this were true, streamlined management standards for spent mercury-containing lamps could decrease the costs associated with managing the lamps and promote greater participation in energy-efficient lighting programs. However, as discussed below, the Agency has found that the cost of these programs appears to be largely independent of the regulatory options chosen by EPA.

F. Notice of Data Availability

On July 11, 1997 (62 FR 37183), the Agency made available to the public additional data on mercury emissions from managing spent lamps. The information provided as part of the Notice of Data Availability (NODA) consisted of an electronic model and a report that assessed mercury emissions from the management of waste mercury-containing lamps under different regulatory approaches. The report, titled "Mercury Emissions From the Disposal of Fluorescent Lamps," discusses the methodology, data and assumptions used in developing the *Mercury Emissions Model*. The report describes inputs used in the model for estimating potential mercury emissions during waste management and disposal activities (such as lamp properties, lamp disposal rates, and lamp mercury emissions rates from specific waste management practices). It also discusses inputs for estimating energy savings from using high-efficiency T8 lamps, and the effects on mercury emissions from electric utilities. The report estimates mercury emissions under baseline conditions (i.e., management of mercury-containing lamps in compliance with full hazardous waste requirements) and under other regulatory options, including the conditional exclusion and universal waste approaches proposed. These estimates include annual and cumulative emissions from disposal of mercury-containing lamps, and net mercury emissions.

The Agency received thirty-five public comments on this NODA, about twenty of which presented substantive information on the model. The Agency has reviewed these comments in great detail and revised the model and report, as appropriate. The Agency also has prepared a comprehensive response to comment document addressing each substantive issue. The revised model, report, and response to comment document are available in the RCRA docket established for this action. A brief summary of the major public comments and the Agency's responses is presented below.

Many commenters raised concerns about the model's Subtitle D landfill emissions rates. Several commenters believed the Agency should not have rounded the high emissions rate of 0.8 percent to one percent. EPA believes this is a valid concern and has revised the model to include the original 0.8 percent emissions rate.

Some commenters raised concerns that EPA had misinterpreted data from the State of Florida on its recycling emissions estimates. EPA has carefully reviewed available recycling emissions data and revised the model's central and low emissions factors for divalent mercury emissions. EPA revised the central estimate from three percent to 1.09 percent and the low estimate from one percent to 0.07 percent.

Various commenters believed that the model should clearly distinguish between CESQG and non-CESQG lamp mercury emissions. These commenters pointed out that CESQG lamp emissions are outside the scope of the rulemaking effort. The Agency agrees with this concern and has revised the model to segregate non-CESQG from CESQG lamp emissions.

Some commenters believed that higher spent lamp management costs would discourage certain building owners from conducting lighting upgrades. These commenters were concerned with the model assumption

that upgrades are independent of policy options. In response to the comments, EPA revisited its assumptions and performed additional calculations on the impact of disposal costs on a lighting upgrade's internal rate of return (IRR). The Agency has found that, holding all other lamp operating costs constant, the cost of lamp disposal has minimal impacts on an upgrading project's IRR. At a $0.50/lamp transportation and recycling cost, the IRR for a typical project over ten years is 51 percent. At a $1.00/lamp transportation and recycling cost, the IRR was 50 percent—only a slight decrease in IRR despite a 100 percent increase in waste management costs. For these reasons, EPA continues to believe that the decision to use T8 lamps is independent of the Agency's policy options.

A number of commenters indicated that the model underestimated lamp recycling rates under the baseline and overestimated the rate of Subtitle C landfilling. Commenters suggested that the national lamp recycling rate is approximately ten percent and that Subtitle C landfilling of lamps is near three percent. EPA believes these estimates may be reasonable, and has revised the baseline's recycling rate to ten percent and reduced the Subtitle C disposal rate to about two percent.

The Agency also conducted an internal review of the model and made additional revisions. First, the Agency revised the model assumptions regarding the effectiveness of pollution control equipment at municipal waste combustor (MWC) emissions from 80 to 95 percent. This revision has the effect of decreasing the MWC high emission factor for divalent mercury from 30 percent to 16 percent. Second, EPA revised the disposal trees under the baseline and options to account for the fact that some CESQGs voluntarily recycle their spent lamps.

II. Relationship to Other Agency Activities

A. Report to Congress on Mercury

As required by the Clean Air Act (CAA) Amendments of 1990, on December 19, 1997, the Agency issued the Mercury Study Report to Congress. The study estimates the quantity of mercury emissions to the air from a number of human activities, estimates the health and environmental impacts associated with these mercury emissions, and describes the technologies available to control mercury emissions from these sources.

The report estimates that annual anthropogenic U.S. emissions of mercury in 1994–1995 were 158 tons. Approximately 87 percent of these mercury emissions came from combustion sources. Approximately 1 percent of mercury emissions are estimated to come from spent mercury-containing lamps.

The report found that anthropogenic emissions of mercury to the air rival or exceed natural inputs. Recent estimates place the annual amounts of mercury released into the air by human activities at between 50 and 75 percent of the total yearly input to the atmosphere from all sources. Some of the air emissions are deposited on land and water within several hundred miles of the source. The remainder enters global circulation, from which it may be deposited on land or water at great distances from the source. Mercury deposited on land or water may be re-emitted and reenter the global circulation to be redeposited elsewhere. When mercury enters water bodies, either through direct deposition or through run-off of mercury deposited on land, a series of transformations occur resulting in conversion of some of the mercury into a methylated form which is more toxic and more conducive to bioaccumulation in fish.

While the report does not quantify the risk from mercury exposure, it concludes that there is cause to seek further reductions in mercury releases and exposures to mercury. The report recommends that cost-effective opportunities to deal with mercury during the product life cycle (rather than just at the point of disposal), should be pursued. The Agency believes that today's rule furthers that goal by including provisions related to management prior to disposal.

In addition, on February 19, 1998, EPA and the Department of Agriculture issued the Clean Water Action Plan, which describes important actions EPA and other federal agencies will take to reduce exposure to toxic pollutants (especially mercury) in the nation's water and fish. Mercury is identified as a pollutant of concern in 60 percent of state-issued fish consumption advisories. The Clean Water Action Plan outlines several important Agency actions aimed at reducing the exposure of people and wildlife to mercury-contaminated fish.

B. Health Effects on Children

In April 1997 President Clinton signed Executive Order 13045 (62 FR 19885), "Protection of Children From Environmental Health Risks and Safety Risks," requiring each federal agency to assess risks that disproportionately affect children, including risks from mercury. Mercury is a toxic, bioaccumulative pollutant. The primary health effects are on the neurological development of children exposed through fish consumption and fetuses exposed through their mothers' consumption of fish. Given equivalent exposure, children absorb more mercury as a percentage of their body weight than do adults. Children are, therefore, more susceptible to the negative health effects of mercury emissions. The results of EPA's analyses (as presented in Modification of the Hazardous Waste Program: Hazardous Waste Lamps—Economic Assessment) indicate that it is likely that emissions from regulated mercury-containing lamps will decrease somewhat as a result of today's final rule. Therefore, it is likely that children may experience a marginal benefit from this action due to these decreased emissions.

III. Rationale for Including Hazardous Waste Lamps in the Scope of the Universal Waste Rule

A. Why Management Controls Are Necessary for Spent Mercury-Containing Lamps

In today's rule, the Agency's primary objective is to promulgate regulations for management of hazardous waste lamps that both protect human health and the environment and are efficient and effective in doing so. EPA believes that management controls for spent mercury-containing lamps are necessary to minimize releases of mercury to the environment during accumulation and transport, to ensure safe handling of such lamps, and to keep spent mercury-containing lamps out of municipal waste management facilities (both landfills and solid waste incinerators). Studies reveal that significant threats of mercury releases from managing spent lamps result from incineration and from breakage during storage and transport. In addition, data available to the Agency show that mercury can be found in municipal landfill leachate, and EPA remains concerned that landfill releases may pose threats over the long term. For these reasons, the Agency has concluded that some management controls are essential for these wastes.

Mercury is easily volatilized; it can be dispersed widely through the air and transported thousands of miles. It undergoes complex chemical and physical changes as it cycles among air, land, and water. Humans, plants, and animals may be exposed to mercury and accumulate it during this cycle, potentially resulting in ecological and human health impacts. The primary health effects from mercury are on the neurological development of children

exposed through fish consumption and on fetuses exposed through their mother's consumption of fish.

Because of its low boiling point, elemental mercury is largely vaporized during municipal waste combustion and, without the use of control technologies specific to mercury, passes out of the municipal waste combustor into the atmosphere with the flue gas. On December 19, 1995, EPA's Office of Air Quality Planning and Standards (OAQPS) promulgated standards for new municipal waste combustors of a certain capacity (60 FR 65387). However, combustors at smaller plants would not be affected by the standards, nor do the standards address the problem of mercury emissions from lamp breakage.

When spent mercury-containing lamps break, the elemental mercury inside becomes available for evaporation, adsorption, or reaction. For example, a study performed by Research Triangle Institute (RTI) estimated emissions from lamps after breakage to be about 6.8 percent of the total mercury content of the broken lamp. The National Electrical Manufacturers Association (NEMA) estimated emissions from lamp breakage to be in the range of 1 percent of the mercury content of the broken lamp. The Electric Power Research Institute's (EPRI) measurements of mercury emissions from uncovered broken lamps totaled 2.8 percent of the total mercury content of the lamp.

Mercury may also be released to the environment as a result of lamp crushing operations. Available studies show that emission percentages from drum top crushing range from 10 to 100 percent of the total elemental mercury in the lamps, depending on the operating conditions and supplemental controls used.

To address these concerns, today's rule moves spent hazardous waste lamps into the universal waste regulatory program. Comments from stakeholders and from other regulatory agencies (especially state solid and hazardous waste authorities) support EPA's conclusion that this approach offers the most effective way to ensure environmentally protective management of these wastes.

B. Why the Universal Waste Approach is Preferable to a Conditional Exclusion for Spent Mercury-Containing Lamps

Although EPA has determined that spent mercury-containing lamps can safely be subject to management requirements that are less stringent than those of full Subtitle C (see discussion in Part III.C below), the Agency does not believe that its proposed conditional exclusion approach would sufficiently protect human health and the environment. It is clear to the Agency that mercury poses an environmental threat and that man-made sources of mercury emissions should be reduced or, where inevitable, managed properly. EPA therefore gave considerable weight to actions that would minimize mercury emissions to the environment while encouraging the collection and environmentally-sound management of spent lamps. The Agency is convinced that the universal waste approach is the best way to further these goals. EPA agrees with those commenters to the proposed rule who stated that the conditional exclusion approach would reduce the quantities of spent mercury-containing lamps that would be recycled, increase disposal of the lamps in municipal landfills, and increase the amount of mercury released to the environment due to increased breakage of lamps during storage, transport, and landfilling. The Agency's analysis predicts that uncontrolled mercury emissions under the conditional exclusion approach are likely to be somewhat greater than under the universal waste approach promulgated in today's rule (see the Economic Assessment discussed in section VII.B of today's preamble).

A principal reason for this conclusion is that some substantive and relatively detailed controls for managing spent mercury-containing lamps are necessary for protection of human health and the environment, although these controls can be structured in a much more simplified and streamlined way than the full Subtitle C management system. The Agency believes that such controls would be difficult to implement and to enforce using a conditional exclusion approach. Such an approach could be appropriate if the regulated universe was less numerous and varied, or more sophisticated about Subtitle C requirements. However, since handlers of spent mercury-containing lamps are widely varied, diffuse, and often not knowledgeable about RCRA regulations, it would be very difficult to monitor compliance and enforce controls such as those included in today's rule if these handlers were completely outside of the Subtitle C universe and the controls were implemented only as conditions for maintaining the exclusion. The Agency believes that the packaging standards and prohibition on treatment included in today's rule are important for preventing potential mercury emissions during storage and transport. Controls of this type can best be implemented through a universal waste-type approach where handlers are operating within a simple, streamlined management system with some limited oversight rather than completely outside of any regulatory structure.

A further reason for selecting the universal waste approach was the Agency's desire to promote further reductions in the quantity of mercury in spent lamps, which will lead to a reduction in total emissions of mercury to the environment. The conditional exclusion approach would have provided less incentive to reduce or eliminate the presence of mercury in lamps, since under that approach spent mercury-containing lamps would not have been classified as hazardous waste.

With respect to mercury, the most significant source reduction achievement has been the reduction and elimination of mercury from alkaline batteries. Although these batteries are still a significant contributor of mercury to municipal solid waste, this contribution is dropping dramatically. Spent mercury-containing lamps are one of the next highest sources of mercury in the municipal solid waste stream, possibly accounting for as much as 3.8 percent of all mercury now going to municipal landfills. Opportunities exist to further reduce mercury content in both standard 4-foot fluorescent lamps and the increasingly popular compact fluorescent lamps.

Commenters on the proposed rule stated that advances in lamp technology have resulted in a 14 percent reduction in lamp mercury content from 1985 to 1990. These commenters also pointed out that projections show an additional 35 percent decline in future mercury levels. Some manufacturers have made considerable progress in reducing levels of mercury in fluorescent lamps. Many commenters urged EPA to continue to encourage industry in these efforts.

The Agency believes that today's final rule will encourage lamp manufacturers to continue reducing or eliminating the amount of mercury used to manufacture lamps. Because mercury-bearing lamps that fail the TCLP are still considered to be hazardous wastes under the universal waste rule, lamp producers will have an incentive to design lamps with a mercury content below the level that will cause the lamps to fail the TCLP. If lamp manufacturers aggressively pursue source reduction, the contribution of mercury to the environment from lamps will continue to decrease over time.

EPA also notes that under the universal waste rule, handlers and destination facilities must comply with the substantive requirements of the

Land Disposal Restrictions (LDR) provisions of the Hazardous and Solid Waste Amendments of 1984 (HSWA). These include (1) a prohibition on accumulating prohibited wastes directly on the land; (2) a requirement to treat waste to meet treatment standards before disposal; (3) a prohibition on dilution; and (4) a prohibition on accumulation except for purposes of accumulating quantities sufficient for proper recovery, treatment, or disposal. Since mercury can be found in municipal landfill leachate and releases remain a concern (especially for the long term), the Agency believes that compliance with the substantive requirements of the LDR program is still necessary to minimize risks from managing spent mercury-containing lamps (studies on the movement of mercury in a variety of land disposal settings are ongoing). Again, the Agency believes that controls of this type are best implemented through a simple, streamlined regulatory approach such as the universal waste rule rather than as a conditional exclusion.

A further reason for today's rule finalizing the universal waste approach is that this approach will provide more consistency between federal and state regulations governing the management of spent hazardous waste lamps. Currently, several states have added mercury-containing lamps to their universal waste programs and others have proposed to do so in the near future. By placing hazardous waste lamps within the federal universal waste rule, EPA hopes to encourage additional states to regulate spent lamps as universal waste and therefore promote greater consistency in regulatory approaches across state borders. This will improve waste management efficiency and reduce compliance costs for waste handlers engaged in interstate commerce.

C. Why Relief From Full Subtitle C Requirements is Warranted Both for Mercury-Containing Hazardous Waste Lamps and Other Hazardous Waste Lamps

Although some controls for management of spent lamps are necessary for protection of human health and the environment, for several reasons the Agency believes that these controls can be successfully applied in a more simple, streamlined system than the full Subtitle C program, and that such an approach is appropriate both for mercury-containing hazardous waste lamps and any other spent lamps that are hazardous.

The Agency believes that relief from full Subtitle C requirements for handlers of hazardous waste lamps is justified (whether the lamps are hazardous because they exhibit the toxicity characteristic for mercury or another constituent, such as lead). First, the principal reason for this belief is that the full Subtitle C regulatory structure is not appropriate for the universe of people handling these materials, and adequate protections can be applied in the more appropriate structure of the universal waste rule. Many handlers of hazardous waste lamps are office buildings, retail establishments, and other building managers, most of whom are not familiar with or equipped to comply with the full Subtitle C regulatory structure. This structure was initially developed with industrial hazardous wastes in mind, and is most appropriate for these materials and for the types of facilities that generate these wastes. The streamlined universal waste structure is more appropriate for the numerous, widely varied universe of spent lamp handlers who are not familiar with or easily able to comply with the full hazardous waste regulatory structure.

In addition, the final universal waste rule included a number of factors to be used to evaluate whether candidate wastes are appropriate to be added to the universal waste regulations. The factors were designed to determine whether regulating a particular hazardous waste under the streamlined standards of the universal waste program would improve overall management of the waste. The factors, which are codified at 40 CFR 273.81, include: (a) The waste must be a hazardous waste generated by a wide variety of generators; (b) the waste, or category of waste, should not be exclusive to a particular industry or group of industries, but generated by a wide variety of establishments; (c) the waste should be generated by a large number of generators and generated frequently, but in relatively small quantities; (d) systems to be used for collecting the waste should ensure close stewardship of the waste; (e) the risks posed by the waste during accumulation and transport should be relatively low compared to the risks posed by other hazardous waste, and specific management standards would be protective of human health and the environment during accumulation and transport; (f) regulation of the waste, or category of wastes, under the universal waste rule should result in the diversion of the waste from management with non-hazardous waste streams (i.e., the municipal solid waste stream); (g) regulation of the waste as a universal waste should improve implementation of and compliance with the hazardous waste regulatory program and/or (h) other factors that may be appropriate.

As the Agency noted in the preamble to the final universal waste rule (60 FR 25513), not every factor must be met for a waste to be appropriately regulated under the universal waste system. However, consideration of all the factors should result in a conclusion that regulating a particular hazardous waste under 40 CFR part 273 will improve waste management. After evaluating spent hazardous waste lamps in the context of the regulatory criteria for adding wastes to the universal waste rule, EPA has determined that on balance, these wastes are highly appropriate for inclusion in the regulatory scheme of 40 CFR part 273. The results of the Agency's evaluation of how these wastes meet the universal waste factors are described below.

A. Spent lamps are often hazardous because they exhibit the characteristic of toxicity by exceeding the regulatory level for mercury or another constituent (most frequently lead).

B. Spent hazardous waste lamps are generated by a wide variety of generators, including retail establishments, manufacturing establishments and office buildings.

C. Spent hazardous waste lamps are generated frequently by a large number of generators; in fact, a large percentage of all office buildings, retail establishments, and manufacturing facilities generate such lamps. Spent lamps are often generated in relatively small quantities.

D. The packaging standards included in today's rule and increased recycling will encourage close stewardship of the waste.

E. The Agency is convinced that the requirements of the universal waste program can be highly effective in mitigating risks posed by breakage of hazardous waste lamps during storage and transport. The universal waste requirements for proper packaging and handling of the lamps to avoid breakage during accumulation and transport should prevent releases of mercury or lead to the environment before recycling or other management, which will make the risks posed during accumulation and transport extremely low.

F. The Agency believes that managing hazardous waste lamps under the universal waste program will result in diversion of at least some of this waste from management in the municipal waste stream. EPA believes that the streamlined requirements of today's rule will encourage all handlers of spent lamps (whether hazardous or not) to

manage them under the requirements of part 273. Under the current RCRA regulatory scheme, the management of a waste differs based on the source of the waste. Wastes (including spent lamps) generated by consumers in their homes are not regulated under Subtitle C when discarded, because they are excluded from the definition of hazardous waste under 40 CFR 261.4(b)(1). Similarly, many spent lamps are largely exempt from the hazardous waste regulations because they are generated by conditionally exempt small quantity generators (CESQGs). Spent lamps generated by households and CESQGs are not distinguishable from those generated by fully regulated generators. Because the waste looks the same, spent lamps that would be more protectively managed in the hazardous waste system are entering municipal solid waste landfills or combustors instead. The simplified regulations will provide an incentive for individuals and organizations to collect the unregulated portions of the waste stream and manage them using the same systems developed for the regulated portion, thereby removing spent mercury or lead-containing lamps from the municipal waste stream and minimizing the amount of hazardous constituents going to municipal landfills and combustors.

G. Finally, managing hazardous waste lamps under the universal waste program will improve implementation of and compliance with the hazardous waste regulatory program. Generation of hazardous waste lamps by facilities which otherwise generate no hazardous waste is widespread. Currently, if a mercury or lead-containing lamp is a hazardous waste, it must be managed under Subtitle C regulation. If more than 100 kilograms of hazardous waste (including spent lamps) are generated in a calendar month, generators are subject to full Subtitle C requirements for storage, packaging, manifesting, and record keeping. Many facilities are therefore required to undergo significant technical and paperwork burdens largely or solely because they replace or upgrade used hazardous waste lamps. These generators may not be in compliance with RCRA regulations because they are unfamiliar with the requirements. EPA believes that the streamlined requirements of the universal waste program will give such "episodic" generators a more accessible starting point for good environmental management. If regulatory requirements are simpler, the compliance rate will improve, more hazardous waste lamps will be handled properly, and more spent lamps will be sent for recycling (or to other Subtitle C facilities) instead of going to solid waste landfills or to municipal waste combustors. Improved management will therefore lead to a reduction in the total amount of hazardous waste emissions to the environment.

In summary, considering these factors, the Agency finds that the universal waste approach is highly appropriate for this waste stream, and that it is in fact exactly this type of waste that the universal waste system was designed for. The Agency believes that the universal waste approach promulgated in today's rule will improve management of hazardous waste lamps, will improve implementation of the hazardous waste regulatory program, and will adequately protect human health and the environment from the risks posed by management of this waste stream.

IV. Summary of Final Rule

A. Waste Covered by Today's Rule

Today's rule adds hazardous waste lamps (waste lamps that are hazardous due to exhibiting one or more of the characteristics of hazardous waste) to the federal universal waste rule. In the proposed mercury-containing lamps rule, the Agency provided definitions for "electric lamp" and "mercury-containing lamp." In response to comments received on the proposed definitions, and to reduce potential confusion regarding the scope of the final rule, in today's final rule the Agency is finalizing a single definition of "lamp" or "universal waste lamp." In addition, in the applicability section of today's rule, the Agency is clarifying that all hazardous waste lamps fall within the scope of the universal waste rule.

B. Summary of Management Requirements for Universal Waste Lamps

Today's final rule for hazardous waste lamps ensures consistency with the universal waste rule. Today's rule adds subsections to §§ 273.13 and 273.33 of the existing universal waste rule, specifically addressing requirements for hazardous waste lamps. New § 273.13(d) includes lamp handling requirements for small quantity handlers of universal waste, and new § 273.33(d) provides lamp handling requirements for large quantity handlers of universal waste lamps. Management standards for transporters of universal waste lamps are the same as those applicable to transporters of other types of universal waste. Destination facilities (e.g., recycling facilities and treatment and disposal facilities) remain subject to all applicable hazardous waste permitting and management requirements under RCRA.

The universal waste management requirements for different participants handling hazardous waste lamps are summarized below. A discussion of the public comments that the Agency received in response to the management requirements for spent lamps contained in the proposed rule is found in Section V of this preamble, along with EPA's responses to comments received on the proposed requirements.

1. Categories of Participants in the Universal Waste System

There are four categories of participants in the universal waste management system: small quantity handlers of universal waste (SQHUW), large quantity handlers of universal waste (LQHUW), transporters, and destination facilities. When the proposed spent lamps rule was published, the Agency chose to categorize the lamps in a manner that was consistent with the proposed universal waste rule. Both proposed rules classified regulated persons managing universal waste into one of four types: generators, consolidation points, transporters, or destination facilities. When the final universal waste rule was published, the Agency modified the four categories. The transporter and destination facility categories were retained essentially as proposed. However, the generator and consolidation point categories were merged to create two new categories of participants: small quantity handlers of universal waste (SQHUWs) and large quantity handlers of universal waste (LQHUWs). In today's final rule, the Agency is categorizing handlers of hazardous waste lamps in a manner consistent with the existing universal waste regulations.

2. Small and Large Quantity Handlers

The term "universal waste handler" is defined under existing 40 CFR 273.6 as a generator of universal waste or the owner or operator of a facility (including all contiguous property) that receives universal waste from other universal waste handlers, accumulates universal waste, and sends universal waste to another universal waste handler, to a destination facility, or to a foreign destination. The definition of "universal waste handler" does not include: (1) A person who treats (except under the provision of §§ 273.13(a) or (c), or §§ 273.33(a) or (c)), disposes of, or recycles universal waste; or (2) a

person engaged in the off-site transportation of universal waste by air, rail, highway, or water, including a universal waste transfer facility. Persons who treat, recycle, or dispose of universal waste remain subject to all applicable hazardous waste regulations as discussed below in Section IV.F. Transporters of universal waste are regulated as discussed below in Section IV.E.

There are two types of entities that are considered handlers of universal waste lamps. The first is a person who generates the lamps, i.e., the person who used the lamps, then determined that they are no longer usable and thus should be discarded. Contractors who remove universal waste lamps from service are considered handlers and co-generators of the waste. The second type of handler is a person who receives universal waste lamps from generators or other handlers, consolidates the lamps, and then sends the lamps on to other universal waste handlers, recyclers, or treatment and disposal facilities. Facilities that accumulate universal waste lamps but do not treat, recycle, or dispose of them are handlers of the lamps. Each separate location, (e.g., generating location or collecting location) is considered a separate handler.

Whether a universal waste handler is a SQHUW or LQHUW depends on the amount of universal waste being accumulated at any time. A small quantity handler of universal waste is defined under 40 CFR 273.6 as a universal waste handler who accumulates 5,000 kilograms or less of universal waste (i.e., batteries, pesticides, thermostats, or lamps, calculated collectively) at any time. A large quantity handler of universal waste is defined under 40 CFR 273.6 as a universal waste handler who accumulates 5,000 kilograms or more of total universal waste (i.e., batteries, pesticides, thermostats, or lamps, calculated collectively) at any time. The 5,000 kilogram accumulation cut-off level refers to the total quantity of all universal waste handled on-site, regardless of the category of universal waste.

On occasion, SQHUWs may accumulate greater than 5,000 kilograms of universal waste on-site at any one time, thus requiring them to comply with the LQHUW regulations. A large quantity handler of universal waste retains this designation for the remainder of the calendar year in which more than 5,000 kilograms of universal waste was accumulated at any given time. A handler may re-evaluate his status as a LQHUW in the following calendar year.

3. Universal Waste Transporters

Under 40 CFR 273.6, the definition of a universal waste transporter is "a person engaged in the off-site transportation of universal waste by air, rail, highway, or water." Persons meeting the definition of universal waste transporter include those persons who transport universal waste from one universal waste handler to another, to a destination facility, or to a foreign destination. These persons are subject to the universal waste transporter requirements of subpart D of part 273.

The proposed regulations for transporters of hazardous waste lamps were designed to be consistent with the proposed universal waste rule. Since the proposed regulations for universal waste transporters were not modified significantly in the final rule, today's requirements for universal waste lamps are essentially identical.

4. Universal Waste Destination Facilities

The definition of "destination facility," found in 40 CFR 273.6, is "a facility that treats, disposes of, or recycles a particular category of universal waste, except those management activities described in paragraphs (a) and (c) of §§ 273.13 and 273.33 of this chapter (40 CFR part 273). A facility at which a particular category of universal waste is only accumulated is not a destination facility for purposes of managing that category of universal waste." Persons meeting the definition of destination facility are subject to the universal waste destination facility requirements of Subpart E of Part 273.

Like the regulations for transporters, the final regulations for destination facilities have changed very little from the proposed rule.

C. Management Requirements for Small and Large Quantity Handlers of Universal Waste Lamps

As mentioned above, the universal waste rule includes different requirements for small and large quantity handlers of universal wastes. Small quantity handlers are those who accumulate 5,000 kilograms or less of all universal waste categories combined at their location at any time. The requirements for small quantity handlers of universal waste are located in subpart B of part 273. Large quantity handlers are those who accumulate more than 5,000 kilograms of all universal waste categories combined at any time. The requirements for large quantity handlers of universal waste are located in subpart C of part 273.

Both small and large quantity handlers must follow specified requirements when handling universal waste lamps. 40 CFR 273.13 specifies packaging standards for waste lamps to prevent breakage of spent lamps during accumulation, storage, and transport of universal waste lamps. Handlers of universal waste lamps must label each universal waste lamp or container holding the lamps with the words "Universal Waste—Lamp(s)" or "Waste Lamp(s)" or "Used Lamp(s)."

In addition, the final rule requires that spent lamps be managed in a way that prevents releases of mercury or other hazardous constituents to the environment during accumulation, storage, and transport. Handlers may accumulate universal waste lamps for one year. If the lamps are stored for longer than one year, the handler must be able to demonstrate that such accumulation is solely for the purpose of accumulating such quantities of universal waste as are necessary to facilitate proper recovery, treatment, or disposal. (Handlers are not required to notify EPA or the authorized state of storage for longer than one year.)

The requirements for responding to releases applicable to small and large quantity handlers of universal wastes (including universal waste lamps) are found in §§ 273.17 and 273.37. Today's rule does not amend these sections. All handlers of universal waste lamps must immediately contain any releases from the lamps and must handle the residues according to all applicable regulatory requirements. The Agency notes that any releases of universal waste not cleaned up could constitute illegal disposal and could incur enforcement action under RCRA. In addition, any releases of hazardous substances (universal wastes are hazardous wastes, and thus are hazardous substances) must be reported under CERCLA if they are above reportable quantity thresholds.

The employee training requirements for small and large handlers of universal waste are found in §§ 273.16 and 273.36. The Agency today is applying these standards to handlers of universal waste lamps. Large quantity handlers must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures related to their responsibilities during normal facility operations and emergencies. Small quantity handlers must inform all employees that handle or have responsibilities for managing universal waste lamps of proper handling and emergency procedures appropriate to such lamps. The Agency believes that basic employee training is

necessary to ensure that employees are specifically familiar with waste lamp handling procedures. Training that is required under other programs (such as OSHA or RCRA) will generally fulfill the part 273 training requirements.

Small quantity handlers are not required to notify EPA of their universal waste management activities and need not obtain an EPA identification number. However, large quantity handlers must notify EPA (or the authorized state) of their universal waste activities and they must obtain an EPA identification number, if they do not already have one.

The Agency has decided to adopt the off-site shipment provisions included in the final universal waste rule for hazardous waste lamps in order to remain consistent with the current universal waste regulations. Handlers of universal waste are prohibited from sending universal waste to a place other than another universal waste handler, a destination facility, or a foreign destination. Handlers who transport universal waste off-site themselves are considered universal waste transporters and must comply with the universal waste transporter requirements. Universal wastes being offered for off-site transportation that meet the Department of Transportation (DOT) definition of hazardous material must comply with the applicable DOT requirements. Large quantity handlers must track waste lamp shipments by maintaining records documenting shipments received by and sent from the facility.

Handlers of universal waste must also comply with requirements for rejected shipments of universal waste. To prevent or limit rejected shipments, facilities that offer universal waste for shipment off-site must ensure, before the shipment is sent, that the receiving facility (another universal waste handler or destination facility) will agree to receive the load. If the shipment is rejected, the handler must take the waste back or agree with the receiving facility on a destination facility to which the shipment will be sent. If a handler rejects a shipment or a portion of a shipment, the handler must contact the originating handler to discuss re-shipment of the load. The handler may send the shipment back to the originating handler or send the shipment to a destination facility agreed upon by both handlers. If a handler receives a shipment containing hazardous waste that is not universal waste, the handler must notify the EPA Regional office of the illegal shipment and receive instruction on further management of the waste. If the handler receives a shipment containing non-hazardous, non-universal waste, the handler may manage the waste according to applicable federal, state, or local solid waste regulations.

D. Effect of Today's Rule on Conditionally-Exempt Small Quantity Generators

Under the universal waste system, conditionally-exempt small quantity generators (CESQGs) can choose to manage their universal waste lamps in accordance with either the CESQG regulations under 40 CFR 261.5 or as universal waste under part 273 (40 CFR 273.8(a)(2)). In addition, handlers and destination facilities that mix universal waste lamps from CESQGs with other universal waste regulated under part 273 are required to manage the combined waste as universal waste under part 273 (40 CFR 273.8(b)).

As discussed in the proposal, hazardous waste lamps that are managed as universal waste under 40 CFR part 273 do not have to be included in a facility's determination of hazardous waste generator status (40 CFR 261.5(c)(6)). Therefore, if a generator manages such lamps under the universal waste system and does not generate any other hazardous waste, that generator is not subject to other Subtitle C hazardous waste management regulations, such as the hazardous waste generator regulations in part 262. A generator that generates more than 100 kilograms of hazardous waste in addition to universal waste lamps would be regulated as a small or large quantity hazardous waste generator and would be required to manage all hazardous wastes not included within the scope of the universal waste rule in accordance with all applicable Subtitle C hazardous waste management standards, depending on the amount of other hazardous waste generated.

E. Requirements for Transporters of Universal Waste Lamps

Transporters of universal waste lamps are subject to the requirements of subpart D of part 273. Under the universal waste system, hazardous waste manifests need not accompany off-site shipments of universal waste. Transporters of universal wastes must, however, comply with any applicable Department of Transportation (DOT) requirements. The Agency notes that the Hazardous Materials Regulations (HMR, 49 CFR parts 171–180) define a hazardous waste as any material that is subject to the Uniform Hazardous Waste Manifest Requirements of U.S. EPA, specified in 40 CFR part 262. Since shipments of universal waste are not required to be accompanied by a manifest, universal wastes are not considered "hazardous wastes" under DOT regulations. Therefore, for any universal waste shipments, transporters of universal waste must decide if the waste falls under any of the other DOT hazard classes to determine if compliance with the DOT requirements for "hazardous materials" under 49 CFR parts 171 through 180 is required. If the waste material does not meet the definition in the HMR for hazardous waste or any other hazardous material, its shipping description on shipping papers will not include a hazard class or identification number shown in the HMR.

Transporters may store universal waste lamps for up to ten days at a transfer facility during the course of transportation. A transporter storing universal waste lamps for more than ten days at one location must comply with the appropriate universal waste handler requirements in managing the wastes accumulated at the site, in addition to complying with the applicable universal waste transporter requirements. Universal waste transporters must transport a shipment of universal waste to a small quantity handler, large quantity handler, or a destination facility.

Today's final rule adopts the release response requirements promulgated in the universal waste rule for transporters of universal waste lamps. These requirements are found in § 273.54. The release response requirements have been adopted essentially as proposed and remain consistent with the current requirements for all universal waste transporters.

F. Requirements for Destination Facilities

A destination facility is a facility that treats, disposes of, or recycles universal wastes. The requirements for destination facilities are found under subpart E of part 273. Under the universal waste rule, destination facilities are subject to all hazardous waste management requirements applicable to permitted or interim status hazardous waste treatment, storage and disposal facilities under parts 264 and 265, as well as applicable standards in parts 268 and 270. Facilities that recycle universal waste lamps without accumulating the lamps before they are recycled are subject to the recycling requirements of § 261.6(c)(2).

G. Import and Export Requirements

The proposed rule for spent lamps did not include provisions for the importation of lamps. Several

commenters on the universal waste proposal pointed out that the Agency did not address the issue of imports. The Agency's intent was that once universal waste entered the United States, it should be subject to the same standards as any other universal waste. The final universal waste regulations therefore included import requirements in § 273.70. Under today's rule, the same requirements apply to universal waste lamps. Universal waste lamps that are imported from another country must be managed, upon entry into the country, in compliance with the appropriate universal waste requirements for transporters, handlers, or destination facilities, depending on the universal waste management activities conducted within the United States. To determine whether a handler importing universal waste is a small or large quantity handler, the universal waste imported from a foreign country is counted toward the quantity of waste accumulated as would any other universal waste. In addition, handlers managing universal waste that is imported from an Organization for Economic Cooperation and Development (OECD) country are subject to the requirements of 40 CFR part 262 subpart H.

The proposed provisions for exports of spent lamps were equivalent to the proposed provisions for exports of universal waste in the universal waste proposal. The requirements for handlers sending universal wastes (including spent hazardous waste lamps) to a foreign destination are found in § 273.20 for small quantity handlers and § 273.40 for large quantity handlers. Handlers exporting universal wastes are subject to the same provisions as generators of hazardous waste in subparts E and H of part 262. The exporting requirements for transporters of universal wastes to a foreign destination are found in § 273.56. Transporters may only accept shipments of universal wastes bound for foreign destinations that conform to the EPA Acknowledgment of Consent. They must ensure delivery of the universal waste to the facility designated by the person initiating the shipment.

The Agency notes that on April 12, 1996 (61 FR 16290), EPA revised the final universal waste regulations on importing and exporting of universal waste to reflect the Organization for Economic Cooperation and Development (OECD) Council Decision Concerning the Control of Transfrontier Movements of Wastes Destined for Recovery Operations (March 30, 1992). These revised regulations are today adopted for universal waste lamps.

H. Land Disposal Restriction Requirements

The proposed spent lamps rule did not include specific provisions on land disposal restrictions (LDR) requirements. However, the proposed and final universal waste regulations included a provision that exempted generators, transporters, and facilities that consolidated universal waste from the notification requirements in 40 CFR 268.7 and the storage prohibition in § 268.50. Destination facilities are subject to the full LDR program.

Pursuant to the LDR provisions of the Hazardous and Solid Waste Amendments of 1984 (HSWA), hazardous wastes listed or identified in accordance with RCRA section 3001 cannot be land disposed until they meet treatment standards (established by EPA), which are sufficient to minimize the short-and long-term threats potentially posed by land disposal. The regulations for the LDR program in 40 CFR part 268 apply to persons who generate or transport hazardous waste, as well as hazardous waste treatment, storage, and disposal facilities, unless they are specifically excluded from regulation in parts 261 or 268. Universal waste, as hazardous waste, remains subject to the requirements of the LDR program.

The applicability of the LDR requirements to universal waste lamps remains the same as the existing requirements for universal waste. Universal waste handlers and transporters must comply with the substantive requirements of the LDR program but are not required to comply with the administrative requirements (e.g., notification to all handlers of applicable treatment standards). The Agency believes that because of the unique nature of universal wastes (i.e., the wastes and treatment standards are easily identifiable), the substantive requirements would be sufficient to ensure that the goals of the LDR program are met for universal waste managed under part 273.

Destination facilities are required to comply with all of the part 268 LDR requirements for universal waste, including both the substantive and administrative requirements. Therefore, all universal waste must be treated or disposed of in compliance with LDR treatment standards, and the appropriate documentation regarding such compliance must be maintained by the destination facilities.

V. Discussion of Comments Received in Response to Proposed Rulemaking and Agency's Response

The following section describes the principal comments the Agency received in response to the proposed rulemaking on mercury-containing lamps. Complete comments and the Agency's responses are located in the docket for this rulemaking.

A. Universe of Lamps Covered Under the Final Rule

1. Summary of Proposed Scope and Definition

The Agency proposed to include within the scope of the universal waste rule those spent mercury-containing lamps that are hazardous because they exhibit the characteristic of toxicity. Common types of electric lamps that may contain sufficient concentrations of mercury (or other constituents) to cause them to be hazardous include, but are not limited to, incandescent, fluorescent, high intensity discharge, and neon lamps. In the proposed rule, the Agency also proposed definitions for "electric lamp" and "mercury-containing lamp" and requested comment on these definitions.

In addition, the Agency requested comment on whether the universal waste approach should address all types of spent lamps that fail the toxicity characteristic. The Agency also requested comment on whether and how frequently other types of spent lamps (such as incandescent and neon lamps) fail the toxicity characteristic test or exhibit other characteristics.

2. Summary of Comments Received

The Agency received a significant number of comments on the proposed definitions of "electric lamp" and "mercury-containing lamp." Many commenters requested that EPA clarify which type of lamps would be included within the scope of the final rule. Other commenters provided suggestions on the types of lamps to include within the definition. Many commenters confirmed that mercury-containing lamps include, but are not limited to, fluorescent lamps, mercury vapor lamps, high pressure sodium vapor lamps, and metal halide lamps.

Many commenters concurred with EPA's findings that mercury lamps consistently fail the toxicity characteristic test for mercury. A few commenters stated that many types of spent mercury-containing lamps (especially HID lamps and incandescent lamps) also frequently exhibit the toxicity characteristic for lead, generally because of lead soldered bases and

leaded glass. These commenters generally supported adding all hazardous waste lamps to the universal waste scheme, because they all fit within the universal waste criteria and it would be more convenient to have the same management requirements for all spent lamps. However, a few other commenters opposed adding lamps other than mercury-containing lamps to the universal waste system, mainly because the Agency lacked data on the effects of other constituents. One commenter claimed to have tested incandescent bulbs at one of its facilities and determined that all the bulbs failed the test for lead, and many failed for cadmium as well.

Some commenters believed that spent fluorescent lamps do not exhibit the toxicity characteristic for mercury under certain circumstances. One commenter, who conducted its own testing of fluorescent light bulbs, stated that test results were highly variable and concluded that the test results on lamps are inconclusive. Some commenters stated that the percentage of lamps that pass the test is rising and will continue to rise due to new technologies employed in lamp manufacturing.

Many commenters said that spent mercury-containing lamps meet the established criteria to be classified as a universal waste, and that managing lamps under the universal waste system will encourage recycling and keep lamps out of the municipal solid waste combustors and landfills. Commenters also stated that the universal waste system for lamps will provide a more consistent national management approach, since many states regulate lamps under regulatory programs that are more stringent than the proposed conditional exclusion option. Many states are also currently adding lamps to the scope of their universal waste programs or have already done so.

3. Agency's Response to Comments and Summary of Promulgated Standards

To simplify the proposed definitions, and in response to comments, the Agency is today finalizing a single definition of "lamp" or "universal waste lamp" which is derived from the proposed definitions of "electric lamp" and "mercury-containing lamp."

The Agency agrees with those commenters who believed that all hazardous waste lamps would be appropriately included in the universal waste program. These lamps appear to meet all of the criteria for inclusion in the universal waste rule (see Section III.C above), and EPA does not believe that the presence of other hazardous constituents (principally lead) in spent lamps should preclude such lamps from being managed as universal wastes. Hazardous waste batteries (including lead-acid batteries) are already part of the universal waste scheme, in part because EPA determined that the environmental risks associated with collection and transportation of these materials was relatively low and can be successfully controlled with the universal waste standards. Lead in hazardous waste lamps is largely found in endcaps and in the glass. Lead is not volatile or widely dispersible in the case of lamp breakage, and EPA also notes that the packaging requirements in today's rule will minimize breakage. For these reasons, the Agency is including all waste lamps that exhibit a characteristic in today's rulemaking.

With respect to incandescent lamps, we note that most of these lamps are generated by households or small facilities. Waste lamps that are household waste remain excluded from hazardous waste regulation under 40 CFR 261.4(b)(1). Facilities that generate less than 100 kilograms of hazardous waste in a calendar month, including any hazardous waste lamps that are not managed as universal waste, qualify as conditionally exempt small quantity generators subject to reduced regulation under 40 CFR 261.5. Spent lamps that do not exhibit any hazardous waste characteristic are not subject to Subtitle C regulation.

EPA also notes that waste lamps must be solid waste (i.e., discarded) before they are considered hazardous wastes and thus subject to regulation under RCRA. Section 273.5(c) describes when lamps become wastes. A used lamp becomes a waste on the date that it is discarded. An unused lamp becomes a waste on the date a handler decides to discard it.

B. Requirements for Handlers of Universal Waste Lamps

1. Prohibition on Treatment

a. Summary of Proposed Provision. The Agency requested comments on the same prohibitions for generators and consolidation points that were proposed in the February 11, 1993 universal waste proposal. The Agency had proposed that generators of hazardous waste lamps and consolidation points managing hazardous waste lamps be prohibited from diluting or disposing of the lamps and from treating them except in response to releases.

The Agency requested comments on management practices for lamps, the risks posed by these practices, and appropriate technical controls to minimize these risks which would not inhibit collection and proper management. The Agency requested comment on whether requirements should be included in the final rule to minimize mercury emissions during storage and transport of the lamps.

The definition of treatment under RCRA (40 CFR 260.10) includes any method, technique or process designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize such waste, or so as to recover energy or material resources from, or render such waste non-hazardous or less hazardous, safer to transport, store or dispose of, amenable for recovery, or storage, or reduced in volume. The crushing of spent mercury-containing lamps clearly falls within this definition. The Agency therefore requested comment on whether generators or consolidation points should be allowed to crush lamps intentionally to minimize volume for storage or shipment and which, if any, standards should be imposed to protect against mercury releases during crushing or the subsequent management of crushed lamps.

b. Summary of Comments Received. Several commenters stated that the Agency should maintain its proposed prohibition on waste treatment, including lamp crushing. These commenters said that lamp crushers are a significant source of mercury emissions and that many lamp recyclers prefer to receive whole lamps. Other commenters stated that generators should be allowed to separate, consolidate, and crush their own lamps. Many commenters supported allowing crushing if it were safely performed, and some commenters stated that crushing is necessary to reduce storage and transportation costs. Information submitted to the Agency on drum top crushing systems for lamps indicates that there is a wide range of air emissions of mercury from these units, depending on the type of controls, and that in some units emissions of mercury exceed the OSHA limit of 0.05 mg/m^3.

c. Agency's Response to Comments and Summary of Promulgated Standards. The Agency is adopting for universal waste lamps the prohibitions in the final universal waste rule promulgated on May 11, 1995. In general, as explained in the preamble to the universal waste rule (60 FR 25519), the Agency does not believe that universal waste handlers, who are not required to comply with the full Subtitle C management standards, should treat universal wastes. Therefore, under today's rule, both small and large quantity handlers of universal waste

lamps are prohibited from diluting or treating universal waste lamps except by responding to releases as provided in §§ 273.17 and 273.37. Prohibitions for small quantity handlers are found in § 273.11 and for large quantity handlers in § 273.31. The prohibition against treatment includes a prohibition of crushing of lamps. EPA is particularly concerned that uncontrolled crushing of universal waste lamps in containers meeting only the general performance standards of the universal waste rule would not sufficiently protect human health and the environment. As stated earlier, the prevention of mercury emissions during collection and transport is one of the principal reasons that the Agency selected the universal waste approach. Allowing uncontrolled crushing would be inconsistent with this goal.

The Agency is aware that a number of states have already added spent lamps to their universal waste programs. Available information indicates that some of these state programs prohibit crushing of spent lamps, but that at least some state programs may allow crushing under regulatory requirements designed to control emissions of hazardous constituents, particularly mercury. The Agency believes that some state programs may include standards for controlling emissions from mercury-containing lamps during crushing that could be equivalent, per RCRA Section 3006, to the federal prohibition.

Therefore, EPA will consider authorization of state programs that include provisions for controlling treatment or crushing of universal waste lamps, where the state program application includes a demonstration of equivalency to the federal prohibition. Factors the Agency would expect such an application to address include the effectiveness of technical requirements in controlling emissions of hazardous constituents, the level of interaction of regulated entities with the regulatory agency to ensure compliance with control requirements, and other factors demonstrating that the state regulatory program would be equivalent to the federal treatment prohibition.

2. Notification Requirement

a. Summary of Proposed Provision. The Agency proposed a notification requirement for generators and consolidation points (i.e., handlers of universal waste lamps) storing more than 35,000 spent lamps. The Agency proposed a numerical rather than a weight limit because lamp packaging (the cardboard boxes in which new replacement lamps are shipped) may constitute a large proportion of the total weight of a shipment or stored quantity of lamps. In addition, industry practice is generally to count lamps by number rather than by weight, calculated by multiplying the number of boxes of lamps in storage or in a shipment by the number of lamps per box. Since a full truckload of fluorescent lamps consists of approximately 35,000 lamps, the Agency proposed that universal waste handlers storing 35,000 lamps or more at any time be required to send a written notification of universal waste lamp storage to the applicable EPA Regional Administrator (or authorized state director) and obtain an EPA Identification Number.

b. Summary of Comments Received. The Agency received only a few comments on the proposed quantity limit for the notification requirement. One commenter suggested increasing the limit to 80,000 lamps. About half the commenters supported the general notification requirement for generators and consolidation points. Other commenters stated that the notification requirement was unnecessary and burdensome since generators may already possess an EPA identification number.

c. Agency's Response to Comments and Summary of Promulgated Standards. In the interest of consistency with the final universal waste rule, the Agency has decided that the 5,000 kilogram limit for the accumulation of all universal wastes will apply to all universal waste handlers (i.e., handlers of batteries, pesticides, mercury thermostats, and lamps). As explained in the preamble to that rule, the Agency believes that the total amount of universal waste at a handler's site is a better indicator of potential risk than the quantity of individual universal wastes being accumulated and handled at that site. EPA has determined that the 5,000 kilogram limit is appropriate for facilities handling universal waste lamps. The Agency believes that it is just as practical to set the notification requirement on the basis of a quantity (or weight) of waste accumulated as on the total number of items generated. Handlers can weigh the amount of waste as easily as they can count the total number of individual light bulbs accumulated, and can also subtract the weight of the packaging.

