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

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THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

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

WHO: The Office of the Federal Register.

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

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

DENVER, CO

WHEN: September 26, at 9:00 am
WHERE: Denver Federal Center, Building 20
(E8 entrance on 2nd Street)
Conference Room B1409, Denver, CO
RESERVATIONS: Federal Information Center
1–800–359–3997

WASHINGTON, DC

WHEN: September 30, at 9:00 am
WHERE: Office of the Federal Register
First Floor Conference Room
1100 L Street, NW, Washington, DC
RESERVATIONS: 202–523–5240

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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1901

Revision of Farmers Home Administration Instruction To Give State Directors a Greater Latitude in Delegating Loan Approval Authority for All Field Loan Officers

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) is amending its regulations to allow FmHA State Directors to delegate, revoke, increase, or decrease loan approval authorities for field officials. The intended effect is to improve credit quality and reduce losses to the Agency. This action is the result of an overall strategic plan to improve Agency oversight and credit quality.

EFFECTIVE DATE: September 24, 1991.

FOR FURTHER INFORMATION CONTACT: Mary Ferguson, Loan Specialist, Insured Loans Branch, Farmer Programs Loan Making Division, FmHA, USDA, room 5428–S, 14th and Independence Avenue, SW., Washington, DC 20250, Telephone (202) 475–4018.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291, and has been determined to be exempt from those requirements because it involves only internal Agency management. It is the policy of this Department to publish for comment rules relating to public property, loans, grants, benefits, or contracts notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This action, however, is not published for proposed rulemaking since it involves only internal agency management, making publication for comment unnecessary.

The amended regulations allow FmHA State Directors to delegate, revoke, increase, or decrease loan approval authorities for all loan approval officers for Farmers Programs loans only. Guidelines are provided to State Directors to ensure that only experienced, knowledgeable, and qualified approval officials are given loan approval authority consistent with the goal of improving credit quality and prevention of loan losses. State Directors will be given latitude to increase or decrease loan officers' loan approval limits.

A minor change is also made with regard to approval of documents to correct an oversight. The language in the Code of Federal Regulations does not reflect current language in FmHA's internal directives, and this change is necessary to broaden the list of guarantee documents which may be approved by specified individuals.

This action affects the following programs listed in the catalog of Federal Domestic Assistance:

10.406 Operating Loans
10.407 Farm Ownership Loans
10.416 Soil and Water Loans
10.404 Emergency Loans

This program/activity is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. The Soil and Water Program, however, is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983) and FmHA Instruction 1940–J, "Intergovernmental Review of Farmers Home Administration Programs and Activities." (December 23, 1983.)

This document has been reviewed in accordance with FmHA Instruction 1940–G, "Environmental Program." FmHA has determined that this final actions does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the National Environment Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

List of Subjects in 7 CFR Part 1901

Agriculture, Authority delegations.

Therefore, chapter XVIII, title 7, Code of Federal Regulations is amended as follows:

PART 1901—PROGRAM-RELATED INSTRUCTIONS

1. The authority citation for part 1901 is revised to read as follows:

Authority: 42 U.S.C. 1480, 7 U.S.C. 1989, 5 U.S.C. 301, 7 CFR 2.23 and 2.70.

Subpart A—Loan and Grant Approval Authorities

2. Section 1901.3 is amended by revising paragraph (b) as follows:

§ 1901.3 Approval documents.

* * * * *

(b) State Directors, District Directors, and County Supervisors are authorized to execute loan guarantee documents in accordance with approval authorities.

3. Section 1901.4 is amended by revising paragraph (f), by redesignating paragraphs (g) and (h) as (h) and (i), and by adding new paragraph (g) to read as follows:

§ 1901.4 Authorities and responsibilities.

* * * * *

(f) *Restrictions of approval authority for other than Farmer Programs loans by State Directors.* A State Director can make written restrictions or revocations, for not more than 6 months, of the authority given to an individual.

(g) *Restrictions of approval authority for Farmer Programs loans.* A State Director may delegate, revoke, increase, or decrease loan approval authority of individuals to amounts indicated in exhibit C and attachment 1 of exhibit C of this subpart.