In response to commenters who said that the notification requirement will be burdensome, the Agency points out that those generators who have already notified EPA of their hazardous waste management activities are not required by the universal waste rule or today's final rule to re-notify EPA or obtain a new identification number. Prior to today's rulemaking, many lamps that are hazardous waste were required to be managed in accordance with all applicable Subtitle C hazardous waste management standards, including the RCRA notification provisions. Therefore, the notification requirement in today's rule is a new requirement only for generators of universal waste lamps that have never generated more than 100 kg of hazardous waste in a calendar month, but now accumulate more than 5,000 kg of universal waste lamps.

3. Prevention of Releases/Packaging Requirements

a. Summary of Proposed Provision. The Agency proposed that generators and consolidation points be required to manage hazardous waste lamps in a manner that minimizes lamp breakage. The proposal required that unbroken lamps be contained in packaging that will minimize breakage during normal handling conditions, and broken lamps be contained in packaging that will minimize releases of lamp fragments and residues.

The Agency requested comment on appropriate management controls for handlers of spent mercury-containing lamps that would minimize potential releases of mercury during collection, accumulation, storage and transport. Approaches suggested by the Agency included requiring performance standards for packaging to minimize lamps breakage. EPA expected that the packaging in which new replacement lamps are shipped from the manufacturer would frequently be reused to store and transport removed, used lamps. The Agency also suggested that requirements could be imposed on storing and transporting spent lamps that are inadvertently broken to prevent further mercury emissions. For example, 55-gallon steel drums or any enclosed container could be used to hold broken lamps for transportation to a recycling facility or a disposal site.

b. Summary of Comments Received. A number of commenters, including both lamp manufacturers and mercury lamp recycling facilities, supported container or packaging standards to minimize lamp breakage during accumulation, storage, and transport. Lamp recycling facilities in particular voiced a preference for spent lamps to be stored and transported in packaging that protects the spent lamps from potential breakage. Commenters representing recycling facilities pointed out that proper packaging will prevent releases of mercury to the environment before the lamps arrive at recycling facilities. These commenters stated that lamp

recycling facilities prefer to receive intact, unbroken lamps so that the lamps can be crushed in a closed, controlled environment at the recycling facility to allow for the capture and recycling of the available mercury. In addition, commenters pointed out that broken lamps and potential releases of mercury can endanger the safety of employees at the recycling facility. Commenters representing both lamp manufacturers and lamp recyclers recommended that intact lamps be stored in original cartons or specially designed containers (e.g., fiber containers with closed lids) that will protect the spent lamps from breakage. Commenters pointed out that unintentionally broken lamps should be stored and transported in closed drums or other puncture-proof containers that are sealed and properly labeled.

Although many commenters supported the promulgation of packaging or container requirements to reduce lamp breakage and reduce mercury emissions during storage and transport, other commenters stated that mercury emissions from broken lamps do not pose a threat to human health and the environment and that therefore protective package may not be necessary.

c. Agency's Response to Comments and Summary of Promulgated Standards. The Agency agrees with the commenters who stated that universal waste lamps should be stored and packaged in a way that minimizes lamp breakage. Recent studies (such as that performed by the Research Triangle Institute) show that significant releases of mercury during storage and transport can occur as a result of lamp breakage. EPA therefore disagrees with those commenters who stated that breakage presents no threat to human health and the environment. Today's final rule adds a subsection (d) for universal waste lamps to the universal waste management §§ 273.13 and 273.33 for small quantity handlers and large quantity handlers respectively. The Agency believes that these standards generally satisfy the concerns of commenters for environmental protection. The packaging provisions generally resemble the universal waste packaging requirements for mercury-containing thermostats.

The final rule requires universal waste handlers to manage universal waste lamps in a way that prevents releases of the lamps or the components of the lamps to the environment. Spent lamps must be packed to minimize breakage and packaging materials must be designed to contain potential releases due to breakage during transport. Universal waste lamps must be stored in containers or packages that remain closed, are structurally sound, adequate to prevent breakage, compatible with contents of lamps, and lack evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions. Examples of acceptable packaging could include placing the lamps evenly spaced in double or triple-ply cardboard containers with closed lids. Handlers also must contain any universal waste lamps that show evidence of breakage, leakage, or damage that could cause the release of mercury or other hazardous constituents to the environment. An example of such containment could include placing unintentionally broken lamps in closed wax fiberboard drums.

The Agency points out that in addition to these container and packaging provisions, universal waste handlers, including handlers of universal waste lamps, must comply with the provisions of 40 CFR 273.17 and 273.37 for responding to releases of universal waste. Handlers of universal waste must immediately contain all releases of universal waste and any residues from universal wastes. In addition, universal waste handlers must determine whether any material resulting from a release is a hazardous waste and, if so, must manage the hazardous waste in compliance with all applicable provisions of 40 CFR parts 260 through 268, as well as all other applicable statutory provisions.

4. Accumulation Time

a. Summary of Proposed Provision. In the proposed spent mercury-containing lamps rule, the Agency proposed to limit the time period in which handlers may accumulate such lamps on-site to one year following the date that a lamp becomes a waste. In addition, the Agency proposed several alternative ways to demonstrate compliance with this provision, and solicited comment on the alternatives. The proposed regulations required that generators and consolidation points either mark the container, mark the individual lamps, maintain an inventory system, or place lamps in a specific storage area while identifying the earliest date a lamp was placed in that area.

b. Summary of Comments Received. Generally, most commenters supported the proposed one-year storage time limitation and compliance demonstration requirements. A few commenters stated that each lamp should be dated as soon as it is removed from the lamp fixture to verify compliance with the one-year time limit. Some commenters stated that the one year storage limit was too long and increased the probability of broken lamps. These commenters suggested reducing the time limit to 180 days, 90 days, or 10 days. Other commenters stated that the one-year limit was too restrictive and did not allow for proper recovery, treatment, or disposal. One commenter suggested that a provision be included for case-by-case extensions to the storage time limit if necessary.

c. Agency's Response to Comments and Summary of Promulgated Standards. In today's rule, the Agency has decided to adopt the accumulation time limit requirements in the universal waste rule (§§ 273.15 and 273.35) for small and large quantity handlers of spent lamps. These requirements are similar to the provisions for the accumulation time limit in the proposed spent mercury-containing lamps rule. However, to remain consistent with the universal waste rule, handlers of universal waste lamps are allowed accumulation for more than one year if such accumulation is solely for accumulating such quantities of universal waste as are necessary to facilitate proper recovery, treatment, or disposal. For any accumulation longer than one year, the handler must be able to prove that such accumulation is solely for accumulating quantities necessary to facilitate proper recovery, treatment, or disposal (it is assumed that any accumulation up to one year is for this purpose). Notification to the EPA Regional Administrator of extended storage is not required; however, authorized states may have more stringent requirements.

The final rule requires that handlers of universal waste lamps comply with one of the following measures to demonstrate compliance with the accumulation time limit: mark the container holding the lamp, mark the individual lamp, maintain an inventory system, place the lamps in a specific storage area marked with the earliest date a lamp is placed in the area identified, or use any other method which demonstrates the length of time that the lamp has been accumulated from the date the lamp becomes a waste or is received.

In response to comments requesting a different accumulation time, the Agency believes that this issue was addressed in the final universal waste rule (60 FR 25526). In that rule, the Agency recognized that one year may not be sufficient for some handlers to accumulate enough universal waste to properly recover, treat, or dispose of the waste. By allowing accumulation for longer than one year, certain facilities will have the additional time they need

to facilitate proper recovery, treatment, or disposal. However, for any accumulation longer than one year, the burden of proof is on the handler to demonstrate that such accumulation is solely for accumulating quantities necessary to facilitate proper recovery, treatment, or disposal. Although the Agency agrees with commenters that it is possible to send spent lamps to a management facility in a shorter period of time, there does not appear to be a strong environmental justification for such a requirement.

Also in response to comments received, the Agency is not modifying the proposed demonstration requirement to show compliance with the accumulation time limit (40 CFR 273.15 and 273.35). Labeling each individual tube with the date that it is removed from the fixture is an acceptable means of identifying the accumulation time. However, the Agency believes that the other measures for showing compliance with the accumulation time limit are adequate and impose a smaller burden, particularly upon small quantity handlers.

5. Tracking of Shipments

a. Summary of Proposed Provision. The Agency requested comment on several ways to track off-site shipments of waste lamps. One suggested approach required the use of a hazardous waste manifest (and thus a hazardous waste transporter) for shipments from the last consolidation point to the destination facility. However, no manifests or other records (or hazardous waste transporters) would be required for shipments from generators to consolidation points or from generators to destination facilities. This approach is the same as that presented in the universal waste proposal. Another approach suggested by the Agency was to require that persons initiating and receiving shipments of spent lamps retain shipping papers documenting all shipments. The last approach suggested was requiring that persons claiming an exemption from the hazardous waste manifesting requirements must keep documentation to show that they qualified for such an exemption (specific shipment records need not be retained). In the proposed spent mercury-containing lamps rule, the Agency stated that because of the large volume of lamp shipments, such shipments are more likely than other universal wastes to be made directly from the generator to the destination facility. Records would be available for such shipments because destination facilities are already required under the hazardous waste regulations to maintain records, including the description and quantity of each hazardous waste received.

b. Summary of Comments Received. Some commenters opposed any tracking and recordkeeping requirements for the shipment of spent lamps. Several commenters said that the use of manifests for generators and consolidation points is not necessary to track the transportation of spent lamps, and that this requirement would create an unnecessary cost burden. These commenters believed that the increased costs and administrative burden of using manifests and hazardous waste transporters would discourage the collection of universal waste and would inhibit removal of these wastes from solid waste landfills and incinerators. Commenters suggested that the documentation requirements for generators and consolidation points should be flexible. However, many commenters, including some of those who opposed manifests, supported some form of tracking requirement to document the transport of universal wastes. These commenters argued that a less burdensome tracking requirement would not inhibit participation in collection programs. Further benefits might include reduction of liability for persons managing universal waste, increased enforceability of the universal waste system, and decreased potential for abuse of the streamlined universal waste requirements. Some commenters supported stringent tracking requirements, and a few stated that all consolidation points should be required to accompany lamp shipments with a manifest to protect generators from potential liability. One commenter stated that receiving facilities should keep documentation of all shipments received until the facility closes.

c. Agency's Response to Comments and Summary of Promulgated Standards. In the final universal waste rule, the Agency decided to require tracking only for large quantity handlers of universal waste. EPA believed that tracking was needed only in cases where facilities are handling larger quantities of universal waste, thus posing potentially greater environmental risk. The Agency decided not to impose these requirements on small quantity handlers of universal waste because it agreed with those commenters who said that the administrative burden of tracking would discourage retail establishments, service centers, and other "front line" collectors managing small quantities of waste from participating in collection programs, thus undermining the goal of the universal waste program. In addition, because these operations accumulate smaller quantities of universal wastes, they will generally pose less risk than facilities accumulating larger quantities.

EPA believes that these arguments apply with equal force to handlers of universal waste lamps. In today's rule, the Agency is therefore adopting the universal waste tracking requirements in part 273 for such lamps. The tracking provisions for small and large quantity handlers of universal waste are found in §§ 273.19 and 273.39, respectively. The universal waste rule includes a recordkeeping requirement to track waste shipments arriving at and leaving from large quantity handlers. Large quantity handlers are required to keep records of each shipment of universal waste lamps received and keep records of each shipment of lamps sent off-site. The record may take the form of a log, invoice, manifest, bill of lading, or other shipping document. The Agency believes that standard business records that are normally kept by businesses will fulfill this requirement. Records must be retained for at least three years from the date of receipt of a shipment of lamps or the date a shipment of lamps leaves the facility. Small quantity handlers are not required to keep records of shipments of universal waste lamps. The Agency believes that these requirements provide consistency with the current universal waste rule and adequately respond to concerns raised by commenters on the proposed rule, including those commenters requesting flexibility in recordkeeping requirements.

C. Storage Time Limitation for Transporters of Universal Waste Lamps

1. Summary of Proposed Provision

The proposed regulations for transporters of mercury-containing lamps were designed to be consistent with the proposed universal waste rule. The Agency proposed to allow transporters of universal waste lamps to store spent lamps for up to ten days at a transfer facility during the course of transportation. A transporter storing spent lamps for more than ten days at one location would have to comply with the appropriate universal waste handler requirements in managing the wastes accumulated at the accumulation site, in addition to complying with the applicable universal waste transporter requirements.

2. Summary of Comments Received

In response to the proposed universal waste rule, the Agency received

comments from two commenters who argued for a longer storage time limit for transporters. In addition, one commenter argued that the Agency should limit the total transportation time allowed for a waste to reach its destination, rather than impose a time limit for storing the waste during transport. The commenters, however, provided little information to justify a longer in-transit storage time limit. The Agency proposed the same accumulation time limit for transporters of universal waste lamps in the proposed rulemaking on mercury-containing lamps. The transporter accumulation time limit in the proposed universal waste rule was not significantly changed in the final universal waste rule, except to clarify that if the waste is stored for greater than 10 days, the transporter is subject to the standards for small or large quantity handlers.

3. Agency's Response to Comments and Summary of Promulgated Standards

Today's final rule adopts the storage time limit standards for transporters of universal waste lamps as promulgated in the universal waste rule. Under 40 CFR 273.53 of the universal waste regulations, transporters can store universal waste at a transfer facility for ten days or less. If the ten day limit is exceeded, the transporter becomes a universal waste handler and must comply with the applicable small or large quantity handler requirements under subparts B or C of part 273 while storing the universal waste. The Agency chose to retain the proposed 10-day accumulation limit for transporters of universal waste, consistent with the limit for transfer facilities handling other types of hazardous waste. In response to the commenter requesting that the Agency limit total transport time, rather than set a limit on the accumulation time at transfer facilities, EPA does not believe that a limit on total transportation time is practicable because of the extreme variation in the time needed to deliver shipments to different parts of the country. It is generally in the economic self-interest of transporters to make deliveries as quickly as possible. Delays in transport usually imply the likelihood of storage, so a limit on such storage seems the most efficient way to protect human health and the environment.

D. Destination Facility Requirements/ Lamp Recycling Facilities

1. Summary of Proposed Provision

Today's rule does not amend the existing standards for destination facilities receiving universal waste. Destination facilities remain subject to full subtitle C regulation, including all applicable requirements of parts 264, 265, 266, 268, 270, and 124. A recycling facility that does not store universal waste lamps before recycling them must comply with § 261.6(c)(2).

The existing requirements for destination facilities (i.e., hazardous waste treatment, storage, and disposal (TSD) facilities, or recycling facilities that do not store hazardous waste before recycling) are found in subpart E of part 273. Subpart E requires that destination facilities remain subject to full subtitle C regulation. These provisions are the same as those proposed in the proposed spent mercury-containing lamps rule.

The proposed spent mercury-containing lamps rule required that destination facilities recycling hazardous waste lamps prior storage must comply with 40 CFR 261.6(c)(2), which requires that facilities recycling universal waste obtain an EPA identification number. If a recycling facility stores hazardous waste lamps before recycling or performs treatment other than recycling. the facility is subject to full subtitle C hazardous waste management regulations, including the RCRA permitting requirements.

2. Summary of Comments Received

The Agency received many comments addressing the regulation of mercury lamp recycling facilities. Some commenters stated that mercury lamp recyclers are a potential threat to the environment because these facilities lack substantive regulation. A number of commenters suggested that the Agency implement standards for recycling facilities, and suggested best management practices that would reduce releases of mercury into the environment from these facilities.

3. Agency's Response to Comments and Summary of Promulgated Standards

Today's rule does not amend the existing standards for recycling facilities receiving universal waste. In general, destination facilities, including recycling facilities, remain subject to full hazardous waste regulation. A recycling facility that does not store universal waste lamps prior to recycling the lamps is subject only to 40 CFR 261.6(c)(2).

The Agency believes that changing requirements for destination facilities (including lamp recyclers) is beyond the scope of today's regulation, which addresses the generation and collection of universal waste lamps rather than final treatment, disposal, or recycling. EPA believes that with adequate state oversight, universal waste lamps can be safely recycled, allowing the mercury and other economically viable materials to be reclaimed. Safe recycling should ensure that residuals from recovery operations are managed in accordance with all applicable solid and hazardous waste management requirements. Residuals that exhibit a characteristic of hazardous waste must be managed as hazardous waste.

The Agency received no comments concerning the provisions for universal waste destination facilities, other than those addressing lamp recycling facilities. Therefore, today's rule does not amend the existing standards for treatment and disposal facilities receiving universal waste. Treatment and disposal facilities that receive universal waste lamps are subject to the same standards that apply to permitted or interim status hazardous waste treatment, storage, and disposal facilities. These standards include notification requirements, general facility standards, unit-specific management standards, and permitting requirements. The Agency notes that facilities that store universal waste lamps, but do not treat, dispose, or recycle them, are considered handlers and not destination facilities.

E. Sunset Provision

1. Summary of Proposed Provision

In the proposed lamps rule, the Agency requested comments on whether to include a three to five-year sunset provision in the final rule. A sunset provision would require EPA to re-evaluate the effectiveness of the universal waste system in addressing the disposal of lamps after three to five years. At that time, the Agency could decide whether fewer controls or more controls were needed to maintain the safe management of lamps.

2. Summary of Comments Received

More than half of the comments received generally supported a three to five year sunset provision. Commenters stated that a sunset provision would allow the Agency to examine any new information on lamp management and the fate and transport of mercury, and re-evaluate options as necessary.

Other commenters did not support the proposed three to five year sunset provision. Commenters stated that a sunset provision or other deadline was not necessary and that the Agency already had the authority to re-evaluate the rule at any time.

3. Agency's Response to Comments and Summary of Promulgated Standards

Today's final rule does not include a sunset provision. The Agency believes that the data and information provided to the Agency, along with the Agency's own studies and analyses (available in the docket for this rulemaking) provide adequate evidence of the behavior of mercury in the environment and potential releases of mercury to support today's final rule. The Agency notes, however, that if additional information about the behavior of mercury becomes available in the future, the Agency may re-evaluate the standards promulgated in today's final rule.

VI. State Authority

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA hazardous waste program within the State. Following authorization, EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the federal program in that State. The federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated or enacted, the State was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized State until the State adopted the federal requirements as State law.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. EPA is directed by the statute to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA related provisions as State law to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the federal program. See also 40 CFR 271.1(I). Therefore, authorized States can, but do not have to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent.

B. Effect on State Authorization

Today's rule is not promulgated pursuant to HSWA. Therefore the rule is applicable on the effective date only in those States that do not have final RCRA authorization. Today's rule is also less stringent than the current federal program. Because States are not required to adopt less stringent regulations, they do not have to adopt the universal waste regulations for spent lamps. A number of States have added spent lamps to their universal waste programs or are in the process of doing so. While these actions are specifically allowed under the universal waste rule, if a State's standards for spent lamps are less stringent than those in today's rule, the State will need to amend its regulations to make them equivalent to today's standards and pursue authorization.

As noted earlier, EPA recognizes that States have been proactive in adopting universal waste standards for spent lamps. Some of these standards allow crushing of lamps under certain conditions. Although today's rule does not provide for crushing, EPA believes that State programs could have standards for crushing which will be equivalent to the federal rules and thus appropriate for authorization. EPA also believes that this flexibility will allow for a minimal level of disruption to existing State programs. The Agency will determine at the time of authorization whether a State regulation that allows crushing is equivalent to the federal standard.

C. Interstate Transport

Due to the fact that not all States will choose to seek authorization for today's rulemaking, there may be only a few destination facilities that will accept and manage universal waste lamps. The Agency believes that it is important to explain how the regulations will apply because interstate transportation will be necessary for these wastes.

First, a waste which is subject to the universal waste regulations may be sent to a State, or through a State, where it is not a universal waste and where it would be subject to the full hazardous waste regulations. In this scenario, for the portion of the trip through the originating State, and any other States where the waste is a universal waste, neither a transporter with an EPA identification number per 40 CFR 263.11 (hazardous waste transporter) nor a manifest would be required. However, for the portion of the trip through the receiving State, and any other States that do not consider the waste to be a universal waste, the transporter must have a manifest, and must move the waste in compliance with 40 CFR Part 263. In order for the final transporter and the receiving facility to fulfill their requirements concerning the manifest (40 CFR 263.20, 263.21, 263.22; 264.71, 264.72, 264.76 or 265.71, 265.72, and 265.76), the initiating facility should complete a manifest and forward it to the first transporter to travel in a State where the waste is not a universal waste. The receiving facility must then sign the manifest and send a copy to the initiating facility. EPA recommends that the initiating facility note in block 15 of the manifest (Special Handling Instructions and Additional Information) that the wastes are covered under the universal waste regulations in the initiating State but not in the receiving facility's State.

Second, a hazardous waste generated in a State which does not regulate it as a universal waste may be sent to a State where it is a universal waste. In this scenario, the waste must be moved by a hazardous waste transporter while the waste is in the generator's State or any other States where it is not a universal waste. The initiating facility would complete a manifest and give copies to the transporter as required under 40 CFR 262.23(a). Transportation within the receiving State and any other States that regulate the waste as a universal waste would not require a manifest and need not be conducted by a hazardous waste transporter. However, it is the initiating facility's responsibility to ensure that the manifest is forwarded to the receiving facility by any non-hazardous waste transporter and sent back to the initiating facility by the receiving facility (see 40 CFR 262.23 and 262.42). EPA recommends that the generator note in block 15 of the manifest (Special Handling Instructions and Additional Information) that the waste is covered under the universal waste regulations in the receiving facility's State but not in the generator's State.

Third, a waste may be transported across a State in which it is subject to the full hazardous waste regulations although other portions of the trip may be from, through, and to States in which it is covered under universal waste regulations. Transport through the State must be conducted by a hazardous waste transporter and must be accompanied by a manifest. In order for the transporter to fulfill its requirements concerning the manifest (Subpart B of Part 263), the initiating facility must complete a manifest as required under the manifest procedures and forward it to the first transporter to travel in a State where the waste is not a universal waste. The transporter must deliver the manifest to, and obtain the signature of, either the next transporter or the receiving facility.

As noted previously, States are not required to adopt today's rule. However, EPA strongly encourages them to do so. As more States add spent lamps in their universal waste program, not only will this assist in achieving the most benefits of the universal waste program, it will also reduce the complexity of interstate transport of these universal wastes.

VII. Regulatory Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735), the Agency must determine whether this regulatory action is "significant" and therefore subject to formal review by the Office of Management and Budget (OMB) and to the requirements of the Executive Order, which include assessing the costs and benefits anticipated as a result of the proposed regulatory action. The Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Pursuant to the terms of Executive Order 12866, the Agency has determined that today's final rule is a significant regulatory action because this final rule contains novel policy issues. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record. Although this rule is not "economically significant", the Agency has prepared the supporting analysis: Modification of the Hazardous Waste Program: Hazardous Waste Lamps—Final Economic Assessment (Economic Assessment). The findings from this analysis are presented below.

B. Economic Assessment

The Economic Assessment conducted in support of today's final rule analyzed impacts associated with this final universal waste action, plus the primary alternative of promulgating a conditional exclusion for lamps. Although the final rule includes all hazardous waste lamps in the universal waste program, this Economic Assessment addresses only mercury-containing fluorescent lamps. The Agency estimates that non-fluorescent lamps represent approximately 0.8 to 1.7 percent of the total universe of lamps addressed under today's rulemaking. The comparatively negligible proportion of other hazardous waste lamps is not expected to appreciably affect the impact estimates presented in this analysis.

Fluorescent lamps contain a small amount of mercury that emits light when stimulated with electrical current. When a fluorescent lamp breaks, the mercury in the lamp is released into the environment and may cause health risks, primarily through consumption of fish. Neurotoxicity is the health effect of greatest concern for humans; death, reduced reproductive success, impaired growth and development, and behavioral abnormalities are effects of concern to fish, birds, and mammals. Lamp mismanagement scenarios indicate that, without government intervention, market failures will likely lead to disposal activities resulting in unnecessarily high releases of mercury to the environment.

Prior to today's final action, spent lamps that failed the toxicity characteristic leaching procedure (TCLP) test were automatically considered hazardous wastes under RCRA and subject to full Subtitle C management requirements, unless the lamps are generated by a household or a conditionally-exempt small quantity generated. EPA recognized the confusion and mismanagement patterns historically associated with maintaining spent hazardous waste lamps within the Subtitle C system. The Agency is taking today's final action of adding spent lamps to the scope of universal waste regulations in an effort to streamline the current regulations governing the management of such lamps, increase lamp management efficiency, and ultimately to cause a potential reduction in aggregate mercury emissions. The Agency's final action of adding spent lamps to the scope of the universal waste system, however, is not expected to completely determine how these lamps will be managed in individual states. States already have the option of including lamps within their universal waste programs. Furthermore, states that have not chosen to adopt universal waste programs, or have not included lamps within their universal waste programs, are not obligated to do so in response to EPA's decision.

The universal waste regulations include requirements for the proper packaging of spent lamps, storage of spent lamps, EPA notification, and responses to releases. EPA selected this action over the other proposed option which would have been based on a conditional exclusion (CE). The CE would have excluded spent mercury-containing lamps from regulation as hazardous waste. The addition of spent lamps to the universal waste regulations is considered a deregulatory action and imposes fewer requirements on generators and transports of spent lamps than the hazardous waste management standards under RCRA Subtitle C. The proposed conditional exclusion would have been deregulatory as well.

The Economic Assessment conducted in support of today's final rule analyzed impacts associated with the final universal waste action, plus the primary alternative of promulgating a conditional exclusion for lamps. Two different compliance scenarios are examined in the baseline, and under each option in an effort to incorporate alternative management practices. The first (high) compliance scenario assumes 100 percent compliance under all regulatory schemes. The second (low) compliance scenario assumes 20 percent compliance under a scenario where handlers of spent mercury-containing lamps are subject to full Subtitle C, 80 percent compliance under the universal waste option, and 90 percent compliance under the conditional exclusion option. The reader should refer to the report: Mercury Emissions From The Disposal of Fluorescent Lamps—Revised Model, Final Report, for a detailed discussion of estimated compliance rates. This report is available in the RCRA docket established for today's action.

The total national annualized costs of compliance and disposal under the baseline are estimated at $80.01 million

and $54.37 million under the high and low compliance scenarios, respectively. Under the universal waste final action these costs are projected at $78.52 million under the high compliance scenario and $56.14 million for the low compliance scenario. In the high compliance scenario, the costs under full Subtitle C and universal waste are close because transportation and disposal costs, which account for approximately 76 percent of total costs, are virtually the same. Under the low compliance scenario, costs under the universal waste final action are higher than under the full Subtitle C baseline because of the higher compliance rate assumed under the universal waste scheme. While costs could increase for some non-exempt entities under the universal waste approach, this would be the result of non-compliance in the baseline. These costs would not appropriately be attributable to this rulemaking. Compliance and disposal costs under the conditional exclusion option also were examined. Aggregate annualized costs under the conditional exclusion option are estimated at $73.90 million and $52.60 million for the high and low compliance scenarios, respectively.

The Economic Assessment also examined economic impacts on affected facilities. EPA's final universal waste action is projected to result in cost savings to affected generators under the high compliance scenario. Adverse impacts on generators, therefore, are not anticipated. However, actual costs to some generators may increase under the low compliance scenario. The magnitude of the potential cost increase under this scenario, however, would not result in meaningful impacts on affected generators. In addition to generators, the Assessment also examined potential economic impacts on consolidation and recycling facilities. The Agency found that few, if any, spent fluorescent lamp consolidation facilities exist at present or are likely to exist in the future as independent economic entities. Impacts on consolidated facilities dedicated to spent fluorescent lamps, therefore, were not examined. Recycling facilities may benefit indirectly due to today's final, which may result in additional revenues for firms owning or operating recycling facilities.

The Economic Assessment projected changes in total nationwide mercury emissions resulting from the universal waste final action and the conditional exclusion option. Average annual emissions corresponding to the management of spent mercury-containing fluorescent lamps (four-foot equivalents) were projected over the 1998 through 2007 period. Under the high compliance scenario, average annual baseline emissions were estimated at 790.4 kilograms. Emissions under the universal waste final action were projected at 790.5 kilograms, resulting in an incremental increase of 0.1 kilograms, or 0.013 percent above the baseline. Emissions under the conditional exclusion option are projected at 798.4 kilograms, or 1.012 percent beyond the baseline. Under the low compliance scenario, average annual baseline emissions are estimated at 822 kilograms. The universal waste final action is projected to result in average annual emissions of 819.2 kilograms. This is a reduction of 2.8 kilograms, or 0.341 percent. Emissions under the conditional exclusion option increase by 10.5 kilograms, or 1.277 percent beyond the baseline.

The examination of cost-effectiveness may help put the above emission increments into perspective. Cost-effectiveness allows for the direct comparison of costs, or cost savings on a per kilogram basis. Under the high compliance scenario, shifting from the baseline to the universal waste final action is projected to result in cost savings of $10.5 million per additional kilogram of mercury emitted. This implies that it would be very expensive, on a per kilogram basis, to keep emissions low by holding to a high compliance baseline. Under the low compliance scenario, shifting from the baseline to the universal waste final action is projected to result in a cost increase of $0.63 million per kilogram of mercury reduced. Furthermore, today's final action is projected to cut emissions by over thirteen kilograms per year compared to the conditional exclusion option, at a cost of approximately $0.27 million per kilogram.

For more information on the cost and emissions impacts associated with today's final rule see the EPA report: Modification of The Hazardous Waste Program: Hazardous Waste Lamps—Economic Assessment. This report is available from the RCRA docket established for this action.

C. Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996) whenever an Agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. The following discussion explains EPA's determination.

The small entity analysis conducted for today's final action indicates that the addition of spent lamps to the universal waste system would generally result in savings to affected entities relative to baseline requirements. Under the full compliance scenario, the rule is not expected to result in a net cost to any affected entity. Thus, adverse impacts are not anticipated. Costs could increase for entities that are not complying with current requirements, but even these costs (which are not properly attributable to the current rulemaking) would not be expected to result in significant impacts on a substantial number of small entities. Based on the foregoing discussion, I hereby certify that this rule will not have a significant adverse economic impact on a substantial number of small entities. Consequently, the Agency has determined that preparation of a formal Regulatory Flexibility Analysis is unnecessary.

For more information on small entity impacts potentially associated with today's final rule see the EPA report: Modification of the Hazardous Waste Program: Hazardous Waste Lamps—Regulatory Flexibility Screening Analysis. This report is available from the RCRA docket established for this action.

D. Environmental Justice

Under Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," as well as through EPA's April 1995 "Environmental Justice Strategy, OSWER Environmental Justice Task Force Action Agenda Report", and the National Environmental Justice Advisory Council, EPA has undertaken to incorporate environmental justice into its policies and programs. EPA is committed to addressing environmental justice concerns, and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population,

regardless of race, color, national origin, or income, bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities, and all people live in clean and sustainable communities. To address this goal, EPA conducted a qualitative analysis of the environmental justice issues under this final rule. Potential environmental justice impacts are identified consistent with the EPA's Environmental Justice Strategy and the OSWER Environmental Justice Action Agenda. In addition, public comments received on the 1994 proposal that relate to environmental justice were reviewed for this analysis.

As mentioned before, the primary concern regarding management of spent mercury-containing lamps is the air emissions as a result of crushing and accidental breakage during transport, lamp management, or disposal. Mercury air emissions can have human health effects through direct contact or indirect human contact by consuming fish and shellfish, or through contamination of drinking water (perhaps from inadequate disposal measures).

From a direct exposure standpoint, the transient nature of mercury air emissions results in less concern to the location of minority and low-income populations than might be expected. Since atmospheric mercury can travel thousands of miles (and beyond U.S. borders), an environmental justice analysis does not require a detailed geographic analysis. However, populations immediately surrounding transportation, incineration, recycling, crushing, or disposal facilities may be exposed to a higher concentration of emissions than those populations living further away. If these types of facilities are located more often in communities characterized by low-income or minority populations, there may be disproportionate impacts to those populations from the promulgation of today's final rule. If the location of such facilities is random with respect to race or income, disproportionate impacts could be said not to exist. The low compliance scenario is examined for the environmental justice analysis.

Of the indirect exposure pathways, the ingestion of mercury-contaminated fish and shellfish has been shown to be of the highest concern due to mercury's propensity to bioaccumulate in the aquatic environment. This can present an environmental justice issue since the bulk of subsistence fisher populations consist of low-income people. These subsistence fisher populations rely on locally-caught fish as an inexpensive source of protein or due to cultural reasons. However, since today's rule is expected to improve compliance, and thus adequate management of mercury-containing lamps, it is expected that there will be a positive impact on these populations, with less mercury available to contaminate aquatic environments.

No disproportional impacts for low-income or minority communities are expected as a result of the final action for the following reasons:

(1) The environmental impact of the final universal waste action is small. The 10-year modeling period projects a net decrease in emissions (low compliance scenario) at approximately 30 kilograms under the universal waste final action. The conditional exclusion option would have shown an increase (approximately 105 kg) in mercury emissions over 10 years. In either case, the wide distribution of mercury emissions is unlikely to create significant impacts on any particular community.

(2) The distribution of the municipal waste combustors and recycling facilities throughout minority and/or low income counties in the United States does not suggest any distributional pattern around communities of concern. Lamps crushing, legal or illegal, is difficult to measure because any building in any area is a potential source. Specific impacts on low income or minority communities, therefore, are undetermined. The Agency believes that emissions during transportation would not be a major contributor to communities of concern through which lamps may be transported. Any lamps broken during transport would be contained in the packaging. The Agency recognizes, however, the potential for some increased risk to transportation workers. Overall, no disproportional impacts to minority and/or low income communities are expected.

For more information on the environmental justice analysis conducted in support of today's final rule see the EPA report: Modification of the Hazardous Waste Program: Hazardous Waste Lamps—Economic Assessment. This report is available from the RCRA docket established for this action.

E. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, though OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rule does not establish technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

F. Executive Order 13045—Children's Health

"Protection of Children From Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that EPA determines (1) "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must: Evaluate the environmental health or safety effects of the planned rule on children; and explain the environmental health or safety effects of the planned rule on children; and explain why the planned regulation is preferable to other potential effective and reasonably feasible alternatives considered by the Agency. We believe this final rule is not subject to E.O. 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) because it is intended to be deregulatory. However, an analysis of the potential effects of this action on children's health in the spirit of the Executive Order and consistent with the Agency's ongoing concern with children's health, is included in section II of today's preamble.

G. Regulatory Issues—Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for the proposed and final rules with "federal mandates" that may result in expenditures by state, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating a rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA established any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enable officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The Agency's analysis of compliance with the Unfunded Mandates Reform Act (UMRA) of 1995 found that today's final rule imposes no enforceable duty on any State, local or tribal government or the private sector. This final rule contains no federal mandates (under the regulatory provisions of Title II of the UMRA) for state, local, or tribal governments or the private sector. In addition, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. The Act generally excludes from the definition of "federal intergovernmental mandate" (in sections 202, 203, and 205) duties that arise from participation in a voluntary federal program. Adopting today's final action, because it is less stringent, is optional. The universal waste final action, therefore, could be interpreted as voluntary and not subject to the Unfunded Mandates Analysis requirement. Furthermore, today's final action is deregulatory and will not impose incremental costs in excess of $100 million to the private sector, or to state, local, or tribal governments in the aggregate.

H. Paperwork Reduction Act

The Information Collection Request (ICR) detailing the information collection requirements associated with today's rule will be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* A copy of the ICR document (ICR No. 1699.02) may be obtained from Sandy Farmer by mail at OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., SW.; Washington, DC 20460, by e-mail at farmer.sandy@epamail.epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the Internet at http://www.epa.gov.icr. The information requirements are not effective until OMB approves them.

The information requirements established for this action, and identified in the Information Collection Request (ICR) supporting today's final rulemaking, are largely a self-implementing process. This process will ensure that: (i) Handlers of lamp wastes are held accountable to the universal waste requirements; and (ii) state inspectors can verify compliance when needed. For example, the universal waste standards require LQHUWs and SQHUWs to demonstrate the length of time that the lamp waste has been accumulated from the date it was received or became a waste. The standards also require LQHUWs and destination sites to keep records of all shipments received and sent. Further, the standards require waste handlers to notify EPA when needed (e.g., notification of illegal shipment).

EPA will use the collected information to ensure that lamp waste is being managed in a protective manner. These data aid the Agency in tracking lamp waste shipments and identifying improper management practices. In addition, information kept in facility records helps handlers and destination sites to ensure that they and other facilities are managing lamp wastes properly. Section 3007(b) of RCRA and 40 CFR part 2, subpart B, which define EPA's general policy on the public disclosure of information, contain provisions for confidentiality. However, no questions of a sensitive nature are included in any of the information collection requirements associated with today's action.

EPA has carefully considered the burden imposed upon the regulated community by the regulations. EPA is confident that those activities required of respondents are necessary and, to the extent possible, has attempted to minimize the burden imposed. EPA believes strongly that if the minimum requirements specified under the regulations are not met, neither the facilities nor EPA can ensure that hazardous waste lamps are being managed in a manner protective of human health and the environment.

The aggregate burden to respondents over the three-year period covered by this ICR is estimated at 385,461 hours, with a cost of approximately $15,247,245. The aggregate burden to the Agency is estimated at 5,583 hours, with a cost of $320,910. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

I. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that

significantly or uniquely affect their communities."

EPA has determined that the requirements of Executive Order 13084 do not apply to today's final rule because the rule does not significantly or uniquely affect Indian tribal governments or communities. Furthermore, the rule does not impose any enforceable duties on these entities, and is not likely to impose substantial direct compliance costs on tribal governments and their communities.

J. Executive Order 12875

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create a mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

VIII. Submission to Congress and General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A "major rule" cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective six months from the date of publication.

List of Subjects

40 CFR Part 260

Administrative practice and procedure, Confidential business information, Hazardous materials, Recycling, Reporting and recordkeeping, Waste treatment or disposal.

40 CFR Parts 261

Hazardous materials, Recycling, Waste treatment and disposal.

40 CFR Parts 264 and 265

Hazardous materials, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Waste treatment and disposal.

40 CFR Part 268

Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Hazardous materials, Packaging and containers, Reporting and recordkeeping requirements, Waste treatment and disposal.

40 CFR Part 273

Environmental protection, Hazardous materials, Packaging and containers.

Dated: June 28, 1999.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations, parts 260 261, 264, 265, 268, 270 and 273, are amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

Subpart B—Definitions

2. Section 260.10 is amended by adding in alphabetical order the definition of "Lamp" and by revising the definition of "Universal Waste" to read as follows:

§ 260.10 Definitions.

* * * * *

Lamp, also referred to as "universal waste lamp", is defined as the bulb or tube portion of an electric lighting device. A lamp is specifically designed to produce radiant energy, most often in the ultraviolet, visible, and infra-red regions of the electromagnetic spectrum. Examples of common universal waste electric lamps include, but are not limited to, fluorescent, high intensity discharge, neon, mercury vapor, high pressure sodium, and metal halide lamps.

* * * * *

Universal Waste means any of the following hazardous wastes that are managed under the universal waste requirements of part § 273 of this chapter:

(1) Batteries as described in § 273.2 of this chapter;

(2) Pesticides as described in § 273.3 of this chapter;

(3) Thermostats as described in § 273.4 of this chapter; and

(4) Lamps as described in § 273.5 of this chapter.

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

3. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

Subpart A—General

4. Section 261.9 is amended by revising paragraphs (b) and (c), and adding paragraph (d) to read as follows:

§ 261.9 Requirements for universal waste.

* * * * *

(b) Pesticides as described in § 273.3 of this chapter;

(c) Thermostats as described in § 273.4 of this chapter; and

(d) Lamps as described in § 273.5 of this chapter.

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

5. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

Subpart A—General

6. Section 264.1 is amended by revising paragraphs (g)(11)(ii) and (g)(11)(iii) and adding a new paragraph (g)(11)(iv) to read as follows:

§ 264.1 Purpose, scope, and applicability.

* * * * *

(g) * * *

(11) * * *

(ii) Pesticides as described in § 273.3 of this chapter;
(iii) Thermostats as described in § 273.4 of this chapter; and
(iv) Lamps as described in § 273.5 of this chapter.
* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE AND DISPOSAL FACILITIES

7. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, and 6937.

Subpart A—General

8. Section 265.1 is amended by revising paragraphs (c)(14)(ii) and (c)(14)(iii) and adding a new paragraph (c)(14)(iv) to read as follows:

§ 265.1 Purpose, scope and applicability.

* * * * *
(c) * * *
(14) * * *
(ii) Pesticides as described in § 273.3 of this chapter;
(iii) Thermostats as described in § 273.4 of this chapter; and
(iv) Lamps as described in § 273.5 of this chapter.
* * * * *

PART 268—LAND DISPOSAL RESTRICTIONS

9. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

Subpart A—General

10. Section 268.1 is amended by revising paragraphs (f)(2) and (f)(3) and adding a new paragraph (f)(4) to read as follows:

§ 268.1 Purpose, scope, and applicability.

* * * * *
(f) * * *
(2) Pesticides as described in § 273.3 of this chapter;
(3) Thermostats as described in § 273.4 of this chapter; and
(4) Lamps as described in 40 CFR 273.5.
* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

11. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

Subpart A—General Information

12. Section 270.1 is amended by revising paragraphs (c)(2)(viii)(B) and (c)(2)(viii)(C) and adding a new paragraph (c)(2)(viii)(D) to read as follows:

§ 270.1 Purpose and scope of these regulations.

* * * * *
(c) * * *
(2) * * *
(viii) * * *
(B) Pesticides as described in § 273.3 of this chapter;
(C) Thermostats as described in § 273.4 of this chapter; and
(D) Lamps as described in § 273.5 of this chapter.
* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

13. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

Subpart A—General

14. Section 273.1 is amended by revising paragraphs (a)(2) and (a)(3) and adding a new paragraph (a)(4) to read as follows:

§ 273.1 Scope.

(a) * * *
(2) Pesticides as described in § 273.3;
(3) Thermostats as described in § 273.4; and
(4) Lamps as described in § 273.5.
* * * * *

15. Section 273.2 is amended by revising paragraphs (a)(1), (b)(2), and (b)(3) to read as follows:

§ 273.2 Applicability—batteries.

(a) * * *
(1) The requirements of this part apply to persons managing batteries, as described in § 273.9, except those listed in paragraph (b) of this section.
* * * * *
(b) * * *
(2) Batteries, as described in § 273.9, that are not yet wastes under part 261 of this chapter, including those that do not meet the criteria for waste generation in paragraph (c) of this section.
(3) Batteries, as described in § 273.9, that are not hazardous waste. A battery is a hazardous waste if it exhibits one or more of the characteristics identified in part 261, subpart C of this chapter.
* * * * *

16. Section 273.3 is amended by revising paragraph (a) introductory text to read as follows:

§ 273.3 Applicability—pesticides.

(a) *Pesticides covered under this part 273.* The requirements of this part apply to persons managing pesticides, as described in § 273.9, meeting the following conditions, except those listed in paragraph (b) of this section:
* * * * *

17. Section 273.4 is amended by revising paragraph (a) to read as follows:

§ 273.4 Applicability—mercury thermostats.

(a) *Thermostats covered under this part 273.* The requirements of this part apply to persons managing thermostats, as described in § 273.9, except those listed in paragraph (b) of this section.
* * * * *

18. Section 273.5 is revised to read as follows:

§ 273.5 Applicability—Lamps.

(a) *Lamps covered under this part 273.* The requirements of this part apply to persons managing lamps as described in § 273.9, except those listed in paragraph (b) of this section.
(b) *Lamps not covered under this part 273.* The requirements of this part do not apply to persons managing the following lamps:
(1) Lamps that are not yet wastes under part 261 of this chapter as provided in paragraph (c) of this section.
(2) Lamps that are not hazardous waste. A lamp is a hazardous waste if it exhibits one or more of the characteristics identified in part 261, subpart C of this chapter.
(c) *Generation of waste lamps.* (1) A used lamp becomes a waste on the date it is discarded.
(2) An unused lamp becomes a waste on the date the handler decides to discard it.

§ 273.6 [Redesignated as § 273.9]

§§ 273.6 and 273.7 [Reserved]

19. Section 273.6 is redesignated as § 273.9 and §§ 273.6 and 273.7 are added and reserved.

20. Section 273.8 is added to read as follows:

§ 273.8 Applicability—household and conditionally exempt small quantity generator waste.

(a) Persons managing the wastes listed below may, at their option, manage them under the requirements of this part:
(1) Household wastes that are exempt under § 261.4(b)(1) of this chapter and

are also of the same type as the universal wastes defined at § 273.9; and/or

(2) Conditionally exempt small quantity generator wastes that are exempt under § 261.5 of this chapter and are also of the same type as the universal wastes defined at § 273.9.

(b) Persons who commingle the wastes described in paragraphs (a)(1) and (a)(2) of this section together with universal waste regulated under this part must manage the commingled waste under the requirements of this part.

21. Newly designated § 273.9 is amended by adding, in alphabetical order, the definition of "Lamp" and revising the definitions of "Large Quantity Handler of Universal Waste," "Small Quantity Handler of Universal Waste" and "Universal Waste" to read as follows:

§ 273.9 Definitions.

* * * * *

Lamp, also referred to as "universal waste lamp" is defined as the bulb or tube portion of an electric lighting device. A lamp is specifically designed to produce radiant energy, most often in the ultraviolet, visible, and infra-red regions of the electromagnetic spectrum. Examples of common universal waste electric lamps include, but are not limited to, fluorescent, high intensity discharge, neon, mercury vapor, high pressure sodium, and metal halide lamps.

* * * * *

Large Quantity Handler of Universal Waste means a universal waste handler (as defined in this section) who accumulates 5,000 kilograms or more total of universal waste (batteries, pesticides, thermostats, or lamps, calculated collectively) at any time. This designation as a large quantity handler of universal waste is retained through the end of the calendar year in which 5,000 kilograms or more total of universal waste is accumulated.

* * * * *

Small Quantity Handler of Universal Waste means a universal waste handler (as defined in this section) who does not accumulate 5,000 kilograms or more total of universal waste (batteries, pesticides, thermostats, or lamps, calculated collectively) at any time.

* * * * *

Universal Waste means any of the following hazardous waste that are subject to the universal waste requirements of this part 273:

(1) Batteries as described in § 273.2

(2) Pesticides as described in § 273.3

(3) Thermostats as described in § 273.4; and

(4) Lamps as described in § 273.5.

* * * * *

Subpart B—Standards for Small Quantity Handlers of Universal Waste

22. Section 273.10 is revised to read as follows:

§ 273.10 Applicability.

This subpart applies to small quantity handlers of universal waste (as defined in 40 CFR 273.9).

23. Section 273.13 is amended by adding a new paragraph (d) to read as follows:

§ 273.13 Waste Management.

* * * * *

(d) *Lamps.* A small quantity handler of universal waste must manage lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) A small quantity handler of universal waste must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions.

(2) A small quantity handler of universal waste must immediately clean up and place in a container any lamp that is broken and must place in a container any lamp that shows evidence of breakage, leakage, or damage that could cause the release of mercury or other hazardous constituents to the environment. Containers must be closed, structurally sound, compatible with the contents of the lamps and must lack evidence of leakage, spillage or damage that could cause leakage or releases of mercury or other hazardous constituents to the environment under reasonably foreseeable conditions.

24. Section 273.14 is amended by adding a new paragraph (e) to read as follows:

§ 273.14 Labeling/marking.

* * * * *

(e) Each lamp or a container or package in which such lamps are contained must be labeled or marked clearly with one of the following phrases: "Universal Waste—Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)."

Subpart C—Standards for Large Quantity Handlers of Universal Waste

25. Section 273.30 is revised to read as follows:

§ 273.30 Applicability.

This subpart applies to large quantity handlers of universal waste (as defined in § 273.9).

26. Section 273.32 is amended by revising paragraphs (b)(4) and (b)(5) as follows:

§ 273.32 Notification.

* * * * *

(b) * * *

(4) A list of all the types of universal waste managed by the handler (e.g., batteries, pesticides, thermostats, lamps);

(5) A statement indicating that the handler is accumulating more than 5,000 kg of universal waste at one time and the types of universal waste (e.g., batteries, pesticides, thermostats, and lamps) the handler is accumulating above this quantity.

27. Section 273.33 is amended by adding a new paragraph (d) to read as follows:

§ 273.33 Management.

* * * * *

(d) *Lamps.* A large quantity handler of universal waste must manage lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) A large quantity handler of universal waste must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions.

(2) A large quantity handler of universal waste must immediately clean up and place in a container any lamp that is broken and must place in a container any lamp that shows evidence of breakage, leakage, or damage that could cause the release of mercury or other hazardous constituents to the environment. Containers must be closed, structurally sound, compatible with the contents of the lamps and must lack evidence of leakage, spillage or damage that could cause leakage or releases of mercury or other hazardous constituents to the environment under reasonably foreseeable conditions.

28. Section 273.34 is amended by adding a new paragraph (e) to read as follows:

§ 273.34 Labeling/marking.

* * * * *

(e) Each lamp or a container or package in which such lamps are

contained must be labeled or marked clearly with any one of the following phrases: "Universal Waste—Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)."

Subpart D—Standards for Universal Waste Transporters

29. Section 273.50 is revised to read as follows:

§ 273.50 Applicability.

This subpart applies to universal waste transporters (as defined in § 273.9).

Subpart E—Standards for Destination Facilities

30. Section 273.60 is amended by revising paragraph (a) to read as follows:

§ 273.60 Applicability.

(a) The owner or operator of a destination facility (as defined in § 273.9) is subject to all applicable requirements of parts 264, 265, 266, 268, 270, and 124 of this chapter, and the notification requirement under section 3010 of RCRA.

* * * * *

Subpart G—Petitions to Include Other Wastes Under 40 CFR Part 273

31. Section 273.81 is amended by revising paragraph (a) to read as follows:

§ 273.81 Factors for petitions to include other wastes under this part 273.

(a) The waste or category of waste, as generated by a wide variety of generators, is listed in subpart D of part 261 of this chapter, or (if not listed) a proportion of the waste stream exhibits one or more characteristics of hazardous waste identified in subpart C of part 261 of this chapter. (When a characteristic waste is added to the universal waste regulations of this part 273 by using a generic name to identify the waste category (e.g., batteries), the definition of universal waste in § 260.10 of this chapter and § 273.9 will be amended to include only the hazardous waste portion of the waste category (e.g., hazardous waste batteries).) Thus, only the portion of the waste stream that does exhibit one or more characteristics (i.e., is hazardous waste) is subject to the universal waste regulations of this part 273;

* * * * *

[FR Doc. 99–16930 Filed 7–2–99; 8:45 am]
BILLING CODE 6560–50–U

federal register

Tuesday
July 6, 1999

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 101, and 115

Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution; Proposed Rule

Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 101, and 115

[Docket Nos. 98N–1230, 96P–0418, and 97P–0197]

RIN 0910–AB30

Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require safe handling statements on labels of shell eggs that have not been treated to destroy *Salmonella* microorganisms. The agency is also proposing to require that, when held by retail establishments, shell eggs be stored and displayed under refrigeration at a temperature of 7.2 °C (45 °F) or less. FDA is taking these actions because of the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella* Enteritidis that are associated with the consumption of shell eggs that have not been treated to destroy this pathogen. These actions complement regulations of the Food Safety and Inspection Service (FSIS) that require that shell eggs be stored and transported at a temperature of 7.2 °C (45 °F) or less and that the consumer containers of shell eggs be labeled to indicate that refrigeration is required. FDA's proposal also responds, in part, to petitions from Rose Acres Farm, Inc., and the Center for Science in the Public Interest (CSPI). FDA expects that by requiring this information, consumers will be able to take measures to protect themselves from illness or deaths associated with consumption of shell eggs that have not been treated to destroy *Salmonella* Enteritidis.

DATES: Written comments by September 20, 1999. See section VII for the proposed effective date of a final rule based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of this proposed rule are available on the Internet at "http://www.fda.gov/cfsan".

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. Epidemiology of Salmonellosis

Salmonella microorganisms are ubiquitous, and are commonly found in the digestive tracts of animals, especially birds and reptiles. Human illnesses are usually associated with ingesting food or drink contaminated with *Salmonella*, although infection may also occur person to person by the fecal-oral route where personal hygiene is poor and by the animal to man route.

The disease salmonellosis results from an intestinal infection with *Salmonella* microorganisms and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Symptoms of salmonellosis usually begin within 6 to 72 hours after consuming a contaminated food or liquid and last for 4 to 7 days. Most healthy people recover without antibiotic treatment. However, the infection can spread to the bloodstream, and then to other areas of the body such as the bone marrow or the meningeal linings of the brain, leading to severe and fatal illness (Ref. 1). This spreading phenomenon of salmonellosis is more likely in children, the elderly, and persons with weakened immune systems. In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis (Ref. 2).

Salmonellosis is a serious health concern. It is a notifiable disease, i.e., physicians are required to report cases (i.e., single occurrences of illness) to the local health departments. These cases are then, in turn, reported to state health departments, which report the annual totals to the Centers for Disease Control and Prevention (CDC). However, these reports are made only if there are test results identifying the *Salmonella* microorganism that caused the illness.

In a 1979 to 1980 epidemiological study, CDC estimated that about 45 percent of those persons from whom *Salmonella* isolates[1] were reported were hospitalized for their illness and that 1.3 percent of them died from complications associated with the illness (Ref. 3). Very similar proportions were found in a 1984 to 1985 study. Using these proportions, CDC estimated that, in 1988, the approximately 43,000 reported cases represented a minimum of 19,000 hospitalizations and 500 deaths. Reported cases likely represent only a small portion of the actual number of illnesses that occur because: (1) Ill individuals do not always seek care by medical professionals, especially if the symptoms are not severe; (2) medical professionals may not establish the cause of the illness but simply treat the symptoms; and (3) medical professionals do not always report *Salmonella* cases to CDC. It is estimated that the actual number of cases per year may be 20-fold to 100-fold greater than the number of reported cases. Therefore, the number of actual cases of salmonellosis in 1988 was estimated to be from 800,000 to 4 million (Ref. 4). In 1996, there were 39,027 confirmed cases[2] of human salmonellosis reported to the CDC.

CDC surveillance data list close to 600 different *Salmonella* serotypes (a group of related microorganisms distinguished by their antigens) that have caused illness in the United States. The three serotypes most frequently reported as

[1] When a physician sees a patient and suspects that the patient has a case of salmonellosis, the physician may obtain a patient's specimen (e.g., stool) for analysis. The specimen is sent to the laboratory to be tested to identify and confirm any *Salmonella* that may be present. Thus, the laboratory obtains the actual isolate of *Salmonella*.

[2] A case of illness is confirmed as salmonellosis only if an isolate is confirmed by a laboratory as being *Salmonella*. Thus, although all cases may not be confirmed, all confirmed cases are associated with isolates of *Salmonella*.

causing illness are *Salmonella* Enteritidis (SE), *S.* Typhimurium, and *S.* Heidelberg (Ref. 5). These microorganisms are found in poultry and eggs.

Since 1976, SE-associated cases of salmonellosis have increased and have been found throughout the country. SE accounted for only about 5 percent of the number of all reported *Salmonella* isolates in 1976. In 1985, 1990, 1994, 1995, 1996, and 1997, SE constituted 9.8 percent, 20.6 percent, 26 percent, 24.7 percent, 24.5 percent, and 22.9 percent, respectively, of all *Salmonella* isolates. Currently, SE is one of the most predominant reported serotypes. There were 7,924 SE isolates reported in 1997 (Ref 7).

CDC surveillance data show that the overall rates of isolation[3] of SE increased 680 percent during the period between 1976 to 1994 (Ref. 6). Initially, the increases in the United States largely occurred in the Northeast. Later, the increase spread throughout the country. While the trends for the years 1990 to 1994 show a 21 percent decrease in the SE isolation rate in the Northeast, the rate increased approximately 300 percent for the Pacific region.

In 1985, the States reported 26 SE-related outbreaks (i.e., occurrences of 2 or more cases of a disease related in time and place) to CDC but 77 outbreaks were reported by 1989. In 1996, there were 51 reported SE outbreaks (Ref. 9). From 1985 through 1996, there have been a total of 660 SE-related outbreaks reported to CDC. Associated with these outbreaks, there have been 25,935 reported cases of illness, 2,508 reported hospitalizations, and 77 reported deaths. Deaths have occurred in all years of this time period. In 1997, there were 44 reported outbreaks (Ref. 10). Many SE outbreaks were attributed to food served in commercial establishments, such as restaurants and other commercial food service establishments, hospitals, nursing homes, schools, prisons, private gatherings, and ships, with the implicated food containing undercooked eggs (Ref. 11). Although most deaths linked to reported SE-related outbreaks in recent years have occurred among the elderly in hospitals and nursing homes (Ref. 3), salmonellosis can be fatal to an otherwise healthy person if a sufficient dose is ingested, and proper treatment is not administered (Ref. 12).

Until the mid-1980's, eggs were not associated with many *Salmonella* outbreaks. Since the mid-1980's, however, the number of egg-associated salmonellosis outbreaks have increased. Shell eggs are now the predominant source of SE-related cases of salmonellosis in the United States where a food vehicle is identified (Ref. 13). From 1985 to 1993, consumption of eggs was associated with 83 percent of SE-related outbreaks where a food vehicle was identified (Ref. 14). Recent data indicate that egg-associated SE outbreaks still represent a significant portion of the total number of all SE outbreaks reported to CDC. In 1996, 1997, and 1998, 60 percent, 70 percent, and 58 percent of the SE outbreaks reported to CDC implicated foods containing eggs (Ref. 14A).[4]

The Foodborne Diseases Active Surveillance Network (FoodNet[5]), an active surveillance system for foodborne pathogens, recently reported a 44 percent decrease in the isolation rate for SE (2.5 to 1.4 per 100,000 U.S. population) from 1996 to 1998 (Ref. 14B). This decrease is substantial; however, the results are preliminary and the reasons for this decrease are under investigation. Implementation of egg quality assurance programs that included microbiological testing and egg diversion may have contributed to this reported decrease. However, the reported decrease may also be explained by a decline in the presence of *Salmonella* isolated from poultry and meat products because of recently implemented HACCP programs, or by some combination of egg quality assurance and meat/poultry HACCP program. In any event, FDA believes that the incidence of SE is still too high and that additional measures can and should be put in place with respect to shell eggs to reduce the incidence even further.

B. Salmonella Contamination of Eggs

Having evolved to protect the developing chick embryo, an egg provides a uniquely inhospitable environment for *Salmonella* and other bacterial contaminants. An egg's natural defenses are both mechanical and chemical. Mechanically, there are four barriers that must be overcome for bacteria to reach the nutrient-rich yolk where they can rapidly multiply: (1) The shell, (2) the two membranes (inner and outer) between the shell and the albumin (egg white), (3) the albumin, and (4) the vitellin (yolk) membrane that holds the yolk. Additionally, when laid, the egg shell is covered on the outside by the cuticle, a substance similar to the shell membrane. When the cuticle dries, it seals the egg's pores, thereby inhibiting initial bacterial penetration. Consequently, a fresh egg is fairly resistant to invasive bacteria. However, the cuticle is generally removed along with debris on the surface of the shell during the cleaning process employed to prepare eggs for commercial sale. Thus, this outermost defense is generally not available to protect against trans-shell penetration of bacteria.

The albumin is probably the most formidable defense against microorganisms that have entered an egg. In a fresh egg, the albumin has a high viscosity that both anchors the yolk in the center of the egg and inhibits movement of microorganisms toward the yolk. Chemical defenses of the albumin include: (1) A very alkaline pH (>9), (2) low available nitrogen, and (3) proteins that have an anti-bacterial effect, specifically, ova-transferrin and lysozyme. If, however, conditions occur that allow SE to transverse the mechanical and chemical barriers in an egg and reach the nutrient rich yolk, the microorganisms may then increase in number.

Until recently, *Salmonella* contamination of shell eggs was thought most likely to be by trans-shell penetration of bacteria present in the egg's environment. The surface of an egg can become contaminated with any microorganism that is excreted by the laying flocks. In addition, contact with nesting materials, dust, feedstuff, shipping and storage containers, human beings and other creatures may be a source of shell contamination. The likelihood of trans-shell penetration increases with the length of time that the eggs are in contact with contaminating materials.

While environmental contamination is still a route for *Salmonella* contamination, it has recently been found that an egg's contents can become contaminated with SE before the egg is laid. Though the mechanism is still not well understood, SE will infect the ovaries and oviducts of some egg laying hens, permitting "transovarian" contamination of the interior of the egg while the egg is still inside the hen (Refs. 15 and 16). The site of contamination is usually the albumin.

It is believed that only a small number of hens in an infected flock shed SE at any given time and that an infected hen

[3] Rates of isolation are the number of reported isolates divided by 100,000 total population.

[4] The total number of SE outbreaks implicating eggs is equal to the total number of SE outbreaks minus the number of outbreaks where the vehicle is unknown or where the implicated food is one other than eggs, i.e., chicken or turkey.

[5] FoodNet is a collaborative project among CDC, FSIS, FDA, and 8 sites in the U.S. where foodborne disease data are being collected. To identify cases of foodborne illness, surveillance personnel contact clinical laboratories weekly or monthly to obtain data on numbers of cases.

may lay many uncontaminated eggs (Refs. 15 and 17). Nonetheless, it has been estimated that of the 47 billion shell eggs consumed annually as shell eggs, 2.3 million are SE-positive, exposing a large number of people to the risk of illness (Ref. 8). FDA believes that it is this transovarian contamination that is responsible for the increased number of SE-related salmonellosis cases described in section I.A of this document.

C. Infectious Dose

In general, the greater the numbers of microorganisms ingested, the greater the likelihood of disease. The likelihood of disease is also affected by the virulence of the microorganism and the susceptibility of the host (Ref. 18). However, there is evidence that the infectious dose (i.e., amount of microorganisms capable of causing disease) for SE can be very low. For example, in a 1994 outbreak attributed to consumption of SE-contaminated ice cream, the highest level of contamination found in the implicated ice cream was only six microorganisms per half-cup (65 gram) serving (Ref. 19). Another report showed that by using a different method of determining levels of SE in the implicated ice cream, the infective dose per serving was 25 microorganisms (Ref. 20). These reports indicate that low level contamination of foods with SE, and thus, low doses, can lead to illness. It is generally believed that SE-contaminated eggs initially contain only a few microorganisms (less than 20 microorganisms (Ref. 21)). Thus, the small number of microorganisms that initially may contaminate the egg may be sufficient to cause illness.

D. Inappropriate Handling of Eggs by Consumers and Other Food Preparers

SE outbreak investigations show that outbreaks commonly occur when foods prepared with SE-contaminated eggs are not appropriately handled by consumers or other food preparers. Common practices inappropriate for foods containing SE-contaminated eggs include temperature abuse (i.e., failing to keep the eggs and foods prepared with eggs refrigerated) and inadequate cooking. Pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked can cause illness in large numbers of people if any of the eggs were initially contaminated with SE.

Temperature abuse gives SE the opportunity to multiply, thereby increasing the number of viable microorganisms ingested, especially when eggs are consumed raw. Temperature abuse and consumption of raw eggs were associated with an SE outbreak at a catered wedding reception in New York, where Caesar salad dressing was implicated as the cause of SE illnesses. The Caesar salad dressing was made with 18 raw shell eggs, left unrefrigerated for 2 hours at the catering establishment, held in an unrefrigerated truck until delivered, and served at the reception 4½ hours later (Ref. 6).

Incomplete cooking of eggs (as in soft-boiled eggs or sunny-side up eggs) also allows ingestion of viable microorganisms if any of the eggs were initially contaminated. Incomplete cooking of eggs was associated with an SE outbreak in Tennessee, where the consumption of Hollandaise sauce served in a restaurant was linked to SE illnesses. Review of the food handling practices showed that the sauce had been prepared from eggs that were pooled, incompletely cooked, and served more than one hour after preparation (Ref. 12). Another outbreak of SE illness in an Indiana nursing home was linked to the consumption of baked eggs. The baked eggs were prepared by pooling 180 Grade A raw shell eggs, mixing with a whisk, and baking in a single pan at 204 °C (400 °F) for 45 minutes to 1 hour. Investigators believed that inadequate cooking occurred because the mixture was not stirred while baked (Ref. 6).

FDA is also aware that many consumers eat foods containing raw or undercooked eggs. An FDA survey indicated that 53 percent of respondents (total 1,620) ate foods containing raw eggs at some time (Ref. 22). Raw egg-containing foods mentioned in this survey included cookie batter, homemade ice cream, homemade eggnog, Caesar salad, frosting, homemade shakes, homemade Hollandaise sauce, and homemade mayonnaise. The Menu Census Survey (1992 to 1995) (Refs. 23 and 24) showed that frosting accounted for 53 percent and salad dressing 19 percent of occasions when raw egg-containing products were consumed.

The 1996 to 1997 Food Consumption and Preparation Diary Survey (Ref. 24) showed that 27 percent of all egg dishes consumed were undercooked (described as being runny or having a runny yolk or runny white). On average, each person consumed undercooked eggs 20 times a year. Within those groups at risk, women over 65 and children under 6 consumed undercooked eggs 21 times a year and 8 times a year, respectively. Moreover, consumer focus group research showed that many participants did not realize that certain foods such as chocolate mousse or key lime pie may contain raw or undercooked eggs, and, therefore, are potentially hazardous (Ref. 25).

E. Current Commercial Practices for Handling Eggs

Egg production facilities are either "in-line" facilities or "off-line" facilities. An in-line facility integrates laying, packing, and processing at one location. Freshly laid eggs go directly into a processing system where they are cleaned, sorted, and packed for distribution. An "off-line" facility receives eggs from laying facilities at other locations. Generally eggs are cleaned before they are packed. Typically, U.S. processors use hot water (43 to 49 °C (110 to 120 °F)) to wash eggs. After the eggs are washed, they are dried with forced ambient air and then packed. At the time that eggs are packed, the internal temperatures are often in the 21 to 27 °C (70 to 80 °F) range. Most processors hold packed eggs in coolers at an ambient temperature of 7 to 16 °C (45 to 60 °F).

Currently, eggs are held at various temperatures for various times prior to purchase by the consumer. The U.S. Department of Agriculture (USDA) estimates the following times and temperatures in the distribution of shell eggs: (1) 2 to 72 hours at temperatures of 7.2 to 32 °C (45 to 90 °F) at the processor, (2) 1 to 24 hours at temperatures of 7.2 to 32 °C (45 to 90 °F) during transportation, (3) 0 to 60 days at temperatures of 4 to 32 °C (40 to 90 °F) at retail (Ref. 8). These data indicate that, especially at retail, eggs are being held, for long periods of time, at temperatures that will not inhibit growth of SE. Currently, 37 States and the District of Columbia require ambient temperatures of 7.2 °C (45 °F) or less for egg storage and handling at retail. The other States either require ambient temperatures of 16 °C (60 °F) or less (i.e., the temperature required under USDA grading standards) or have no temperature requirements for egg storage and handling at retail.

These ambient temperatures, however, do not correlate to the internal temperature of the egg. The internal temperature of the egg when the eggs are transported ranges between 10 and 27 °C (50 and 80 °F), depending on the egg's temperature at the time of packing, the way the eggs are packaged, how the crates are packed and stacked, and the length of time they are in the cooler before they are shipped (Ref. 26).

F. Limiting the Numbers of Salmonella Microorganisms in Eggs

Because studies suggest that infectious dose for SE can be low, FDA

believes that the ideal solution to this public health problem would be to adopt measures to eliminate viable SE in shell eggs, either through preventing transovarian and trans-shell contamination or through processing to destroy viable SE in shell eggs, with distribution safeguards to prevent subsequent recontamination. However, FDA has tentatively concluded that eliminating viable SE in shell eggs in either of these two ways is not yet practicable. Other measures that can limit SE and inform consumers how to avoid the risks posed by SE are, however, practicable and thus FDA is proposing in this regulation to put such measures in place. The agency has also, jointly with USDA, published an advance notice of proposed rulemaking (ANPRM) (63 FR 27502, May 19, 1998; "the 1998 ANPRM") that requests comments on farm-to-table actions that will decrease the food safety risks associated with shell eggs.

As mentioned previously, although fresh shell eggs provide a particularly inhospitable environment for *Salmonella* and other microorganisms to multiply, the chemical and physical barriers against bacterial movement and growth degrade over a period of time. Consequently, as a result of degradation, SE and other bacteria, if present, are better able to move into the nutrient rich yolk, which provides a favorable environment for growth of SE.

Studies demonstrate that the rate of this degradation is time and temperature related. C. J. Kim et al. (Ref. 27) found that SE inoculated into the albumin of whole shell eggs multiplied to high numbers if the inoculated eggs were not properly refrigerated. This study examined the growth of SE inoculated into the albumin of shell eggs in numbers ranging from approximately 2 to 200,000 organisms per egg and held for 10, 20, or 30 days at 1 of 5 different temperatures from 4 °C (39 °F) to 27 °C (81 °F).

The investigators in this study found that, of the variables studied, temperature was the most important in determining the growth of SE (Ref. 27). Furthermore, they found that the growth response was directly proportional to the temperature at which the inoculated eggs were held. The study demonstrated that SE inoculated in shell eggs can multiply to substantial levels if held at 10 °C (50 °F) or higher for up to 30 days. The authors concluded that "because the number of SE present at the time an infected egg is laid is probably very low, egg storage at 4 °C (39 °F) could be expected to result in a smaller risk to the public health than higher storage temperatures" (Ref. 27). Thus, although albumin is inhibitory to *Salmonella*, these experiments show that SE inoculated into shell egg albumin, even at low levels, can multiply to substantial levels if held at 10 °C (50 °F) or higher for a significant period of time.

A subsequent study by Humphrey et al., (Ref. 21), of 5,700 eggs from flocks naturally infected with SE, appears to show that albumin is seeded with SE during passage of the egg through the oviduct. These SE microorganisms remain dormant even in eggs stored at room temperature (21 °C (70 °F)) for 2 to 3 weeks. However, after that period of time, nutrients or factors that negate the inhibitory properties of albumin appear to leak out of the yolk, possibly because of changes in the yolk membrane. These substances obtain levels close to the yolk in a sufficiently high concentration to support large populations of SE.

In a study of laying hens that were experimentally infected with SE, R. K. Gast and C. W. Beard (Ref. 28) also found that infected hens can produce eggs with SE contaminated contents. Their study indicates that transovarian infection followed by limited room temperature storage (25 °C (77 °F)) resulted in contamination of the yolk membrane or albumin, or both, but not the contents of the yolk. In the Gast and Beard experiments, all eggs were held at room temperature for 4 days before sampling. Although the number of microorganisms per egg was not measured, indirect evidence, such as the higher recovery frequency of SE from egg contents when incubated in broth for 48 hours versus 24 hours, suggests that the number of microorganisms per egg was low after holding the eggs for 4 days at room temperature.

Clay and Board (Ref. 29), by inoculating SE into the air cell of eggs, were able to show that the movement of the microorganism from the shell membrane to albumin and to the yolk was associated with aging related changes in the egg structure. These changes, such as changes in the relative densities of the albumin and yolk and enlargement of the air cell, result in movement of the yolk towards the inoculated SE during storage. These changes have the effect of bringing the yolk closer to the contaminated shell membranes when the egg is incubated in a position with the air cell uppermost. These investigators found that gross contamination of the albumin with SE was inhibited when the eggs were stored at 4 °C (39 °F) although the microorganism was viable throughout 30 days of storage. However, storage of eggs at 4 °C (39 °F) or 10 °C (50 °F) for 20 days followed by an increase in temperature to 25 °C (77 °F) led to generalized infection of the egg contents. Clay and Board state that their observations suggest that refrigerated storage of eggs should be a part of a protective barrier between the laying flock and the consumer, and to be effectively realized, refrigerated storage would have to be imposed shortly after the egg is laid and continue until immediately before cooking and consumption.

T. J. Humphrey (Ref. 30) studied the effect of storage temperatures of 8, 10, 12, and 15 °C (46, 50, 54, and 59 °F) on *Salmonella* growth in artificially inoculated eggs. No growth was observed after 3 weeks at 8 °C (46 °F). Growth of SE phage type 4 and 13a was observed at 10, 12, and 15 °C (50, 54, and 59 °F). SE phage 8 showed no growth at temperatures below 12 °C (54 °F).

Bradshaw et al. (Ref. 30A) studied the effect of storage temperatures on the growth of SE inoculated into the yolks of shell eggs. The inoculated yolks were incubated at 37, 15.5 and 7 °C (99, 59, and 45 °F). They observed no significant growth when the eggs were held at 7 °C (45 °F) for up to 94 days.

FDA finds that the scientific evidence on the growth of SE in eggs shows that control of storage temperature of shell eggs can effectively prevent the multiplication of any SE that may be present. While there is some debate about the precise optimum storage temperature for eggs, the research cited previously clearly indicates that refrigerating shell eggs at 8 °C (46 °F) and 7.2 °C (45 °F) or less greatly extends the time that an egg can maintain its defenses against movement of contaminating bacteria such as *Salmonella* to the nutrient rich yolk, and, therefore, substantially reduces the likelihood that any SE that is present will be able to increase in numbers. Moreover, there is evidence that cooling eggs reduces the heat resistance of SE microorganisms, making any microorganisms that may be present in an egg more likely to be killed when the egg is less than completely cooked (Refs. 30 and 31). Thus, FDA believes that sustained refrigeration of eggs plays an important role in reducing the likelihood that any SE present will reproduce.

Although continued refrigeration of eggs reduces likelihood of outgrowth of any SE that may be present, another measure a consumer may take to reduce the likelihood of consuming contaminated eggs is to thoroughly cook eggs. CDC reports that thorough cooking normally kills *Salmonella* that may be present in eggs (Ref. 32). However, some

cooking techniques commonly used for eggs or egg-containing foods do not thoroughly cook the eggs. For example, eggs that are liquid or runny after light cooking (e.g., soft boiled eggs, and sunny-side up eggs) can still contain viable *Salmonella* microorganisms. FDA's Food Code (a model code that is published by FDA and intended for adoption by States and local authorities for governing food retail and food service establishments) requires that raw eggs that are broken and prepared in response to a consumer's order be cooked at 63 °C (145 °F) for 15 seconds. Other raw eggs are required to be cooked 15 seconds at 68 °C (155 °F) (Ref. 33).

G. Current Efforts

FDA and the Food Safety and Inspection Service (FSIS) of the USDA share Federal authority to regulate eggs for safety. FDA has jurisdiction over the safety of foods (except meat and poultry) generally, including shell eggs, under section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, *et seq.*) and under the Public Health Service Act (PHS Act) (42 U.S.C. 201 *et seq.*).

USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). Under the EPIA, FSIS, and USDA's Agricultural Marketing Service (AMS) share responsibility to inspect processed egg products and to ensure proper distribution of eggs that are cracked or otherwise unsuitable for sale as whole shell eggs.

Federal agencies are working cooperatively with egg producers and others to enhance the safety of eggs that are sold to consumers. USDA's Extension Service, FSIS, AMS, and FDA all provide educational material on egg production methods that enhance food safety. FDA and FSIS work with States to encourage uniformity among state laws in retail and food service establishments through adoption of the Food Code. In addition, FDA, which has responsibility for investigating reports of SE outbreaks from foods in interstate commerce, performs trace backs to identify the source of the implicated eggs, environmentally tests flocks, diverts eggs from SE positive flocks, collects flock data to help track the spread of SE among layer flocks, and encourages better quality control.

In recent years, several programs have been created for the purpose of controlling the spread of SE on farms. One such program, the National Poultry Improvement Plan (NPIP), a cooperative Federal-State program sponsored by USDA's Animal Plant Health Inspection Service (APHIS), was developed to provide assistance to breeders and hatcheries in keeping flocks free of egg-transmitted diseases. In 1989, the NPIP developed an SE control program to reduce the prevalence of SE in hatching eggs and chicks through sanitation and other control measures. Another APHIS-sponsored joint Federal, State, and academic program, the *Salmonella* Enteritidis Pilot Program, was started in Pennsylvania in 1992. The objectives of the program were to develop effective and efficient procedures for monitoring SE and effective and efficient ways to prevent SE from contaminating eggs. The findings from the pilot program were incorporated into the Pennsylvania Egg Quality Assurance Program (PEQAP). The success of the PEQAP was indicated by a study, conducted in 1995, that demonstrated a decline in the number of SE-positive samples in houses that had been in the program from 1992 to 1995 (Ref. 34). Other programs have been developed to address the spread of SE to eggs, such as California's Egg Quality Assurance Plan, the New England Risk Reduction Program for SE, the United Egg Producers' Five Star Program, and the United States Animal Health Association's Best Management Practices for a *Salmonella* Enteritidis Reduction Program For Egg Producers.

A spent hen and liquid egg survey conducted by USDA in 1991 and repeated in 1995 showed that, despite the efforts described previously, the nation-wide prevalence of SE-positive flocks and the incidence of SE in shell eggs increased (Ref. 35). Because of the number of human illnesses and deaths attributable to SE in shell eggs, FDA and USDA are concerned that the current regulatory program for shell eggs is not adequate. Consequently, FDA and USDA are looking at ways of addressing the "farm to table" safety of shell eggs. FDA and FSIS recently have taken several steps to address the issue of reducing the risk of SE associated with shell eggs.

For example, in 1990, FDA reclassified eggs as a "potentially hazardous food" in the Food Code. The 1999 Food Code stipulates that potentially hazardous foods, including eggs, be maintained at 5 °C (41 °F) or less (Ref. 33). However, because of the number of illnesses associated with eggs and the fact that not all States have adopted this aspect of the Food Code, FDA tentatively concludes that stronger measures are necessary regarding handling of shell eggs.

On November 18 to 20, 1996, FDA and FSIS sponsored a 3-day technical conference that provided a forum for discussion on temperature control interventions and verification techniques in the transportation and storage of meat, poultry, seafood, and eggs and egg products. FSIS and FDA also published a joint ANPRM (61 FR 59372, November 22, 1996) soliciting information on issues related to ensuring the safety of potentially hazardous foods during transportation and storage. Comments to that document are being analyzed.

In addition, in December 1996, FSIS began a science based risk assessment for shell eggs and egg products. This project was conducted by a multidisciplinary team of scientists from academia and USDA. The project goals were to provide an understanding of egg-associated foodborne disease, assist in evaluating farm to table risks and ways to reduce risks, and verify additional data needs. The final report was issued June 12, 1998.

On September 3, 1997, FDA and FSIS jointly held a public meeting to review the current science, including technological and safety factors, relating to shell eggs and egg products and to identify intervention options that are most effective in reducing the public health risk in a cost-effective manner. Experts from industry, academic, regulatory, and consumer sectors presented information on illnesses and the epidemiology of outbreaks arising from shell eggs and foods containing raw and undercooked eggs; current concerns with emerging pathogens; procedures for processing eggs; and new and existing technology to control pathogens in shell eggs and egg products. Comments from this meeting were considered in the risk assessment project.

In addition, FDA and USDA recently published in the **Federal Register** an ANPRM seeking to identify farm-to-table actions that will decrease the food safety risks associated with shell eggs. Information gathered from the foregoing measures will be considered as part of the two agencies' approaches for a comprehensive program to address the safety of shell eggs from farm to table. Because rulemaking to address a comprehensive program will likely take considerable time, FDA believes that it can meet an immediate goal of reducing the risk of foodborne illness from SE by ensuring that shell eggs at retail are held at appropriate temperatures and by providing safe handling statements for shell eggs. In addition, as stated in section II.A of this document, USDA published a final rule in the **Federal Register** of August 27, 1998 (63 FR 45663), amending its regulations to require that shell eggs packed for

consumer use be stored and transported at an ambient temperature that does not exceed 7.2 °C (45 °F) and that containers of shell eggs be labeled to indicate that refrigeration is required. Both FDA and FSIS will consider actions based on comments to the ANPRM to address issues other than labeling and refrigeration of eggs while held for retail distribution.

H. Petitions to the Agency

FDA received a petition from Rose Acres Farms, Inc., (filed November 4, 1996, Docket No. 96P–0418) requesting, among other things, that the agency amend § 101.17 (21 CFR 101.17) by adding a requirement that shell eggs bear a label statement that informs consumers of safe handling practices for the product. In support of its request, the petition contended that practically all SE outbreaks and deaths have involved mishandling of eggs. The petition stated that, therefore, reducing practices such as temperature abuse or inadequately cooking eggs would virtually eliminate the problem. The petition also asserted that some egg producers may not wish voluntarily to include safe handling information on their labels because they fear their competitors may not include the same information, and, therefore, their product would seem less safe by comparison. However, if FDA required safe handling instructions on all cartons of shell eggs, then no producer would be at a competitive disadvantage. The petition suggested the following label statement: "Keep refrigerated and cook thoroughly before eating. Use pasteurized egg products for any recipe which does not require that the eggs be thoroughly cooked."

FDA also received a petition from CSPI (filed May 14, 1997, Docket No. 97P–0197) requesting, among other things, that the agency require that the carton of shell eggs bear a label statement cautioning consumers that eggs may contain harmful bacteria, and that consumers should not eat raw or undercooked eggs. In support of its request, CSPI stated that SE in eggs is a serious health problem and that illnesses caused by SE in the United States have increased. CSPI further stated that consumers have no way of knowing that an egg is contaminated because eggs that are contaminated with SE have a normal appearance. The petition suggested the following label statement: "Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm."

The petition also requested, among other measures, that the agency require that eggs be refrigerated to an internal temperature of 5 °C (41 °F) as soon as possible and kept at that temperature at all points up to and including the point of retail sale. This temperature, according to CSPI, will ensure that SE cannot multiply.

USDA/FDA received approximately 73 responses to the 1998 ANPRM, each containing one or more comments. Responses were received from egg farmers, egg packers, associations for the egg industry, other trade associations, consumers, consumer interest groups, animal interest groups, academia, State government agencies, and foreign government agencies. Many of these comments addressed issues not relevant to this proposed rule, e.g., implementation of national standards for QA programs, implementation of HACCP, transportation of shell eggs, sell-by and expiration dates for shell eggs, housing and forced molting of chickens, repacking of eggs, and exportation of SE-contaminated into other countries. FDA will not address those comments in this proposed rule. There were, however, several comments that did raise issues relevant to this proposed rule such as the extent of the SE problem, refrigeration of shell eggs, and safe handling instructions on consumer packages of shell eggs. Although most of these comments supported the approach proposed in this document, some comments suggested different approaches than those in this proposal. These latter comments are addressed below in the appropriate sections of this document.

II. The Proposal to Require Refrigeration of Shell Eggs in Retail Establishments

A. Rationale for Proposal

As noted previously, the incidence and geographical distribution of egg-associated SE illnesses have made SE a significant public health concern. As discussed in section I.F of this document, one currently practicable measure that can limit the number of viable SE present in shell eggs is refrigeration, because it helps to maintain the effectiveness of the egg's natural defenses against SE and slows the growth rate of SE. Many of the comments to the 1998 ANPRM maintained that refrigeration of eggs is an essential measure to inhibit the growth of SE. Although there is the potential for SE to be present in shell eggs in infective doses regardless of adequate handling, temperature abuse increases the likelihood for the growth of any microorganisms present, thus increasing the risk of illness.

As noted previously, USDA has the responsibility of implementing the EPIA. Amendments to the EPIA in 1991 (Pub. L. 102–237) require that shell eggs packed for consumers be stored and transported under refrigeration at an ambient temperature (i.e., the air temperature maintained in an egg storage facility or transport vehicle) not to exceed 45 °F and that the egg containers be labeled to indicate that refrigeration is required. FSIS has amended its regulations to require that no shell egg handler shall possess any shell eggs that are packed in containers destined for the ultimate consumer unless they are stored and transported under refrigeration at an ambient temperature of no greater than 45 °F (7.2 °C). In its regulation, FSIS defines an egg handler as any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs or processing any egg products, or otherwise using any eggs in the preparation of human food. FSIS defines an ultimate consumer as any household consumer, restaurant, institution, or other party who has purchased or received shell eggs or egg products for consumption. This regulation is effective August 27, 1999.

Once the amendments to the EPIA are implemented, requirements will be in place for the refrigeration of packed shell eggs up to the point of retail distribution except that egg producers with a flock of 3,000 hens or less are exempt from this requirement. However, without the continued refrigeration of shell eggs up to the time the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of SE to occur. FSIS's regulation does not require the ultimate consumer to maintain shell eggs under refrigeration. Consequently, the failure to refrigerate shell eggs in facilities such as restaurants and institutions could result in SE outgrowth. Therefore, to ensure that shell eggs are maintained under refrigeration throughout retail distribution up until they are cooked. FDA tentatively concludes that it should propose requirements that shell eggs throughout retail distribution be kept refrigerated until they are cooked. Without these requirements, the effectiveness of refrigeration in any part of the farm-to-table continuum would not be maximized.

B. Legal Authority for FDA to Require Refrigeration of Shell Eggs

FDA is proposing these regulations under both the PHS Act and the act. FDA's legal authority to require refrigeration of eggs at retail derives from the provisions of sections 311, 361,

and 368 of the PHS Act (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Department of Health and Human Services (DHHS) to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State" (section 361(a) of the PHS Act (42 U.S.C. 264(a))).

Salmonellosis is a communicable disease that can be caused by SE-contaminated eggs. Temperature abuse can lead to the multiplication of SE in shell eggs, and thereby, increase the likelihood of illness if the eggs are not thoroughly cooked. Therefore, the agency tentatively concludes that a regulation to require refrigeration is necessary to prevent the spread of communicable disease.

Although the egg market is largely regional, it involves significant shipment of eggs from State to State. Moreover, shipment of SE-contaminated eggs from one State to another has contributed to the geographical spread of disease outbreaks in the U.S. human population. For example, eggs from Pennsylvania were implicated in an outbreak of SE infection reported in Asbury Park, NJ, involving at least 47 persons, and eggs from Maryland were implicated in an outbreak in Livonia, NY, where 12 patrons of a restaurant reported gastroenteritis illness linked to consumption of omelets made from pooled grade A eggs (Ref. 36). As discussed in section I.D of this document, an SE outbreak at a wedding reception in New York was associated with the consumption of Caesar salad dressing. Eggs used to make the dressing were traced to a Pennsylvania producer (Ref. 6).

FDA tentatively concludes that a regulation to require refrigeration of shell eggs at retail (proposed § 115.50(b)) also should apply to eggs that are not shipped across State lines by producers or retailers because there have been SE outbreaks that were associated with such eggs (Ref. 37). Therefore, the agency believes a regulation to require refrigeration of eggs produced and sold within a State would reduce the risk of illness. In addition, the agency tentatively concludes that the spread of salmonellosis among States from SE-contaminated eggs cannot be fully controlled without extending the refrigeration requirement to sales within one State. FDA believes that consumers who shop across State borders may purchase SE-contaminated shell eggs from one State and carry the eggs across State lines. Thus, FDA is concerned that if it does not require refrigeration of shell eggs that are laid, processed, and sold in one State, the regulations will not prevent the introduction of SE contaminated eggs into other States and, thus, will not prevent the introduction of salmonellosis from one State to another.

The agency also notes that in the normal course of business, many food service establishments, e.g., restaurants, serve out-of-State customers, e.g., truck drivers, tourists, and others who regularly travel for work. The agency is concerned that if these out-of-State consumers become ill with salmonellosis from SE-contaminated eggs purchased through intrastate commerce, the disease could spread from one State to another. For these reasons, the agency tentatively concludes that refrigeration should also be required on all shell eggs to prevent the spread of a communicable disease among States.

FDA's legal basis to require refrigeration of shell eggs also derives from sections 402(a)(4), and 701(a) of the act (21 U.S.C. 342(a)(4) and 371(a)). Under section 402(a)(4) of the act, a food is adulterated if it is prepared, packed, or held in insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health. Under section 701(a) of the act, FDA is authorized to issue regulations for efficient enforcement of the act. Thus, a regulation that prohibits food from being held under insanitary conditions would provide for efficient enforcement.

FDA has traditionally not conducted enforcement activities in retail establishments. The agency has, instead relied on State and local authorities to provide enforcement at the retail level. Nonetheless, the agency has been active in the retail arena in a number of ways. First and foremost, FDA participates in the Conference on Food Protection which is the cooperative body responsible for making recommendations to FDA concerning the Food Code. FDA also publishes the Food Code. In addition, FDA interacts with State and local regulatory agencies in a number of ways to coordinate retail enforcement efforts. Within FDA, the Division of Federal-State Relations, located in the Office for Regulatory Affairs, in the Office of the Commissioner, was created to enhance interactions between Federal, State, and local officials. The Division of Federal-State Relations serves as the focal point for providing cohesive and uniform food policies to State associations and cooperating State and local officials. Retail food specialists work with State and local retail food regulatory agencies to assist them, when the Code has been adopted, in implementing the Food Code and to ensure through standardization of local and State health officials that the Food Code criteria are uniformly applied. Retail food specialists are located in FDA regional offices. Some districts may have partnership agreements with States. Goals of these partnerships include increasing staff proficiency, improving consistency of enforcement activities, and empowering cooperating organizations. This may also include assisting with implementation of retail food programs. FDA has structured the proposed regulation to take into account the traditional sharing of responsibilities of food safety at retail, augmented by a clear quantitative Federal standard for temperature control.

Under the PHS Act, the Federal, State, and local governments have a long tradition of cooperation, and the PHS Act specifically recognizes cooperation between the Federal government and State and local governments as an important tool for public health officials. Previously, in the area of food safety, FDA has used those portions of the PHS Act (e.g., sections 310 and 311 (42 U.S.C. 242n and 243)) that focus on Federal assistance to the States. Indeed, the Conference on Food Protection and the Model Food Code are a result of Federal/State/Local cooperation and Federal assistance to the States and localities under the PHS Act. However, section 311 of the PHS Act not only recognizes Federal assistance to the States, it also recognizes that the States and localities may be able to assist the Federal Government. This section provides in part: "The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this chapter which such authorities may be able and willing to provide."

FDA believes that, under sections 311 and 361 of the PHS Act, there are several ways the agency could accept assistance from the States in the enforcement of the egg refrigeration regulation. For example, FDA could accept State and local assistance in the inspection of retail establishments and then use those inspections as the basis for detention and diversion or destruction under proposed § 115.50(f) (as discussed in section II.C of this document) or as the basis for an enforcement action under the act. Another option would be to authorize

the States and localities to conduct inspections and enforce the refrigeration requirement through the administrative enforcement remedies set out in proposed § 115.50(f) (as discussed in section II.C of this document), while FDA could hear appeals, with judicial review available after FDA's decision. FDA also believes it could follow the example set out in the Nutrition Labeling and Education Act, which allows the States, if certain conditions are met, to bring an action to enforce various food labeling provisions in the act. See 21 U.S.C. 337; 21 CFR 100.2. Finally, FDA believes that section 311 of the PHS Act, in conjunction with section 361 of the PHS Act, authorizes the agency to issue a regulation that would allow States and localities to enforce the refrigeration regulation themselves.

After examining these options, FDA is concerned that all except the last option (allowing States and localities to enforce the regulation themselves) would prove too cumbersome, especially in light of the straightforward requirement at issue. Although a few comments maintained that the regulatory responsibility of egg handling and preparation in retail establishments remains at the State and local level, other comments supported a federal-State cooperative approach. FDA agrees that a cooperative approach would be the most effective means to enforce the refrigeration requirement. Therefore, FDA has tentatively concluded to propose to allow agencies of those States and localities that are able and willing under section 311 of the PHS Act, and that are authorized to inspect or regulate retail establishments, to enforce the refrigeration regulation along with FDA. FDA has tentatively concluded that this option will allow for the most effective and efficient use of Federal, State, and local food safety resources because it recognizes that States and localities, more than FDA, currently do this kind of enforcement. Accordingly, proposed § 115.50(e) provides that those States and localities that are able and willing are authorized under sections 311 and 361 of the PHS Act to enforce proposed § 115.50(b) as set out in proposed § 115.50(f). With respect to the hearing procedures, the proposed regulation recognizes that many States and localities already have administrative procedures in place for hearings by allowing them to use a similar hearing process as long as that process satisfies basic due process requirements.

FDA recognizes that some of these approaches are new approaches to the enforcement of food safety regulations, and accordingly is soliciting, and will carefully review, comments on this aspect of this proposed regulation. FDA is particularly interested in comments on how State, local, and Federal food safety authorities can best interface to ensure effective and efficient implementation and enforcement of food safety standards.

C. Proposed Refrigeration Requirements at Retail

FDA is proposing in new § 115.50 to require that shell eggs held for retail distribution be promptly placed under refrigeration and be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at the retail establishment.

The evidence discussed in section I.A of this document shows that shell eggs have been vehicles for salmonellosis. USDA's proposed requirement for refrigeration of shell eggs includes storage at the producer and storage during transportation, but does not include storage or holding at all retail establishments. FDA tentatively finds that the weight of the available evidence on the growth of SE in eggs shows that this microorganism can multiply to high levels in eggs if the eggs are not properly refrigerated during their shelf-life. Failure to refrigerate shell eggs during retail handling of shell eggs provides favorable conditions for degradation of the egg's defenses, movement of SE to the yolk, and subsequent multiplication of SE. Therefore, FDA tentatively concludes that it is necessary to require that eggs at retail be held at temperatures that will help maintain the natural defenses of the egg and limit the growth and reproduction of SE.

As discussed in section I.F of this document, research indicates that SE multiplies at temperatures of 10 °C (50 °F) and above but that multiplication of SE is inhibited at lower temperatures, e.g., 8 °C (46 °F), 7.2 °C (45 °F), and 4 °C (39 °F). Therefore, the agency tentatively concludes that it should require a refrigeration temperature lower than 10 °C (50 °F) to ensure the safety of shell eggs. As noted as follows in this section, the Food Code recommends that potentially hazardous foods be maintained at a temperature of 5 °C (41 °F). A temperature of 5 °C (41 °F) not only inhibits the growth of *Salmonella*, but also, inhibits the growth of *Listeria monocytogenes*, which has been shown to grow at 7.2 °C (45 °F). The agency also notes that, as required under the Egg Products Inspection Act, USDA has amended its regulations to require that shell eggs packed for consumer use be stored and transported at an ambient temperature of 7.2 °C (45 °F). Based upon the data discussed in section I.F of this document, FDA tentatively concludes that 7.2 °C (45 °F), i.e., the same temperature required by USDA under the EPIA for the storage and transportation of shell eggs, is sufficient to protect the public health. Because eggs cool down only slightly faster at 5 °C (41 °F) than at 7.2 °C (45 °F), the lower temperature would have a negligible effect on the SE risk.

FDA notes that it is proposing an ambient and not an internal temperature requirement for shell eggs displayed and stored in retail establishments. The majority of comments to the 1998 ANPRM supported refrigeration of shell eggs throughout the distribution chain from packer to consumer. Most of these comments supported a requirement for an ambient temperature of 7.2 °C (45 °F). A few of these comments encouraged the agency to consider an internal temperature requirement of 7.2 °C (45 °F) or ambient or internal temperature requirements of 5 °C (41 °F), which, it was asserted, would result in an additional margin of safety.