* * * * *

Dated: August 16, 1991.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 91–22973 Filed 9–23–91; 8:45 am]

BILLING CODE 3410–07–M

DEPARTMENT OF ENERGY

Office of Fossil Energy

10 CFR Part 1048

Trespassing on the Strategic Petroleum Reserve

AGENCY: Strategic Petroleum Reserve, Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) is adopting final regulations providing for the security of persons and property in or upon the Strategic Petroleum Reserve. These regulations, which implement section 662 of the Department of Energy Organization Act, as amended (42 U.S.C. 7270b), prohibit unauthorized: (1) Entry into or upon Strategic Petroleum Reserve facilities or other real property subject to the jurisdiction, or in the custody of the Department of Energy under part B of title I of the Energy Policy and Conservation Act; or (2) carrying, transporting, or otherwise introducing or causing to be introduced into or upon such property a dangerous weapon, explosive, or other dangerous material likely to produce substantial injury or damage to persons or property. The regulations require posting of notices on Strategic Petroleum Reserve property stating the prohibitions of the regulations and the penalties for their violation. DOE issued these regulations on an interim final basis on January 17, 1991 (56 FR 1908).

EFFECTIVE DATE: October 24, 1991.

FOR FURTHER INFORMATION CONTACT: Durinda Robinson, Office of Chief Counsel, Department of Energy, Strategic Petroleum Reserve, 900 Commerce Road East, New Orleans, Louisiana 70123, (504) 734–4312.

SUPPLEMENTARY INFORMATION:

I. Background

On January 17, 1991, DOE published a notice of interim final rulemaking to implement section 662 of the Department of Energy Organization Act, which was added to the Act by Public Law No. 100–531, October 25, 1988, 102 stat. 2652, to assure adequate security of the Strategic Petroleum Reserve and other associated real property under DOE jurisdiction. Section 662(a) authorizes the Secretary of Energy to issue regulations concerning unauthorized (1) entry into or upon the Strategic Petroleum Reserve, its storage or related facilities, or real property subject to the jurisdiction, administration, or in the custody of the Secretary under part B of title I of the Energy Policy and Conservation Act (42 U.S.C. 6231–6247); and (2) carrying, transporting, or otherwise introducing or causing to be introduced into or upon such property any dangerous weapon, explosive, or other dangerous instrument or material likely to produce substantial injury or damage to persons or property.

Section 662(b) of the Act provides that any person who willfully violates regulations implementing section 662(a) is guilty of a misdemeanor, and shall be punished upon conviction by a fine of not more than $5,000, imprisonment of not more than one year, or both. Under the Sentencing Reform Act of 1984, as amended (18 U.S.C. 3571), which contains alternative fines, a person found guilty of a misdemeanor under Federal law is subject to an increased fine of up to $250,000.

In the preamble to the interim final rule, DOE invited interested persons to submit comments on the interim regulations by March 15, 1991. DOE did not receive any comments, and the interim regulations are being adopted as final regulations with one technical change. DOE is deleting § 1048.7, which prescribes the effective date of the regulations, as unnecessary.

II. Summary of the Final Regulations

For a detailed description of the final regulations, see the preamble to the interim final rule at 56 FR 1908. Briefly summarized, the final regulations: (1) Prohibit unauthorized entry and unauthorized introduction of weapons or dangerous materials into Strategic Petroleum Reserve facilities or other real property subject to the jurisdiction, or in the custody of the Department of Energy under part B of title I of the Energy Policy and Conservation Act; and (2) provide for the posting of notices on property subject to the regulations, stating the prohibitions contained in the regulations and the penalties for violations of the regulations.

III. Procedural Requirements

1. Review Under Executive Order No. 12291

As stated in the preamble to the interim final rule, DOE has determined that these regulations do not constitute a "major rule" subject to the requirements of Executive Order No. 12291 because they are not likely to result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovations, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Executive Order, these regulations have been reviewed by the Office of Management and Budget.

2. Review Under the Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), DOE has concluded that sections 603 and 604 of the Act do not apply to the final regulations adoped today because the regulations will not have a significant economic impact on a substantial number of small entities.

3. Environmental Review

DOE has concluded that the regulations do not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act.

4. Review Under Executive Order No. 12612

Pursuant to Executive Order No. 12612, DOE has concluded that these regulations will not have any substantial direct effects on State and local governments within the meaning of the Executive Order and, accordingly, a Federalism assessment is not required.

List of Subjects in 10 CFR Part 1048

Security measures, Government contracts, Arrest authority, and Use of force.