As discussed in section I.F, research indicates that refrigeration of shell eggs at 7.2 °C (45 °F) greatly extends the time that an egg can maintain its natural defenses, and, thus, inhibit the growth of SE. FDA acknowledges that an internal temperature of 5 °C (41 °F) or 7.2 °C (45 °F) would also achieve this goal. However, FDA believes that a uniform requirement for an internal temperature would be difficult to monitor. As discussed in section I.E of this document, the internal temperature of eggs when they are transported depends on the temperature of the eggs when they are packed, the way the eggs are packaged, how the crates are packed and stacked, and the length of time they are in the cooler before they are shipped. Further, according to one comment to the 1998 ANPRM, transportation of eggs in refrigerated trucks do not provide cooling, but rather maintain the temperature of the eggs. Moreover, it may be impracticable for egg retailers to determine the internal temperatures of shell eggs. Therefore, the agency tentatively concludes that, to provide a level playing field for all egg retailers, it is appropriate to propose an ambient temperature requirement for the display and storage of shell eggs at retail. FDA requests comment on its tentative conclusion.

The agency notes that some States or localities may have temperature requirements lower than 7.2 °C (45 °F). The agency does not intend that this proposed regulation would, when finalized, preempt the requirements of

the Food Code or other State or local requirements that require a lower temperature. The proposed regulation would, however, preempt any State or local requirements that allow a temperature greater than 7.2 °C (45 °F).

The agency notes that the proposed temperature for storage of shell eggs addresses growth of SE in shell eggs, whereas the temperature required by the Food Code addresses all pathogens that may be present in different types of potentially hazardous foods. Thus, in addressing holding temperatures for potentially hazardous foods generally, the Food Code requires a temperature for retail storage that will prevent or slow the growth of most pathogens, including cold-tolerant pathogens such as *L. monocytogenes*. As previously discussed in this section, the agency tentatively concludes that a maximum storage temperature of 7.2 °C (45 °F) will be effective in inhibiting the growth of SE that may be present in shell eggs. FDA notes that a requirement that shell eggs be stored at 7.2 °C (45 °F) or less does not preclude retailers from maintaining shell eggs at lower refrigeration temperatures. In fact, the agency would encourage it. Moreover, it may be most practicable for establishments to have one requirement for a maximum refrigeration temperature for all potentially hazardous foods. FDA requests comment on the safety implications in the difference between the proposed temperature requirement of 7.2 °C (45 °F) for storage of shell eggs at retail and the refrigeration temperature of 5 °C (41 °F), recommended in the Food Code.

Because failure to refrigerate shell eggs would provide conditions for SE to multiply, the agency tentatively concludes that failure to refrigerate eggs would constitute insanitary conditions that may render the product injurious to health. Accordingly, the agency is proposing that failure of responsible individuals in a retail establishment to comply with the requirements of § 115.50(b) will render the shell eggs adulterated under section 402(a)(4) of the act.

Some shell eggs now available for retail sale have been pasteurized in the shell (in-shell pasteurized) prior to packing and distribution to destroy any *Salmonella* that may have been present in the egg (e.g., *Salmonella* in the egg due to transovarian contamination). FDA is proposing in § 115.50(c) that these eggs be exempt from the refrigeration requirement. However, such pasteurization would not prohibit the in-shell pasteurized egg from subsequently becoming contaminated with harmful microorganisms, if the egg were to come in contact with *Salmonella* or other potentially hazardous microorganisms during distribution and retail sale. The scientific evidence indicates that it is possible for *Salmonella* as well as other potentially harmful microorganisms to pass through the pores of the egg shell and reach the egg yolk, which can then support subsequent growth of the microorganisms, especially when adequate refrigeration is not provided (Ref. 38). Because this proposed regulation addresses the control of SE in shell eggs that are contaminated by transovarian transmission, the agency considers pasteurization an effective means to kill SE that may be present inside the egg when it is laid. Thus, the scope of this proposed regulation does not extend to contamination of eggs other than by transovarian transmission. FDA expects that manufacturers of this premium product would ensure its continued safety. Therefore, although this proposal would not require the refrigeration of in-shell pasteurized shell eggs or any shell eggs that have been otherwise processed to destroy *Salmonella*, because such eggs would not be expected to contain transovarian transmitted *Salmonella*, FDA recommends that such eggs be refrigerated by retail establishments.

In addition, FDA notes that shell eggs that have been processed to destroy *Salmonella* are still considered to be potentially hazardous foods under provisions in the Food Code in part because they are raw eggs that are capable of supporting the growth of SE. Because these eggs are considered potentially hazardous foods, State and local regulations established under the recommendations in the Food Code may have specific refrigeration requirements for these eggs in retail establishments that this regulation would not preempt.

As discussed in section II.B of this document, the agency tentatively concludes that the spread of salmonellosis among States from SE-contaminated eggs cannot be fully controlled without extending the refrigeration requirement to all eggs. Accordingly, FDA is proposing in § 115.50(d) that the requirements of this section are applicable to all shell eggs.

As previously noted, FDA is proposing these regulations under both the act and the PHS Act. Failure to comply with the refrigeration requirement in proposed § 115.50 would render the eggs adulterated under section 402(a)(4) of the act. Enforcement of adulteration regulations under the act is conducted under sections 301 to 304. However, section 361 of the PHS Act authorizes the Secretary, and by delegation FDA, to issue regulations that provide for the destruction of articles and for other measures that are judged by the Secretary to be necessary to carry out and enforce communicable disease regulations. FDA tentatively concludes that the shell egg refrigeration regulation can be most efficiently and effectively enforced through administrative procedures. Accordingly, FDA is proposing procedures in § 115.50(f) under which FDA may order the diversion or destruction of shell eggs that have been held in violation of the regulations. Under proposed § 115.50(f), FDA may issue to the person holding the shell eggs a written order that the product be diverted or destroyed. The proposed regulations would provide for diversion for processing in accordance with the EPIA because FDA tentatively concludes that it may be possible to produce safe egg products from shell eggs that have been held in violation of the regulation. Because the EPIA requires pasteurization of egg products, any *Salmonella* present would be eliminated. The written order would identify the shell eggs that are affected, and the grounds for issuing the order and would provide that, unless the order is appealed, either by filing a written appeal or by requesting a hearing, the shell eggs must be diverted or destroyed within 10-working days of receipt of the order.

In addition, authority for the enforcement of section 361 of the PHS Act is provided for in part under section 368 of the PHS Act. Under section 368(a) of the PHS Act any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559 and 3571(b)). Organizations may be fined up to $200,000 per violation not resulting in death and $500,000 per violation resulting in death (18 U.S.C. 3559 and 3571(c)). In addition, Federal district courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act.

III. The Proposal for Shell Egg Labeling

A. Rationale for Shell Egg Labeling Proposal

As discussed in section I.D of this document, data from SE outbreaks show that outbreaks commonly occur when contaminated eggs are mishandled by consumers or other food preparers. Furthermore, consumption data

establish that some consumers eat raw or undercooked eggs.

The CSPI petition contends that the increase in the incidence of foodborne illness has likely occurred, at least in part, because consumers do not realize that partial cooking of raw eggs (e.g., soft-boiled, sunny-side-up) or egg-containing foods will not prevent illnesses. In addition, the petition from Rose Acres Farm, Inc., contends that practically all SE outbreaks and deaths associated with eggs occurred because of mishandling of the eggs.

As discussed previously, FDA believes that it will be difficult for the industry to rapidly design and implement a program that will produce *Salmonella*-free eggs. However, as discussed in section I.F of this document, in the meantime, there are measures that can reduce risks to consumers: Refrigeration, which lengthens the effectiveness of the eggs' natural defenses against SE and slows the growth rate of SE, and thorough cooking, which kills viable SE that may be present. Many comments to the 1998 ANPRM maintained that proper handling of shell eggs is an important measure that could reduce the incidence of foodborne illness. According to a few of the comments, the majority of outbreaks occur because of improper handling of eggs, e.g., pooling and incomplete cooking by food preparers. Most comments to the 1998 ANPRM that addressed labeling supported labeling cartons of eggs with instructions for proper handling. Although some comments supported the use of short messages, such as "keep refrigerated," others supported safe handling instructions that also included instructions on proper cooking of eggs.

The agency is concerned that unless consumers and food preparers are advised about both the risks presented by eggs contaminated with SE and the ways they can reduce these risks, consumers, particularly those at greatest risk, could suffer serious illness or death from the consumption of raw or undercooked eggs and egg-containing foods. Accordingly, FDA tentatively concludes that there is an immediate need to require label statements that inform consumers of the public health risks associated with consumption of raw or improperly cooked shell eggs and provide safe handling instructions.

B. Legal Authority for FDA to Require Label Statements

FDA is proposing these regulations under both the act and the PHS Act. FDA's legal authority under the act to require label statements on food products derives from sections 201(n), 403(a)(1), and 701(a) of the act (21 U.S.C. 321(n), 343(a)(1), and 371(a)). FDA's legal basis to require safe handling instructions on shell eggs also derives from the provisions of sections 311, 361, and 368 of the PHS Act that relate to communicable disease. Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act provides that in determining whether labeling is misleading, the agency shall take into account not only representations made about the product, but also the extent to which the labeling fails to reveal facts that are material in light of such representations made or suggested in the labeling or material with respect to consequences that may result from use of the product under conditions of use prescribed in the labeling or under customary or usual conditions of use. Section 701(a) of the act authorizes FDA to issue regulations for the efficient enforcement of the act. FDA previously has relied on these authorities when it required label warning statements to alert consumers to the potential hazards of certain ingredients of foods and dietary supplements, e.g., protein products (49 FR 13679, April 6, 1984) and iron-containing dietary supplements (62 FR 2218, January 15, 1997). Likewise, the agency is relying on these authorities in proposing to require label statements on shell eggs not processed to destroy all viable *Salmonella*.

As discussed previously, it is well documented that shell eggs may contain *Salmonella*, especially transovarian transmitted SE, which can result in serious, life-threatening illness. The risk is greatest for children, the elderly, and persons who are immune compromised (Ref. 18). Therefore, the agency tentatively concludes that information disclosing the risk of foodborne illness associated with consumption of raw or undercooked shell eggs is material information that must be given to consumers at the point of purchase.

However, the consequences that may result from consumption of SE-contaminated eggs may be reduced or eliminated by proper handling techniques that first limit the number of SE microorganisms and then kill those microorganisms. Thus, consumers have effective ways, other than avoidance of shell eggs, to reduce the risk of illness from consumption of SE-contaminated shell eggs. In light of this, the agency tentatively concludes that information on safe handling practices that consumers can use to protect themselves from illness is material information about the product that must be included in its labeling to ensure that the product is not misbranded.

As discussed in section II.B of this document, the PHS Act authorizes the Secretary of DHHS to make and enforce regulations that prevent the introduction, transmission, or spread of communicable disease from State to State. As discussed in that section, temperature abuse of shell eggs can lead to the multiplication of SE in shell eggs, and thus, increase the likelihood of illness if the eggs are not thoroughly cooked. The agency tentatively concludes that, in addition to a refrigeration requirement, a regulation requiring safe handling instructions that inform consumers to properly refrigerate and cook shell eggs (as fully discussed in section III.D of this document) is also necessary to prevent the spread of communicable disease.

FDA tentatively concludes that a regulation to require label statements that provide safe handling instructions on shell eggs (proposed § 101.17(h)(1)) also should apply to eggs that are not shipped across State lines by producers or retailers (proposed § 101.17(h)(6)). As noted in section II.B of this document, there have been outbreaks of salmonellosis associated with such eggs. Therefore, FDA is concerned that if it does not require safe handling instructions on shell eggs that are laid, processed, and sold in one State, consumers will not have material information that would inform them of ways to handle and cook eggs to prevent illness. Thus, without the inclusion of all eggs in the scope of this proposed regulation, FDA could not ensure that consumers who purchase eggs laid, processed, and sold in one State would have information that would help protect them from the risk of salmonellosis. In addition, as discussed in section II.B of this document, the agency believes that consumers who shop across State borders may purchase SE-contaminated shell eggs from one State and carry them across State lines. Therefore, without the inclusion of all eggs in the scope of this proposed regulation, the agency would be hampered in preventing the spread of salmonellosis from one State to another. The agency tentatively concludes that safe handling instructions should be required on all shell eggs to prevent the interstate spread of a communicable disease from one State to another. FDA requests comment on its tentative conclusion.

Failure to comply with the requirements of proposed § 101.17(h) would render the food misbranded under section 403(a)(1) of the act and would violate regulations issued under

section 361 of the PHS Act. As discussed in section II.C of this document, enforcement of regulations is conducted under sections 301 to 304 of the act. Section 361 of the PHS Act authorizes FDA to issue those regulations that are necessary to enforce communicable disease provisions of the statute. Thus, the agency is proposing procedures in § 101.17(h)(8) that it may use to order the relabeling, diversion, or destruction of shell eggs that do not comply with the regulation. Under proposed § 101.17(h)(8)(i)(A), FDA may issue to the person holding the shell eggs a written order that the product must be relabeled, diverted, or destroyed. As also discussed in section II.C of this document, violations of the PHS Act are subject to injunctions and criminal prosecutions.

As discussed in section II.B of this document, FDA has examined several options on how the agency could accept assistance from the States and localities in enforcement of the refrigeration provision of this proposed regulation. The agency has considered similar options on how it could accept State and local enforcement assistance of the labeling provision. Because this proposed labeling requirement would affect shell eggs that laid, processed, and sold in one State, the agency believes that it would be an efficient use of resources for State and local agencies to assist in enforcing the labeling regulations. Moreover, FDA believes that sections 311 and 361 of the PHS Act authorize the agency to issue a regulation that would allow States and localities to enforce the labeling regulation themselves. Therefore, the agency has tentatively concluded that it should allow State and local regulators that are able and willing under section 311 of the PHS Act, and are authorized to regulate the labeling of shell eggs within their States or localities, to enforce the requirement for safe handling instructions. Accordingly, proposed § 101.17(h)(7) provides that those States and localities that are able and willing are authorized under sections 311 and 361 of the PHS Act to enforce proposed § 101.17(h)(1) as set out in proposed § 101.17(h)(7). With respect to the hearing procedures, the proposed regulation recognizes that many States and localities already have administrative procedures in place for hearings allowing them to use a similar hearing process as long as that process satisfies basic due process requirements.

C. Covered Products

As discussed in section II.C of this document, technology to process shell eggs in a manner to destroy SE in the egg would significantly reduce or eliminate the risk of transovarian transmitted SE, and would thereby render the label statements unnecessary. Accordingly, FDA is proposing in § 101.17(h)(4) that shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* be exempt from the labeling requirements.

The standards of identity for liquid, dried, and frozen egg white, egg yolk, and whole egg products (21 CFR part 160) require that these products be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Further, the agency expects that the standardized egg product ingredients in any nonstandardized egg product, such as scrambled egg mixes, would also be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. FDA has no information about the existence of egg products that have not been pasteurized or otherwise treated to destroy all viable SE and other *Salmonella*. However, the agency specifically requests data or other information that suggests that such products are commercially available. Should such products exist, FDA tentatively concludes that any final label statement required for shell eggs also be applicable to these products as well.

The safe handling statement is intended to inform consumers of ways that they may safely handle eggs to reduce their risk of foodborne illness. Likewise, the use of the safe handling statement on cartons of shell eggs that are not for direct sale to consumers, e.g., shell eggs that are to be labeled or repacked at a site other than originally processed or are shipped for use in food service establishments such as schools, hospitals, and restaurants also serves to inform repackers and food preparers of the safe handling procedures. However, FDA tentatively concludes that the same goal of conveying the safe handling labeling to repackers and food preparers could also be accomplished by customary trade practices. For example, the safe handling statement could be included on an invoice or product specifications sheet. Accordingly, FDA is proposing in § 101.17(h)(5) that the safe handling statement for shell eggs that are not for direct sale to consumers, e.g., those that are to be repacked or labeled at a site other than where originally processed or are sold for use in food service establishments may be provided on cartons or in labeling, e.g., invoices or bills of lading in accordance with the practice of the trade. FDA requests comment on whether allowing this practice will accomplish its intended goal.

D. Essential Elements of Specific Label Statements

Consumer research available to the agency indicates that when consumers generally believe that a product is safe, messages that note that the product is unsafe without providing information on the nature of the hazard are likely to confuse or frighten them (Ref. 25). This research also indicates that certain elements may be essential in label statements to effectively inform consumers of a potential hazard (Ref. 25). Recently, the agency has used such consumer research to develop effective warning labels. For example, the agency used such information to craft a warning statement for iron-containing supplements in § 101.17(e). As discussed in the final rule requiring that iron-containing supplements bear a warning statement (62 FR 2218), the agency found that elements essential for an effective warning statement for these products included an informational statement that describes the nature and magnitude of the hazard and a handling instruction on how to avoid the hazard. In addition, because the hazard associated with iron-containing products was associated with accidental overdose rather than ordinary conditions of use, essential elements for this warning statement also included a provisional statement that describes situations that require mitigation and an instructional statement that describes what action to take under those circumstances.

In determining what information is essential in the proposed statement, FDA tentatively concluded, based on the continued predominance of SE in foodborne outbreaks, that consumers may not know that there is a food safety hazard associated with shell eggs. Consumption data indicating that some consumers eat raw or undercooked eggs reinforce this tentative conclusion (Refs. 22 to 24). Therefore, FDA tentatively concludes that it is essential that the label statement describe the potential hazard, i.e., that eggs may contain pathogens known to cause serious, life-threatening illness.

In addition, the young, elderly, and persons with immune deficiencies are more susceptible to foodborne illness than others (Ref. 18) but may not realize that they are particularly at risk for serious illness from a food long recognized to be a safe and inexpensive source of good nutrition. These people, especially, along with their caregivers, need the information necessary to make informed decisions about avoiding,

reducing, or eliminating the risk of salmonellosis from eggs and egg-containing foods. Therefore, FDA tentatively concludes that the information needed by consumers about the potential hazard should also include information about the at-risk groups, so that they or their caregivers are aware of their greater risk.

In some circumstances in which the agency has required a label statement to inform consumers of consequences that could result from consumption of a product, FDA has presumed that consumers' reaction to a label statement would be a decision whether to avoid the product. For example, in its recent rulemaking to require a label statement on juice products that have not been processed to control pathogenic microorganisms, FDA stated its belief that it was implicit in its description of the hazard that at-risk groups could avoid the hazard by not consuming the product (63 FR 20486 at 20489, April 24, 1998). Consistent with this belief, one comment to the 1998 ANPRM opposed "warning labels" stating that eggs are potentially harmful because the statement would alarm consumers and would reduce egg consumption. However, as previously discussed, the consequences that may result from consumption of SE-contaminated eggs may be reduced or eliminated by proper handling techniques. Failure to make clear that there is a way other than avoidance to reduce this risk could imply to consumers that, similar to their options when faced with other label statements, their only available option is to avoid the product. Therefore, FDA tentatively concludes that an instructional statement that describes measures (i.e., safe handling practices) that consumers can take to reduce or eliminate the risk associated with consumption of SE-contaminated eggs should be an essential element of the label statement. Because temperature has been reported to play a role in suppressing the growth of *Salmonella* microorganisms (see discussion in section I.F of this document), and because thorough cooking kills SE (see discussion in section I.F of this document), FDA also tentatively concludes that the safe handling instructional statement should advise that eggs be refrigerated until they are ready to be cooked and that eggs be thoroughly cooked before they are eaten.

Because the more likely option for consumers who are presented with a label statement that describes a hazard is avoidance, FDA believes that a linking statement that clarifies that the recommended safe handling practices are measures that consumers can take to reduce or eliminate the risk is important to alleviate a potential misperception that avoidance is their only option. Therefore, FDA tentatively concludes that a linking statement that relates the informational statement to the instructional statement is an essential element of the label statement. These essential elements are similar to those contained in other required label statements in § 101.17.

FDA's consumer research on label statements for iron-containing products also shows that the first sentence of a label statement is likely to influence a consumer's decision to continue reading the remainder of the statement (Ref. 25). Moreover, as a result of the safe handling instructions that appear on raw meat and poultry under rulemaking conducted by FSIS (59 FR 14528, March 28, 1994), consumers are already accustomed to reading information about the risk before reading the safe handling practices that can reduce or eliminate the risk. Accordingly, FDA tentatively concludes that the first sentence of the label statement should be an informational statement about the potential hazard to consumers.

Applying the essential elements described previously, FDA crafted examples of label statements. The agency notes that some of the examples of acceptable label statements incorporate language suggested by Rose Acres Farms, Inc., and CSPI. These examples illustrate some of the variations in label statements developed by applying the essential elements. Four such examples are provided as follows:

SAFE HANDLING INSTRUCTIONS: Shell eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated and cook eggs and foods containing eggs thoroughly before eating.

SAFE HANDLING INSTRUCTIONS: Shell eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated and cook eggs until yolks are firm.

SAFE HANDLING INSTRUCTIONS: Eggs may contain illness-causing bacteria. The risk of life-threatening illness is greatest for children, the elderly, and persons with weakened immune systems. For your protection, keep eggs refrigerated until cooked, and cook eggs thoroughly until yolks are firm.

SAFE HANDLING INSTRUCTIONS: Some shell eggs have been found to contain harmful bacteria known to cause life-threatening illness, especially in children, the elderly, and persons with weakened immune systems. Consumers may protect themselves by keeping eggs refrigerated until cooked, by cooking eggs until the yolk is firm, and by cooking foods containing eggs thoroughly.

In order to evaluate the label statements developed through use of the essential elements and to test the effectiveness of such examples in informing consumers of the risks associated with shell eggs and of the safe handling practices that may be used to mitigate the risks, FDA conducted focus group research to evaluate consumer understanding of several possible safe handling instructions.

Six focus groups were conducted to test possible safe handling statements (Ref. 39). All participants examined and discussed five safe handling statements, including the four examples presented previously. The participants had some awareness of the potential dangers associated with eating eggs, and most were concerned about the safety of the eggs that they were purchasing. They were aware that the main food safety hazard posed by eggs was *Salmonella* contamination. Most of the participants kept their eggs refrigerated. However, many of them reported that they ate foods containing raw eggs, e.g., cookie batter, cake batter, homemade ice cream, and Caesar salad. The participants stated that most of the time they were aware when the foods they ate contained raw eggs, although some were surprised that Caesar salad could contain raw eggs. Generally, the participants were aware that they should thoroughly cook eggs, although they often cooked eggs according to their personal tastes, e.g., sunny-side up.

The participants were generally positive toward the idea of handling instructions on egg packages. Although many of them were already aware of the information presented in the handling statements, they saw the handling statements as useful reminders. To some of the participants, however, some of the information in the handling statements was new. Further, the participants appreciated the fact that with relatively simple steps they could be confident that their eggs were likely to be safe to eat. In addition, many participants thought that egg producers would not object to placing information presented in the example statements on the labels of egg cartons if all egg producers had to do so.

There were some discussions about certain words in the messages that the

groups thought were unnecessary, e.g., "shell" eggs, and "refrigerated until cooked." However, participants generally understood the messages and found them to be informative and not misleading. Further, they liked messages that were clear and easy to read.

While the label statements that were tested effectively informed the consumers of the potential hazard associated with the consumption of eggs, the agency did not test all conceivable variations of label statements incorporating the required information. Previous focus group research (i.e., for juice warning labels) indicated that minor wording differences may lead to confusion among consumers. The results of that research led the agency to prescribe the language of the label statement on juice products to ensure that consumers would not be misled (63 FR 37030, July 8, 1998). Similarly, the agency believes that it is also appropriate to prescribe the language of the safe handling statement on eggs. Therefore, the agency tentatively concludes that prescribing the language of each of the essential elements will be the most effective way to ensure that consumers are not misled and will correctly understand the safe handling instructions. This will ensure that consumers know of the risks of consuming raw or undercooked eggs and that they know the measures they can take to protect themselves. In addition, a prescriptive label statement is consistent with label statements for other food products.

FDA believes that a regulation requiring a label statement on cartons of shell eggs must be sufficiently clear to allow the regulated industry to determine that its labeling complies with that regulation. Furthermore, the regulation should establish a so-called "level playing field" for all products covered by the regulation by requiring that each product's labeling provide the same information. FDA tentatively concludes that prescribing the specific language for a label statement for shell eggs would accomplish these two goals, as well as ensure a message to consumers that is not confusing, misleading, or otherwise ineffective.

Accordingly, based on information from the focus groups, FDA is proposing in § 101.17(h)(1) to require that the label of shell eggs bear the following statement:

SAFE HANDLING INSTRUCTIONS: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection: keep eggs refrigerated; cook eggs until yolks are firm: and cook foods containing eggs thoroughly before eating.

The agency notes that the language in the first sentence of this prescribed label statement for eggs is similar to the label statement that FDA recently required for some juice products. As discussed in the final rule requiring warning statements on juice products that have not been processed to control pathogenic microorganisms (63 FR 37030 at 37045), FDA concluded that the term "serious illness" is an accurate description of the hazard caused by foodborne microorganisms that may be present in juice. The agency based its conclusion on results of focus group research which indicated that the term "serious illness" was understood and conveyed a strong message without being too extreme. Participants of the focus group research viewed such terms as "life threatening" or "death" less credible.

Also in that final rule, FDA recognized that the terms children and elderly are not precise. Rather, they are terms chosen by the Council for Agricultural Science and Technology to reflect groups that, in general, have incompletely developed or declining immune systems. Because the exact ages at which a child's immune systems is fully developed and at which an elderly person's immune system has declined are not precisely defined, FDA concluded that it had no basis to specify particular ages for these at-risk groups nor to use terms other than "children" or "elderly."

Several comments to the 1998 ANPRM expressed concerns about the suggested language that would appear in a proposed label statement. The issues raised in these comments were among those issues considered when FDA developed this proposed rule.

The agency requests comments on other aspects of the proposed safe handling statement and whether it effectively conveys information necessary to adequately inform consumers of measures that they can take to ensure the safety of the food. The agency tentatively concluded that the cooking instructions in the safe handling statement, i.e., "cook eggs until yolks are firm and cook foods containing eggs thoroughly" is adequate to inform consumers of ways to prepare eggs in order to reduce the risk of illness. The agency notes that part of the cooking instruction, i.e., "cook eggs until yolks are firm," is one way to describe proper cooking of an egg when consumed as an egg dish. For example, it is expected that when an egg, e.g. fried egg, is cooked until the yolk is firm, then the white would be sufficiently cooked.

For other foods that contain eggs, the safe handling statement must convey to consumers that the food should be cooked thoroughly. Focus group research showed that although many consumers are aware that foods that contain raw or undercooked egg whites only, e.g., meringue, can be a potential health hazard, many did not. However, the reason some consumers were unaware of the potential health risk was that they were unaware that foods like meringue may contain raw egg whites. When informed that such foods may contain raw egg whites, consumers understood the health risk. Thus, the agency tentatively concludes that there is no reason to believe that, when informed of the risk of illness associated with raw or undercooked eggs, consumers would differentiate the potential health risk based on what part of the egg is consumed. Therefore, FDA tentatively concluded that the part of the statement that instructs consumers to cook foods containing eggs thoroughly, would address foods that include any component of the egg, e.g., whole egg, egg white, or egg yolk. The agency requests comments on its tentative conclusion that this statement adequately instructs consumers on the safe handling instruction for foods containing eggs. Comments should include data or a rationale to provide a basis for the agency to adopt alternate phrasing.

As previously discussed, certain subpopulations are at greatest risk of serious illness and death caused by SE. For example, many deaths have occurred in nursing homes (Ref. 3). Because certain consumers, especially those at greatest risk, may want to avoid the risk altogether by avoiding the product, the agency requests comment on whether it should require a statement that the product should not be used for certain purposes, e.g., "use pasteurized eggs for recipes requiring raw or partially cooked eggs." The agency also requests comment on whether it should require an explicit instruction to avoid the product for at-risk consumers or for individuals (e.g., parents, nursing home staff) who are responsible for preparing foods for at-risk consumers.

As discussed in section II.A of this document, FSIS amended its regulations to require that shell eggs packed for consumer use be stored and transported at an ambient temperature that does not exceed 7.2 °C (45 °F) and that the containers of such eggs be labeled to indicate that refrigeration is required. The labeling statement proposed in this document, if finalized, will permit

uniform label statements with the FSIS rule. Consequently, this safe-handling statement would replace the label currently required by FSIS.

In the **Federal Register** of February 24, 1997 (62 FR 8248), FDA published a notice, entitled "Guidance on Labeling of Foods That Need Refrigeration by Consumers" ("the Refrigeration Guidance"). In that document, FDA noted that refrigeration is only one of many barriers (e.g., acidification, preservatives, and reduced water activity) that can be used to control microbial risks. However, for many foods (classified as "Group A foods"[6]), refrigeration is the only practicable barrier to reduce or retard pathogenic growth. The agency also noted that Group A foods, including shell eggs, are potentially hazardous foods, that, if subject to temperature abuse, will support the growth of infectious or toxigenic microorganisms that may be present. Growth of these microorganisms would render the food unsafe (62 FR 8248). As stated in that document, FDA concluded that the appropriate label statement for Group A foods is "IMPORTANT Must be kept refrigerated to maintain safety."

In the Refrigeration Guidance document, FDA stated that most consumers seem to understand that foods displayed only in the refrigerated sections of grocery stores such as dairy products, eggs, cold cuts, fresh meats, poultry and seafood, must be refrigerated to maintain quality. Further, the agency stated that, although it is unlikely that consumers are aware of the hazards that temperature abuse can present, it is likely that consumers will refrigerate these products in the absence of labeling. Therefore, the agency did not specifically address these products in the document. However, the agency concluded that the fact that the foods are refrigerated provides no evidence of the effectiveness of the "keep refrigerated" label. Although the guidance provided in that document was specifically directed toward products that appeared to be shelf stable or ones for which consumers seemed to not understand the importance of a "keep refrigerated" statement, the agency did not specifically exclude any foods from the guidance.

In light of information regarding outbreaks of SE associated with the temperature abuse of eggs and egg-containing products, FDA tentatively concludes that it is important that consumers be informed of the need for refrigeration of shell eggs. Further, the agency believes that the "keep refrigerated" statement in the suggested safe handling instructions in the proposed label statement conveys the same message as the label statement in the Refrigeration Guidance. Because the proposed linking statement, i.e., "for your protection," shows that there are measures that consumers can take to reduce or eliminate the risk of foodborne illness, the agency believes that it is implicit in the proposed safe handling instructions that refrigeration helps to maintain the safety of shell eggs. Thus, FDA tentatively concludes that there is no need for both statements in labeling of shell eggs.

Focus group participants responded favorably to a graphic format that used bullets for the safe handling instructions. FDA encourages the use of such a presentation. However, the agency recognizes that all egg cartons may not be able to accommodate this format and, therefore, FDA is not proposing to require it. The agency requests comment on this tentative decision. The agency also requests comments on whether graphics would enhance the visibility of the statement.

The agency notes that, under FSIS regulations (7 CFR 317.2 and 381.125), the safe handling statements that are currently required on raw meats and poultry include graphic illustrations. As discussed in the FSIS final rule (59 FR 14528), participants in consumer research indicated that safe handling instructions accompanied with graphics were preferred to those without graphics. As previously discussed in this section, FDA conducted its own consumer focus group research to evaluate consumer understanding of several safe handling labeling statements for shell eggs. Based on its focus group research, the agency tentatively concluded that the safe handling statement that it is proposing is adequate and effectively informs consumers of the risks associated with the consumption of shell eggs and of measures they can take to reduce their risk of foodborne illness. Therefore, the agency tentatively concludes that additional information, including graphic illustrations, is not necessary to convey the safe handling instructions to consumers. However, although FDA is not proposing to require graphic illustrations in the safe handling statement for shell eggs, the agency encourages use of illustrations similar to those used on raw meat and poultry on the cartons of shell eggs. While the agency did not specifically test the graphic illustrations with the consumer focus groups, the agency believes that, because graphic illustrations have been on meat and poultry product labels for some time, consumers have become familiar with these kinds of symbols. The agency requests comment on whether graphics should be required as part of the safe handling statement for shell eggs.

The agency has solicited specific comments on various aspects of this proposal as well as additional requirements. Any comments supporting additional requirements should include data, information, or a rationale in support of the position advocated. FDA will consider such comments and depending on the administrative record that is developed through the rulemaking process, may adopt as part of a final rule additional requirements. The agency notes, however, that it does not intend that this proposed regulation would, if finalized, preempt any State or local requirements for additional safe handling labeling, e.g., graphics, as long as it does not conflict with Federal requirements.

The agency notes that current regulations in § 101.17 use the terms "warning" or "notice." As previously discussed, FDA has presumed that consumers' reaction to a warning statement about the possible presence of harmful bacteria in eggs would be a decision whether to avoid the product. The term "notice" could be used, but does not draw attention to the important fact that there are ways to reduce or eliminate the risks of foodborne illness other than avoidance of the product. The agency tentatively concludes, therefore, that the required elements of the label statement are best described as "safe handling instructions." In light of this fact, the agency is proposing in this rulemaking to amend the title of § 101.17 to include the use of the term "safe handling statements."

E. Placement and Prominence of Label Statements

Section 403(f) of the act requires mandatory label information to be prominently placed on the label with such conspicuousness (compared with other words, statements, designs, or devices, in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of use. Two comments to the

[6] Group A foods as defined in the Refrigeration Guidance are potentially hazardous foods, which if subjected to temperature abuse, will support the growth of infectious or toxigenic microorganisms that may be present. They have the following characteristics: (1) A pH of >4.6, (2) a water activity of >0.85, (3) do not receive a thermal or other process in the final package that is adequate to destroy foodborne pathogens that can grow under conditions of temperature abuse, and (4) have no barriers built into the product formulation that would prevent the growth of foodborne pathogens that can grow under abuse conditions.

1998 ANPRM requested that FDA provide flexibility in any food labeling statement, e.g., placement of the statement could occur on the inside of the carton, or elsewhere on the package, as long as it is conspicuous. The comments argued that existing federal regulations already require certain label information, such as grading information and nutrition labeling. In addition, the comments maintained that many States also require additional information on egg cartons such as product codes and sell-by dates. Moreover, one comment contended that some States may require certain information in type sizes of 10-point type or 3/8 inch. Thus, the comment argued, there is limited label space for additional information. One comment requested that FDA consider allowing the use of a modified format for small packages (packages of less than a dozen eggs) similar to that permitted for nutrition labeling. The comment questioned whether federal requirements would duplicate or preempt State requirements. One comment stated that some States require the phrase "Keep refrigerated at or below 45 °F." Another comment estimated that approximately 40 percent of egg cartons on the market carry some form of "warning label." The comment pointed out that prior to the beginning of 1998, only 10 percent of the cartons on the market bore safe handling instructions. The comment requested that if existing safe handling instructions meet or exceed federal requirements, FDA should allow manufacturers to retain such labels. The issues raised in these comments were among those considered by FDA as it developed this proposed rule.

In the past, FDA has generally determined that the information panel is the appropriate location for label statements that are required by § 101.17. As discussed in the agency's rulemaking requiring label statements on iron-containing dietary supplements (62 FR 2218), consumer focus group studies indicated that the label statement need not be placed on the principal display panel (PDP) to be effective in informing consumers of the hazard. Participants in the focus group reasoned that the front of the product was used for marketing purposes, and consumers were used to looking at the "back of products" for nutrition and factual information including label statements such as warning messages. Thus, the agency required that the warning statement for iron-containing supplements appear on the information panel, the portion of the label where most mandatory information is located. The agency tentatively concludes that for label statements on shell eggs, the requirement for prominence and conspicuousness would similarly be met if the statements appeared on the information panel. However, the agency would not object to firms placing the label statement on the PDP, since the PDP would provide even more prominence. Accordingly, FDA is proposing to require in § 101.17(h)(2) that the label statement appear either on the information panel or on the PDP.

The requirement in the act for prominent display means that the label statement must appear in a manner that makes the statement readily observable and likely to be read. The agency notes that 21 CFR 101.2(c) requires that mandatory information appearing on the PDP and information panel, including information required by § 101.17, appear prominently and conspicuously in a type size no less than 1/16 inch. The agency also notes that 21 CFR 101.15(a) provides that information required on the label appear uncrowded and with sufficient contrast to background material. The agency has concluded that it is not necessary to repeat these requirements for prominence and conspicuousness in the proposed regulation and, therefore, is not including them in this proposal.

Current agency regulations that require a label "warning" statement (e.g., the statement required by § 101.17(e) on iron-containing dietary supplements in solid oral dosage form) or a label "notice" statement (e.g., the statement required by § 101.17(d)(3) on protein products that are not covered by the requirements of § 101.17(d)(1) and (d)(2)) require that the identifying term "WARNING" or "NOTICE" be capitalized and immediately precede the language of the applicable label statement. Likewise, consistent with these examples, the agency is proposing in § 101.17(h)(1) to require that the capitalized words "SAFE HANDLING INSTRUCTIONS" immediately precede the message of the label statement.

Previous agency regulations that require cautionary information on labels, e.g., on products containing aspartame (39 FR 27317, July 26, 1974), utilized bold type to make the information more prominent. In addition, FDA regulations on nutrition labeling (21 CFR 101.9(d)(1)(iv)) require that certain nutrient information in the Nutrition Facts panel be in bold type to provide more prominence. Therefore, consistent with these examples, the agency is proposing in § 101.17(h)(2) to require that the words "SAFE HANDLING INSTRUCTIONS" be in bold type to help alert the consumer that there is new and critically important information about the egg product.

The agency notes that experience has shown that the prominence of some labeling information may be enhanced by the use of a box around the information. The agency's experience with the new nutrition label has been that the box surrounding the nutrition information greatly increases the prominence of the information. In addition, consumer focus group research has shown that boxes around important messages help consumers to distinguish the message from other information (Ref. 25). Therefore, the agency tentatively concludes that the use of a box around the label statement for shell eggs will similarly increase the prominence of the message by setting it off, thereby enhancing the likelihood that consumers will notice and read the message. Accordingly, FDA is including in the proposal a requirement (proposed § 101.17(h)(3)) that the label statement be set off in a box by use of hairlines.

The agency requests comments on the prominence and placement of the proposed label statement and whether the proposal provides sufficient flexibility to accomodate the many types of egg cartons in the marketplace. FDA is particularly interested in comments on whether other measures, e.g., color enhancement, are necessary to focus the consumer's attention on the label statement.

IV. Analysis of Impacts

A. Benefit/Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million; adversely affecting some sector of the economy in a material way; or adversely affecting jobs or competition. A regulation is also considered a significant regulatory action under Executive Order 12866 if it raises novel, legal, or policy issues. Under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requiring cost-benefit and other analyses, a significant rule is defined in section

1531 (a) as "a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year * * *." Finally, the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S. based enterprises to compete with foreign-based enterprises in domestic or export markets.

FDA tentatively finds that this proposed rule is economically significant under Executive Order 12866. FDA has determined that this proposed rule, based on the median estimate of cost contained in the economic analysis, does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Furthermore, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1995 (Pub. L. 104–121) it has been determined that this proposed rule would be a major rule for the purpose of congressional review.

This section summarizes the preliminary regulatory impact analysis of the proposed rule. The full analysis and a list of references is available in a separate document entitled "Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels" (PRIA/IRFA) published elsewhere in this issue of the **Federal Register.**

One comment to the 1998 ANPRM suggested that FDA consider mandatory sell-by dates, prohibition of re-packaging, and mandatory pasteurization of shell eggs intended for at-risk consumers (such as residents of nursing homes). Several comments stated that in-shell pasteurization was costly; according to one comment, pasteurization equipment would cost $1.5 million. Several comments stressed the cost and difficulty of placing the safe handling statement on egg cartons, which are already crowded with printing. In one comment, a carton manufacturer estimated that designing and producing new plates for all of its egg cartons would cost about $2 million.

1. Regulatory Options

FDA considered several regulatory options for dealing with SE in shell eggs. The options considered include: (1) No new regulatory action, (2) labeling only, (3) refrigeration at 7.2 °C (45 °F) only, (4) refrigeration at 5 °C (41 °F), (5) Hazard Analysis Critical Control Point (HACCP) for shell eggs, (6) in-shell pasteurization, (7) longer compliance periods, and (8) limited retail sell-by period.

FDA believes that relying on current safeguards (option 1) would not greatly reduce the number of illnesses from SE in shell eggs. Even though the benefits from either labeling alone or refrigeration alone (options 2 and 3) exceed the costs, the combined benefits of refrigeration and labeling (the proposed rule) are much greater than either taken separately. FDA found that option 4 (refrigerate shell eggs at 5 °C (41 °F) in retail establishments and institutions) would not have a significant additional effect on SE in shell eggs, but would increase costs substantially. FDA believes that a HACCP-like program (option 5) is currently not feasible. However, FDA is evaluating whether in the future, a HACCP-like program including possibly in-shell pasteurization, may be necessary to further ensure the safety of shell eggs. In-shell pasteurization (option 6) would greatly reduce SE, but FDA believes other interventions between farm and table could reduce SE at lower cost. The main disadvantage of longer compliance periods for the labeling provision (option 7) is that the option would delay the realization of the benefits of the rule. Finally, FDA finds that limiting the retail sell-by period to 30 days (option 8) would have small public health benefits but could impose substantial costs.

2. Benefits

Benefits from the proposed rule to require a safe handling label and the refrigeration of shell eggs at 7.2 °C (45 °F) come from reducing SE-related illness. The basic model for estimating benefits is: "marginal health benefits = baseline risk (number of SE illnesses related to shell eggs) x expected reduction in the number of illnesses brought about by the proposed rule x health cost per illness".

FDA used the results of the USDA SE risk assessment for one estimate of the baseline risk and the CDC *Salmonella* surveillance data for another estimate of the baseline. FDA also used the risk assessment model to estimate the expected reduction in illnesses attributed to the proposed rule. The design of the USDA SE risk assessment model allowed FDA to estimate the number of illnesses prevented by comparing the baseline number of illnesses with the number of illnesses under the provisions of the proposed rule. The range (5th to 95th percentile) of estimated annual illnesses prevented for the USDA SE risk assessment baseline was 12,000 to 407,000, with a median of 66,000. The range (5th to 95th percentile) of estimated illnesses prevented for the CDC surveillance baseline was 7,000 to 107,000, with a median of 25,000.

FDA calculated the health cost per illness prevented by classifying SE illnesses into the following outcomes based on severity: Mild, moderate, and severe acute gastrointestinal illnesses; resolved and chronic reactive arthritis; and death. FDA then multiplied the estimated monetary health cost per type of illnesses by the number of illnesses prevented of each type. Total health benefits from the proposed rule were calculated as follows:

total health benefits = (number of mild cases prevented x $ per case) + (number of moderate cases prevented x $ per case) + (number of severe-acute cases prevented x $ per case) + (number of resolved cases of arthritis prevented x $ per case) + (number of chronic cases of arthritis prevented x $ per case) + (number of deaths x $ per death)

The baseline risk, the expected reduction in risk, and the health costs per illness are all uncertain. FDA therefore estimated a distribution of possible health benefits for the proposed rule, with the distribution based on the probability distributions associated with the main uncertainties. The range (5th to 95th percentile) of estimated annual benefits for the USDA SE risk assessment baseline was $87 million to $6.6 billion, with a median of $700 million. The range (5th to 95th percentile) of estimated annual benefits for the CDC surveillance baseline was $50 million to $1.7 billion, with a median of $300 million. The benefits are large, although FDA estimates that 95 percent of shell eggs are already held at ambient temperatures of 7.2 °C (45 °F) or less.

3. Costs

The costs of the proposed rule are the sum of the costs of changes in manufacturing practices—labeling and refrigeration and changes in consumer practices—egg preparation and consumption.

a. *Labeling.* The costs of labeling are the sum of administrative compliance, inventory disposal, and label redesign costs. FDA calculated labeling costs with the following model: "labeling cost = ($ administrative costs per firm x

number of affected firms) + ($ value of cartons manufactured x disposal percentage of carton inventory) + (number of affected labels x $ redesign cost per label)".

FDA estimated the total labeling cost for a 6-month compliance period to be a one-time cost of approximately $18 million. The total cost included administrative costs of $280,000, inventory disposal costs of $3 million, and label redesign costs of $15 million.

b. *Refrigeration.* FDA estimated the refrigeration costs to be the cost of the additional equipment required for all establishments to maintain an ambient temperature of 7.2 °C (45 °F). FDA calculated the cost by multiplying the estimated number of establishments that would require new (or upgraded) equipment by the cost of equipment. Both the number of establishments affected and the cost of equipment are uncertain. FDA estimated the number of establishments that would require new equipment by assuming that no establishments in States that had adopted the Food Code and an uncertain fraction—with one-third the most likely value—of establishments in States that had not adopted the Food Code would require new equipment. FDA used industry sources to obtain estimates of the range of costs of new or additional equipment necessary to meet the refrigeration provision of the proposed rule. The estimated costs per establishment ranged from close to zero for small equipment upgrades to $6,000 for a large new refrigerator.

FDA estimated a distribution of possible refrigeration costs for the proposed rule. The range (5th to 95th percentile) of estimated one-time refrigeration costs was $7 million to $228 million, with a median of $31 million.

c. *Changes in consumer practices.* FDA estimated the annual costs to consumers of changing the way eggs are prepared and consumed as follows:

cost of changes in consumer practices = annual number of eggs consumed x baseline fraction of eggs consumed undercooked x fractional reduction in undercooked eggs in response to safe handling label x $ value of undercooking one egg

The cost to consumers is uncertain. The range (5th to 95th percentile) of annual costs was $2 million to $20 million, with a median of $10 million. The cost of changes in consumer practices is an annual recurring cost of the proposed rule.

4. Summary of Benefits/Cost Analysis

Table 1 of this document shows the median estimated benefits and costs of the proposed rule.

TABLE 1.—MEDIAN ANNUAL ESTIMATED BENEFITS AND COSTS OF THE PROPOSED RULE (IN MILLIONS OF DOLLARS)

Incidents of Benefit and Cost Analysis	First Year	All Other Years
Median estimated benefits (USDA SE risk assessment baseline)	$700	$700
Median estimated benefits (CDC surveillance baseline)	$300	$300
Median estimated costs	$60	$10

B. Small Entity Analysis

1. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

2. Economic Effects on Small Entities

a. *Number of small entities affected.* The proposed rule would affect many small entities, including egg processors, grocery stores and other stores including roadside stands, restaurants and other food service establishments. FDA has not been able to determine how many of the 669 egg processors registered with the USDA are small businesses (Ref. 40). Egg processors generally fall into two industrial classifications: Poultry slaughtering and processing (standard industrial classification (SIC code 2015)) and whole poultry and poultry products (SIC code 5144). The two classifications roughly correspond to in-line and off-line processors. In-line processors package the eggs at the egg laying facility. Off-line processors ship the eggs to packers.

The Small Business Administration (SBA) defines in-line egg processors (SIC code 2015–03) to be small businesses if they employ 500 or fewer people. According to a search in Dun's Market Identifiers (Ref. 41), 25 in-line egg processing firms would be defined as small. SBA defines off-line processors (SIC code 5144) to be small if they employ 100 or fewer people. Dun's Market Identifiers did not have a subcategory for egg processors. For the entire category of poultry and poultry products (SIC code 5144), 80 percent of establishments employ fewer than 100 workers. If the same proportion holds for the subcategory composed of egg processors, then 470 firms would be classified as small.[7] FDA estimated the total number of small egg processors to be 495 (= 25 + 470).

The refrigeration provision would affect small establishments that are not currently refrigerating at 7.2 °C (45 °F). The SBA defines grocery stores (SIC code 5411) to be small if annual gross revenue is less than $20 million. Other food stores (SIC codes 5431, 5451, and 5499), which include fruit and vegetable markets, dairy product stores, and miscellaneous food stores, are small if annual sales are less than $5 million. Restaurants are small if annual sales are less than $5 million; institutions are small if sales are less than $15 million.

As set out in Table 2 of this document, FDA estimates that the number of small establishments affected by the proposed refrigeration provision would be 25,400. The number of establishments (small and large) currently not keeping eggs at an ambient temperature of 7.2 °C (45 °F) is approximately 44,400, which includes 10,700 grocery and other food stores, 24,000 restaurants, and 9,700 institutions (see the PRIA/IRFA document elsewhere in this issue of the **Federal Register**). FDA assumed that the proportion of small establishments affected by the refrigeration provision would be the same as the fraction of institutions for the entire industry in that category. According to SBA size standards for small entities, 71 percent of grocery and other food stores and 54 percent of restaurants are small. Institutions are more complicated, because they cut across SIC codes. FDA assumed that 50 percent of institutions serving eggs are small. The agency asks for comments on this assumption. FDA estimated the number of small establishments affected by the

[7] The estimated total number of in-line establishments is 134, but 52 are branches of firms. If the total number of in-line firms is 82 (= 134 - 52), and the number of processors is 669, then 587 firms are off-line processors. If 80 percent are small, then 470 off-line (= 0.8 x 587) processors are small.

refrigeration provision by multiplying the fraction in each category defined to be small by the total number of establishments affected. Table 2 of this document shows the number of small entities likely to be affected by the refrigeration provision of the proposed rule.

TABLE 2.—NUMBER OF SMALL ENTITIES LIKELY TO BE AFFECTED BY THE REFRIGERATION PROVISION OF THE PROPOSED RULE

Category	Number of Small Establishments Currently Storing Eggs Above 45 °F (7 °C)
Grocery and other stores	7,600
Restaurants	13,000
Institutions	4,800
Total	25,400

b. *Costs to small entities.* Redesigning the label accounts for most of the estimated additional labeling costs for small processors. For a 6-month compliance period, redesign costs would be $1,000 per stockkeeping unit (SKU) for pulp cartons and $500 per SKU for foam cartons. The cost of the labeling provision borne by small processors will vary with the number of SKU's. The average number of SKU's per processor for the industry is 30; FDA assumes that the output of small processors falls in the range of 2 to 20 SKU's. Additional redesign costs could therefore be as high as $20,000 per processor (= 20 x $1,000).

Refrigeration costs vary across establishments, depending on the age of current refrigerators, the planned replacement cycle, and whether the small establishments is currently keeping eggs at or below 7.2 °C (45 °F). Additional refrigeration costs for small retailers would average $633, with $700 the most likely value. FDA assumed that the proportion of additional refrigeration costs borne by small entities would be the same as the proportion of small entities in each category of establishments. The cost of the refrigeration provision to small entities is shown in Table 3 of this document. The agency requests comments on the effect of the refrigeration provision on roadside stands and the practices they follow in marketing eggs.

TABLE 3.—COSTS TO SMALL ENTITIES OF THE REFRIGERATION PROVISION OF THE PROPOSED RULE

Category	Total Costs to Small Entities	Mean Cost per Small Entity
Grocery and other stores	$4.8 million	$633
Restaurants	$8.2 million	$633
Institutions	$3.1 million	$633

3. Regulatory Options

a. *Exemption for small entities.* The burden on small entities would be lifted if they were exempt from the provisions of the proposed rule. Most of the entities affected by this proposed rule, however, are small. Thus, exempting small entities from its provisions would effectively negate the rule.

b. *Longer compliance periods.* Lengthening the labeling compliance period from 6 months to 18 months and lengthening the refrigeration compliance period from the proposed rule's effective date to 12 months after the effective date would provide regulatory relief (cost reduction) to small entities. In order to estimate the regulatory relief from lengthening the refrigeration compliance period, the agency assumed that the cost reduction would equal the interest (discounted at 7 percent per year) on the cost of refrigeration equipment over the extension of the compliance period. If the compliance period were extended by 12 months, the interest on the cost of equipment would be over $1 million (= $16.1 x 0.07). For the most likely equipment cost of $700 per small establishment, the interest saving would be about $50 (=0.07 x $700).

In order to estimate the regulatory relief to small retail entities from a longer labeling compliance period, FDA estimated that total industry costs would fall by $11 million if the compliance period were extended from 6 months to 18 months (see the PRIA/IRFA document elsewhere in this issue of the **Federal Register**). Most of the relief to small businesses would come from the reduced costs of redesigning the carton label. For pulp cartons, extending the compliance period to 18 months would reduce redesign costs from $1,000 (for a 6-month compliance period) to $500 per SKU. For foam cartons, extending the compliance period to 18 months would reduce redesign costs from $500 (for a 6-month compliance period) to $100 per SKU.

Although lengthening the compliance periods would provide some regulatory relief to small entities, they make up such a large part of the affected industries that longer compliance periods would significantly delay the full public health benefits of the proposed rule.

4. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping and recording required for compliance with this rule. This rule does not require the preparation of a report or a record.

5. Worst Case to Small Entities

The greatest impact to a small retail establishment as a consequence of the refrigeration provision would be to cause the entity to bear the entire cost for the purchase of a new refrigerator. The agency estimates that the cost of a new refrigerator is between $2,500 and $6,000 (see the PRIA/IRFA document published elsewhere in this issue of the **Federal Register**). In order to estimate the worst possible outcome for a small entity, FDA assumed that some small retail establishment would purchase a new refrigerator at the maximum estimated cost of $6,000. If the latter

cost were amortized over a 10-year period (using a discount rate of 7 percent) then the approximate annual expense would be $850 per year for 10 years. According to Dun and Bradstreet, 85 percent of all grocery stores have annual sales of less than $20 million, and 71 percent of all restaurants have annual sales of less than $5 million (Ref. 41). Among the smallest 10 percent of these establishments, the average sales volume is $100,000 per year for a grocery store and $50,000 per year for a restaurant. Therefore, the additional expense of $850 per year amounts to approximately 1 to 2 percent of average sales volume per year. Grocery stores and restaurants typically have profit margins on sales of 1 to 5 percent, so a reduction of the profit margin by 40 to 100 percent would be the worst-case outcome for the smallest entities in retail.

The worst case to a small entity attributable to the labeling provision would occur if a small packer were unable to pass along any of the cost to its customers. As shown previously, FDA estimated that the redesign cost to a small processor could be as high as $20,000. If the one-time cost could be amortized over a 10-year period at an annual discount rate of 7 percent, the small packer would incur an additional annual expense of approximately $3,000. FDA has not estimated the annual sales revenues of the smallest egg packers and is therefore unable to compare the estimated amortized cost to annual profits. FDA requests comments on this relationship.

6. Summary of Small Entity Analysis

FDA estimated that the labeling provisions could impose costs of up to $20,000 on 495 small processing establishments. The refrigeration provision would impose estimated costs of $633 per small entity on approximately 25,400 small establishments. FDA finds that, under the Regulatory Flexibility Act, this proposed rule would have a significant economic impact on a substantial number of small entities.

V. Executive Order 12612: Federalism

FDA has examined the effects of the two requirements in this proposal, i.e., refrigeration of shell eggs at retail and safe handling labeling of shell eggs, on the relationship between the Federal Government and the States, as required by Executive Order 12612 on "Federalism." The agency concludes that preemption of State or local rules that establish requirements for refrigeration of shell eggs that would be less stringent than Federal law is consistent with this Executive Order. The agency also concludes that the preemption of State or local rules that establish requirements for safe handling instructions on shell eggs that would not include, at a minimum, the language required by the Federal law is also consistent with this Executive Order.

Section 3(b) of Executive Order 12612 recognizes that Federal action limiting the discretion of State and local governments is appropriate "where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope." The constitutional basis for FDA's authority to regulate the safety and labeling of foods is well established.

Section 4(a) of Executive Order 12612 expressly contemplates preemption when there is a conflict between the exercise of State and Federal authority under Federal statute. Moreover, section 4(b) of the Executive Order authorizes preemption of State law in the Federal rulemaking context when there is "firm and palpable evidence compelling the conclusion that the Congress intended to delegate to the * * * agency the authority to issue regulations preempting State law." State and local laws and regulations that would impose less stringent requirements for refrigeration of shell eggs held for retail distribution would undermine the agency's goal of ensuring that shell eggs are properly refrigerated to prevent the growth of SE, and, thus, reduce the risk of foodborne illness. Similarly, State and local requirements for safe handling labeling that do not include, at a minimum, the language required by Federal law would undermine the agency's effort to provide consumers with material information that would inform them how to properly handle and cook eggs so as to reduce their risk of foodborne illness. FDA believes that a single temperature requirement will ensure that all shell eggs for retail distribution would meet minimal standards to ensure safety. The agency also believes that consistent safe handling instructions are necessary so consumers can find essential information in a message that is not confusing or misleading.

The proposed rule would establish national minimum standards with respect to refrigeration and labeling of shell eggs. However, the refrigeration requirements of this proposed rule do not preempt State and local laws, regulations, and ordinances that establish more stringent requirements with respect to the refrigeration requirements, e.g., lower storage temperature requirements. In addition, the labeling provisions of this proposed rule do not preempt State and local laws, regulations, and ordinances that require additional safe handling instructions, e.g., graphics, on shell eggs that do not conflict with the proposed Federal requirements.

As required by the Executive Order, States and local governments will be given, through this notice of proposed rulemaking, an opportunity to participate in the proceedings to preempt State and local laws (section 4(e) of Executive Order 12612). In addition, under the Order, appropriate officials and organizations will be consulted before this proposed action is implemented (section 3(a) of Executive Order 12612).

The agency concludes that the policy proposed in this document has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; that this policy is not inconsistent with that Order; that this policy will not impose additional costs and burdens on the States; and that this policy will not affect the ability of the States to discharge traditional State governmental functions.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(j) and (k) 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. Effective Date

FDA is proposing that any final rule that may be issued based upon this proposal become effective 180 days after its publication in the Federal Register. However, because FDA believes that it is in the best interest of all consumers for manufacturers to label shell eggs as soon as possible, the agency urges manufacturers and packers of shell eggs to label their products with safe handling statements consistent with this proposal immediately. FDA recognizes that it is possible that the requirements for the label statements in the final rule may be different from those in the proposal. However, to encourage manufacturers to use the label statements as soon as possible, the agency advises that it intends to allow the continued use of any label that complies with the proposed regulation and is printed prior to date of publication of any final rule resulting from this proposal until that inventory is depleted.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather the proposed safe handling instructions would be a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

IX. Comments

Interested persons may, on or before September 20, 1999, 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.

X. References

The following references have been placed on display at 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. Centers for Disease Control and Prevention Memorandum from Chief, Foodborne Diseases Epidemiology Section, February 8, 1996.

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16. Snoeyenbos, G. H., C. F. Smyser, and H. Van Roekel, "Research Note: *Salmonella* Infections of the Ovary and Peritoneum of Chickens," *Avian Diseases*, 13:668–670, 1969.

17. *Salmonella Enteritidis* Pilot Project Progress Report, May 22, 1995.

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33. U.S. Public Health Service, "Food Code: 1999, Recommendations of the United States Public Health Service, Food and Drug Administration," Sections 3–401.11 and 3–501.16.

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35. *Salmonella Enteritidis* Review Team Report, January 18, 1997.

36. Centers for Disease Control and Prevention, "Update: *Salmonella enteritidis* Infections in Grade A Shell Eggs—United

States," *Morbidity and Mortality Weekly Report*, 37:490, 495–496, 1988.

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40. FDA memorandum, Peter Vardon to the Record, October 7, 1998.

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 101

Administrative practice and procedure, Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 115

Administrative practice and procedure, Eggs, Refrigeration.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Services Act, and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.5 is amended by adding paragraph (a)(4) to read as follows:

§ 16.5 Inapplicability and limited applicability.

(a) * * *

(4) A hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), §§ 101.17(h) and 115.50 of this chapter.

* * * * *

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

4. Section 101.17 is amended by revising the section heading and by adding paragraph (h) to read as follows:

§ 101.17 Food labeling warning, notice, and safe handling statements.

* * * * *

(h) *Shell eggs.* (1) The label of shell eggs shall bear the following statement:

SAFE HANDLING INSTRUCTIONS: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection: keep eggs refrigerated; cook eggs until yolks are firm; and cook foods containing eggs thoroughly.

(2) The label statement required by paragraph (h)(1) of this section shall appear prominently and conspicuously, with the words "SAFE HANDLING INSTRUCTIONS" in bold type, on the information panel or the principal display panel of the container.

(3) The label statement required by paragraph (h)(1) of this section shall be set off in a box by use of hairlines.

(4) Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of this paragraph (h).

(5) The safe handling statement for shell eggs that are not for direct sale to consumers, e.g., those that are to be repacked or labeled at a site other than where originally processed, or are sold for use in food service establishments, may be provided on cartons or in labeling, e.g., invoices or bills of lading in accordance with the practice of the trade.

(6) The requirements of this section are applicable to all shell eggs.

(7) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraphs (h)(1) through (h)(5) of this section, and is authorized to inspect or regulate establishments handling packed shell eggs, may in its own jurisdiction, enforce paragraphs (h)(1) through (h)(5) of this section through inspections under paragraph (h)(9) of this section and through administrative enforcement remedies identified in paragraph (h)(8) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing such assistance, a State or locality may follow the hearing procedures set out in paragraphs (h)(8)(ii)(C) through (h)(8)(ii)(D) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

(8) This paragraph (h) is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food misbranding provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the relabeling, diversion, or destruction of shell eggs and informal hearings under the PHS Act:

(i) Upon finding that any shell eggs are in violation of this section, an authorized FDA representative or State or local representative in accordance with paragraph (h)(7) of this section may order such eggs to be relabeled under the supervision of said representative, diverted, under the supervision of said representative for processing in accordance with the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the State or locality, in accordance with the following procedures:

(A) *Order for relabeling, diversion, or destruction under the PHS Act.* Any district office of the FDA or any State or locality acting under paragraph (h)(7) of this section, upon finding shell eggs held in violation of this regulation, may serve upon the person in whose possession such eggs are found a written order that such eggs be relabeled with the required statement in paragraph (h)(1) of this section before further distribution. If the person chooses not to relabel, the district office of the FDA or, if applicable, the appropriate State or local agency may serve upon the person a written order that such eggs be diverted (from direct consumer sale, e.g., to food service) under the supervision of an officer or employee of the issuing entity, for processing in accordance with the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*)) or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order.

(B) *Issuance of order.* The order shall include the following information:

(*1*) A statement that the shell eggs identified in the order are subject to relabeling, diversion for processing in

accordance with the Egg Products Inspection Act, or destruction;

(2) A detailed description of the facts that justify the issuance of the order;

(3) The location of the eggs;

(4) A statement that these eggs shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (h)(8)(i)(E) of this section;

(5) Identification or description of the eggs;

(6) The order number;

(7) The date of the order;

(8) The text of this entire section;

(9) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(10) The name and phone number of the person issuing the order; and

(11) The location and telephone number of the responsible office or agency and the name of its director.

(C) *Approval of director.* An order, before issuance, shall be approved by the director of the office or agency issuing the order. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(D) *Labeling or marking of shell eggs under order.* An FDA, State, or local representative issuing an order under paragraph (h)(8)(i)(A) of this section shall label or mark the shell eggs with official tags that include the following information:

(1) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(2) A statement that the shell eggs shall not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*i*) Relabel, divert them for processing in accordance with the Egg Products Inspection Act, or destroy them: or

(*ii*) Move them to another location for holding pending appeal.

(3) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act, 42 U.S.C. 271).

(4) The order number and the date of the order, and the name of the government representative who issued the order.

(E) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(1) Relabel, divert, or destroy them as specified in paragraph (h)(8)(iv) of this section; or

(2) Move them to another location for holding pending appeal.

(ii) The person on whom the order for relabeling, diversion, or destruction is served may either comply with the order or appeal the order to the regional food and drug director.

(A) *Appeal of a detention order.* Any appeal shall be submitted in writing to the FDA District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(B) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the regional food and drug director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the regional food and drug director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(C) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the regional food and drug director or his designee, and a written summary of the proceedings shall be prepared by the regional food and drug director.

(1) The regional food and drug director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The regional food and drug director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(2) Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(3) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(4) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the regional food and drug director's report of the hearing.

(5) The regional food and drug director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the regional food and drug director may give the parties the opportunity to review and comment on the report of the hearing.

(6) The regional food and drug director shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(D) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the regional food and drug director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(E) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the regional food and drug director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be relabeled, diverted under the supervision of an officer or employee of the FDA for processing under the Egg Products Inspection Act, or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the regional food and drug director shall issue a written notice that the prior order is withdrawn. If the regional food and drug director affirms the order he shall order that the

relabeling, diversion, or destruction be accomplished within 10-working days from the date of the issuance of his decision. The regional food and drug director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the regional food and drug director shall constitute final agency action, reviewable in the courts.

(F) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to relabel, divert, or destroy them within 10-working days, or if the demand is affirmed by the regional food and drug director after an appeal and the person in possession of such eggs fails to relabel, divert, or destroy them within 10-working days, the FDA district office, or, if applicable, the State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(9) Persons engaged in handling or storing packed shell eggs for retail distribution shall permit authorized representatives of FDA to make at any reasonable time such inspection of the establishment in which shell eggs are being held, including inspection and sampling of the labeling of such eggs as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

5. New part 115 is added to read as follows:

PART 115—SHELL EGGS

Subpart A—General Provisions

Sec.

115.50 Refrigeration of shell eggs held for retail distribution.

Authority: 21 U.S.C. 342, 371; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 115.50 Refrigeration of shell eggs held for retail distribution.

(a) For purposes of this section a "retail establishment" is an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption directly to consumers.

(b) Except as provided in paragraph (c) of this section, shell eggs held for retail distribution:

(1) Shall promptly be placed under refrigeration as specified in paragraph (b)(2) of this section upon receipt at a retail establishment; and

(2) Shall be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at a retail establishment.

(c) Shell eggs that have been specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (b) of this section.

(d) The requirements of this section are applicable to all shell eggs.

(e) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraph (b) of this section, and is authorized to inspect or regulate retail establishments. may. in its own jurisdiction, enforce paragraph (b) of this section through inspections under paragraph (g) of this section and through administrative enforcement remedies identified in paragraph (f) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing assistance under paragraph (f) of this section, a State or locality may follow the hearing procedures set out in paragraphs (f)(2)(iii) through (f)(2)(v) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

(f) This section is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food adulteration provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act:

(1) Upon finding that any shell eggs have been held in violation of this section, an authorized FDA representative or a State or local representative in accordance with paragraph (e) of this section may order such eggs to be diverted, under the supervision of said representative, for processing in accordance with the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the state or locality in accordance with the following procedures:

(i) *Order for diversion or destruction.* Any district office of FDA or any State or local agency acting under paragraph (e) of this section, upon finding shell eggs held in violation of this regulation, may serve upon the person in whose possession such eggs are found a written order that such eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of said district office, within 10-working days from the date of receipt of the order.

(ii) *Issuance of order.* The order shall include the following information:

(A) A statement that the shell eggs identified in the order are subject to diversion for processing in accordance with the Egg Products Inspection Act or destruction;

(B) A detailed description of the facts that justify the issuance of the order;

(C) The location of the eggs;

(D) A statement that these eggs shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (g)(4) of this section;

(E) Identification or description of the eggs;

(F) The order number;

(G) The date of the order;

(H) The text of this entire section;

(I) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(J) The name and phone number of the person issuing the order; and

(K) The location and telephone number of the office or agency and the name of its director.

(iii) *Approval of District Director.* An order, before issuance, shall be approved by the Food and Drug Administration (FDA) District Director in whose district the shell eggs are located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(iv) *Labeling or marking of shell eggs under order.* An FDA, State or local agency representative issuing an order under paragraph (g)(1) of this section shall label or mark the shell eggs with official tags that include the following information:

(A) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(B) A statement that the shell eggs shall not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*1*) Divert them for processing in accordance with the Egg Products Inspection Act or destroy them; or

(2) Move them to an another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act, 42 U.S.C. 271).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(v) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(A) Divert or destroy them as specified in paragraph (f)(1)(i) of this section; or

(B) Move them to another location for holding pending appeal.

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to the regional food and drug director in accordance with the following procedures:

(i) *Appeal of a detention order.* Any appeal shall be submitted in writing to FDA's District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the regional food and drug director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the regional food and drug director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the regional food and drug director or his designee, and a written summary of the proceedings shall be prepared by the regional food and drug director.

(A) The regional food and drug director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The regional food and drug director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(B) Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(C) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the regional food and drug director's report of the hearing.

(E) The regional food and drug director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the regional food and drug director may give the parties the opportunity to review and comment on the report of the hearing.

(F) The regional food and drug director shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the regional food and drug director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the regional food and drug director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be diverted, under the supervision of an officer or employee of the FDA for processing under the Egg Products Inspection Act or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the regional food and drug director shall issue a written notice that the prior order is withdrawn. If the regional food and drug director affirms the order he shall order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The regional food and drug director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the regional food and drug director shall constitute final agency action, reviewable in the courts.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the regional food and drug director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or appropriate State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(g) *Inspection.* Persons engaged in retail distribution of shell eggs shall permit authorized representatives of FDA to make at any reasonable time such inspection of the retail establishment in which shell eggs are being held, including inspection and sampling of such eggs and the equipment in which shell eggs are held and any records relating to such equipment or eggs, as may be necessary in the judgement of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

Dated: June 10, 1999.
Jane E. Henney,
Commissioner of Food and Drugs.
Donna E. Shalala,
Secretary of Health and Human Services.
[FR Doc. 99–17122 Filed 7–1–99; 11:12 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 101, and 115

[Docket No. 99N–1307]

RIN 0910–AB30

Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Preliminary regulatory impact analysis and initial regulatory flexibility analysis.

SUMMARY: The Food and Drug Administration (FDA) is publishing both the preliminary regulatory impact analysis prepared under Executive Order 12866 and the initial regulatory flexibility analysis prepared under the Regulatory Flexibility Act on the proposed rule (published elsewhere in this issue of the **Federal Register**) to require shell eggs to contain safe handling statements and to be stored and displayed under refrigeration at 7.2 °C when held by retail establishments. FDA is issuing the proposed rule because of the large number of illnesses and deaths caused by *Salmonella enteritidis* (SE) associated with shell eggs that have not been treated to destroy the pathogen. The proposed rule is intended to ensure that consumers will have the information necessary to protect themselves from eggs contaminated with SE and to ensure that eggs will be held at retail at temperatures that discourage pathogen growth.

DATES: Submit written comments on the analysis of the proposed rule by September 20, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket numbers found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Clark Nardinelli, Center for Food Safety and Applied Nutrition (HFS–726), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8702.

SUPPLEMENTARY INFORMATION:

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I. Preliminary Regulatory Impact Analysis

A. Introduction

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive effects; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: (1) Having an annual effect on the economy of $100 million, (2) adversely affecting a sector of the economy in a material way, (3) adversely affecting competition, or (4) adversely affecting jobs. A regulation is also considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues.

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as "a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year." The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: (1) An annual effect on the economy of $100 million; (2) a major increase in costs or prices; (3) significant effects on competition, employment, productivity, or innovation; or (4) significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In the **Federal Register** of May 19, 1998 (63 FR 27502), USDA and FDA published an advance notice of proposed rulemaking (ANPRM) entitled "*Salmonella* Enteritidis in Eggs." Among other things, this ANPRM solicited public comment on what regulations might be required to reduce the public health risk of SE in shell eggs. USDA received approximately 73 responses to this ANPRM, each containing one or more comments. Responses were received from egg farmers, egg packers, associations for the egg industry, other trade associations, consumers, consumer interest groups, animal interest groups, academia, State

government agencies, and foreign government agencies. Included in these responses were several comments concerning the economic implications raised by the approaches discussed in the ANPRM. One comment suggested that FDA consider mandatory sell-by dates, prohibition of re-packaging, and mandatory pasteurization of shell eggs intended for at-risk consumers (such as residents of nursing homes). Several comments stated that in-shell pasteurization was costly; according to one comment, pasteurization equipment would cost $1.5 million. Several comments stressed the cost and difficulty of placing the safe handling statement on egg cartons, which are already crowded with printing. In one comment, a carton manufacturer estimated that designing and producing new plates for all of its egg cartons would cost about $2 million. One comment suggested allowing existing safe handling labels. Several comments advocated some form of HACCP for shell eggs. Comments regarding the regulatory impact of the proposed rule are addressed below.

B. Failure of the Existing Regime

The proposed rule addresses the handling and preparation of shell eggs by retail establishments and consumers, and should reduce the illnesses and deaths that can occur from consumption of eggs contaminated with SE.

Private markets operate within the framework of legal institutions. The tort system of the common law evolved, in part, to provide remedies to injuries suffered in transactions in private markets. Under this system, if a defective product injures someone, then the injured person may recover damages from the producer of the defective product. The recovery of damages requires the injured person to prove that his/her injuries were caused by the producer's product. However, regardless of the legal theory chosen (negligence, warranty, or strict liability), to recover damages the injured person must be able to link his/her injury to the specific product of a specific producer.

In most instances, consumers experiencing illness from food consumption do not recognize the illness as foodborne or are unable to link the illness to consumption of a particular food. This inability to connect illness and food exists because many symptoms do not occur immediately after consumption of the product. The proposed rule addresses the inability of the tort system to address adequately the mishandling of eggs by retailers and the failure to provide consumers with information needed to reduce SE-related illnesses.

The proposed refrigeration provision addresses the possible market failure (because illnesses are not easily traced to processors) that occurs when eggs are not held at appropriate temperatures at retail and consumers are put at greater risk from SE-contaminated eggs. The increased risk resulting from SE-contaminated eggs that are not held at appropriate temperatures in retail establishments can lead to involuntary health effects for consumers who do not know about the temperature abuse or do not know about the associated increased risk from SE. Indeed, retailers may be as poorly informed as consumers about the SE-related health effects from temperature abused eggs. Because both retailers and consumers may be ignorant or uncertain about the risk, the implicit contract between consumers and retailers does not incorporate the potential harm to consumers caused by the hidden health risk associated with shell eggs. Furthermore, the uncertainty and ignorance may persist about the risk—despite the occurrence of illnesses—because of the long time lapse between the purchase of the SE-contaminated eggs and the onset of SE-related illnesses.

By requiring safe handling statements, the proposed rule will provide information about the potential adverse health effects of SE-contaminated eggs. The information will persuade some consumers to change potentially risky handling practices and thereby reduce the number of illnesses associated with SE in shell eggs. The proposed labeling provision helps correct the failure of the existing regime that occurs when consumers lack relevant information about the safe handling (refrigeration and thorough cooking) of eggs. Because this information is associated with a negative characteristic of the product, and this negative characteristic is not easily differentiated among egg products, processors have little incentive to make this information available to consumers. Without the relevant information, some consumers may not properly refrigerate or may not adequately cook eggs, and some may consume foods containing raw eggs. Information about shell eggs is not complete if people do not know the potential health risks associated with SE-contaminated eggs. The lack of information places consumers, especially the young, the elderly, and persons with immune deficiencies, at a greater health risk.

C. Regulatory Options

1. No New Regulatory Action

Under this option, FDA would rely on current regulations, publicizing risks, voluntary changes in behavior, and current or enhanced State and local enforcement activity to bring about a reduction in illnesses caused by SE in shell eggs. State and local governments that adopt and enforce the 1999 Food Code as issued by FDA will meet the goals of the proposed refrigeration rule. Adopting the Food Code as issued by FDA will also reduce undercooking of eggs in restaurants, which will accomplish part of the goals of the proposed labeling provision. The 1999 Food Code requires raw shell eggs to be cooked 15 seconds at 63 °C (145 °F) if prepared for immediate service in response to a consumer's order. Other raw eggs are required to be cooked 15 seconds at 68 °C (155 °F). Because the 1999 Food Code has not been adopted everywhere and because billions of shell eggs are prepared in the home, the coverage of this option would be less than with the proposed rule.

The threat of litigation might also help bring about the goals of the proposed rule. If victims could sue sellers of SE-contaminated eggs for damages, the incentives to retailers to eliminate SE from shell eggs would increase. Creating incentives for individual retailers to refrigerate eggs, however, may not create incentives for all retailers. Furthermore, the effectiveness of litigation is questionable because the link between the consumption of SE-contaminated eggs and illnesses may be difficult to establish for outbreaks and is nearly impossible to establish for sporadic cases. Moreover, if the link could be established it is not clear whether retailers would be held liable, although new techniques such as deoxyribonucleic acid (DNA) finger printing may someday make it possible to link cases to individual retailers.

2. Labeling Provision Only

The agency could require that egg cartons contain the instructions to food handlers to "keep refrigerated", "cook until yolks are firm", and "cook foods containing eggs thoroughly" described in the context of the microbial hazard and the persons at risk. Requiring the safe handling label alone would place the burden of reducing risk from SE-contaminated eggs solely on food handlers, which includes consumers, restaurants, and institutions. If food handlers follow good sanitation practices and eggs are cooked thoroughly, the risk of salmonellosis

from SE-contaminated shell eggs can be virtually eliminated. FDA believes that the safe handling label will improve cooking practices but will not eliminate SE. The additional safeguard of proper refrigeration is therefore needed to slow the growth of SE and thereby reduce the risk of illness from mishandling. The median estimated annual benefits from labeling only are $261 million for the U.S. Department of Agriculture (USDA) SE risk assessment baseline and $124 million for the Centers for Disease Control and Prevention (CDC) surveillance baseline; the costs from labeling only are $28 million in the first year, with a recurring annual cost of $10 million.[1]

3. Refrigeration Provision Only

The agency could require that retailers refrigerate shell eggs to 7.2 °C (45 °F), without also requiring safe handling labeling. Refrigeration at less than 10 °C (50 °F) slows the growth of SE. Because the level of *Salmonella* that initially contaminates eggs is usually low, refrigeration following laying should keep the numbers of pathogens low until the egg reaches the consumer. Retail refrigeration is particularly important because it occurs later in the flow of eggs from farm to table and, therefore, it can play an important role in postponing yolk membrane breakdown and the consequent rapid growth of SE. Even if SE can be attenuated by refrigeration, some illnesses may still occur because small numbers of SE can cause illness. Moreover, improper storage by consumers after proper retail refrigeration could result in rapid growth of SE. The median estimated benefits from refrigeration alone are $387 million for the USDA SE risk assessment baseline and $211 million for the CDC surveillance baseline; refrigeration alone would impose a one-time cost of $31 million.

4. Refrigerate at 5 °C (41 °F)

Instead of requiring an ambient temperature of 7.2 °C (45 °F) for egg-containing refrigerators at retail, FDA could require an ambient temperature of 5 °C (41 °F), the internal temperature for potentially hazardous foods in the 1999 Food Code. Although current studies show *Salmonella* growth at ambient temperatures under 50 °F is significantly slowed, the advantage of a lower standard is that eggs will cool down slightly faster. FDA could require those establishments to reduce ambient temperatures to 5 °C (41 °F), with a 5-year compliance period. FDA estimated the present value of the total cost of reaching 5 °C (41 °F) in 5 years to be $65 million.[2] Because eggs cool down only slightly faster at 5 °C (41 °F)than at 7.2 °C (45 °F), the lower temperature would not generate additional benefits.

5. Implement a HACCP-Style System for Shell Eggs

The agency could require that a Hazard Analysis and Critical Control Point (HACCP) system be implemented at any or all levels of the shell egg production and distribution chain. In order to match the coverage of the proposed rule, the HACCP-style rule would have to be limited to the same set of establishments covered by the safe handling label. The advantage of a full farm-to-table HACCP is that it could eliminate, reduce, or control SE and other hazards at the source and keep them out throughout the egg processing chain. The disadvantage is that the technological knowledge needed to identify the critical control points and remedial steps to eliminate SE from shell eggs is incomplete. FDA believes that a HACCP-like program, possibly including in-shell pasteurization, is currently not feasible. However, FDA is evaluating whether a HACCP-like program in the future may be necessary to further ensure the safety of eggs.

6. In-Shell Pasteurization

The agency could require that all eggs be pasteurized. Pasteurization of shell eggs should practically eliminate SE. The time and temperatures required to pasteurize shell eggs, however, are close to the combination that will cook the eggs. Successful in-shell pasteurization on a large scale is therefore likely to be quite costly. Currently, pasteurized shell eggs sell for approximately $0.30 more per dozen than regular shell eggs (Ref. 1). Assuming that average cost remained constant with the increased output, to pasteurize all 47 billion shell eggs sold each year (around 4 billion dozen) would cost approximately $1.2 billion per year. In addition to the annual costs, the changeover to pasteurization would require large capital costs. Another potential disadvantage is that pasteurization might lead some consumers to erroneously believe that other safety measures, such as refrigeration and avoiding cross-contamination, might no longer be necessary. Because pasteurization eliminates competing microorganisms, recontamination after pasteurization might lead to rapid growth of SE. Finally, FDA believes that other interventions between farm and table could reduce the risk at lower cost.

7. Longer Compliance Periods

FDA is giving firms 180 days to meet the labeling and refrigeration provisions of this proposed rule. Lengthening the compliance period for labeling to 18 months would reduce labeling costs by allowing some of the changes to be incorporated into planned label changes. Total labeling costs, as shown in Table 14 of this document, fall from $18 million to $7 million if the compliance period is extended to 18 months. Total refrigeration costs fall by about $2 million, which is the difference (at a 7 percent discount rate) in the capital costs of refrigeration in 6 months and refrigeration in 18 months. The total cost savings from extending the compliance period to 18 months, then, are approximately $13 million. One disadvantage would be that a longer compliance period would delay the realization of the public health benefits of the proposed rule. Those benefits substantially exceed $13 million per year. As shown in Table 9 of this document, estimated median annual benefits are $300 million for the CDC surveillance baseline and $700 million for the SE risk assessment baseline.

8. Limit the "Sell By" Period

The agency could introduce a "sell by" date. Limiting the "sell by" period, which is the time within which retailers must sell shell eggs, would limit the SE growth period, thereby reducing the potential dose of SE when it is already in the egg. The disadvantage of this option is that it could not take the place of the proposed refrigeration or labeling provisions. Introducing a "sell by" provision without the proposed refrigeration provision would not necessarily prevent the growth of SE in the egg. Moreover, introducing the shortened "sell by" provision without the labeling provision would not inform consumers that they should still refrigerate and cook eggs thoroughly. Proper refrigeration is important because it will prevent the rapid growth of SE beyond the "sell by" date. The benefit of a "sell by" provision is it

[1] The two baselines are explained in section I.E.1 of this document.

[2] FDA estimated that 236,500 retail establishments hold eggs at ambient temperatures greater than 5 °C (41 °F). FDA assumed that the mean and median additional cost per establishment of moving to 5 °C to be $3,500 in current dollars. FDA also assumed that establishments would have 5 years beyond the 7.2 °C compliance period to reach 5 °C, that refrigerators last 20 years, and that additional costs would be zero for those establishments already planning to replace refrigerators within 5 years. The $65 million therefore represents the discounted (at 7 percent) additional costs of refrigeration from 5 to 20 years after the labeling and the 7.2 °C provisions would take effect.

would reduce the likelihood of membrane breakdown and shorten the time for growth should breakdown occur. FDA estimated the benefits from a limited "sell by" period by calculating the reduction in average retail storage time if all eggs were sold within 30 days (the USDA period used for pull dating). The benefits of a limited retail storage time are $1.3 million for the USDA SE risk assessment baseline and $600,000 for the CDC surveillance baseline.

The limited shelf life would impose the additional cost of reducing the egg supply, which raises the price of eggs to consumers. If limiting the shelf life were to reduce the egg supply by 5 percent, the additional cost would be approximately $150 million. If limiting the shelf life were to reduce the egg supply by 15 percent, the additional cost would be approximately $450 million.

Other options could reduce the storage time of eggs. A "use by" date on the label might lead more people to consume eggs before membrane breakdown occurs. If the storage time in retail establishments, institutions, and homes is reduced by 1 percent, the USDA SE risk assessment model generates about a 0.5 percent decrease in the number of illnesses.

D. Coverage

1. Establishments

Table 1 of this document lists the establishments covered by the proposed rule. FDA expects that the initial costs of labeling will fall on egg processors, until ultimately the costs are passed on to consumers. Refrigeration will affect the entire retail sector, including noncommercial establishments.

TABLE 1.—COVERAGE BY ESTABLISHMENT

Establishment	Affected by Safe Handling Labeling	Affected by Refrigeration at 7.2 °C (45 °F)
Grocery stores	No	Yes
Restaurants	No	Yes
Health food stores	No	Yes
Roadside stands	Yes	Yes
Convenience stores	No	Yes
Prisons	No	Yes
Nursing homes	No	Yes
Schools	No	Yes
Hospitals	No	Yes
Military	No	Yes
Shell egg packers	Yes	No
Transportation	No	No
Farm	No	No

2. Products

Table 2 of this document lists the products covered by the two provisions of the proposed rule.

TABLE 2.—COVERAGE BY PRODUCT

Product	Affected by Safe Handling Labeling	Affected by Refrigeration at 7.2 °C (45 °F)
Shell eggs in cartons	Yes	Yes
Bulk shell eggs in cases	Yes	Yes
Egg products[1]	No	No[1]

[1] Egg products include pasteurized egg products and other eggs treated to remove pathogens. The USDA regulates these products.

E. Benefits

The benefits of the proposal come from reducing the incidence of SE-related illness. FDA will estimate health benefits with the following model of marginal benefits (MB):

$$MB = R \times M \times V$$

where:

R = the baseline risk. In this case, the baseline risk is the estimate of the annual incidence of SE-related illnesses associated with shell egg consumption, proportionally broken down by severity of health effects.

M = the expected marginal reduction in the number of SE-related illnesses attributable to the two provisions of the proposed rule.

V = the cost per type of SE-related illness, including personal utility losses (pain and suffering, productivity) and direct medical expenditures.

The refrigeration and labeling provisions will reduce but not eliminate the consumption of contaminated shell eggs. Requiring refrigeration at all retail outlets and requiring labeling that states that the product should be kept refrigerated, however, should decrease the number of eggs that suffer temperature abuse in retail establishments and in homes. The labeling rule will also generate health benefits by reducing the consumption of raw or undercooked eggs.

In order to estimate the reduction in cases of SE-related illnesses likely to be brought about by the proposed rule, FDA relied mainly on the USDA's *Salmonella Enteritidis* Risk Assessment (Ref. 2). Indeed, FDA could not have carried out the following assessment of benefits without the USDA SE risk assessment. FDA slightly modified the risk assessment in light of data that have become available since the completion of the final version of the model, but the analysis closely followed that of the USDA SE risk assessment team. FDA estimated the benefits of its proposed rule by combining the USDA SE risk assessment's estimated reductions in illnesses with FDA's estimates of the health cost per illness.

1. The Shell Eggs and Egg Products Risk Assessment Model

The USDA's *Salmonella Enteritidis* Risk Assessment uses a farm-to-table model of the production and consumption of eggs. The model consists of five parts: (1) Egg

production, (2) shell egg processing and distribution, (3) egg products processing and distribution, (4) food preparation and consumption, and (5) public health outcomes.

Because the proposed rule will not affect the number of shell eggs contaminated with SE, FDA did not directly use the first three parts of the model. FDA estimated the effects of the proposed rule by introducing the provisions of the proposed rule into the preparation and consumption part of the model and then calculating the changes in public health outcomes.

The presence of SE in the raw egg is not sufficient to ensure that people will become ill from eating contaminated eggs. If the eggs are continuously refrigerated from the time they leave the processor up until the time they are cooked, and if they are thoroughly cooked, then the risk assessment model predicts that the SE will not multiply before cooking and cooking will eliminate the surviving pathogens. The large number of outbreaks and sporadic cases identified—and the larger number thought to occur—suggest that the conditions for pathogen kill-off are not being met. In 1996, the CDC's surveillance found 9,566 confirmed SE isolates, or 25 percent of the 39,000 confirmed cases of salmonellosis (Ref. 3). In 1997, the CDC's surveillance found 7,924 confirmed SE isolates, or 23 percent of the 34,608 confirmed cases of salmonellosis (Ref. 3). From 1988 through 1992, SE accounted for more than 40 percent of all bacterial foodborne outbreaks with known etiology and about 33 percent of all outbreaks with known etiology (Ref. 4).

The two requirements of this proposed rule form part of a farm-to-table approach to shell egg safety. These requirements address the table end of the hazard. Although they will lead to lower pathogen counts, reduced pathogen strength, and reduced pathogen consumption, they will not eliminate SE in shell eggs.

The baseline for the cases of salmonellosis prevented is the number of illnesses attributable to shell eggs before the proposed rule. The USDA SE risk assessment estimated the number of illnesses with a full farm-to-table model. The first stage of the model estimated the number of infected eggs laid with a simulation that incorporated the estimates of the number of infected flocks and the likelihood of frequency of infected eggs in an infected flock. The next stage of the model took the estimated number of infected raw shell eggs and estimated the number of infected eggs likely to be consumed. The model followed the eggs through possible paths from the farm to the table. Depending on how processors, transporters, and cooks treated the infected eggs, the SE could be killed, remain stagnant, multiply, or (if pooled) spread to other eggs. The last stages of the model used a dose-response function to estimate the number and severity of illnesses caused by SE in shell eggs. All stages of the model used computer simulations to generate ranges and distributions rather than point estimates. FDA generated a modified USDA SE risk assessment baseline by substituting more recent data on the proportion of establishments not refrigerating shell eggs at 7.2 °C (45 °F).

The CDC surveillance baseline estimated the distribution of illnesses based on the number of confirmed cases as indicated by SE isolates reported to CDC. The CDC surveillance baseline estimated the number of illnesses as actual reported cases plus estimated unreported cases.

Table 3 of this document shows the results of three Monte Carlo simulations for the baseline estimates of SE-related illnesses caused by shell eggs. All simulations used the Microsoft Excel version of the Palisade@Risk® quantitative risk assessment software. The first simulation, shown in part a of Table 3 of this document, is the baseline result of the SE risk assessment team model. The second simulation is the baseline model with 95 percent rather than 90 percent probability that shell eggs are refrigerated at 7.2 °C (45 °F) in retail establishments and institutions. FDA modified the original model because the agency had more recent information (see the next paragraphs) on the number of establishments not refrigerating shell eggs at 7.2 °C (45 °F). Part b of Table 3 of this document presents the results of the simulation based on the more recent information.

Part c of Table 3 of this document presents the third baseline estimation, which is the result of estimating the number of cases directly from CDC *Salmonella* surveillance data. FDA used the same procedure as the USDA SE risk assessment team to estimate the number of SE cases from surveillance data. The data collected by the CDC *Salmonella* surveillance project show that from 1988 through 1997 the number of SE isolates ranged from a low of 6,578 in 1992 to a high of 10,201 in 1995, with about 8,400 per year on average. The USDA SE risk assessment estimated the probability that an isolate would be reported to be 0.01431. With 8,400 isolates reported and a probability of reporting equal to 0.01434, FDA simulated a distribution for all SE illnesses, including those caused by foods other than shell eggs (not shown in Table 3 of this document).[3] The USDA SE risk assessment assumed that shell eggs accounted for 20 to 100 percent of all illnesses from SE. FDA assumed that shell eggs accounted for approximately 10 to 60 percent of all illnesses from SE.[4] The assumption that 10 to 60 percent of all SE illnesses came from the consumption of shell eggs, combined with the estimated number of illnesses, generated the estimates shown in part c of Table 3 of this document.

All three baselines in Table 3 of this document are estimates of the current incidence of SE from shell eggs. FDA estimated the health benefits of the proposed rule based on the baselines in parts b and c of Table 3 of this document. The baselines, however, could change before the proposed rule takes effect. Other Federal or State regulations, consumer education, and voluntary SE eradication by farms or processors could reduce the baseline number of SE illnesses. If such a reduction were to occur before or at the same time as the proposed rule took effect, then FDA would be using a baseline that was too high and, therefore, would over-estimate health benefits from the proposed rule. FDA recognizes the potential bias, but believes that changes in the baseline number of illnesses are likely to be small or negligible before the proposed rule takes effect.

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[3] FDA simulated the number of SE illnesses not reported with a negative binomial distribution. The simulation calculated the total number of illnesses (reported and not reported) as: Number reported + Negative binomial (number reported + 1, frequency of reporting) = 8,400 + NEGATIVE BINOMIAL (8,401, 0.01434).

[4] According to the results of outbreak analyses for the years 1988 through 1992, eggs were the food vehicle in 64 percent of the SE outbreaks for which the food vehicle could be identified (Ref. 4). Therefore, FDA assumed that 60 percent represented the maximum fraction of cases attributable to eggs. More than half of the SE outbreaks, however, did not have a known food vehicle. If outbreaks with unknown vehicles are added to the total, then eggs accounted for only 29 percent of all SE outbreaks (including outbreaks with known and unknown vehicle) from 1988 through 1992. Furthermore, the causes of outbreaks may not be the same as the causes of sporadic cases. FDA believes that shell eggs may be less important cause of sporadic SE cases than of SE outbreaks. Many outbreaks have been linked to the pooling of large numbers of eggs in nursing homes and other institutional settings. Because pooling eggs would have little effect on the probability of a sporadic case occurring, eggs are not likely to account for as large a proportion of sporadic cases as of outbreaks. FDA believes it plausible that eggs account for only one-third as high a fraction of all SE cases as of outbreaks. For a lower bound on the fraction of cases caused by eggs, FDA multiplied the fraction of all outbreaks caused by eggs (29 percent) by the relationship between the egg fraction of all cases and the egg fraction of outbreaks (one-third). Therefore, FDA estimated that 10 percent represented the minimum fraction of SE cases attributable to eggs.

TABLE 3.—THREE BASELINE ESTIMATES OF SE FROM SHELL EGGS

	5th percentile	Median	Mean	95th percentile
a. *USDA SE Risk Assessment*				
Illnesses	126,374	504,082	661,633	1,742,592
Arthritis	3,631	14,864	19,994	55,915
Deaths	68	301	391	1,050
b. *USDA SE Risk Assessment as Modified by FDA*				
Illnesses	115,645	416,156	569,231	1,508,814
Arthritis	3,372	12,548	17,175	48,594
Deaths	66	250	354	985
c. *CDC Surveillance Model*				
Illnesses	63,884	189,599	191,511	319,275
Arthritis	1,330	5,533	5,727	12,202
Deaths	37	122	115	197

2. Cases of Salmonellosis Prevented

FDA cannot precisely estimate the number of cases likely to be prevented by the proposed rule; therefore, the agency used a range of cases prevented to estimate the benefits of the proposed rules. For the refrigeration provision, FDA used the USDA SE risk assessment model (as modified by FDA) to determine the effects of eliminating virtually all temperature abuse in retail and institutional establishments. In the simulation of the model, the number of illnesses fell as the proportion of establishments assumed to be holding eggs at 7.2 °C (45 °F) or less increased from 95 percent to virtually 100 percent.

FDA used a study of changes in consumer behavior as a result of the USDA safe handling label for meat to estimate the effects of the safe handling label for shell eggs. The Food Marketing Institute (Ref. 5) found that 59 percent of shoppers were aware of the USDA safe handling labels for meat. Of those aware of the labels, 43 percent changed their behavior as a result of the labels. Of those who changed their behavior, the changes ranged from 1 percent (use of antibacteria soap to wash hands) to 41 percent (washing or disinfecting counters, cooking areas, and utensils after contact with meat). The behavioral changes most similar to what the proposed rules aim to bring about for shell eggs were the 19 percent increase in proper cooking of meats and the 7 percent increase in proper refrigeration. If the meat cooking and refrigeration results indicate the likely effects of the proposed label for eggs, then the likelihood that shell eggs will be undercooked or consumed raw will decline by approximately 5 percent (= 59 percent x 43 percent x 19 percent) and the likelihood that consumers will fail to properly refrigerate eggs will decline by approximately 2 percent (= 59 percent x 43 percent x 7 percent).[5]

The USDA SE risk assessment model treats proper cooking as a kill step for SE. Whatever the baseline, if undercooking falls by 5 percent, so will the number of illnesses, all else the same. The effects of retail refrigeration come early in the life of the egg. The effects of the safe-handling label come later in the life of the egg than refrigeration, so the effects of proper cooking in reducing illnesses will be net of the effects of refrigeration. Safe cooking will reduce the number of illnesses remaining—after the effect of refrigeration—by 5 percent.

In separate simulations, FDA used the USDA SE risk assessment model to estimate the effects of the labeling provision, the refrigeration provision, and the proposed rule combining the provisions. In another simulation, FDA estimated the effects of including a "sell by" date on the label or some equivalent policy to reduce retail storage time. If the "sell by" date were 30 days after receiving the eggs, the average retail storage time would be reduced by 6 percent (Ref. 2).[6] FDA used 6 percent as the potential shortening of average retail storage time. FDA did not include shortened storage time in the simulations that estimated the effects of the proposed rule.

FDA estimated policy effects for both the modified SE risk assessment and the surveillance baselines. FDA first simulated the possible regulatory approaches in the modified USDA SE risk assessment model. The simulations generated distributions of the number of illnesses prevented by those approaches. The results are shown in part a of Table 9 and part a of Table 10 of this document. The CDC surveillance baseline began with the final result—a distribution of the number and severity of illnesses. No farm-to-table steps entered the model. The CDC surveillance model could not estimate how the illnesses occurred; the model only produced an estimate of the number of illnesses. Because the CDC surveillance baseline was not an outcome of a model, FDA could not directly estimate effects with the surveillance baseline. Instead, FDA assumed that the policy effects would be proportionally the same for both the CDC surveillance and the USDA SE risk assessment baselines. The estimated effects of the proposed rule on the surveillance baseline, then, equaled the percentage effects from the SE risk assessment applied to the CDC baseline.[7] The results are shown in part

[5] The sample size was 1,007. The reduction in undercooked eggs likely to be brought about by safe handling instructions rested on several assumptions. The most important assumptions were that: (1) The 5 percent reduction in unsafe cooking practices and the 2 percent reduction in unsafe refrigeration practices implied by the survey results for the USDA meat handling labels accurately reflected people's practices in their home, (2) the results for home food handlers would hold for restaurant food handlers, (3) the results for the meat label would hold for egg labels, (4) the change in behavior would extend to raw eggs as well as undercooked eggs, and (5) the sample of 1,007 consumers was reasonably representative (Ref. 5). The greatest uncertainty in extrapolating from the meat handling results is in assuming that the effects will hold for those products that contain raw eggs. Cookie dough, cake and brownie batter, egg nog, and other homemade products are major sources of the consumption of raw eggs, but the desire to consume them also appears to be deeply ingrained among consumers.

[6] In the risk assessment, retail storage time for eggs is a truncated exponential distribution, with the unconstrained (that is, nontruncated) expected storage time equal to 7 days, minimum storage equal to 0, and maximum equal to 60. If the maximum is changed to 30, mean storage time falls by 6 percent.

[7] Comparing the illnesses prevented in Tables 9 and 10 of this document with the appropriate baseline in Table 3 of this document can

Continued

b of Table 9 and part b of Table 10 of this document.

3. Health Benefits From Preventing Salmonellosis

The health benefits associated with preventing salmonellosis are: (1) Lessening the loss of productivity, (2) the reduction in pain and suffering, and (3) the reduced expenditures on medical treatment. In order to quantify the losses suffered by victims of salmonellosis, it is first necessary to develop an index to measure the losses associated with pain, suffering, mobility, and other problems associated with becoming ill. FDA estimated the utility losses caused by pain and suffering with a symptom-problem health utility index. Lost productivity was indirectly estimated by measures of body movement, physical location, and functional state. FDA estimated medical costs directly. The symptoms of salmonellosis vary by serotype and the immune status of the victim. Diarrhea, nausea, vomiting, fever, and headache lasting from 1 day to 1 week or more characterize a typical case of salmonellosis. Mild cases last 1 to 3 days, moderate cases last 2 to 12 days, and severe cases last 11 to 21 days (Ref. 6). Some acute cases are followed by post-*Salmonella* reactive arthritis, with symptoms that include pain and possible functional disability (Ref. 7, 31, and 32). Moreover, some acute cases lead to death, especially among elderly victims.

Tables 4 through 7 of this document contain descriptions of the health effects associated with salmonellosis. Table 4 of this document lists the codes associated with salmonellosis of varying levels of severity. Tables 5 and 6 of this document explain the codes.

TABLE 4.—HEALTH EFFECTS AND SYMPTOMS OF ILLNESSES ASSOCIATED WITH SALMONELLOSIS

Severity	Functional Status	Symptom-Problem Complex Code
Mild	MOB(4) + PAC(3) + SAC(3)	9
Moderate	MOB(4) + PAC(3) + SAC(3)	9
Severe—acute	MOB(2) + PAC(1) + SAC(1)	9
Reactive arthritis, resolved in 4 months	MOB(5) + PAC(3) + SAC(3 and 4)	7
Reactive arthritis—chronic, intermittent, waxing and waning, or unremitting	MOB(5) + PAC(3) + SAC(3 and 4)	7

Table 5.—DESCRIPTION OF FUNCTIONAL STATUS CODES (USED TO MEASURE PRODUCTIVITY LOSS)

Function Status Code	Scale	Weight or Utility Loss
Mobility (MOB)		
5	No limitations	0.000
4	Did not drive car; other limitations	0.062
2	In hospital	0.090
Physical Activity (PAC)		
4	No limitations	0.000
3	Walked with physical limitations	0.060
1	In bed or wheelchair	0.077
Social Activity (SAC)		
5	No limitations	0.000
4	Limited in other activities	0.061
3	Limited in primary activity	0.061
2	Performed self-care	0.061
1	Help with self-care	0.106

TABLE 6.—DESCRIPTION OF SYMPTOM-PROBLEM COMPLEX CODES (USED TO MEASURE LOSS FROM PAIN AND SUFFERING)

Symptom-Problem Complex	Description	Utility Weight
9	Sick or upset stomach, vomiting, or diarrhea (watery bowel movements)	0.290
7	Pain, stiffness, numbness, or discomfort of neck, hands, feet, arms, legs, ankles, or several joints together	0.299

FDA estimated the health loss per day for the different levels of illness severity by summing the lost productivity (as measured by functional status) and the loss from pain and suffering (as measured by the symptom-problem index). These losses per day can be interpreted as the difference between 1 day of perfect health and 1 day of suffering the productivity loss and pain and suffering associated with one of the health conditions. The numerical scale is based on the notion of a quality-adjusted life day. The quality-adjusted life day for a day of perfect health equals 1; the quality-adjusted life day for death equals 0. For illnesses, the quality-adjusted life day falls between 0 and 1. A day spent suffering a mild case of salmonellosis has a quality-adjusted life day equal to 0.527 (= 1 – 0.473).

The loss of utility per illness equals the daily loss multiplied by the duration of the illness. For example, mild salmonellosis lasts 1 to 3 days. The total utility losses for a mild case lasting 2 days equal 2 x 0.473 = 0.946, or about 1 quality-adjusted life day. The resolved cases of post-*Salmonella* reactive arthritis may last 1 day to 4 months (Ref. 7). FDA assumed that chronic cases of reactive arthritis last for the rest of the victim's life. FDA used a distribution for the age of onset for salmonellosis, based on FoodNet results for 1996 and 1997 (Ref. 8). FDA also used a distribution for the age of onset for reactive arthritis. FDA combined the two distributions to generate a single distribution for the

approximate the percentage effects. FDA also independently estimated the proportional effects of the proposed rule. In that simulation, the mean fraction of baseline illnesses prevented was 19 percent, the median was 15 percent, the 5th percentile was 6 percent, and the 95th percentile was 49 percent.

length of time that post-*Salmonella* reactive arthritis would be expected to last.

TABLE 7.—UTILITY LOSSES FROM SALMONELLOSIS

Severity	Functional Utility per Day	Symptom-Problem Utility Weight per Day	Total Utility Loss per Day	Duration (days per year)	Utility Losses per Case per Year	Medical Costs per Case per Year
Mild	0.183	0.290	0.473	1 to 3	0.473 to 1.419	0
Moderate	0.183	0.290	0.473	2 to 12	0.946 to 5.676	$800
Severe—acute	0.273	0.290	0.563	11 to 21	6.193 to 11.823	$9,100
Reactive arthritis—resolved	0.121	0.299	0 to 0.42	1 to 121	0 to 50.4	$100
Reactive arthritis—chronic	0.121	0.299	0 to 0.42	365	0 to 153.3	$400

FDA assumed that the most likely value of a quality-adjusted life day was $630, a value derived from the statistical estimate of the benefit for a small reduction in the probability of death, commonly called the value of a statistical life. If the value of a statistical life is $5 million, and the average discounted number of life years (in the studies that generated this estimate) lost is 21.8, then the value of a single quality-adjusted life day is ($5 million ÷ 21.8) ÷ 365 = $630.[8] The value of utility losses for nonfatal cases of acute salmonellosis would therefore equal the losses of quality-adjusted life days multiplied by $630.

The value of a quality-adjusted life day is highly uncertain. Therefore, FDA used a distribution, not a point estimate, to value the utility losses from salmonellosis. FDA based the distribution on a most likely value, a minimum, and a maximum. The most likely value, as shown previously, was $630. FDA based the minimum value of a quality-adjusted life day on the average daily gross domestic product per person, which was approximately $80 per day in 1997 (($8 trillion ÷ 268 million) ÷ 365) (Ref. 9). FDA believes that the gross domestic product per person understates willingness to pay, because most studies of the value of a statistical life indicate that people are willing to pay more than their average earnings to avoid all of the costs associated with illnesses. FDA used gross domestic product per person as a strict lower bound, because it is not plausible that people on average would be willing to pay less than the value of output per person. FDA based the maximum value of a quality-adjusted life day on the literature on the value of a statistical life. In a survey of the literature on the value of a statistical life, the most plausible upper-bound estimate was approximately $8.4 million in 1997 prices (Ref. 10). The upper-bound value of a quality-adjusted life day would, therefore, be about $1,000 (($8.4 million ÷ 21.8) ÷ 365).

In addition to utility losses (lost productivity, pain, and suffering), salmonellosis leads to direct medical expenditures. The medical costs of acute salmonellosis vary from nothing for a mild case to more than $9,000 for severe cases (Ref. 11). The medical costs for chronic cases vary from $100 for resolved cases to $400 per year for long-lasting cases (Ref. 12).

The total health costs per case are the sum of utility losses (which include productivity and pain and suffering) and medical expenditures. The total costs of SE illnesses would be the costs per case of each severity multiplied by the number of illnesses of each severity. For chronic illnesses that are not resolved, the utility losses and medical costs stretch indefinitely into the future. FDA calculated the present value of chronic medical expenditures and utility losses with a discount rate of 7 percent. For example, medical costs for reactive arthritis of $400 per year take a present value of $5,400 for cases that last 44 years. The annual costs of reactive arthritis are the net present value of the costs of new cases.

FDA based the distribution of cases by severity on the FoodNet results for diarrheal illness, which indicate that 92 percent of victims do not seek medical attention (Ref. 8). The FoodNet population survey could not determine the causes of diarrhea for people who did not seek treatment. *Salmonella* accounts for a large portion of isolates of the people who do seek medical treatment for diarrhea and is therefore assumed to account for a large portion of all diarrheal illness. FoodNet used the fraction of all victims who seek medical attention Consistent with the FoodNet approach, FDA assumed that 92 percent of victims of salmonellosis do not seek medical treatement. FDA assumed that these cases were mild. Also, the agency assumed that 15 percent of those who sought medical attention for SE would be hospitalized (Ref. 8).[9] Of those who were hospitalized, about 5 percent would die. The case-fatality rate simulated by the model equaled the probability of hospitalization multiplied by the conditional probability of death given hospitalization. In most simulations it was around 0.05 to 0.06 percent.[10] The proportion of acute cases that lead to post-salmonellosis reactive arthritis has been estimated at 2 to 3 percent (Ref. 13) and 6.4 percent (Ref. 7). The USDA SE risk assessment used a 2 to 4 percent range, with the mean equal to 3 percent. FDA used the same mean, but with a 0 to 6 percent range, reflecting the continued wide uncertainty associated with reactive arthritis after acute

[8] FDA calculated the discounted life expectancy based on 36 years lost, which was approximately the loss in the injury studies used to estimate the value of a statistical life. The workers were around 40 years old. The rate of time preference used to discount the years if life lost was 3 percent, often identified as the pure rate of time preference. If 36 years are continuously discounted at 3 percent per year, the result is 21.8 years.

[9] FDA revised the USDA SE risk assessment's distribution of illnesses by severity in light of FoodNet results (Ref. 8). The FoodNet results were not available at the time the risk assessment was carried out. The revisions to the USDA SE risk assessment, however, were small. FDA used 92 percent as the fraction of illnesses that are mild, compared with 94 percent in the USDA SE risk assessment. The USDA SE risk assessment assumed that 10 percent were hospitalized. FoodNet found that 15 percent of all persons with foodborne pathogens (and sought medical care) were hospitalized. Because the FoodNet data were more recent, FDA assumed that 15 percent of those who consulted physicians for SE illness were subsequently hospitalized.

[10] Many sources (Ref. 13) state that about 0.1 percent of cases of salmonellosis lead to death. The SE risk assessment, however, generated lower case-fatality rates for SE. Because the result was specific to SE, FDA used the lower estimate generated by the SE risk assessment. FoodNet has not generated enough cases to compute a meaningful case-fatality rate for SE illnesses.

salmonellosis. FDA estimated the distribution of cases by severity for reactive arthritis based on an outbreak study (Ref. 7). The lost quality-adjusted life days for post *Salmonella* reactive arthritis are also uncertain. With only one study of severity, FDA did not have sufficient information to justify a point estimate; therefore, the agency used a range of 0 to 0.42 for the daily loss of quality-adjusted life days.

Most of the deaths attributed to SE are elderly persons. Of the 27 deaths linked to foodborne SE disease outbreaks from 1988 through 1992, 23 fatalities (85 percent) occurred in nursing homes (Ref. 4). To estimate benefits from preventing deaths, FDA assumed that the probability that the victim was age 75 or older was 80 percent. The loss of quality-adjusted life years is much less for victims age 75 and older than for victims from rest of the population. The use of the same value for the benefits of preventing fatalities among the general population and preventing fatalities among those age 75 and older (especially the nursing home population) would therefore not be appropriate. FDA assumed that the average loss of discounted quality-adjusted life years would be about 6 for victims age 75 and older and about 26 for other victims.[11]

4. Total Health Benefits

FDA estimated the effects of the proposed rule by combining the distribution of effects on the number of illnesses with the distribution of monetary values associated with the illnesses prevented. The calculations involved two steps. In the first step FDA used the USDA SE risk assessment model to estimate the number of illnesses prevented. In the second step, FDA estimated the health benefits associated with preventing those illnesses. The uncertainties associated with several important parts of the formula led FDA to use Monte Carlo computer simulations to estimate the total health benefits of the proposed rule.[12]

In the Monte Carlo simulation, the computer repeatedly calculated health benefits based on the following formula:

total health benefits = (number of mild cases prevented x $ per case) + (number of moderate cases prevented x $ per case) + (number of severe-acute cases prevented x $ per case) + (number of resolved cases of arthritis prevented x $ per case) + (number of chronic cases of arthritis prevented x $ per case) + (number of deaths prevented x $ per death)

Instead of calculating the total health benefits once, based on single estimates for each value in the formula, the simulation calculated the health benefits over and over again. Each calculation (or iteration) used different values, with the values drawn from probability distributions. The probability distributions used in the simulation are shown in Table 8 of this document.[13]

TABLE 8.—DISTRIBUTIONS USED TO ESTIMATE THE MONETARY VALUE OF CASES OF SALMONELLOSIS PREVENTED

Variable	Distribution	Source
Number of illnesses prevented	Cumulative	Ref. 2
Number of mild illnesses	Binomial (number of illnesses, 0.92)	Ref. 8
Number of moderate illnesses	Binomial (number at least moderate, 0.85)	Ref. 8
Number of severe, acute illnesses	Binomial (number at least severe, 0.95)	Ref. 2
Number of deaths	Residual	Ref. 2
Value of a quality-adjusted life day ($)	Beta-Pert (80, 630, 1,000)	See text
Fraction of illnesses resulting in reactive arthritis	Beta-Pert (0, 0.03, 0.06)	See text
Fraction of reactive arthritis cases resolved	Beta (10, 19)	Ref. 7
Quality-adjusted life day lost per day of reactive arthritis	Uniform (0, 0.42)	Ref. 15
Duration of mild illnesses	Uniform (1,3)	Ref. 6
Duration of moderate illnesses	Uniform (2, 12)	Ref. 6
Duration of severe illnesses	Uniform (11, 21)	Ref. 6
Duration of resolved reactive arthritis	General (1, 121; uniform (2,7), uniform (8,28), uniform (29,120); 0.2222, 0.6666, 0.1111)	Ref. 7
Duration of chronic reactive arthritis	Normal (35, 3.5)	Refs. 8 and 16
Distribution of deaths between elderly and general population of deaths that are old people	Binomial (number of deaths, 0.8)	Ref. 4
Discounted years of life lost per death of elderly victims	6.2	See text
Discounted years of life lost per death of other victims	26.4	See text

Each simulation calculated health benefits 1,000 times. FDA simulated the

[11] FDA divided victims into 2 age groups, those age 75 and over and all others. FDA then assumed that within the 2 categories of those age 75 and over and all other, the age of vitims of fatal SE illnesses was the same as the age of victims of all cases of salmonellosis in the 1996 through 1997 FoodNet data base. The average age of salmonellosis victims under age 75 was about 24, for an estimated average years of life lost of 53. If 53 years of life lost are discounted at 3 percent per year, the result is 26 discounted years lost. The average age of salmonellosis victims age 75 and over was about 82, for an estimated average years of life lost of 7. The discounted years of life lost (at 3 percent per year) is 6.

[12] The simulations all used Latin Hypercube sampling, which first sorts the samples in stratified groups and then samples equally from each group. The one-stage simulations contained 1,000 iterations. The two-stage simulations used 50 uncertainty iterations, then 50 simulations of 500 iterations each.

[13] The agency selected distributions based on the underlying data or common assumptions about the variables being modeled. The main innovations were the use of Beta and Beta-Pert distributions. The Beta distribution is part of the Bernoulli family of distributions and is closely related to the Binomial. The Binomial gives the distribution of the number of successes (s) in n trials if the probability of success in each trial is p. The Beta shows the distribution of the value of p when s successes occur in n trials. The Beta-Pert distribution is a Beta distribution that has been rescaled to run between values other than 0 and 1. The Beta-Pert uses a minimum, maximum, and most likely value to generate a distribution running from the minimum to the maximum, with a mean equal to (minimum + (4 x most likely) + maximum) ÷ 6. In contrast to the Triangular, which has a mean of (minimum + most likely + maximum) ÷ 3, the Beta-Pert is less sensitive to extreme values and generates more outcomes close to the mean. For those reason, the agency used the Beta-Pert rather than the triangular when only the minimum, most likely, and maximum values were given. For discussions of the nature and use of these distributions in Monte Carlo simulation see Ref. 14.

effects of the proposed rule, the separate effects of the refrigeration and labeling components of the proposed rule, and the effects of a decline in retail storage time. Tables 9 and 10 of this document present the 5th percentile, mean, median, and 95th percentile simulated health benefits.

TABLE 9.—TOTAL ANNUAL HEALTH BENEFITS FROM THE REDUCTION IN SALMONELLOSIS ATTRIBUTABLE TO THE PROPOSED SHELL EGG RULES: USDA *Salmonella* ENTERITIDIS RISK ASSESSMENT BASELINE AND CDC SURVEILLANCE BASELINE

Variable	5th Percentile	Median	Mean	95th Percentile
a. Modified USDA SE Risk Assessment Baseline				
Illnesses prevented	12,369	65,801	115,848	407,064
Mild	11,391	60,479	106,580	374,192
Moderate	831	4,484	7,878	27,900
Severe	142	747	1,321	4,685
Arthritis—resolved	147	588	1,171	4,453
Arthritis—chronic	468	1,146	2,313	8,317
Death	6	39	69	246
Health benefits	$86.7 million	$703 million	$1,700 million	$6,610 million
b. CDC Surveillance Baseline				
Illnesses prevented	7,032	25,132	36,937	107,230
Mild	6,476	23,092	33,982	98,607
Moderate	475	1,691	2,511	7,286
Severe	80	284	421	1,235
Arthritis—resolved	47	240	382	1,182
Arthritis—chronic	95	488	714	2,073
Death	3	16	22	66
Health benefits	$49.2 million	$303 million	$501 million	$1,679 million

TABLE 10.—TOTAL ANNUAL HEALTH BENEFITS FROM THE REDUCTION IN SALMONELLOSIS ATTRIBUTABLE TO THE VARIOUS REGULATORY APPROACHES: USDA *Salmonella* ENTERITIDIS RISK ASSESSMENT BASELINE AND CDC SURVEILLANCE BASELINE

Variable	5th Percentile	Median	Mean	95th Percentile
Reduced Retail Storage Time				
a. Modified USDA SE Risk Assessment Baseline				
Illnesses prevented	0	162	3,000	13,9[illegible]8
Health benefits (millions)	0	$1.3	$29.8	$1[illegible]9
b. CDC Surveillance Baseline				
Illnesses prevented	0	88	997	4,998
Health benefits (millions)	0	$0.6	$2.1	$71.2
Refrigeration to 7.2 °C (45 °F) Only				
a. Modified SE Risk Assessment Baseline				
Illnesses prevented	997	34,791	86,512	340,387
Health benefits (millions)	$9.6	$387	$1,260	$5,500
b. CDC Surveillance Baseline				
Illnesses prevented	548	15,812	27,447	94,317
Health benefits (millions)	$3.2	$163	$372	$1,476
Labeling only				
a. Modified SE Risk Assessment Baseline				
Illnesses prevented	6,500	23,097	32,191	84,147
Health benefits (millions)	$43.8	$261	$444	$1,460
b. CDC Surveillance Baseline				
Illnesses prevented	3,339	10,008	10,531	17,672

TABLE 10.—TOTAL ANNUAL HEALTH BENEFITS FROM THE REDUCTION IN SALMONELLOSIS ATTRIBUTABLE TO THE VARIOUS REGULATORY APPROACHES: USDA *Salmonella* ENTERITIDIS RISK ASSESSMENT BASELINE AND CDC SURVEILLANCE BASELINE—Continued

Variable	5th Percentile	Median	Mean	95th Percentile
Health benefits (millions)	$20.2	$103	$150	$421

5. Additional Benefits

a. *Reduced risk from other pathogens.* Refrigeration and thorough cooking may reduce the risk from pathogens other than SE in eggs. These other product-pathogen combinations include other serotypes of *Salmonella* in eggs and pathogenic organisms in other foods. Because other foods are often stored in the same refrigerator cases as shell eggs, refrigerating shell eggs at 7.2 °C (45 °F) will reduce the ambient temperature for all foods stored in the same case. If some of these other foods are ready-to-eat potentially hazardous foods, the requirement to refrigerate at 7.2 °C (45 °F) may generate additional health benefits by reducing the illnesses associated with those products.

b. *Fewer recalls.* The rule could lead to fewer recalls. Although FDA had no recalls of shell eggs in the most recent year, recalls that might have occurred in the future could be prevented by the proposed rule.

6. Uncertainty of Estimated Benefits

As Table 9 of this document shows, the range of potential benefits from the proposed rule is wide. With the USDA SE risk assessment baseline, the 95th percentile benefits are 75 times the 5th percentile benefits. With the CDC surveillance baseline, the 95th percentile benefits are 35 times the 5th percentile benefits. However they are calculated, the estimated benefits from the proposed rule are uncertain.

The uncertainty comes from many sources. Some uncertainty comes from the ordinary variation of known factors. For example, the duration and severity of the illnesses associated with acute salmonellosis vary. The age of victims also varies. Many of the estimated factors affecting the size of health costs, such as the division of deaths between the elderly and younger people, the severity of reactive arthritis, and the number of illnesses that progress from mild salmonellosis to more serious illnesses can vary from year to year. Because of this ordinary variability, it is impossible to generate a single number representing the effects of the proposed rule. As the variable factors change, the effects of the proposed rule change.

The wide range of outcomes shown in Table 9 of this document, however, is not generated solely by the variability of known factors such as ages of victims and severity of illness. Much of the range in Table 9 of this document comes from uncertainty about the values of several elements of estimated health benefits. Fundamental uncertainty exists in that the agency does not know and may never know some of those values. The principal fundamental uncertainties associated with the benefit assessment are:

- Uncertainty about the baseline number of illnesses associated with SE in shell eggs,
- Uncertainty about the proportion of cases of salmonellosis that lead to reactive arthritis,
- Uncertainty about the number of illnesses likely to be prevented by the proposed rule, and
- Uncertainty about the monetary value of illnesses caused by SE in shell eggs.

The effects of these uncertainties can be characterized with a series of figures.[14] In Figure 1 of this document, the agency shows how the distribution of estimated health benefits changes when the baseline distribution of estimated SE illnesses associated with shell eggs changes. As the figure shows, there is much overlap, but the USDA SE risk assessment baseline leads to higher estimated benefits than does the CDC surveillance baseline. The figure also shows that even if the agency knew which distribution the USDA SE risk assessment or the CDC surveillance was the appropriate baseline, large uncertainty would remain. The ranges of outcomes for each baseline distribution cover several billion dollars.

As FDA acquires more information, the uncertainties caused by the agency's lack of knowledge of the incidence of reactive arthritis caused by salmonellosis, the effectiveness of the proposed rule, and the monetary value of the illnesses caused by SE may be reduced but will not be eliminated. Better estimates of the incidence of arthritis are likely to become available in the future, but some uncertainty will remain. The agency will never precisely know the effectiveness of the rule or the average monetary value of preventing a case of salmonellosis. The uncertainty about the effects of policy stem from the many other factors that affect the number of illnesses, including other policies, changes in consumer behavior (perhaps because of education), changes in the pathogen itself, and possible technological changes in processing and other sectors of the industry. All of these changes will affect the baseline distribution of estimated illnesses and, therefore, change the distribution of estimated effects of the proposed rule. The other remaining uncertainty, the monetary value of preventing a case, is based on estimates of the average person's willingness to pay to avoid a small increase in the probability of illness, injury, or death. FDA believes that although it is possible to identify a range of plausible values for the willingness to pay, the true average willingness to pay is probably unknowable.

FDA illustrates the effects of the principal uncertainties in Figures 2 and 3 of this document. In Figure 2 of this document, the uncertainties are assumed away. In other words, Figure 2 of this document is constructed on the assumption that FDA knows the correct baseline, knows the incidence of post-*Salmonella* reactive arthritis, knows the effectiveness of the proposed rule, and knows the value of a statistical life year. If FDA knew those values, one possible distribution of health benefits would be that shown in Figure 2 of this document. In this figure, the values of the main uncertain variables are fixed.[15]

The problem with Figure 2 of this document is that FDA does not know if the selected values of the uncertain variables (which were chosen randomly from the distributions of possible values) are correct. Different values for the principal uncertainties would generate different distributions. Ten values for the uncertain variables would generate 10 different distributions, not one as in Figure 2 of this document. Figure 3 of this document contains the distribution illustrated in Figure 2 of

[14] The next several paragraphs and the figures are based on Ref. 14.

[15] The values for the baseline illnesses, incidence of reactive arthritis, effectiveness of the proposed rule, and the monetary value of preventing illnesses were randomly selected and then fixed for the simulation illustrated in Figure 2 of this document.

this document, as well as nine others—four more from the CDC surveillance baseline and five from the USDA SE risk assessment baseline. The agency does not know which of the 10 distributions pictured in Figure 3 of this document is correct. Indeed, the correct distribution could be another one entirely. In Figure 4 of this document, 100 different values of the uncertain variables generate 100 different simulated distributions of health benefits. The best estimate of health benefits is somewhere in the thick mass of Figure 4 of this document, but it is impossible to tell where.

The uncertainty does not mean that nothing can be concluded about the benefits of the proposed rule. The distributions shown in Figures 3 and 4 of this document tend to be of two types: (1) Narrow distributions concentrated in the low end of the benefits scale, and (2) wide distributions encompassing everything from small benefits to enormous benefits. The narrow distributions bunched at the low end of the scale represent large health benefits. For example, the 5th percentile benefits from the CDC surveillance baseline are, as shown in Table 9 of this document, approximately $50 million per year—a large health benefit. The distributions shown in Figures 1 through 4 of this document suggest that although there is some small probability of small benefits, most of the values generated by the simulations represent large public health benefits.

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Figure 3. Uncertainty of Health Benefits: 10 Simulations

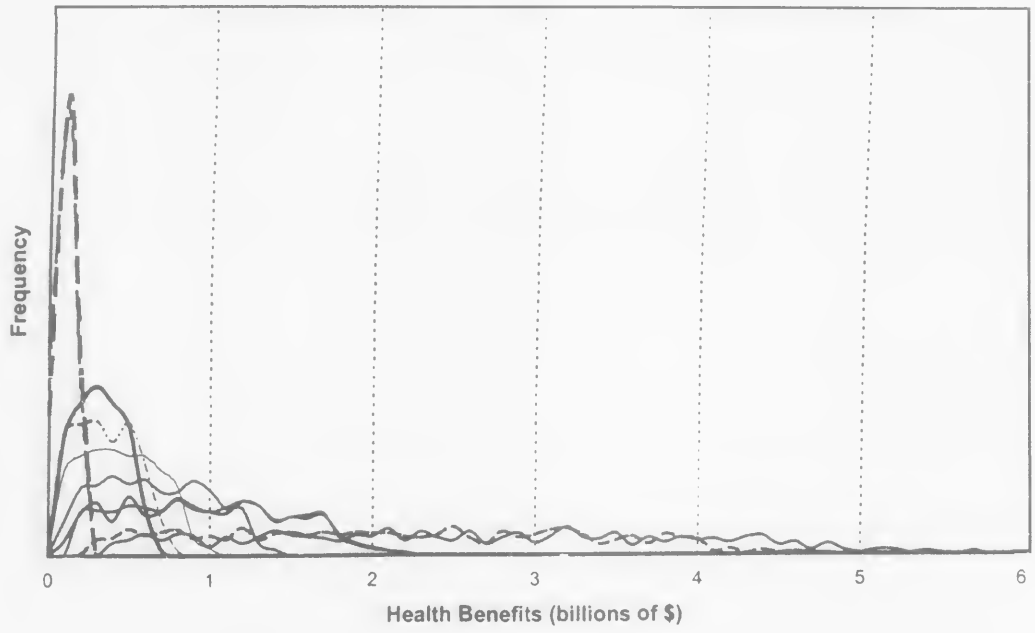
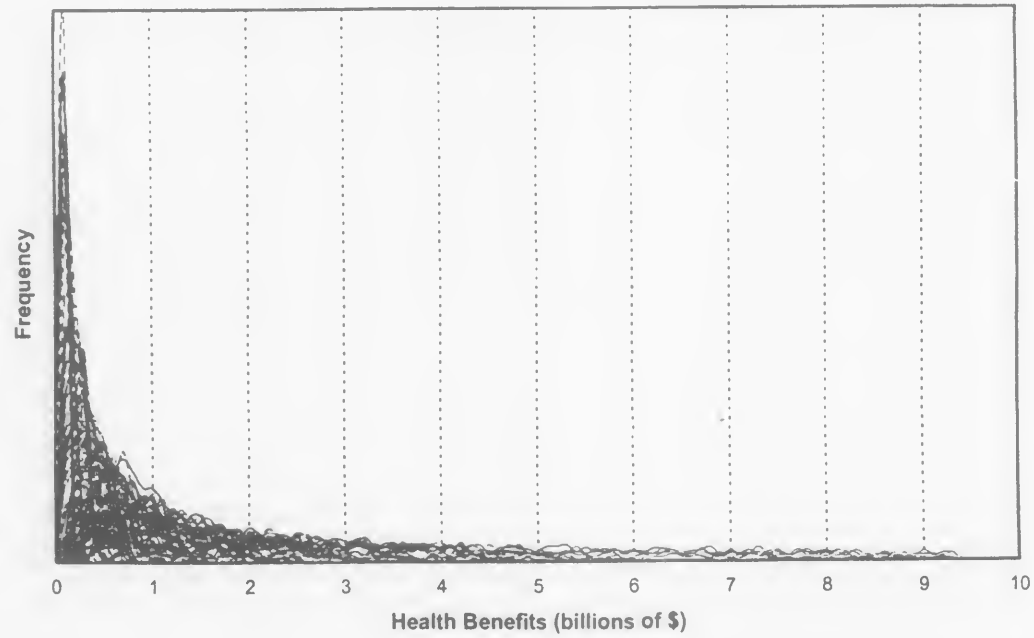


Figure 4. Uncertainty of Health Benefits: 100 Simulations



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F. Costs

The costs of the proposed rule include the redesign of egg cartons, the other costs necessary to add the safe handling label to egg cartons, the additional equipment and energy costs to achieve the specified refrigeration temperatures for shell eggs, and the costs of changes in consumer practices resulting from the safe handling label.

1. Types of Establishments Covered

The labeling provision and the refrigeration provision will affect different parts of the food industry.

a. *Labeling provision coverage.* The labeling provision covers shell eggs sold in labeled cartons or in cases for bulk sale. The labeling provision would affect all egg packers, processors, and distributors (hereinafter collectively referred to as "packers"). There are 669 packers registered with USDA (Ref. 17).

b. *Refrigeration provision coverage.* The refrigeration provision covers all retail establishments that sell or otherwise provide eggs as products to consumers (such as grocery stores selling cartons of eggs) or that use shell eggs in the production of other products sold or provided to consumers (such as hospitals providing prepared eggs to patients). These retail establishments include grocery stores, restaurants, health food stores, convenience stores, other retail establishments, as well as such institutions as prisons, nursing homes, schools, hospitals, and the military establishments.

2. Cost Estimates by Requirement and Type

a. *Egg container labels.* The proposed labeling provision requires shell egg containers to have a safe handling statement. The cost of the proposed provision may be estimated by measuring the additional costs either where they first occur—at the carton manufacturers—or at the segments of the industry that bear the costs of relabeling. Because the egg industry, which includes egg producers, carton manufacturers, egg distributors, and retailers is competitive, the carton manufacturers will likely pass some or all of the costs of relabeling on to packers.[16] The cost of relabeling if measured correctly will be the same no matter where in the carton market they are measured; therefore, the agency used the most readily accessible cost information for its estimates, which came from the carton manufacturers. It is irrelevant for purposes of cost estimation that packers are covered by the rule and carton manufacturers are not, because the costs are the same wherever measured.

The agency assumed that the carton manufacturer's additional costs or relabeling would be for administration, inventory disposal, and label redesign. The one-time costs include the costs of replacing existing printing plates (if the planned useful life of plates expires after the start of the compliance period), the loss of existing carton inventory (if the inventory does not meet label requirements at the start of the compliance period), and an additional administrative expense to interpret and execute the firm's compliance with the rule. The agency does not expect any firms in the industry to shut down as a consequence of the rule, because the increased costs from the rule are one-time costs that are not expected to be large enough to make shutting down the best option.

FDA calculated labeling costs with the following formula:

labeling costs = ($ administrative costs per firm x number of affected firms) + ($ value of cartons manufactured x disposal percentage of carton inventory) + ($ redesign cost per label x number of affected labels)

FDA calculated, separately, each of the three costs: Administrative, inventory disposal, and label redesign.

i. *Administrative costs.* To estimate the administrative costs, the agency used the following formula:

$AC = A \times F$

where:

AC = administrative costs.

A = administrative costs per firm.

F = number of firms in the industry.

Administrative costs include the firm's additional management and other overhead expenses needed to implement the proposed rule. Total administrative cost for the industry will be the administrative cost per firm multiplied by the number of firms that manufacture egg cartons. The Food Serving and Packaging Institute supplied information on the number of carton manufacturers (Ref. 19). Table 11 of this document shows FDA's estimates of the administrative cost per firm for different compliance periods. Administrative costs tend to decrease with the length of the compliance period, because longer compliance periods allow carton producers more time to incorporate the mandated label changes into regularly planned design, equipment, and personnel changes. In addition, fewer overtime hours would be required and possibly a lower level of management would be involved. Industry sources provided the agency with estimates of the cost per firm for a 12 month-compliance period (Refs. 19 through 24). FDA inferred the amounts shown for the 6-month and 18-month compliance periods from the estimate for the 12-month compliance period. The agency assumed that a firm would require more hours with a shorter compliance period, and fewer hours with a longer compliance period.

TABLE 11.—ADMINISTRATIVE COSTS (ESTIMATED FOR CARTON MANUFACTURERS)

Compliance Period	6 Months	12 Months	18 Months
Number of firms	8	8	8
Cost per firm	$35,000	$25,000	$15,000
Total	$280,000	$200,000	$120,000

[16] If both segments of the egg industry are competitive, the measured costs of carton manufactures could equal the costs borne by packers. Competition is a reasonable assumption for the packers because there are at least 669 firms in the industry. Competition may also be assumed for the carton manufacturers because their segment of the industry is contestable, meaning that it is a market with the potential for firm entry and exit. The economic theory of contestable markets suggests that when there is relatively free entry and exit into the market, prices will be set just high enough to cover the additional costs of production caused by the rule. The carton manufacturing industry four-firm concentration ratio is 85 percent, which is high. Despite a high concentration ratio, carton-manufacturing firms will still set carton prices at competitive levels or risk entry from new competitors. Anecdotal evidence exists that a new carton manufacturing firm did attempt to enter the market a few years ago (Ref. 18). It failed to be profitable and left the market shortly after entering, implying that the existing industry structure is competitive. The agency does not expect existing firms in the industry to exit as a consequence of the rule, because the increased costs from the rule are one-time costs. The remaining question is how those one-time costs will be split between carton manufacturers and packers. Although the question is important from the standpoint of the distribution of the burden of labeling costs, it does not affect the size of those costs.

ii. *Inventory disposal costs.* To estimate the inventory disposal costs, the agency used the following formula:

ID = IV x I

where:

ID = inventory disposal costs.

IV = total value of egg cartons manufactured annually.

I = lost carton stock as a percent of industry volume.

Inventory disposal costs are the costs of discarding otherwise useable carton inventory that does not comply with the new rule. The agency estimated inventory disposal costs by multiplying the total dollar value of the cartons produced annually by an estimate of the percentage of stock left over after the proposed rule would take effect.

Many egg packers have carton turnover rates of once or twice a week, while other firms turn over their carton stock once or twice a year. Egg packers, whatever their rate of turnover, never hold a large number of cartons in inventory. Inventory disposal costs tend to decrease with longer compliance periods, because longer compliance periods allow packers to use up their carton inventory. Based on information provided by industry sources, the agency estimated the likely percentage of stock remaining for three compliance periods: 6 months, 12 months, and 18 months (Refs. 19 through 24). Table 12 of this document shows FDA's estimate of the inventory disposal costs.

TABLE 12.—INVENTORY DISPOSAL COSTS

Compliance Period	6 Months	12 Months	18 Months
Total industry volume	$150,000,000	$150,000,000	$150,000,000
Lost stock as percent of industry	2 percent	1 percent	0.5 percent
Total inventory disposal cost	$3,000,000	$1,500,000	$750,000

iii. *Label redesign costs.* To calculate the label redesign costs the agency used the following formula:

LRC = $ per SKU x SKU's

where:

LRC = label redesign cost.

$ per SKU = cost per stock keeping unit.

SKU's = number of stock keeping units.

Label redesign costs are associated with the redesign of the carton's printed label that would be needed to incorporate the proposed safe handling statement. FDA estimated the costs by multiplying the number of affected separable labels on cartons or containers, referred to as stock keeping units (SKU's), by the estimated cost per SKU. The total number of SKU's for the industry is about 20,000 (Refs. 19 through 24). Although the labels affected would only be those without safe handling statements consistent with the proposed rule, the agency assumed that because the proposed rule requires specific language, no existing statements would be acceptable. Therefore, the agency estimated the costs based on the assumption that all labels would be changed.

Label redesign costs decrease with a longer compliance period, partly because the carton's design, printing plates, and other capital investments must be changed periodically regardless of regulatory initiatives. If the compliance period were as long as the useful life of the existing carton design, the label redesign costs of the proposed rule would be greatly reduced.

Redesign costs are lower, the more surface area on the carton, and are higher, the less surface area on the carton. Surface area is a major problem for labeling egg cartons, because of the relative absence of large, flat surfaces suitable for labels. When the surface area is not large enough to accommodate the proposed safe handling statement, the costs of redesign may also include redesigning the carton itself. Surface area is a significant issue for pulp paper carton manufacturers, because virtually all pulp paper cartons are "view style" cartons. View style cartons have a significantly reduced printable area. The additional cost of carton redesign to the pulp paper sector of the industry would put it at a competitive disadvantage. The alternative to pulp paper as carton material is foam. Foam cartons can more easily accommodate the proposed safe handling statement than can pulp paper cartons and, therefore, the cost of redesign would be less for foam cartons. The agency estimated the costs to redesign the labels per SKU, for both the pulp paper and foam carton segments of the industry, from information provided by industry sources (Refs. 19 through 24). Table 13 of this document shows a summary of the estimated costs for the foam carton segment of the industry for three compliance periods. Table 13a of this document shows the estimated costs for the pulp paper segment for three compliance periods. Table 13b of this document shows the total cost for both segments of the industry for the three compliance periods.

TABLE 13.—FOAM CARTON LABEL REDESIGN COSTS

Compliance Period	6 Months	12 Months	18 Months
Cost per SKU	$500	$250	$100
SKU's	10,000	10,000	10,000
Subtotal foam carton	$5,000,000	$2,500,000	$1,000,000

TABLE 13a.—PULP PAPER CARTON LABEL REDESIGN COSTS

Compliance Period	6 Months	12 Months	18 Months
Cost per SKU	$1,000	$750	$500
SKU's	10,000	10,000	10,000
Subtotal pulp paper carton label redesign	$10,000,000	$7,500,000	$5,000,000

TABLE 13b.—TOTAL INDUSTRY LABEL REDESIGN COSTS

Compliance Period	6 Months	12 Months	18 Months
Subtotal foam carton label redesign	$5,000,000	$2,500,000	$1,000,000
Subtotal pulp paper carton label redesign	$10,000,000	$7,500,000	$5,000,000
Total label redesign cost	$15,000,000	$10,000,000	$6,000,000

iv. *Summary of costs to incorporate safe handling labeling.* Table 14 of this document summarizes the estimated costs to incorporate safe handling statements on egg cartons.

TABLE 14.—ESTIMATED TOTAL INDUSTRY COSTS TO INCORPORATE SAFE HANDLING STATEMENTS

Compliance Period	6 Months	12 Months	18 Months
Total administrative costs	$280,000	$200,000	$120,000
Total inventory disposal costs	$3,000,000	$1,500,000	$750,000
Total label redesign costs	$15,000,000	$10,000,000	$6,000,000
Total labeling costs	$18,000,000	$12,000,000	$7,000,000

b. *Refrigeration costs.* The refrigeration provision of the proposed rule requires retailers to refrigerate shell eggs at 7.2 °C (45 °F) or less within 6 months from the date of publication of the final rule. The refrigeration provision potentially generates two additional costs to retailers: (1) An additional one-time capital cost to replace existing refrigeration equipment if the existing equipment is unable to cool to the proposed temperature, and (2) the cost of the additional energy needed to achieve and maintain the lower cooling temperature.

i. *Equipment costs to refrigerate at 7.2 °C (45 °F).* FDA used the following formula to estimate the additional equipment costs to refrigerate eggs at 7.2 °C (45 °F):

C = R x $ per R

where:

C = cost to refrigerate at 7.2 °C (45 °F).

R = number of retailers that would incur an additional cost.

$ per R = cost per retailer.

The baseline number of establishments affected was the number of retailers that were not already required to refrigerate at 7.2 °C (45 °F) by State or local requirements, and who did not have refrigerators cooling at 7.2 °C (45 °F).

The number of establishments and the additional refrigeration cost per establishment were both uncertain. The agency did not know: (1) How many and which retail establishments sell eggs, (2) the temperature at which the eggs are refrigerated in the establishments that sell eggs, (3) the age and temperature capability of the refrigerators, or (4) the price of refrigerators and components. FDA used ranges for the uncertain values and then estimated costs with Monte Carlo computer simulations similar to those described in section I.E of this document.

To estimate the total number of retail establishments likely to be affected by the refrigeration provision, the agency first determined the number of establishments in each State with data from Dun's Market Identifiers (Ref. 25).[17] If a State had already adopted the 1997 Food Code as issued by FDA or a similar code that required refrigeration to the proposed temperature, FDA assumed that there would be no additional equipment costs attributable to the proposed rule. The agency assumed that retailers in States with a refrigeration rule that met or exceeded the Federal requirement would incur no additional equipment costs.

Table 15 of this document illustrates how the agency estimated the number of establishments likely to be affected by the requirement to refrigerate eggs at 7.2 °C (45 °F). Column A of Table 15 of this document lists each State. Column B shows the maximum allowable refrigeration temperature for each State, where there is a State requirement.[18] Column C shows the total number of grocery or similar stores per State. Using Standard Industrial Classification (SIC) categories, the retail establishments included in this column are grocery stores (SIC 5411), poultry stands (SIC 5144), fruit and vegetable markets (SIC 5431), and dairy products stores (SIC 5451). Column D shows the number of grocery or similar stores that would be required to lower their refrigeration temperatures because of the proposed Federal provision. The agency assumed that between 0 and 100 percent of all establishments without a 7.2 °C or lower refregeration requirement, with 33 percent the most likely value, would be required to reduce their refrigeration temperatures.[19] FDA combined the estimated number of establishments refrigerating at 7.2 °C in States without a requirement with the number of establishments in the 37 States (and the District of Columbia) with such a requirement, the result was that 95 percent of all establishments were estimated to refrigerate shell eggs at 7.2 °C or less. The agency based the assumption on the belief that most establishments in States that did not have a refrigeration rule would nevertheless refrigerate eggs at 7.2 °C (45 °F) or less. FDA assumed that these establishments would either be required to refrigerate by a local rule or would choose to refrigerate at 7.2 °C (45 °F) in order to satisfy consumer demand. The agency seeks comments on this assumption. Column E shows the total number of restaurants (eating places) (SIC 5812) per State. Column F shows the number of restaurants that would be required to lower their refrigeration temperatures because of the proposed rule. The agency assumed that the most likely fraction of restaurants that would be required to lower their temperature would also be 33 percent of the total restaurants in those States without a State requirement. Column G shows the total number of institutions that serve eggs to consumers in each State. Institutions include prisons, military establishments, hospitals, nursing homes, public and private schools grades kindergarten through 12, colleges, and universities. Column H

[17] See Table 15 of this document.

[18] If a State has no temperature requirement, FDA used 100 as the default value.

[19] In the calculations shown in Table 15 of this document, FDA used a Beta-pert distribution (0,33,1). For an explanation (see Ref. 14).

shows the number of institutions that would be required to lower refrigeration temperatures because of the proposed rule. Column I shows the total number of retailers, including grocery stores, restaurants, and institutions in each State. Column J shows the total number of retailers that would be required to lower their refrigeration temperatures because of the proposed rule.

TABLE 15.—ESTIMATED EFFECTS OF REFRIGERATION PROVISION BY STATE

A	B	C	D	E	F	G	H	I	J
State	State Temp. Requirement	Total Grocery Stores	Affected Grocery Stores	Total Restaurants	Affected Restaurants	Total Institutions	Affected Institutions	Total Retail	Total Affected Retail
AL	45	4,142	0	5,957	0	2,443	0	12,542	0
AK	100	327	126	971	375	664	257	1,962	759
AZ	60	1,990	769	6,970	2,695	1,760	681	10,720	4,145
AR	45	2,341	0	3,702	0	1,883	0	7,926	0
CA	41	16,230	0	57,209	0	14,880	0	88,319	0
CO	45	1,733	0	7,260	0	2,369	0	11,362	0
CT	45	2,192	0	6,317	0	1,870	0	10,379	0
DE	41	467	0	1,340	0	375	0	2,182	0
DC	45	516	0	1,651	0	390	0	2,557	0
FL	41	10,223	0	27,256	0	5,629	0	43,108	0
GA	41	6,287	0	12,229	0	3,454	0	21,970	0
HI	45	596	0	2,187	0	450	0	3,233	0
ID	45	790	0	2,017	0	917	0	3,724	0
IL	41	5,916	0	19,158	0	7,358	0	32,432	0
IN	45	3,023	0	8,692	0	3,740	0	15,455	0
IA	45	2,214	0	4,783	0	2,755	0	9,752	0
KS	60	1,595	617	4,183	1,617	2,637	1,020	8,415	3,254
KY	45	3,550	0	5,806	0	2,449	0	11,805	0
LA	45	4,317	0	6,630	0	2,737	0	13,684	0
ME	100	1,396	540	2,328	900	1,143	442	4,867	1,882
MD	45	2,982	0	8,162	0	2,442	0	13,586	0
MA	45	3,467	0	11,819	0	3,609	0	18,895	0
MI	40	5,716	0	14,321	0	5,632	0	25,669	0
MN	45	2,795	0	6,561	0	3,022	0	12,378	0
MS	41	3,332	0	3,806	0	11,726	0	18,864	0
MO	60	3,440	1,330	7,876	3,045	3,998	1,546	15,314	5,921
MT	41	642	0	1,589	0	1,318	0	3,549	0
NE	45	1,186	0	2,515	0	2,239	0	5,940	0
NV	100	704	272	2,431	940	652	252	3,787	1,464
NH	100	866	335	2,407	931	846	327	4,119	1,593
NJ	60	5,619	2,173	15,234	5,890	4,133	1,598	24,986	9,661
NM	100	1,419	549	2,801	1,083	1,187	459	5,407	2,091
NY	45	14,757	0	35,667	0	8,207	0	58,631	0
NC	45	6,635	0	11,316	0	3,559	0	21,510	0
ND	41	883	0	984	0	894	0	2,761	0
OH	45	5,988	0	17,434	0	6,886	0	30,308	0
OK	60	2,741	1,060	4,877	1,886	3,071	1,187	10,689	4,133
OR	45	2,204	0	6,088	0	1,951	0	10,243	0
PA	45	7,868	0	19,864	0	7,006	0	34,738	0
RI	41	642	0	2,033	0	614	0	3,289	0
SC	45	3,827	0	6,315	0	1,888	0	12,030	0
SD	41	570	0	1,236	0	1,043	0	2,849	0
TN	100	5,264	2,035	8,634	3,338	2,954	1,142	16,852	6,516
TX	41	15,307	0	31,907	0	10,488	0	57,702	0
UT	41	956	0	2,911	0	1,060	0	4,927	0
VT	100	719	278	1,064	411	564	218	2,347	908
VA	45	4,872	0	10,483	0	3,229	0	18,584	0
WA	45	3,467	0	10,438	0	3,085	0	16,990	0
WV	100	1,703	658	2,349	908	1,414	547	5,466	2,114
WI	40	2,635	0	7,688	0	3,931	0	14,254	0
WY	45	309	0	926	0	586	0	1,821	0
Total		183,360	10,743	448,382	24,022	163,137	9,676	794,879	44,440

The agency assumed that each retailer not already in compliance with a State or local refrigeration rule would incur additional equipment costs in order to comply with the proposed rule. The agency also assumed that each retail establishment would have only one refrigerator that would be affected by the proposed rule. The equipment cost would be either the cost to replace old refrigerator components before the end of the component's useful life or the cost to purchase a new refrigerator after deducting the remaining useful value of the old refrigerator. Not all current refrigerators or refrigerator components such as compressors and coils are capable of cooling to the proposed lower temperatures. Older cooling equipment may not be able to achieve lower cooling temperatures, or if able to do so

cannot maintain a uniform temperature. Many older compressors lack sufficient horsepower (compressor power) and many older refrigeration coils lack the surface area for sufficient heat exchange. Attempting to meet the temperature requirements of the proposed rule with under-capacity refrigerators in a multishelf display case can cause both under-cooling and over-cooling of the products (Ref. 26). Excessively cold temperatures for products located at the top of display shelves can occur when the bottom shelves are targeted to meet the temperature requirement; excessively warm temperatures can occur at the bottom if the top shelves are targeted to meet the temperature requirement. Furthermore, products must be cooled to an even lower temperature than the proposed rule to ensure that at the end of the defrost cycle, when there is no cooling, the refrigerator does not exceed the allowable temperature. Maintaining a uniformly cool temperature in display cases, then, is not feasible when refrigerator components lack sufficient capacity. Because attempting to maintain the temperature with insufficient cooling capacity can adversely affect the safety, quality, and shelf life of the food products, some establishments would be forced to purchase new refrigerators or components.

All commercial refrigerators eventually wear out and have to be replaced. The cost of replacement resulting from the proposed rule only occurs if replacement becomes necessary before the planned end of the useful life of the existing equipment. Commercial refrigeration industry sources say that the useful life of a commercial refrigerator can be as long as 20 years, although on average commercial refrigerators last about 10 years (Ref. 27). The life of the refrigerator matters, because the longer the useful life of existing refrigerators, the greater will be the foregone capital cost borne by firms compelled to replace them. It follows that the longer the compliance period, the smaller will be the useful life left at the time of replacement and the smaller will be the cost borne by firms.

Retailers whose equipment could not reach the proposed safe cooling temperature and who were not planning to purchase a refrigerator or components during the compliance period would be forced to make a one-time purchase of refrigerators or components. The difference between the planned capital replacement cost without the proposed rule and the capital cost with the proposed rule would be the equipment cost of the refrigeration provision (the new equipment cost minus the salvage value of the old equipment). It would be a one-time cost, because all future purchases would occur at the end of the useful life of the refrigerator and not in response to the proposed rule.

The agency assumed that only one refrigerator per retailer would be potentially affected by the provision, because even the largest retail outlets (such as supermarkets) rarely have more than one refrigerator or display case exclusively devoted to selling eggs. Some large grocery stores might have more than one refrigerator containing eggs such as when eggs are displayed in island refrigerators for marketing purposes or in display cases in the dairy section. The agency assumed that for every retailer with more than one refrigerator devoted to eggs, there would be one, probably a smaller retailer, who did not sell eggs.

The agency assumed that additional equipment costs per affected establishment varied from close to 0 to approximately $6,000. This range of estimated equipment costs combined two separate ranges, one for small equipment costs and one for large equipment costs. The small equipment costs ranged from 0 to $1,000, with $700 the most likely value. The large equipment costs ranged from $1,000 to $6,000, with $4,000 the most likely value. FDA assumed that equipment expenditures would be highly correlated with the size of establishment, so that small firms would have small equipment costs and large firms would have large equipment costs. With 80 percent of establishments classified as small, the assumption that costs and establishment size were correlated led to the assumption that 80 percent of refrigeration costs would fall in the small range and 20 percent would fall in the large range.[20] FDA recognized, however, that the correlation would likely not be perfect; some small firms could have large equipment costs and some large firms could have small equipment costs.

FDA estimated total equipment costs with a Monte Carlo simulation of 1,000 calculations (or iterations). Each calculation consisted of an estimate of the number of affected establishments multiplied by an estimate of the equipment cost per establishment. The 5th percentile, median, mean, and 95th percentile of simulated total equipment costs are shown in Table 16 of this document.

TABLE 16.—TOTAL ANNUAL EQUIPMENT COSTS TO REFRIGERATE TO 7.2 °C (45 °F)

5th Percentile	Median	Mean	95th Percentile
$7,000,000	$31,000,000	$56,000,000	$228,000,000

ii. *Energy costs.* The additional energy costs likely to be caused by the proposed rule appear to be negligible, because new commercial refrigerators are significantly more energy efficient than older refrigerators. As retailers replace their existing equipment to comply with the rule, the agency expects retailers to adopt energy-efficient technologies, which will reduce their energy consumption by approximately the amount of additional energy used to lower their existing refrigeration temperature to 7.2 °C (45 °F). FDA therefore assumed that the proposed rule would lead to no additional energy costs.

iii. *Shares of estimated refrigeration costs by type of establishment.* The shares of total refrigeration costs by type of establishment are shown in Table 17 of this document. FDA assumed that equipment costs accounted for all refrigeration costs of the proposed rule.

[20] In the simulation used to estimate total equipment costs, the distributions of small and large equipment costs were characterized as Beta-pert distributions with small costs distributed as Beta-Pert (0,700,1000) and large costs distributed as Beta-pert (1000,4000,6000). The two distributions were combined with a discrete distribution that assumed that the probability that costs were small was 0.8 and the probability that costs were large was 0.2. The full distribution for the simulation was: Discrete ((Beta Pert (0,700,1000),,Beta-Pert (1000,4000,6000)), (0.8, 0.2)).

TABLE 17.—REFRIGERATION COST SHARES BY TYPE OF ESTABLISHMENT

Type of Establishment	Share of Total Refrigeration Cost (in percent)
Grocery stores	25
Restaurants	54
Institutions	21

iv. *Comparison with other studies of estimated refrigeration costs.* The agency found only two studies, by Dunn and Madison (Ref. 28) and by Madison (Ref. 29), that have estimated the costs of a similar proposed refrigeration rule. Dunn and Madison estimated the statewide impact from lowering the refrigeration requirement from 55 °F to 45 °F. They assumed that the statewide average refrigeration temperature before the proposed rule was 55 °F. They estimated the most likely cost to egg packers to reduce refrigerator temperatures from 55 °F to 45 °F to be $0.05 per dozen eggs, but that the cost could be as low as $0.02 per dozen. The smaller cost held when the eggs were produced from larger flocks and were cooled in refrigerators with larger capacity. The estimates were based on the cost to modify the existing cooling systems to increase cooling capacity. Although egg packers and not retailers incurred the additional costs, the agency believes that the costs to one segment of the industry would be passed on to a downstream segment and would be nearly equal on a per carton basis.[21]

The Dunn and Madison estimates can be compared to the agency's estimate of the cost to refrigerate eggs at 7.2 °C (45 °F). The higher estimate of refrigeration costs (Refs. 28 and 29) of $0.05 per dozen eggs equals $0.08 per dozen eggs in current (1998) dollars. The lower estimate of refrigeration costs (Refs. 28 and 29) of $0.02 per dozen eggs equals $0.032 per dozen eggs in current (1998) dollars. The agency multiplied both the lower and the higher estimates of cost per dozen eggs by the agency's estimate of the total number of eggs sold at retail in States without a current refrigeration rule.

For the comparison with the Dunn and Madison estimates, FDA assumed that there were no regional or State differences in consumption per person of shell eggs across the country. The agency got the number of shell eggs produced and consumed nationwide from the USDA Economics Research Service (Ref. 30). The agency assumed that the national consumption of eggs equaled to the national production of eggs after subtracting for net exports, breakers, and diverted eggs. FDA further assumed that a State's share of the national consumption of eggs equaled the State's share of national population. Table 18 of this document shows the resulting estimate of the number of affected eggs sold in States that do not currently meet the proposed refrigeration provision.

TABLE 18.—STATE EGG CONSUMPTION

State	State Temperature Requirement	Number of Eggs Consumed (Millions)
Alabama	45	
Alaska	None	106
Arizona	60	691
Arkansas	45	
California	41	
Colorado	45	
Connecticut	45	
Delaware	41	
District of Columbia	45	
Florida	41	
Georgia	41	
Hawaii	45	
Idaho	45	
Illinois	41	
Indiana	45	
Iowa	45	
Kansas	60	455
Kentucky	45	
Louisiana	45	
Maine	None	223
Maryland	45	
Massachusetts	45	
Michigan	40	
Minnesota	45	
Mississippi	41	
Missouri	60	936
Montana	41	
Nebraska	45	
Nevada	None	239
New Hampshire	None	200
New Jersey	60	1,405

[21] The costs could be passed on if all segments of the industry were competitive.

TABLE 18.—STATE EGG CONSUMPTION—Continued

State	State Temperature Requirement	Number of Eggs Consumed (Millions)
New Mexico	None	285
New York	45	
North Carolina	45	
North Dakota	41	
Ohio	45	
Oklahoma	60	579
Oregon	45	
Pennsylvania	45	
Rhode Island	41	
South Carolina	45	
South Dakota	41	
Tennessee	None	906
Texas	41	
Utah	41	
Vermont	None	103
Virginia	45	
Washington	45	
West Virginia	None	327
Wisconsin	40	
Wyoming	45	
Total[1]		6,500

[1] Rounded

The agency used the following formula to calculate the cost to refrigerate at 7.2 °C (45 °F) using Dunn and Madison's estimated average cost per dozen eggs:

RC = DE x $ per D

where:

RC = cost to refrigerate to 7.2 °C (45 °F).

DE = total number of eggs (in dozens) in States where eggs not currently refrigerated to 7.2 °C (45 °F).

$ per D = cost per dozen eggs to refrigerate to 7.2 °C (45 °F).

The agency estimated that 6.5 billion eggs were not refrigerated at 7.2 °C (45 °F) (see Table 18 of this document). The number of dozens not refrigerated at 7.2 °C (45 °F) would therefore be 540 million (= 6.5 billion ÷ 12). The high estimated cost of refrigeration would be about $43 million (= 540 million dozen eggs x $0.08 per dozen). The low estimated cost of refrigeration would be about $17 million (= 540 million dozen eggs x $0.032 per dozen).

Table 19 of this document compares FDA's estimate of the costs of refrigeration with estimates based on Dunn and Madison's high and low average refrigeration cost per dozen eggs. As the table shows, FDA's median estimate of total refrigeration costs fall between Dunn and Madison's high and low estimates.

TABLE 19.—COMPARATIVE SUMMARY OF COSTS FROM THE REFRIGERATION PROVISION (MILLIONS)

Method	FDA (Median)	Dunn and Madison (High)	Dunn and Madison (Low)
7.2 °C (45 °F)	$31	$43	$17

c. *Changes in consumer practices.* A safe handling label will not by itself lead to safer eggs. The changes people make in response to the label lead to safer eggs. In the calculation of benefits from the safe handling label, FDA assumed that some people would respond to the proposed safe handling label by cooking eggs more thoroughly or by switching away from foods that require raw or undercooked eggs. FDA recognizes that if people for reasons of safety reduce their consumption of foods they would have otherwise preferred, they bear the costs of changing their preparation and consumption practices. If it were possible to do so, many people would be willing to pay more to continue to be able to eat the unsafe food, supposing it could be made safe. The extra willingness to pay is the measure of the cost of changing consumer practices when consumers are unable to purchase or prepare a safe version of the preferred food.

The agency calculated the cost of changing consumer practices with the following formula:

CS = E x UP x ΔUP x $ per U

where:

CS = annual cost of changing consumer practices.

E = total eggs consumed per year.

UP = baseline percentage of total eggs that were not cooked thoroughly before the rule.

ΔUP = percentage reduction in eggs that are not cooked thoroughly because of the rule.

$ per U = value of undercooking one egg.

The estimated number of eggs consumed was 46.8 billion. Based on results of the Food Consumption and Preparation Survey, the USDA SE risk assessment used a distribution with a most likely value of 33 percent to estimate the baseline percentage of eggs that were not cooked thoroughly before the proposed rule.[22] FDA estimated the percentage reduction of consumption of undercooked eggs as a distribution, with a most likely value of about 5 percent.[23] The agency assumed that $0.025 (= $0.30 ÷ 12), the cost per egg for in-shell pasteurization, would be the upper bound that consumers would be willing to pay for safe handling. The agency assumed that the lower bound cost would be 1/25th of the upper bound

[22] The minimum was 27 percent and the maximum was 46 percent. The distribution used in the simulation was Beta-Pert (0.27, 0.33, 0.46).

[23] FDA used a Beta distribution to characterize the reduction in undercooking. The Beta distribution (50,959) was based on survey results for the USDA safe handling label for meat (Ref. 5). FDA used the same survey to estimate the benefits of the proposed safe handling label.

cost, or $0.001. The agency further assumed that the value to consumers of one undercooked egg would vary uniformly between the lower bound ($0.001) and the upper bound ($0.025)[24]

Because of the uncertainty associated with the calculation, the agency estimated the costs of changing consumer practices with a Monte Carlo simulation. Table 20 of this document shows the results of the 1,000 calculations of the annual cost of changes in consumer practices brought about by the proposed rule.

TABLE 20.—ESTIMATED ANNUAL COST OF CHANGES IN CONSUMER PRACTICES ATTRIBUTABLE TO THE PROPOSED SAFE HANDLING LABEL

Variable	5th Percentile	Median	Mean	95th Percentile
Annual cost to consumers	$2,000,000	$10,000,000	$10,000,000	$20,000,000

G. Summary of Benefits and Costs

The agency estimated the median annual benefits of this proposed rule to be about $300 million for the CDC surveillance baseline model and about $700 million for the USDA SE risk assessment baseline model. The estimated median costs to refrigerate shell eggs at 7.2 °C (45 °F) were $31 million in the first year. The agency estimated the cost to incorporate safe handling statements as $18 million for a 6-month compliance period. The median estimated cost of changing consumer practices was $10 million per year. Therefore, the agency estimated the total cost of the proposed rule in the first year to be about $60 million. After the first year, the only continuing cost would be reduced consumer satisfaction, which recurs year after year as long as consumers have a preference for undercooked eggs. FDA concludes that the effects of the proposed rule would be economically significant under Executive Order 12866. The proposed rule, based on the median estimate of cost contained in the economic analysis, would not be significant under the Unfunded Mandates Reform Act.

TABLE 21.—MEDIAN ANNUAL ESTIMATED BENEFITS AND COSTS OF THE PROPOSED RULE (IN MILLIONS OF $)

	First year	All other years
Median estimated benefits (USDA SE risk assessment baseline)	$700	$700[1]
Median estimated benefits (CDC surveillance baseline)	$300	$300[1]
Median estimated costs	$60	$10

[1] The benefits remain high after the first year if no other interventions affect SE in shell eggs. If other Federal or State regulations, consumer education, and producer initiatives reduce the baseline incidence of SE illness from shell eggs, then the benefits from the proposed rule will decline over time. The decline will be roughly proportional to the decline in baseline incidence of SE illness from shell eggs.

II. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of these proposed rules as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

B. Economic Effects on Small Entities

1. Number of Small Entities Affected

The proposed rule would affect many small entities, including egg processors, grocery stores, restaurants, and other food service establishments. Of the 669 egg processors registered with the USDA, FDA has not been able to determine how many are small businesses (Ref. 17). Egg processors generally fall into two industrial classifications: Poultry slaughtering and processing (SIC code 2015) and whole poultry and poultry products (SIC code 5144). The two classifications roughly correspond to in-line and off-line processors. In-line processors package the eggs at the egg laying facility. Off-line processors ship the eggs to packers.

The Small Business Administration (SBA) defines in-line egg processors (SIC code 2015–03) to be small businesses if they employ 500 or fewer people. According to a search in Dun's Market Identifiers (Ref. 25), 25 in-line egg processing firms would be defined as small. SBA defines off-line processors (SIC code 5144) to be small if they employ 100 or fewer people. Dun's Market Identifiers did not have a subcategory for egg processors. For the entire category of poultry and poultry products (SIC code 5144), 80 percent of establishments employ fewer than 100 workers. If the same proportion holds for the subcategory composed of egg processors, then 470 firms would be classified as small.[25] FDA estimated the total number of small egg processors to be 495 (= 25 + 470).

The refrigeration provision would affect small establishments that are not currently refrigerating at 7.2 °C (45 °F). The SBA defines grocery stores (SIC code 5411) to be small if annual gross revenue is less than $20 million. Other food stores (SIC codes 5431, 5451, and 5499), which include fruit and vegetable markets, dairy product stores, and miscellaneous food stores, are small if annual sales are less than $5 million. Restaurants are small if annual sales are less than $5 million; institutions are small if sales are less than $15 million.

As set out in Table 22 of this document, FDA estimated that the number of small establishments affected by the proposed refrigeration provision would be 25,400. The number of establishments (small and large) currently not keeping eggs at an ambient temperature of 7.2 °C (45 °F) is approximately 44,400, which includes 10,700 grocery and other food stores,

[24] In the simulation, the value of an undercooked egg was characterized as a uniform distribution: Uniform ($0.001, $0.025).

[25] The estimated total number of in-line establishments is 134, but 52 are branches of firms. If the total number of in-line firms is 82(=134—52), and the number of processors is 669, then 587 firms are off-line processors. If 80 percent are small, then 470 off-line (=0.8 x 587) processors are small.

24,000 restaurants, and 9,700 institutions (see Table 15 of this document). FDA assumed that the proportion of small establishments affected by the refrigeration provision would be the same as the fraction of institutions for the entire industry in that category. According to SBA size standards for small entities, 71 percent of grocery and other food stores and 54 percent of restaurants are small. Institutions are more complicated because they cut across SIC codes. FDA assumed that 50 percent of institutions serving eggs are small. The agency asks for comments on this assumption. FDA estimated the number of small establishments affected by the refrigeration provision by multiplying the fraction in each category defined to be small by the total number of establishments affected. Table 22 of this document shows the number of small entities likely to be affected by the refrigeration provision of the proposed rule.

TABLE 22.—NUMBER OF SMALL ENTITIES LIKELY TO BE AFFECTED BY THE REFRIGERATION PROVISION OF THE PROPOSED RULE

Category	Number of Small Establishments Currently Storing Eggs Above 7.2 °C (45 °F)
Grocery and other stores	7,600
Restaurants	13,000
Institutions	4,800
Total	25,400

2. Costs to Small Entities

Redesigning the label accounts for most of the estimated additional labeling costs for small processors. For a 6-month compliance period, redesign costs would be $1,000 per SKU for pulp cartons and $500 per SKU for foam cartons. The cost of the labeling provision borne by small processors will vary with the number of SKU. The average number of SKU's per processor for the industry is 30; FDA assumes that the output of small processors falls in the range of 2 to 20 SKU's. Additional redesign costs could therefore be as high as $20,000 per processor (= 20 x $1,000).

Refrigeration costs vary across establishments, depending on the age of current refrigerators, the planned replacement cycle, and whether the small establishments is currently keeping eggs at or below 7.2 °C (45 °F). Additional costs of refrigeration for small retailers would average $633 per establishment, with $700 the most likely cost. FDA assumed that the proportion of additional refrigeration costs borne by small entities would be the same as the proportion of small entities in each category of establishments. Table 23 of this document shows the estimated total cost of the refrigeration provision to small entities. The agency requests comments on the effect of the refrigeration provision on roadside stands.

TABLE 23.—COSTS TO SMALL ENTITIES OF THE REFRIGERATION PROVISION OF THE PROPOSED RULE

Category	Total Costs to Small Entities	Mean Cost per Small Entity
Grocery	$4.8 million	$633
Restaurants	$8.2 million	$633
Institutions	$3.1 million	$633
Total	$16.1 million	$633

C. Regulatory Options

1. Exemption for Small Entities

The burden on small entities would be lifted if they were exempt from the provisions of the proposed rule. Most of the entities affected by this proposed rule, however, are small. Thus, exempting small entities from its provisions would effectively negate the rule.

2. Longer Compliance Periods

Lengthening the labeling compliance period from 6 months to 18 months and lengthening the refrigeration compliance period from the proposed rule's effective date to 12 months after the effective date would provide regulatory relief (cost reduction) to small entities. In order to estimate the regulatory relief from lengthening the refrigeration compliance period, the agency assumed that the cost reduction would equal the interest (discounted at 7 percent per year) on the cost of refrigeration equipment over the extension of the compliance period. If the compliance period were extended by 12 months, the interest on the cost of equipment would be over $1 million (= $16.1 x 0.07). For the most likely equipment cost of $700 per small establishment, the interest saving would be about $50 (= 0.07 x $700).

In order to estimate the regulatory relief to small retail entities from a longer labeling compliance period, FDA first estimated the decline in total industry costs and then multiplied it by the small business share of total costs. Total industry costs would fall by $11 million if the compliance period for labeling were extended from 6 months to 18 months (see Table 14 of this document). Most of the relief to small businesses would come from the reduced costs of redesigning the carton label. For pulp cartons, extending the compliance period to 18 months would reduce redesign costs from $1,000 (for a 6-month compliance period) to $500 per SKU. For foam cartons, extending the compliance period to 18 months would reduce redesign costs from $500 (for a 6-month compliance period) to $100 per SKU.

Although lengthening the compliance periods would provide some regulatory relief to small entities, they make up such a large part of the affected industries that longer compliance periods would significantly delay the full public health benefits of the proposed rule.

D. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping and recording required for compliance with this rule. This rule

does not require the preparation of a report or a record.

E. Worst Case to Small Entities

The greatest impact to a small retail establishment as a consequence of the refrigeration provision would be to cause the entity to bear the entire cost for the purchase of a new refrigerator. The agency estimates that the cost of a new refrigerator is between $2,500 and $6,000. In order to estimate the worst possible outcome for a small entity, FDA assumed that some small retail establishment would purchase a new refrigerator at the maximum estimated cost of $6,000. If the latter cost were amortized over a 10-year period (using a discount rate of 7 percent) then the approximate annual expense would be $850 per year for 10 years. According to Dun and Bradstreet, 85 percent of all grocery stores have annual sales of less than $20 million, and 71 percent of all restaurants have annual sales of less than $5 million (Ref. 25). Among the smallest 10 percent of these establishments, the average sales volume is $100,000 per year for a grocery store and $50,000 per year for a restaurant. Therefore, the additional expense of $850 per year would be approximately 1 to 2 percent of average sales volume per year. Grocery stores and restaurants typically have profit margins on sales of 1 to 5 percent, so a reduction of the profit margin by 40 to 100 percent would be the worst-case outcome for the smallest entities in retail.

The worst case to a small entity attributable to the labeling provision would occur if a small packer were unable to pass along any of the cost to its customers. As shown previously, FDA estimated that the redesign cost to a small processor could be as high as $20,000. If the one-time cost could be amortized over a 10-year period at an annual discount rate of 7 percent, the small packer would incur an additional annual expense of approximately $3,000. FDA did not estimate the annual sales revenues of the smallest egg packers and, therefore, it was unable to compare the estimated amortized cost to annual profits. FDA requests comments on this relationship.

F. Summary

FDA estimated that the labeling provisions could impose costs of up to $20,000 on 495 small processing establishments. The refrigeration provision would impose estimated average costs of $633 per small entity (and up to $6,000) on approximately 25,400 small establishments. FDA finds that, under the Regulatory Flexibility Act, this proposed rule would have a significant economic impact on a substantial number of small entities.

III. 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.

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18. Memorandum of conversation between Carlton Lofgren, McAnally Enterprises, and Peter Vardon, FDA, January 21, 1998.

19. Letter from Richard B. Norment, Food Serving and Packaging Institute, to Peter Vardon, FDA, February 23, 1998.

20. Memorandum of telephone conversation between Norman Patterson, Dalco Packaging Corp., and Peter Vardon, FDA, January 28, 1998.

21. Memorandum of telephone conversation between Norman Patterson, Dalco Packaging Corp., and Peter Vardon, FDA, February 4, 1998.

22. Memorandum of telephone conversation between Barbara Walters and Alan Andrews, Tenneco Packaging Co., and Peter Vardon, FDA, January 15, 1998.

23. Memorandum of telephone conversation between Alan Andrews, Tenneco Packaging Co., and Peter Vardon, FDA January 30, 1998.

24. Memorandum of telephone conversation between Dale Gerber, Cascade Diamond Corp., and Peter Vardon, FDA, February 9, 1998.

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IV. Request for Comments

Interested persons may, on or before September 20, 1999, submit to the Dockets Management Branch (address above) written comments regarding this preliminary regulatory impact analysis and initial regulatory flexibility analysis. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers 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.

Dated: June 10, 1999.

Jane E. Henney

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–17121 Filed 7–1–99; 11:12 am]

BILLING CODE 4160–01–F

federal register

Tuesday
July 6, 1999

Part VI

Department of Education

William D. Ford Federal District Loan Program; Notice

DEPARTMENT OF EDUCATION

William D. Ford Federal Direct Loan Program

AGENCY: Department of Education.

ACTION: Notice of the annual updates to the income contingent repayment plan formula.

SUMMARY: The Secretary announces the annual updates to the income percentage factors for 1999. Under the William D. Ford Federal Direct Loan (Direct Loan) Program, borrowers may choose to repay their student loans under the income contingent repayment plan, which bases the repayment amount on the borrower's income and family size, loan amount, and interest rate. Each year, the formula for calculating a borrower's payment is adjusted to reflect changes due to inflation. This Notice contains updated sample income contingent repayment amounts for single and married or head-of-household borrowers at various income and debt levels. These updates are effective from July 1, 2000 to June 30, 2001.

FOR FURTHER INFORMATION CONTACT: Donald Watson, U.S. Department of Education, Room 3045, ROB–3, 400 Maryland Avenue, SW, Washington, DC 20202–5400. Telephone: (202) 708–8242. If you use a telecommunications device for the deaf (TDD) you may call the Federal Information relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape or computer diskette) on request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION: Direct Loan Program borrowers may choose to repay their Direct Loans under the income contingent repayment plan. The attachment to this Notice provides updates to four sources of information used to calculate the borrower's monthly payment amount: examples of how the calculation of the monthly ICR repayment amount is performed, the income percentage factors, the constant multiplier chart, and charts showing sample repayment amounts.

We have updated the income percentage factors to reflect changes based on inflation. We have revised the income percentage factor table by changing the dollar amounts of the incomes shown by a percentage equal to the estimated percentage change in the Consumer Price Index for all Urban Consumers from December 1998 to December 1999. Further, we provide examples of monthly repayment amount calculations and two charts. the charts show sample repayment amounts for single, and married or head of household borrowers at various income and debt based on the updated income percentage factors.

The updated income percentage factors, at any given income, may cause a borrower's payments to be slightly lower than they were in prior years. This updated amount more accurately reflects the impact of inflation on a borrower's current ability to repay.

Electronic Access to This Document

You may review this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following sites:

http://ocfo.ed.gov/fedreg.htm
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To use the PDF, you must have the Adobe Acrobat Reader Program with search, which is available free at either of the previous sites. If you have questions about using the PDF, call the U.S. Government Printing Office (GPO), toll free at 1–888–293–6498 or in the Washington, D.C., area at (202) 512–1530

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(Catalog of Federal Domestic Assistance Number 84.268 William D. Ford Federal Direct Loan Program)

(*Program Authority:* 20 U.S.C. 1087 *et seq.*)

Dated: June 30, 1999.

Greg Woods,

Chief, Operating Officer.

Attachment—Examples of the Calculations of Monthly Repayment Amounts

Example 1. This example assumes you are a single borrower with $15,000 in Direct Loans, the interest rate being charged is 8.25 percent, and you have an adjusted gross income (AGI) of $23,912.

Step 1: Determine your annual payments based on what you would pay over 12 years using standard amortization. To do this, multiply your principal balance by the constant multiplier for 8.25 percent interest (0.1315449). The constant multiplier is a factor used to calculate amortized payments at a given interest rate over a fixed period of time. (See the constant multiplier chart below to determine the constant multiplier you should use for the interest rate on your loan. If your exact interest rate is not listed, use the next highest for estimation purposes.)

- $0.1315449 \times \$15,000 = \$1,973.17$

Step 2: Multiply the result by the income percentage factor shown in the income percentage factor table that corresponds to your income (if your income is not listed, you can calculate the applicable income percentage factor by following the instructions under the interpolation heading below):

- $80.33 \times \$1,973.18 \div 100 = \$1,585.06$

Step 3: Determine 20 percent of your discretionary income. Because you are a single borrower, subtract the poverty level for a family of one, as published in the **Federal Register** on March 18, 1999 (64 FR 13428), from your income and multiply the result by 20%:

- $\$23,912 - \$8,240 = \$15,672$
- $\$15,672 \times 0.20 = \$3,134.40$

Step 4: Compare the amount from step 2 with the amount from step 3. The lower of the two will be your annual payment amount. In this example, you will be paying the amount calculated under step 2. To determine your monthly repayment amount, divide the annual amount by 12.

- $\$1,585.06 \div 12 = \$132.09$

Example 2. In this example, you are married. You and your spouse have a combined AGI of $30,035 and are repaying your loans jointly under the income contingent repayment plan. You have no children. You have a Direct Loan balance of $10,000, and your spouse has a Direct Loan balance of $15,000. Your interest rate is 8.25 percent.

Step 1: Add you and your spouse's Direct Loan balances together to determine your aggregate loan balance.

- $\$10,000 + \$15,000 = \$25,000$

Step 2: Determine the annual payment based on what you would pay over 12 years using standard amortization. To do this, multiply your aggregate principal balance by the constant multiplier for 8.25 percent interest (0.1315452). (See the constant multiplier chart to determine the constant multiplier you should use for the interest rate on your loan. If your exact interest rate is not listed, choose the next highest rate for estimation purposes.)

- $0.1315449 \times \$25,000 = \$3,288.62$

Step 3: Multiply the result by the income percentage factor shown in the income percentage factor table that corresponds to you and your spouse's income (if you and your spouse's aggregate income is not listed, you can calculate the applicable income percentage factor by following the instructions under the interpolation heading below):

- $87.61 \times \$3,288.63 \div 100 = \$2,881.17$

Step 4: Determine 20 percent of your aggregate income. To do this, subtract the poverty level for a family of 2, as published in the **Federal Register** on March 18, 1999 (64 FR 13428), from your aggregate income and multiply the result by 20 percent:

- $\$30,035 - \$11,060 = \$18,975$
- $\$18,975 \times 0.20 = \$3,795$

Step 5: Compare the amount from step 3 with the amount from step 4. The lower of the two will be your annual payment amount. You and your spouse's will be paying the amount calculated under step 3.

To determine your monthly repayment amount, divide the annual amount by 12.

- $2,881.17 ÷ 12 = $240.10

Interpolation: If your income does not appear on the income percentage factor table, you will have to calculate the income percentage factor through interpolation. For example, assume you are single and your income is $30,000.

Step 1: Find the interval between the closest income listed that is less than your income of $30,000 and the closest income listed that is greater than your income of $30,000.

Step 2: Subtract these numbers (for this discussion, we will call the result the "income interval"):

- $30,035 − $23,912 = $6,123

Step 3: Find the interval between the two income percentage factors that are given for these incomes (for this discussion, we will call the result, the "income percentage factor interval"):

- 88.77% − 80.33% = 8.44%

Step 4: Subtract the income shown on the chart that is immediately less than $30,000 from your income of $30,000:

- $30,000 − $23,912 = $6,088

Step 5: Divide the result by the number representing the income interval:

- $6,088 ÷ $6,123 = 0.9943

Step 6: Multiply the result by the income percentage factor interval:

- 0.9943 × 8.44% = 8.39%

Step 7: Add the result to the lower income percentage factor used to calculate the income percentage factor interval for $30,000 in income:

- 8.39% + 80.33% = 88.72%

The result is the income percentage factor that will be Used to calculate the monthly repayment amount under the Income contingent repayment plan.

BILLING CODE 40001–01–P

Income Percentage Factors			
(Based on Annual Income)			
Single		Married/ Head of Household	
Income	% Factor	Income	% Factor
7,851	55.00%	7,851	50.52%
10,803	57.79%	12,389	56.68%
13,901	60.57%	14,765	59.56%
17,070	66.23%	19,302	67.79%
20,096	71.89%	23,912	75.22%
23,912	80.33%	30,035	87.61%
30,035	88.77%	37,668	100.00%
37,669	100.00%	45,304	100.00%
45,304	100.00%	56,757	109.40%
54,450	111.80%	75,842	125.00%
69,721	123.50%	102,563	140.60%
98,747	141.20%	143,439	150.00%
113,223	150.00%	234,390	200.00%
201,670	200.00%		

CONSTANT MULTIPLIER CHART FOR 12-YEAR AMORTIZATION

Interest Rate	Annual Constant Multiplier
7.00%	0.1234057
7.25%	0.1250107
7.46%	0.1263678
7.50%	0.1266272
7.75%	0.1282550
8.00%	0.1298943
8.25%	0.1315449
8.38%	0.1324076
8.50%	0.1332067
8.75%	0.1348796
9.00%	0.1365637

Sample First-Year Monthly Repayment Amounts for a Single Borrower at various Income and Debt Levels

Income	Initial Debt																							
	$2,500	$5,000	$ 7,500	$10,000	$12,500	$15,000	$17,500	$20,000	$22,500	$25,000	$30,000	$35,000	$40,000	$45,000	$50,000	$55,000	$60,000	$65,000	$70,000	$75,000	$80,000	$85,000	$90,000	$100,000
$ 1,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9,000	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13
10,000	16	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29	29
12,500	16	33	49	65	71	71	71	71	71	71	71	71	71	71	71	71	71	71	71	71	71	71	71	71
15,000	17	34	51	69	86	103	113	113	113	113	113	113	113	113	113	113	113	113	113	113	113	113	113	113
17,500	18	37	55	73	92	110	129	147	154	154	154	154	154	154	154	154	154	154	154	154	154	154	154	154
20,000	20	39	59	79	98	118	138	157	177	196	196	196	196	196	196	196	196	196	196	196	196	196	196	196
22,500	21	42	63	85	106	127	148	169	190	212	238	238	238	238	238	238	238	238	238	238	238	238	238	238
25,000	22	45	67	90	112	135	157	179	202	224	269	279	279	279	279	279	279	279	279	279	279	279	279	279
30,000	24	49	73	97	122	146	170	195	219	243	292	340	363	363	363	363	363	363	363	363	363	363	363	363
35,000	26	53	79	105	132	158	184	211	237	263	316	369	421	446	446	446	446	446	446	446	446	446	446	446
40,000	27	55	82	110	137	164	192	219	247	274	329	384	438	493	529	529	529	529	529	529	529	529	529	529
45,000	27	55	82	110	137	164	192	219	247	274	329	384	438	493	548	603	613	613	613	613	613	613	613	613
50,000	29	58	87	116	145	174	203	233	262	291	349	407	465	523	581	639	696	696	696	696	696	696	696	696
55,000	31	62	92	123	154	185	215	246	277	308	369	431	492	554	615	677	738	779	779	779	779	779	779	779
60,000	32	64	95	127	159	191	223	254	286	318	382	445	509	572	636	700	763	827	863	863	863	863	863	863
65,000	33	66	99	131	164	197	230	263	296	329	394	460	526	591	657	723	789	854	920	946	946	946	946	946
70,000	34	68	102	136	169	203	237	271	305	339	407	474	542	610	678	746	813	881	949	1017	1029	1029	1029	1029
75,000	35	69	104	139	174	208	243	278	313	347	417	486	556	625	695	764	833	903	972	1042	1111	1113	1113	1113
80,000	36	71	107	142	178	213	249	285	320	356	427	498	569	640	711	782	854	924	996	1067	1138	1196	1196	1196
85,000	36	73	109	146	182	218	255	291	328	364	437	510	582	655	728	801	874	946	1019	1092	1165	1238	1279	1279
90,000	37	74	112	149	186	223	261	298	335	372	447	521	596	670	745	819	894	968	1043	1117	1192	1266	1340	1363
95,000	38	76	114	152	190	228	266	305	343	381	457	533	609	685	761	838	914	990	1066	1142	1218	1294	1371	1446
100,000	39	78	117	156	195	233	272	311	350	389	467	545	622	700	778	856	934	1012	1089	1167	1245	1323	1401	1529

Sample repayment amounts are based on an interest rate of 8.25%.

Sample First-Year Monthly Repayment Amounts for a Married or Head-of-household Borrower at various Income and Debt Levels

Family Size = 3

Income	Initial Debt																					
	$ 2,500	$ 5,000	$ 7,500	$ 10,000	$ 12,500	$ 15,000	$ 17,500	$ 20,000	$ 22,500	$ 25,000	$ 30,000	$ 35,000	$ 40,000	$ 45,000	$ 50,000	$ 55,000	$ 60,000	$ 65,000	$ 70,000	$ 75,000	$ 80,000	$ 85,000	$ 90,000	$ 100,000
$ 1,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10,000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12,500	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15,000	16	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19
17,500	18	35	53	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60
20,000	19	38	57	76	94	102	102	102	102	102	102	102	102	102	102	102	102	102	102	102	102	102	102	102
22,500	20	40	60	80	100	120	140	144	144	144	144	144	144	144	144	144	144	144	144	144	144	144	144	144
25,000	21	42	64	85	106	127	149	170	185	185	185	185	185	185	185	185	185	185	185	185	185	185	185	185
30,000	24	48	72	96	120	144	168	192	216	240	269	269	269	269	269	269	269	269	269	269	269	269	269	269
35,000	26	52	79	105	131	157	184	210	236	262	315	352	352	352	352	352	352	352	352	352	352	352	352	352
40,000	27	55	82	110	137	164	192	219	247	274	329	384	435	435	435	435	435	435	435	435	435	435	435	435
45,000	27	55	82	110	137	164	192	219	247	274	329	384	438	493	519	519	519	519	519	519	519	519	519	519
50,000	28	57	85	114	142	171	199	228	256	285	342	398	455	512	569	602	602	602	602	602	602	602	602	602
55,000	30	59	89	118	148	178	207	237	266	296	355	414	473	533	592	651	685	685	685	685	685	685	685	685
60,000	31	61	92	123	154	184	215	246	276	307	368	430	491	553	614	676	737	769	769	769	769	769	769	769
65,000	32	64	95	127	159	191	223	255	286	318	382	446	509	573	637	700	764	828	852	852	852	852	852	852
70,000	33	66	99	132	165	198	231	264	297	329	395	461	527	593	659	725	791	857	923	935	935	935	935	935
75,000	34	68	102	136	170	204	238	273	307	341	409	477	545	613	681	749	818	886	954	1019	1019	1019	1019	1019
80,000	35	70	105	140	175	210	244	279	314	349	419	489	559	629	698	768	838	908	978	1048	1102	1102	1102	1102
85,000	36	71	107	143	179	214	250	286	322	357	429	500	572	643	714	786	857	929	1000	1072	1143	1185	1185	1185
90,000	37	73	110	146	183	219	256	292	329	365	438	511	584	657	730	803	877	950	1023	1096	1169	1242	1269	1269
95,000	37	75	112	149	187	224	261	299	336	373	448	523	597	672	746	821	896	970	1045	1120	1194	1269	1344	1352
100,000	38	76	114	152	191	229	267	305	343	381	457	534	610	686	762	839	915	991	1067	1144	1220	1296	1372	1435

Sample repayment amounts are based on an interest rate of 8.25%.

[FR Doc. 99–17084 Filed 7–2–99; 8:45 am]
BILLING CODE 4000–01–C

federal register

Tuesday
July 6, 1999

Part VII

The President

Proclamation 7207—To Extend Nondiscriminatory Treatment (Normal Trade Relations Treatment) to Products of Mongolia and To Implement an Agreement To Eliminate Tariffs on Certain Pharmaceuticals and Chemical Intermediates

Federal Register
Vol. 64, No. 128
Tuesday, July 6, 1999

Presidential Documents

Title 3—

The President

Proclamation 7207 of July 1, 1999

To Extend Nondiscriminatory Treatment (Normal Trade Relations Treatment) to Products of Mongolia and To Implement an Agreement To Eliminate Tariffs on Certain Pharmaceuticals and Chemical Intermediates

By the President of the United States of America

A Proclamation

1. The United States has had in effect a bilateral Agreement on Trade Relations with Mongolia since 1991 and has provided normal trade relations treatment to the products of Mongolia since that time. I have found Mongolia to be in full compliance with the freedom of emigration requirements of title IV of the Trade Act of 1974 (the "Trade Act") (19 U.S.C. 2432).

2. Pursuant to section 2424(b)(1) of Public Law 106–36, and having due regard for the findings of the Congress in section 2424(a) of said Law, I hereby determine that title IV of the Trade Act (19 U.S.C. 2431–2441) should no longer apply to Mongolia.

3. On November 13, 1998, members of the World Trade Organization (WTO), including the United States and 21 other major trading countries, announced in the WTO an agreement to eliminate tariffs on certain pharmaceuticals and chemical intermediates that were the subject of reciprocal duty elimination negotiations during the Uruguay Round of Multilateral Trade Negotiations (the "Uruguay Round"). A similar agreement between the United States and 16 other major trading countries eliminating tariffs on enumerated pharmaceuticals and chemical intermediates was implemented for the United States on April 1, 1997, by Proclamation 6982, adding such goods to the scope of the agreement on pharmaceutical products reached at the conclusion of the Uruguay Round and reflected in Schedule XX–United States of America, annexed to the Marrakesh Protocol to the General Agreement on Tariffs and Trade (1994) (Schedule XX).

4. Section 111(b) of the Uruguay Round Agreements Act (URAA) (19 U.S.C. 3521(b)) authorizes the President to proclaim the modification of any duty or staged rate reduction of any duty set forth in Schedule XX for products that were the subject of reciprocal duty elimination negotiations during the Uruguay Round, if the United States agrees to such action in a multilateral negotiation under the auspices of the WTO, and after compliance with the consultation and layover requirements of section 115 of the URAA (19 U.S.C. 3524). Section 111(b) also authorizes the President to proclaim such modifications as are necessary to reflect such duty treatment in Schedule XX by means of rectifications thereof.

5. On April 29, 1999, pursuant to section 115 of the URAA, the United States Trade Representative (USTR) submitted a report to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate ("the Committees") that sets forth the proposed tariff eliminations, together with the advice received from the appropriate private sector advisory committee and the United States International Trade Commission regarding the proposed tariff eliminations. During the 60-day period thereafter, the USTR consulted with the Committees on the proposed actions.

6. Section 604 of the Trade Act, as amended (19 U.S.C. 2483), authorizes the President to embody in the Harmonized Tariff Schedule of the United States (HTS) the substance of the relevant provisions of that Act, and of other acts affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

7. Pursuant to section 111(b) of the URAA, I have determined that Schedule XX should be modified to reflect the implementation by the United States of the multilateral agreement on certain pharmaceuticals and chemical intermediates negotiated under the auspices of the WTO. In addition, I have determined that the pharmaceuticals appendix to the HTS should be modified to reflect the duty eliminations provided in such agreement, and to make certain minor technical corrections in the identification of particular products in order to ensure that products are accorded the intended duty treatment.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States, including but not limited to section 2424(b)(2) of Public Law 106–36, section 111(b) of the URAA, and section 604 of the Trade Act, do hereby proclaim that:

(1) Nondiscriminatory treatment (normal trade relations treatment) shall be extended to the products of Mongolia, which shall no longer be subject to title IV of the Trade Act.

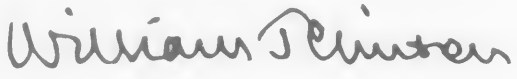
(2) The extension of nondiscriminatory treatment to the products of Mongolia shall be effective as of the date of signature of this proclamation.

(3) In order to implement the multilateral agreement negotiated under the auspices of the WTO to eliminate tariffs on certain pharmaceutical products and chemical intermediates, and to make technical corrections in the tariff treatment accorded to such products, the HTS is modified as set forth in the Annex to this proclamation.

(4) Such modifications to the HTS shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the dates set forth in the Annex for the respective actions taken.

(5) Any provisions of previous proclamations and Executive orders that are inconsistent with the actions taken in this proclamation are superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of July, in the year of our Lord nineteen hundred and ninety-nine, and of the Independence of the United States of America the two hundred and twenty-third.



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ANNEX

MODIFICATIONS TO THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

The Harmonized Tariff Schedule of the United States (HTS) is modified as provided herein, effective on the dates set forth for each annex section.

Section A. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after July 1, 1999, the following products are to be accorded duty-free treatment:

1. For subheadings 2905.22.50, 2910.30.00, 2921.43.40, 2922.19.20, 2924.29.05, and 2933.39.20, the Rates of Duty 1-Special subcolumn is modified by inserting, in alphabetical order, the symbol "K" in the parentheses following the "Free" rate of duty in such subcolumn for each such subheading.

2. The Pharmaceutical Appendix to the HTS is modified as provided below:

(a). Table 1 of the Appendix is modified by adding the following new INNs, in alphabetical order, in the "Product" column and their CAS numbers in the "CAS No." column:

Product	CAS Number	Product	CAS Number
*abacavir	136470-78-5	eperezolid	165800-04-4
abafungin	129639-79-8	eplerenone	107724-20-9
abarelix	183552-38-7	eptifibatide	148031-34-9
abiraterone	154229-19-3	fabesetron	129300-27-2
acreozast	123548-56-1	fandofloxacin	164150-99-6
agomelatine	138112-76-2	faralimomab	167816-91-3
alatrofloxacin	157182-32-6	fasidotril	135038-57-2
alinastine	154541-72-7	fasoracetam	110958-19-5
almotriptan	154323-57-6	felvizumab	167747-20-8
almurtide	61136-12-7	fexofenadine	83799-24-0
amelometasone	123013-22-9	fidarestat	136087-85-9
amlintide	122384-88-7	filaminast	141184-34-1
apadoline	135003-30-4	flibanserin	167933-07-5
arcitumomab	154361-48-5	follitropin beta	150490-84-9
aripiprazole	129722-12-9	fomivirsen	144245-52-3
arofylline	136145-07-8	forasartan	145216-43-9
aseripide	153242-02-5	foropafant	136468-36-5
asimadoline	153205-46-0	frovatriptan	158747-02-5
atiprimod	123018-47-3	fudosteine	13189-98-5
atizoram	135637-46-6	fulvestrant	129453-61-8
atliprofen	108912-17-0	furomine	142996-66-5
atreleuton	154355-76-7	gacyclidine	68134-81-6
aviptadil	40077-57-4	ganaxolone	38398-32-2
avitriptan	151140-96-4	gatifloxacin	160738-57-8
avorelin	140703-49-7	gavestinel	153436-22-7
avotermin	182212-66-4	glaspimod	134143-28-5
bamaquimast	135779-82-7	glufosfamide	132682-98-5
basiliximab	179045-86-4	hemoglobin crosfumaril	142261-03-8
becaplermin	165101-51-9	ibutamoren	159634-47-6
bectumomab	158318-63-9	icopezil	145508-78-7
belaperidone	156862-51-0	igovomab	171656-50-1
beloxepin	135928-30-2	indinavir	150378-17-9
bepotastine	125602-71-3	indisetron	141549-75-9
bibapcitide	153507-46-1	infliximab	170277-31-3
bincodar	159997-94-1	insulin aspart	116094-23-6
blonanserin	132810-10-7	insulin glargine	160337-95-1
brasofensine	171655-91-7	interferon alfacon-1	118390-30-0
brinzolamide	138890-62-7	iocanlidic acid (123 I)	74855-17-7
carafiban	177563-40-5	ioflupane (123 I)	155798-07-5
caniporide	159138-80-4	iometopane (123 I)	136794-86-0
cedelizumab	156586-90-2	ipamorelin	170851-70-4
ceftizoxime alapivoxil	135821-54-4	iroplact	154248-96-1
celgosivir	121104-96-9	israpafant	117279-73-9
cemadotin	159776-69-9	ivabradine	155974-00-8
cerivastatin	145599-86-6	keliximab	174722-30-6
cetermin	157238-32-9	lagatide	157476-77-2
cevimeline	107233-08-9	landiolol	133242-30-5
choriogonadotropin alfa	177073-44-8	lanepitant	170566-84-4
cizolirtine	142155-43-9	lasinavir	175385-62-3
clenoliximab	182912-58-9	ledoxantrone	113457-05-9
clevidipine	166432-28-6	lefradafiban	149503-79-7
clevudine	163252-36-6	levocetirizine	130018-77-8
colesevelam	182815-43-6	levosalbutamol	34391-04-3
dabelotine	118976-38-8	licostinel	153504-81-5
dalcotidine	120958-90-9	linetastine	159776-68-8
danaparoid sodium	83513-48-8	linezolid	165800-03-3
daniplestim	161753-30-6	lintitript	136381-85-6
dapitant	153438-49-4	lintuzumab	166089-32-3
declopramide	891-60-1	lirexapride	145414-12-6
deitibant	140661-97-8	lodenosine	110143-10-7
dexefaroxan	143249-88-1	lotrafiban	171049-14-2
dexsotalol	30236-32-9	lumefantrine	82186-77-4
donepezil	120014-06-4	lurtotecan	149882-10-0
dronedarone	141626-36-0	mazokalim	164178-54-5
droxinavir	159910-86-8	melagatran	159776-70-2
dutasteride	164656-23-9	meluadrine	134865-33-1
ecenofloxacin	162301-05-5	mespiperone (11 C)	94153-50-1
edrecolomab	156586-89-9	metesind	138384-68-6
efavirenz	154598-52-4	milacainide	141725-10-2
elacridar	143664-11-3	milameline	139886-32-1
eldacimibe	141993-70-6		
eletriptan	143322-58-1		
elinafide	162706-37-8		
embusartan	156001-18-2		
emoctakin	142298-00-8		
eniluracil	59989-18-3		
enlimomab pegol	169802-84-0		
ensaculin	155773-59-4		

Annex (con.)
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Section A (con.)
2. (con.)
(a). (con.)

Product	CAS Number	Product	CAS Number
milfasartan	148564-47-0	ritonavir	155213-67-5
milodistim	137463-76-4	rituximab	174722-31-7
minalrestat	129688-50-2	rivastigmine	123441-03-2
minodronic acid	127657-42-5	rizatriptan	144034-80-0
miproxifene	129612-87-9	robalzotan	169758-66-1
mitiglinide	145375-43-5	roflumilast	162401-32-3
mivobulin	122332-18-7	rosiglitazone	122320-73-4
moxifloxacin	151096-09-2	roxifiban	170902-47-3
moxilubant	146978-48-5	rupatadine	158876-82-5
nagrestipen	166089-33-4	sabcomeline	159912-53-5
nateglinide	105816-04-4	samarium (153 Sm) lexidronam	154427-83-5
nelfinavir	159989-64-7	sampatrilat	129981-36-8
nelzarabine	121032-29-9	saredutant	142001-63-6
nepadutant	183747-35-5	scopinast	145574-90-9
nepafenac	78281-72-8	seocalcitol	134404-52-7
nepaprazole	156601-79-5	sevelamer	52757-95-6
nepicastat	173997-05-2	sibrafiban	172927-65-0
nerelimomab	162774-06-3	sildenafil	139755-83-2
nifekalant	130636-43-0	silperisone	140044-31-6
nolatrexed	147149-76-6	sinapultide	138531-07-4
nolpitantium besilate	155418-06-7	sinitrodil	143248-63-9
nonacog alfa	113478-33-4	sipatrigine	130800-90-7
oberadilol	114856-44-9	sitafloxacin	127254-12-0
omapatrilat	167305-00-2	sivelestat	127373-66-4
omiloxetine	176894-09-0	soretolide	130403-08-6
opanixil	152939-42-9	sulesomab	167747-19-5
opratonium iodide	146919-78-0	sunepitron	148408-65-5
oprelvekin	145941-26-0	taltirelin	103300-74-9
orazipone	137109-78-5	talviraline	169312-27-0
orbofiban	163250-90-6	targinine	17035-90-4
osanetant	160492-56-8	tasonermin	94948-59-1
osutidine	140695-21-2	tazomeline	131987-54-7
pagoclone	133737-32-3	technetium (99m Tc) nofetumomab merpentan	165942-79-0
palinavir	154612-39-2	technetium (99m Tc) pintumomab	157476-76-1
palonosetron	135729-56-5	technetium (99mTc) apcitide	178959-14-3
pamaqueside	150332-35-7	temiverine	173324-94-2
pamiteplase	151912-42-4	temocaprilat	110221-53-9
paricalcitol	131918-61-1	terbogrel	149979-74-8
pegmusirudin	186638-10-8	tererstigmine	147650-57-5
peldesine	133432-71-0	ticolubant	154413-61-3
pelubiprofen	69956-77-0	tifacogin	148883-56-1
pemetrexed	137281-23-3	tilnoprofen arbamel	159098-79-0
perifosine	157716-52-4	tivirapine	137332-54-8
pexiganan	172820-23-4	tobicillin	151287-22-8
pibutidine	103922-33-4	trafermin	131094-16-1
pifonakin	112721-39-8	trastuzumab	180288-69-1
pleconaril	153168-05-9	trecovirsen	148998-94-1
pralmorelin	158861-67-7	tresperimus	160677-67-8
pramlintide	151126-32-8	upenazime	95268-62-5
pranazepide	150408-73-4	urokinase alfa	99821-47-3
pregabalin	148553-50-8	valganciclovir	175865-60-8
prucalopride	179474-81-8	valnemulin	101312-92-9
pumaprazole	158364-59-1	valspodar	121584-18-7
quetiapine	111974-69-7	vatanidipine	116308-55-5
quilostigmine	139314-01-5	vedaclidine	141575-50-0
raltitrexed	112887-68-0	vinflunine	162652-95-1
ranelic acid	135459-90-4	xaliproden	135354-02-8
rapacuronium bromide	156137-99-4	xemilofiban	149820-74-6
resocortol	76675-97-3	ziconotide	107452-89-1
retigabine	150812-12-7	zinostatin stimalamer	123760-07-6
revatropate	149926-91-0	zolmitriptan	139264-17-8"
rifalazil	129791-92-0		
rismorelin	146706-68-5		

(b). Table 2 of the Appendix is modified by adding the following chemical or INN derivative names in alphabetical order:

"BENZOATE MONOBENZOATE
DIFUMARATE TETRAISOPROPYL"
DIPIVOXIL

(c). Table 3 of the Appendix is modified by adding the following product names, in alphabetical order, along with their CAS numbers:

Product	CAS Number
"(S)-but-3-yn-2-ol	2914-69-4
2-(4-fluorobenzyl)thiophene	63877-96-3
5-amino-N,N'-bis[2-acetoxy-1-(acetoxymethyl)ethyl]-2,4,6-triiodoisophthalamide	148051-08-5
5-amino-N,N'-bis[2,3-dihydroxypropyl)-2,4,6-triiodoisophthalamide	76801-93-9
(S)-alpha-chloroformylethyl acetate	36394-75-9
diethyl dipropylmalonate	6065-63-0
5-methyl-N-[4-(sulfamoyl)phenethyl]pyrazine-2-carboxamide	33288-71-0
(5aR,11bS)-9,10-dimethoxy-2-propyl-4,5,5a,6,7,11b-hexahydrobenzo[f]thieno[2,3-c]-quinoline hydrochloride	178357-37-4
methyl N-(phenoxycarbonyl)-L-valinate	153441-77-1
(+-)-6-fluoro-1-methyl-4-oxo-7-(piperazin-1-yl)-4H-[1,3]thiazeto-[3,2-a]quinoline-3 -carboxylic acid	112984-60-8
methyl 3-amino-4,6-dibromo-o-toluate	119916-05-1
4,6-dibromo-3-fluoro-o-toluic acid	119916-27-7
7-bromo-1-cyclopropyl-6-fluoro-5-methyl-4-oxo-1,4-dihydroquinoline-3-carboxylic acid	119916-34-6

Annex (con.)
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Section A. (con.)
2. (con.)
(c). (con.)

Product	CAS Number
2-mercapto-5-(trifluoromethyl)anilinium chloride	4274-38-8
2-(3-bromophenoxy)tetrahydropyran	57999-49-2
6-chloro-5-(2-chloroethyl)indol-2(3H)-one	118289-55-7
6-chloroindol-2(3H)-one	56341-37-8
6-methoxy-1,2,3,4-tetrahydro-1-naphthone	1078-19-9
N-[N-(tert-butoxycarbonyl)-L-alanyl]-L-alanine hydrate	90303-36-9
2,2'-dithlodibenzonitrile	33174-74-2
2-ethoxy-5-[(4-methylpiperazin-1-yl)sulfonyl]benzoic acid	194602-23-8
1-methyl-4-nitro-3-propylpyrazole-5-carboxamide	139756-01-7
(S)-2-(4-fluorophenyl)-3-methylbutyric acid	55332-37-1
[3-(benzimidazol-2-yl)propyl]methylamine	54137-52-6
7-chloro-5-(2-fluorophenyl)-1H-1,4-benzodiazepin-2(3H)-one	2886-65-9
2-bromo-4'-chloro-2'-(2-fluorobenzoyl)acetanilide	1584-62-9
2'-benzoyl-2-bromo-4'-chloroacetanilide	41526-21-0
(RS)-semnohydrazide hydrochloride	55819-71-1
2,3,4-trihydroxybenzaldehyde	2144-08-3
dimsthyl chloromalonate	28868-76-0
4,6-dichloro-5-(2-methoxyphenoxy)-2,2'-bipyrimidinyl	150728-13-5
4-tert-butylbenzenesulfonamide	6292-59-7
methyl 3-[(methoxycarbonylmethyl)sulfamoyl]thiophene-2-carboxylate	106820-63-7
methyl 4-hydroxy-2-methyl-2H-thieno[2,3-e][1,2]thiazine-3-carboxylate 1,1-dioxide	59304-25-0
tert-butyl (1S,9S)-6,10-dioxo-9-phthalimidooctahydropyridazo[1,2-a][1,2]diazepine-1-carboxylate	106928-72-7
ethyl (R)-2-hydroxy-4-phenylbutyrate	90315-82-5
1-benzyl hydrogen (S)-4-phthalimidoglutarate	88784-33-2
(S)-1-(benzyloxycarbonyl)hexahydropyridazine-3-carboxylic acid	65632-62-4
methyl [(1S,2R)-1-benzyl-3-[(3S,4aS,8aS)-3-(tert-butylcarbamoyl)decahydro-2-isoquinolyl]-2-hydroxypropyl]carbamate	178680-13-2
(3S,4aS,8aS)-2-[(2R,3S)-3-amino-2-hydroxy-4-phenylbutyl]-N-tert-butyldecahydroisoquinoline-3-carboxamide	
136522-17-3	
4-[(S)-3-amino-2-oxopyrrolidin-1-yl)benzonitnle hydrochloride	175873-08-2
ethyl 3-(3-[(S)-1-[4-(N'2-hydroxyamidino)phenyl]-2-oxopyrrolidin-3-yl]ureido)propionate	175873-10-6
4-[5-(p-tolyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide	169590-42-5
4-hydrazonobenzenesulfonamide hydrocholoride	17852-52-7
4'-amidinosuccinanilic acid hydrochloride	149177-92-4
ethyl (S)-3-aminopent-4-ynoate hydrochloride	154772-45-9
11-alpha-hydroxy-7-alpha-(methoxycarbonyl)-3-oxopregn-4-ene-21,17-alpha-carbolactone	192704-56-6
11-alpha-hydroxy-3-oxopregna-4,6-diene-21,17-alpha-carbolactone	73726-56-4
4-(5-methyl-3-phenylisoxazol-4-yl)benzenesulfonamide	181695-72-7
5-methyl-3,4-diphenyl-4,5-dihydroisoxazol-5-ol	181696-73-1
N-[4-(5-methyl-3-phenylisoxazol-4-yl)phenylsulfonyl]propionamide, sodium salt	198470-85-8
pivaloyloxymethyl 7-((Z)-2-[2-(tert-butoxycarbonylamino)thiazol- 4-yl]pent-2-enamido}-3-(carbamoyloxymethyl)-3-cephem-4-carboxylate	105889-80-3
benzhydryl 6-(4-methylbenzamido)penicillanic acid 4-oxide	77887-68-4
benzhydryl 7-((Z)-2-[2-(tert-butoxycarbonylamino)thiazol-4-yl]-4-(3-methylbut-2 -enyloxycarbonyl)but-2-enamido)-3-cephem-4-carboxylate	174761-17-2
N-(2-quinolylcarbonyl)-L-asparagine	136465-98-0
methyl N-(methoxycarbonyl)-L-phenylalaninate	41844-71-7
N-[(2,6-diisopropylphenoxy)sulfonyl]-2-(2,4,6-triisopropylphenyl)acetamide	166518-60-1
(2S,3S)-3-methyl-2-(3-oxo-2,3-dihydro-1,2-benzisothiazol-2-yl)valeric acid	177785-47-6
(1S,4R)-1-azabicyclo[2.2.1]heptan-3-one O-[(Z)-(3-methoxyphenyl)ethynyl]oxime--maleic acid (1:1)	180050-34-4
N-[(R)-9-methyl-4-oxo-1-phenyl-3,4,6,7-tetrahydro[1,4]diazepino[6,7,1-hi]indol-3- yl]isonicotinamide	179024-48-7
4-acetamido-2'-aminobenzanilide	112522-64-2
N,N'-bis[3-(ethylamino)propyl]propane-1,3-diamine tetrahydrochloride	156886-85-0
ethyl 5-(but-3-enyl)thiophene-2-carboxylate	208337-82-0
ethyl 5-[(3R)-3,4-dihydroxybutyl]thiophene-2-carboxylate	208337-83-1
ethyl 5-[(3R)-4-amino-3-hydroxybutyl]thiophene-2-carboxylate	208337-84-2
ethyl 5-[(3R)-4-(tert-butoxycarbonylamino)-3-hydroxybutyl]thiophene-2-carboxylate	186521-38-0
ethyl 5-[(3R)-4-(tert-butoxycarbonylamino)-3-(mesyloxy)butyl]thiophene-2-carboxylate	186521-39-1
ethyl 5-[(3S)-3-(acetylthio)-4-(tert-butoxycarbonylamino)butyl]thiophene-2-carboxylate	186521-40-4
dimethyl 2-[(S)-1-(tert-butoxycarbonylaminomethyl)-2- (5-ethoxycarbonyl-2-thienyl)propylthio] malonate	186521-41-5
methyl (S)-6-[2-[5-ethoxycarbonyl)-2-thienyl]ethyl]-3-oxo-1,4-thiazinane-2-carboxylate	186521-42-6
ethyl (6S)-5-[2-(2-amino-4-oxo-4,6,7,8-tetrahydro-3H-pyrimido[5,4-b][1,4]thiazin-6-yl)ethyl] thiophene-2-carboxylate	186521-44-8
(6S)-5-[2-(2-amino-4-oxo-4,6,7,8-tetrahydro-3H-pyrimido[5,4-b][1,4]thiazin-6-yl)ethyl]thiophene-2-carboxylic acid	186521-45-9
diethyl N-[5-[2-((6S)-2-amino-4-oxo-4,6,7,8-tetrahydro-3H-pyrimido[5,4-b][1,4]thiazin-6-yl)-ethyl]-2-thenoyl]-L-glutamate	177575-19-8
4-chloropyridine hydrochloride	7379-35-3
4-phenoxypyridine	4783-86-2
4-(4-pyridyloxy)benzenesulfonic acid	192329-80-9
4-(4-pyridyloxy)benzenesulfonyl chloride hydrochloride	192330-49-7
(3S)-2,2-dimethyl-1,4-thiazinane-3-carboxylic acid	84915-43-5
(3S)-2,2-dimethyl-4-[4-(4-pyridyloxy)phenylsulfonyl]-1,4-thiazinane-3-carboxylic acid	192329-83-2
2-amino-5-bromo-6-methylquinazolin-4(1H)-one	147149-89-1
3-acetoxy-o-toluic acid	168899-58-9
(4R,5R)-4,5-bis(mesyloxymethyl)-1,3,2-dioxathiolane 2,2-dioxide	208338-09-4
(2R,3R)-1,4-bis(mesyloxy)butane-2,3-diol	1947-62-2
3,7,11-trimethyldodeca-1,6,10-trien-3-ol	7212-44-4
(6E,10E,14E)-3,7,11,15-tetramethylhexadeca-1,6,10,14-tetraen-3-ol	1113-21-9
methyl 4-amino-5-nitro-o-anisate	59338-84-0
methyl 5-(ethylsulfonyl)-o-anisate	62140-67-4
methyl 5-sulfamoyl-o-anisate	33045-52-2
3-methoxy-5-sulfamoyl-o-anisic acid	66644-80-2
1-benzylpiperidine-4-carbaldehyde	22065-85-6
{(E)-3-[(6R,7R)-7-amino-2-carboxylato-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]allyl}-(carbamoylmethyl)(ethyl)methylammonium	160115-08-2
[4-(3-methoxypropoxy)-3-methyl-2-pyridyl]methanol	118175-10-3
(Z)-2-(5-amino-1,2,4-thiadiazol-3-yl)-2-[(fluoromethoxy)imino]acetic acid	116833-10-4
2-(ethylmethylamino)acetamide	116833-20-6
4-chloro-2-[(Z)-(methoxycarbonyl)methoxyimino]-3-oxobutyric acid	84080-70-6
2-(5-ethyl-2-pyridyl)ethanol	5223-06-3
2-(4-aminophenoxymethyl)-2,5,7,8-tetramethyl-4-oxochroman-6-yl acetate	107188-37-4
chloromethyl pivalate	18997-19-8
7-ethyl-3-[2-(trimethylsilyloxy)ethyl]indole	185453-89-8
5-amino-2,4,6-triiodoisophthalic acid	35453-19-1
4-hydroxyindole	2380-94-1
thiazolidine-2,4-dione	2295-31-0
2-bromo-3-methylthiophene	14282-76-9
5-methyluracil	65-71-4

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Product	CAS Number
thymidine	50-89-5
3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridylmethanol	103577-66-8
3-(cyanoimino)-3-piperidinopropiononitrile	56488-00-7
N-acetyl-3-(3,4-dimethoxyphenyl)-DL-alanine	27313-65-1
2,5,7,8-tetramethyl-2-(4-nitrophenoxymethyl)-4-oxochroman-6-yl acetate	107188-34-1
methyl 4-(bromomethyl)-m-anisate	70264-94-7
9-bromononyl 4,4,5,5,5-pentafluoropentyl sulfide	148757-89-5
2-(phenylthio)aniline	1134-94-7
4,4,5,5,5-pentafluoropentan-1-ol	148043-73-6
methyl (S)-2-amino-4-(1H-tetrazol-5-yl)butyrate	127105-49-1
(3-chloro-4-fluorophenyl)[7-methoxy-6-(3-morpholinopropoxy)quinazolin-4-yl]amine	184475-35-2
5-hydroxy-1,2,3,4-tetrahydro-1-naphthone	28315-93-7
(R)-1-chloro-2,3-epoxypropane	51594-55-9
methyl 4-acetamido-o-anisate	4093-29-2
4-acetamido-5-chloro-o-anisic acid	24201-13-6
methyl (1S,2S)-1-benzyl-3-chloro-2-hydroxypropylcarbamate	176972-62-6
ethyl 2-chloronicotinate	1452-94-4
ethyl 6-chloronicotinate	49608-01-7
6-hydroxynicotinic acid	5006-66-6
6-chloronicotinic acid	5326-23-8
1-acetylpiperazine	13889-98-0
8-azaspiro[4.5]decane-7,9-dione	1075-89-4
(S)-2-(4-{[(2,7-dimethyl-4-oxo-3,4-dihydroquinazolin-6-yl)methyl](prop-2-ynyl)amino}-2- fluorobenzamido)- 4-(1H-tetrazol-5-yl)butyric acid	153537-73-6
SC-59735	116638-33-6
SC-70935	193700-51-5
6,7-dichloro-2,3-dimethoxyquinoxalin-5-ylamine	178619-89-1
4-(2-methyl-1H-imidazo[4,5-c]pyridin-1-yl)benzoic acid	132026-12-1
methyl(4'-nitrophenethyl)amine hydrochloride	166943-39-1
2-chloroethyl 4-nitrophenyl ether	3383-72-0
(2RS,3SR)-2-(2,4-difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1H-1,2,4-triazol-1-yl)butan-2-ol-(1R,4S)-2-oxobornane-10-sulfonic acid (1:1)	188416-34-4
6-ethyl-5-fluoropyrimidin-4(1H)-one	137234-87-8
diphenyl[(S)-pyrrolidin-3-yl]acetonitrile hydrobromide	194602-27-2
(2,3-dihydrobenzofuran-5-yl)acetic acid	69999-16-2
cyclohexylammonium 1-[(S)-2-(tert-butoxycarbonyl)-3-(2-methoxyethoxy)propyl]-cyclopentanecarboxylate	167944-94-7
cis-4-(benzyloxycarbonyl)cyclohexylammonium tosylate	67299-45-0
5-bromo-3-[(R)-1-methylpyrrolidin-2-ylmethyl]indole	143322-57-0
meso-3-benzyl-6-nitro-3-azabicyclo[3.1.0]hexane	151860-16-1
diethyl (6-chloro-9H-carbazol-2-yl)methylmalonate	71208-55-4
beta-cyclodextrin sulfobutyl ethers, sodium salts	182410-00-0
N-(2-chloroethyl)pyrrolidine hydrochloride	7250-67-1
6,7-bis(2-methoxyethoxy)quinazolin-4(1H)-one	179688-29-0
ethyl 3,4-dihydroxybenzoate	3943-89-3
3-(Z)-1-[4-(2-dimethylaminoethoxy)phenyl]-2-phenylbut-1-enyl}phenol	83647-29-4
2-[1-(tert-butoxycarbonyl)-4-piperidyl]acetic acid	157688-46-5
4-pyridylacetic acid hydrochloride	6622-91-9
a,a,a-trifluoro-4-nitro-m-toluidine	393-11-3
methyl 1-(2,3,5-tri-O-acetyl-beta-D-ribofuranosyl)-1H-1,2,4-triazole-3-carboxylate	39925-10-5
N'a-(tert-butoxycarbonyl)-N'w-nitro-L-arginine	2188-18-3
N'a-(tert-butoxycarbonyl)-N-methoxy-N-methyl-N'w-nitro-L-argininamide	139976-34-4
(2S,3S)-3-amino-2-ethoxy-N-nitropiperidine-1-carboxamidine hydrochloride	180250-77-5
(S)-O-benzyllactaldehyde-N-(tert-butoxycarbonyl)hydrazone	192802-28-1
phenyl (4-[4-(4-hydroxyphenyl)piperazin-1-yl]phenyl}carbamate	184177-81-9
[(3S,5S)-5-(2,4-difluorophenyl)-5-(1H-1,2,4-triazol-1-ylmethyl)tetrahydrofuran-3-yl]methyl 4-chlorobenzenesulfonate	175712-02-4
8-chloro-11-(4-piperidylidene)-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridine	100643-71-8
2-hydroxy-2-methyl-4'-nitro-3'-(trifluoromethyl)propionanilide	52806-53-8
5-acetylsalicylamide	40187-51-7
8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-one	31251-41-9
1-nitro-4-(1,2,2,2-tetrachloroethyl)benzene	4714-32-3
3-chloropropyldimethylammonium chloride	5407-04-5
3-(trichlorovinyl)aniline hydrochloride	81972-27-2
2-[1-(mercaptomethyl)cyclopropyl]acetic acid	162515-68-6
3-(4-bromobenzyl)-2-butyl-4-chloro-1H-imidazol-5-ylmethanol	151015-31-6
4-chloro-1-methylpiperidine hydrochloride	5382-23-0
methyl 2-[(S)-3-{(E)-3-[2-(7-chloro-2-quinolyl)vinyl]phenyl}-3-hydroxypropyl]benzoate	181139-72-0
methyl 2-[3-{(E)-3-[2-(7-chloro-2-quinolyl)vinyl]phenyl}-3-oxopropyl]benzoate	149968-11-6
2-(2-trityl-2H-tetrazol-5-yl)phenylboronic acid	143722-25-2
(3aS,8aR)-3-[(2R,4S)-2-benzyl-4,5-epoxyvaleryl]-2,2-dimethyl-3,3a,8,8a-tetrahydro-2H -indeno[1,2-d]oxazole	158512-24-4
N-[(4S,6S)-6-methyl-7,7-dioxo-5,6-dihydro-4H-thieno[2,3-b]thiopyran-4-yl]acetamide	147086-83-7
N-[(4S,6S)-6-methyl-7,7-dioxo-2-sulfamoyl-5,6-dihydro-4H-thieno[2,3-b]thiopyran-4-yl] acetamide	147200-03-1
5-iodouracil	696-07-1
N'1-methyl-1H-pyrazole-1-carboxamidine hydrochloride	59194-35-3
(S)-tetrahydrofuran-3-ol	86087-23-2
ethyl 4,6-dichloro-3-formylindole-2-carboxylate	153435-96-2
3-oxoandrost-4-ene-17-beta-carboxylic acid	302-97-6
alpha,alpha,alpha,alpha',alpha',alpha'-hexafluoro-2,5-xylidine	328-93-8
(±)-2-azabicyclo[2.2.1]hept-5-en-3-one	61865-48-3
(1R,4S)-2-azabicyclo[2.2.1]hept-5-en-3-one	79200-56-9
[(1S,4R)-4-(2-amino-6-chloro-9H-purin-9-yl)cyclopent-2-enyl]methanol hydrochloride	172015-79-1
N-(2-amino-4,6-dichloropyrimidin-5-yl)formamide	171887-03-9
4-fluorobenzyl 4-(methylthio)phenyl ketone	87483-29-2
2-amino-3-pyridyl methyl ketone	65326-33-2
6-methoxy-1H-purin-2-ylamine	20535-83-5
1-beta-D-arabinofuranosylpyrimidine-2,4(1H,3H)-dione	3083-77-0
(2R)-4-methyl-2-[(S)-2,2-dimethyl-5-oxo-1,3-dioxolan-4-yl]valeric acid	157518-70-2
(S)-2-amino-3,3-dimethyl-N-2-pyridylbutyramide	171764-07-1
3-nitro-4-pyridone	5435-54-1
2,6-difluorobenzylamine	69385-30-4
L-ribose	24259-59-4
(5,6-dichloro-1H-benzimidazol-2-yl)isopropylamine	176161-55-0
(R)-2-amino-2-ethylhexan-1-ol	151851-75-1
3-methylenecyclobutanecarbonitrile	15760-35-7
4-tert-butylbenzyl 2-{(2R,3S)-3-[(R)-1-(tert-butyldimethylsilyloxy)ethyl]- 2-[(1R,3S)-3-methoxy-2-oxocyclohexyl]-4-oxoazetidin-1-yl}-2-oxoacetate	159593-17-6
methyl (3aR,4R,7aR)-2-methyl-4-[(1S,2R)-1,2,3-triacetoxypropyl]-3a,7a-dihydro-4H-pyrano-[3,4-d]oxazole-6-carboxylate	78850-37-0
(4S,5R,6R)-5-acetamido-4-amino-6-[(1R,2R)-1,2,3-trihydroxypropyl]-5,6-dihydropyran-2 -carboxylic acid	130525-62-1

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Product	CAS Number
pyrazole-1-carboxamidine hydrochloride	4023-02-3
2-acetoxy-5-acetylbenzyl acetate	24085-06-1
(R)-1,2,3,4-tetrahydropapaverine hydrochloride	54417-53-7
trans-2-chloro-3-[4-(4-chlorophenyl)cyclohexyl]-1,4-naphthoquinone	153977-22-1
1,3-dichloroacetone	534-07-6
3,5-dimethylpiperidine	35794-11-7
2,6-diaminopyrimidin-4-ol	56-06-4
1-(2-chloroethyl)piperidinium chloride	2008-75-5
diethyl L-glutamate hydrochloride	1118-89-4
tert-butyl (1R,4S)-4-(hydroxymethyl)cyclopent-2-enylcarbamate	168960-18-7
2-butyl-1,3-diazaspiro[4.4]non-1-en-4-one hydrochloride	151257-01-1
tert-butyl 2-[[1-(2-aminothiazol-4-yl)-2-(benzisothiazol-2-ylthio)-2-oxoethylidene] aminooxy]-2-methylpropionate	89604-92-2
bis[(isopropyloxycarbonyloxy)methyl [(R)-2-(6-amino-9H-purin-9-yl) -1-methylethoxy]methyl phosphonate--fumaric acid (1:1)	202138-50-9
(R)-[2-(6-amino-9H-purin-9-yl)-1-methylethoxy]methylphosphonic acid	147127-20-6
(R)-propylene carbonate	16606-55-6
6-amino-9H-purin-9-ylethanol	707-99-3
(R)-2-(6-amino-9H-purin-9-yl)-1-methylethanol	14047-28-0
chloromethyl isopropyl carbonate	35180-01-9
diethyl (tosyloxy)methylphosphonate	31618-90-3
(R)-3-chloropropane-1,2-diol	57090-45-6
(S)-[(trityloxy)methyl]oxirane	129940-50-7
(S)-2-(2-amino-5-chlorophenyl)-4-cyclopropyl-1,1,1-trifluorobut-3-yn-2-ol	154598-58-0
10,10-bis[(2-fluoro-4-pyridyl)methyl]anthrone	160588-45-4
(S)-N-((1S,2R)-3-[(1,3-benzodioxol-5-ylsulfonyl)(isobutyl)amino]-1-benzyl-2-hydroxypropyl)-3,3-dimethyl-2-(sarcosylamino)butyramide	183556-68-5
(4R,5S,6S,7R)-1-[(3-amino-1H-indazol-5-yl)methyl]-4,7-dibenzyl-3-butyl-5,6-dihydroxyhexahydro-2H-1,3-diazepin-2-one	188978-02-1
(2S)-N-[(R)-1-(1,3-benzodioxol-5-yl)butyl]-3,3-diethyl-2-(4-[(4-methylpiperazin-1-yl)-carbonyl]phenoxy}-4-oxoazetidine-1-carboxamide	157341-41-8
2-(piperazin-1-yl)pyrimidine	20980-22-7
4-bromo-2,2-diphenylbutanenitrile	39186-58-8
bromomethylcyclopropane	7051-34-5
cyclobutanecarboxylic acid	3721-95-7
2-phenyl-2-pyridylacetonitrile	5005-36-7
5-methyl-2,3,4,5-tetrahydro-1H-pyrido[4,3-b]indol-1-one	122852-75-9
4-(2-methyl-2-phenylhydrazino)-5,6-dihydro-2-pyridone	139122-76-2
4,5,6,7-tetrahydrothieno[3,2-c]pyridine hydrochloride	28783-41-7
methyl 2-(2-chlorophenyl)-2-(4,5,6,7-tetrahydrothieno[3,2-c]pyridin-5-yl)acetate hydrochloride	130209-90-4
2-bromo-2-(2-chlorophenyl)acetic acid	141109-25-3
disodium (2S,3R)-2-hydroxy-3-isobutylsuccinate	157604-22-3
7-amino-3-(2-furoylthiomethyl)-3-cephem-4-carboxylic acid	80370-59-8
methyl 5-chloro-o-anisate	33924-48-0
4-[(4-mesylamino)phenyl]-4-oxobutyric acid	100632-57-3
benzyl (3-fluoro-4-morpholinophenyl)carbamate	168328-81-7
(3R)-3-[(S)-1-(methylamino)ethyl]pyrrolidine	155322-92-2
(4-carboxybutyl)triphenylphosphonium bromide	17814-85-6
(3aS,9aS,9bR)-3a-methyl-6-[2-(2,5,5-trimethyl-1,3-dioxan-2-yl)ethyl]-1,2,4,5,8,9,9a,9b-octahydro-3aH-cyclopenta[a]naphthalene-3,7-dione	88128-61-4
2-amino-2',5-dichlorobenzophenone	2958-36-3
21-chloro-16-alpha-methylpregna-1,4,9(11)-triene-3,20-dione	151265-34-8
3,20-dioxopregna-1,4,9(11),16-tetraen-21-yl acetate	37413-91-5
uracil	66-22-8
tetrabutylammonium (6-iodo-1H-purin-2-yl)amide	156126-48-6
(1S,2S,3S)-2,3-bis(benzoyloxymethyl)cyclobutanol	132294-17-8
5-methyluridine	1463-10-1
benzyl (1-carbamoyl-2-hydroxypropyl)carbamate	91558-42-8
5,8-dihydro-1-naphthol	27673-48-9
potassium (R)-N-(3-ethoxy-1-methyl-3-oxoprop-1-enyl)-2-phenylglycine	961-69-3
triethylaniline	33881-72-0
1-[4-(2-dimethylaminoethoxy)[14C]phenyl]-1,2-diphenylbutan-1-ol	82407-94-1
o-chlorothiophenol	6320-03-2
cytidine 5'-(dihydrogen phosphate)	63-37-6
2-[benzyl(methyl)amino]ethyl acetoacetate	54527-65-0
2-methyl-1-nitrosoindoline	85440-79-5
inosine 5'-disodium phosphate	4691-65-0
4-[1-hydroxy-2-(methylamino)ethyl]phenol--L-tartaric acid (2:1)	16589-24-5
4-phenylpiperidin-4-ol	40807-61-2
1-(4-benzyloxyphenyl)-2-(4-hydroxy-4-phenyl-1-piperidyl)propan-1-one	188591-61-9
7-chloro-2-(4-methoxy-2-methylphenyl)-2,3-dihydro-5H-pyridazino[4,5-b]quinoline-1,4,10- trione, sodium salt	170142-29-7
N'-[N-methoxycarbonyl-L-valyl]-N-[(S)-3,3,3-trifluoro-1-isopropyl-2-oxopropyl]-L- prolinamide	182073-77-4
3-methyl hydrogen 7-chloro-1,4-dihydro-4-oxoquinoline-2,3-dicarboxylate	170143-39-2
(S)-N-[5-[2-(2-amino-4-oxo-4,6,7,8-tetrahydro-1H-pyrimido[5,4-b][1,4]thiazin-6-yl)ethyl} -2-thenoyl]-L-glutamic acid	177575-17-6
(S)-2,2-dimethyl-N-hydroxy-4-[4-(4-pyridyloxy)phenylsulfonyl]-1,4-thiazinane-3 -carboxamide	192329-42-3
urate oxidase	9002-12-4
(Z)-1-[3-(3-chloro-4-cyclohexylphenyl)prop-2-enyl]hexahydro-1H-azepine hydrochloride	139592-99-7
(Z)-N-[3-(3-chloro-4-cyclohexylphenyl)prop-2-enyl]-N-ethylcyclohexylamine hydrochloride	132173-07-0
trans-2'-fluoro-4-hydroxychalcone O-[(Z)-2-(dimethylamino)ethyl]oxime--fumaric acid (2:1)	130580-02-8
N',N'-diethyl-2-methyl-N-(6-phenyl-5-propylpyridazin-3-yl)propane-1,2-diamine--fumaric acid (2:3)	137733-33-6
2-[[1-(7-chloro-4-quinolyl)-5-(2,6-dimethoxyphenyl)-1H-pyrazol-3-yl]carbonylamino]-adamantane-2-carboxylic acid	146362-70-1
(S)-N-[4-(4-acetamido-4-phenyl-1-piperidyl)-2-(3,4-dichlorophenyl)butyl]-N- methylbenzamide--fumaric acid (1:1)	176381-97-8
N'-[(2R,3S)-5-chloro-3-(2-chlorophenyl)-1-[(3,4-dimethoxyphenyl)sulfonyl]-3-hydroxy-2,3-dihydro-1H-indol-2-ylcarbonyl]-L-prolinamide	150375-75-0
1-(6-chloro-2-pyridyl)-4-piperidylamine hydrochloride	77145-61-0
ethyl ((7S)-7-[[(2R)-2-(3-chlorophenyl)-2-hydroxyethyl]amino}-5,6,7,8-tetrahydro-2 -naphthyloxy)-acetate hydrochloride	121524-09-2
methyl O-2-deoxy-6-O-sulfo-2-(sulfoamino)-alpha-D-glucopyranosyl-(1,4)-O-beta-D-glucopyranuronosyl-(1,4)-O-2-deoxy-3,6-di-O-sulfo-2-(sulfoamino)-alpha-D- -glucopyranosyl-(1,4)-O-2-O-sulfo- alpha-L-idopyranuronosyl-(1,4)-2-deoxy-2-(sulfoamino)-6-(hydrogensulfate)-alpha-D-glucopyranoside, decasodium salt	114870-03-0
3-[[4-[4-amidinophenyl)thiazol-2-yl][1-(carboxymethyl)-4-piperidyl]amino]propionic acid	180144-61-0
ethyl 3-[(4-[4-(N-ethoxycarbonylamidino)phenyl]thiazol-2-yl}[1-(ethoxycarbonylmethyl)-4 -piperidyl]amino) propionate	190841-79-3
(S)-1-[2-[3-(3,4-dichlorophenyl)-1-(3-isopropoxyphenacyl)-3-piperidyl]ethyl]-4-phenyl-1 -azoniabicyclo-[2.2.2]octane chloride	153050-21-6
5-(4-chlorophenyl)-1-(2,4-dichlorophenyl)-4-methyl-N-piperidino-1H-pyrazole-3 -carboxamide	168273-06-1
(R)-N-(1-{3-[1-benzoyl-3-(3,4-dichlorophenyl)-3-piperidyl]propyl}-4-phenyl-4-piperidyl)-N-methyl-	

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Product	CAS Number
acetamide hydrochloride	173050-51-6
dibenzyl 1-(2,4-difluorophenyl)-2-(1H-1,2,4-triazol-1-yl)-1-(1H-1,2,4-triazol-1-ylmethyl)ethyl phosphate	194602-25-0
(S)-2-[3-[(2-fluorobenzyl)sulfonylamino]-2-oxo-2,3-dihydro-1-pyridyl]-N-(1-formyl-4 -guanidinobutyl)acetamide	179524-67-5
4-[4-(4-[4-[(3R,5R)-5-(2,4-difluorophenyl)-5-(1H-1,2,4-triazol-1-ylmethyl)tetrahydrofuran-3-ylmethyloxy]phenyl}piperazin-1-yl)phenyl]-1-[(1S,2S)-1-ethyl-2-hydroxypropyl]-1,2,4-triazol-5(4H)-one	171228-49-2
4-(4-[(11R)-3,10-dibromo-8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-yl]piperidinocarbonylmethyl}piperidine-1-carboxamide	193275-84-2
4-(4-[(11S)-3,10-dibromo-8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-yl]piperidinocarbonylmethyl}piperidine-1-carboxamide	193275-85-3
N-(1-ethyl-1,4-diphenylbut-3-enyl)cyclopropanecarboxamide	137246-21-0
(1S,3S,4S)-1-azabicyclo[2.2.1]heptan-3-ol	142034-92-2
(±)-1-azabicyclo[2.2.1]heptan-3-one	21472-89-9
ethyl[3-(4-bromo-2-fluorobenzyl)-7-chloro-2,4-dioxo-1,2,3,4-tetrahydroquinazolin-1-yl] acetate	112733-28-5
2,6-diisopropylphenyl sulfamate	92050-02-7
diethyl (1-cyano-3-methylbutyl)malonate	186038-82-4
2-imino-1,3-thiazol-4-one	556-90-1
3,5-di-tert-butyl-4-hydroxybenzaldehyde	1620-98-0
N-(biphenyl-2-yl)-4-[(2-methyl-4,5-dihydro-1H-imidazo[4,5-d][1]benzazepin-6-yl)carbonyl]benzamide	79528-39-3
3-(aminomethyl)-5-methylhexanoic acid	128013-69-4
2-(2,4,6-triisopropylphenyl)acetic acid	4276-85-1
N,N'-[dithiobis(o-phenylenecarbonyl)]bis-L-isoleucine	182149-25-3
(1R,4S)-1-azabicyclo[2.2.1]heptan-3-one	142034-97-7
3-amino-7-methyl-5-phenyl-1H-1,4-benzodiazepin-2(3H)-one	70890-50-5
1-ethyl-1,4-diphenylbut-3-enylamine	129140-12-1
sodium 1,2,3-triazole-5-thiolate	59032-27-8
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2. (con.)
(c). (con.)

Product	CAS Number
(2R,4R)-4-(2,6-diamino-9H-purin-9-yl)-1,3-dioxolan-2-ylmethanol	145514-04-1
(4R,5S,6S,7R)-1,3-bis(3-aminobenzyl)-4,7-dibenzyl-5,6-dihydroxyhexahydro-2H-1,3-diazepin-2-one dimethanesulfonate	177932-89-7"

Section B. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after April 1, 1997, the following technical corrections are made to the enumerated subheading:

1. For subheading 2918.13.50, the Rates of Duty 1-Special subcolumn is modified by inserting, in alphabetical order, the symbol "K" in the parentheses following the "Free" rate of duty in such subcolumn.

2. The Pharmaceutical Appendix to the HTS is modified by adding to Table 3 of the Appendix the following product, with the product name inserted in alphabetical order in the "Product" column and its Chemical Abstracts Service (CAS) registry number in the "CAS No." column:

"1-{N2-[(S)-1-ethoxycarbonyl-3-phenylpropyl]-N6-trifluoroacetyllsyl}proline	103300-91-0"

Section C. Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 1995, the following technical corrections are made to the enumerated subheadings:

For subheadings 2904.90.47, 2917.39.30, 2918.29.20, 2935.00.05, and 3402.20.10, the Rates of Duty 1-Special subcolumn is modified by inserting, in alphabetical order, the symbol "K" in the parentheses following the "Free" rate of duty in such subcolumn for each such subheading.

[FR Doc. 99–17291
Filed 7–2–99; 11:02 am]
Billing code 3190–01–C

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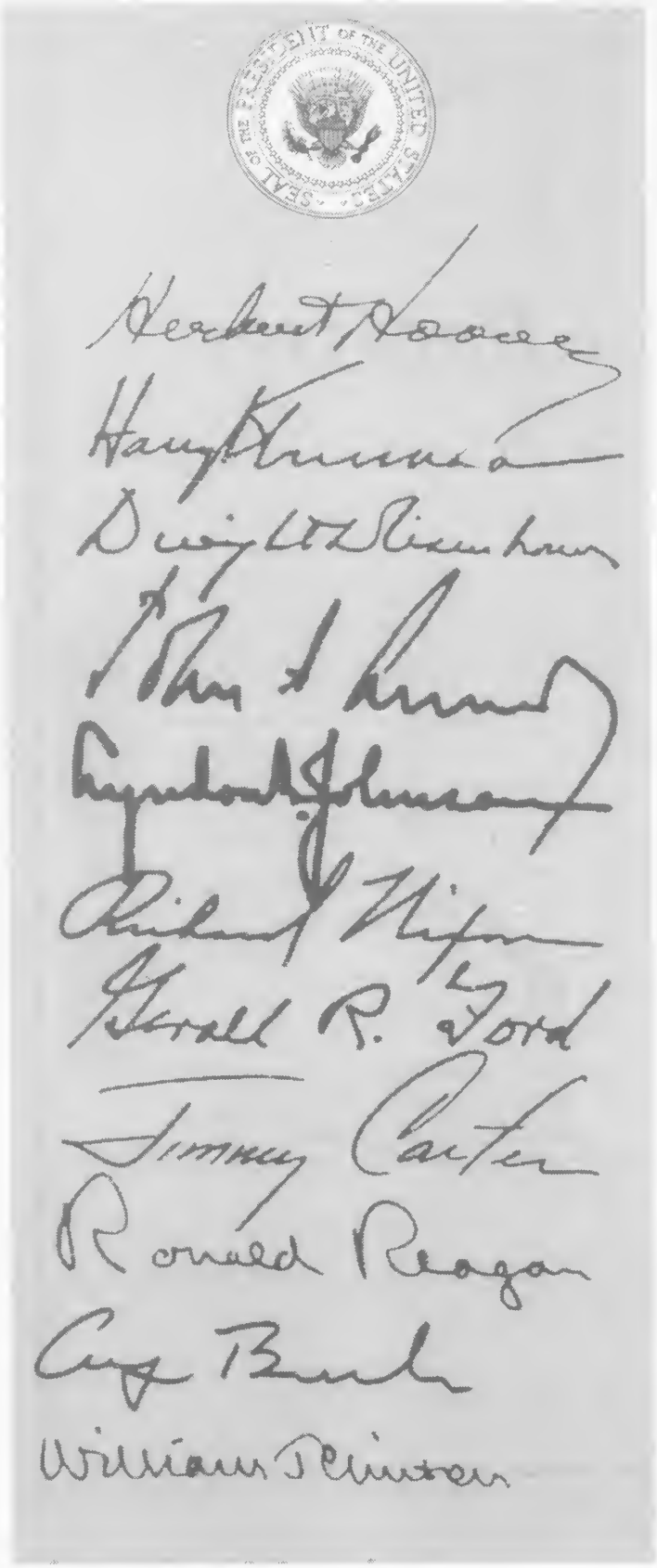

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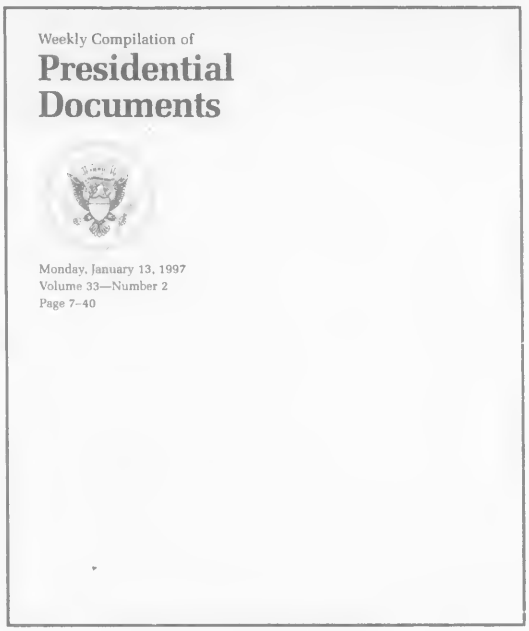

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