Issued in Washington, DC on September 17, 1991.

Linda G. Stuntz,

Acting Assistant Secretary for Fossil Energy.

Accordingly, the interim final rule establishing 10 CFR part 1048, which was published at 56 FR 1908 (January 17 1991), is adopted as a final rule with the following changes:

PART 1048—TRESPASSING ON STRATEGIC PETROLEUM RESERVE FACILITIES AND OTHER PROPERTY

1. The authority citation continues to read as follows:

Authority: Sec. 662, Pub. L. No. 100–531, 102 Stat. 2652 (42 U.S.C. 7270b); section 6, Pub. L. No. 100–185, 101 Stat. 1280 (18 U.S.C. 3571(b)(5)).

§ 1048.7 [Removed]

2. Section 1048.7 is removed and § 1048.8 is redesignated as § 1048.7.

[FR Doc. 91–22981 Filed 9–23–91; 8:45 am]

BILLING CODE 6450–01–M

FARM CREDIT ADMINISTRATION

12 CFR Part 612

RIN 3052-AB21

Personnel Administration; Effective Date

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA) published final regulations under part 612 on July 18, 1991 (56 FR 32956). The final regulations amend 12 CFR part 612 to delete requirements for FCA prior approval of salary ranges for bank senior officers, salaries of bank chief executive officers, and compensation plans other than retirement and thrift plans. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is September 23, 1991.

EFFECTIVE DATE: September 23, 1991.

FOR FURTHER INFORMATION CONTACT:

James T. Judge, Special Assistant to the Chief, Human Resources Division, Office of Resources Management, Farm Credit Administration, McLean, VA 22102-5090, (703) 883-4135,

Rebecca S. Orlich, Attorney, Regulatory and Legislative Law Branch, Office of General Counsel, Farm Credit Administration, McLean, VA 22102-5090, (703) 883-4020, TDD (703) 883-4444.

Authority: 12 U.S.C. 2252(a) (9) and (10).

Dated: September 19, 1991.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 91-22967 Filed 9-23-91; 8:45 am]

BILLING CODE 6705-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21 and 25

[Docket No. NM-58; Special Conditions No. 25-ANM-49]

McDonnell Douglas DC-9 Airplanes; Lightning and High Intensity Radiated Fields

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued to ABX Air, Inc. for modification of certain McDonnell Douglas DC-9 airplanes. These airplanes are equipped with high-technology digital avionics systems that perform critical and essential functions. The applicable regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of lightning and high-intensity radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to ensure that the critical and essential functions that these systems perform are maintained when the airplane is exposed to lightning and HIRF.

EFFECTIVE DATE: September 12, 1991.

FOR FURTHER INFORMATION CONTACT:

Woody Boyce, FAA, Standardization Branch, ANM-113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055-4046; telephone (206) 227-2137.

SUPPLEMENTARY INFORMATION:

Background

On November 2, 1990, ABX Air Inc. of Wilmington, Ohio, applied for a supplemental type certificate to modify Douglas DC-9-11, -12, -13, -14, -15, -21, -31, -32, -32F, -33F, -34, -34F, -41, and -51 airplanes. The DC-9 is a two-crew, two-engine, turbine airplane with a maximum takeoff weight up to 122,200 lbs. The modification incorporates the installation of an Electronic Flight Information System (EFIS) and Flight Director. The equipment originally installed in these airplanes presented the required information in the form of analog displays. The information presented is both flight critical and essential. The EFIS as a digital system is vulnerable to lightning and high-intensity radiated fields external to the airplane.

Supplemental Type Certification Basis

Under the provisions of § 21.115, subchapter C, of the FAR, ABX Air, Inc. must show that the modified DC-9 airplanes meet the regulations incorporated by reference in Type Certificate No. A6WE, as specified in § 21.101(a), unless: (1) Otherwise specified by the Administrator; (2) compliance with later effective amendments is elected or required under §§ 21.101(a) or (b); or (3) special conditions are prescribed by the Administrator.

Based on the provisions of §§ 21.101(a) and (b), ABX Air, Inc. will have to show compliance with the basic type certification basis per Type Certificate Data Sheet (TCDS) No. A6WE, plus the following FAR part 25 requirements, up to Amendment 25-7?, that are deemed necessary to provide an adequate level of safety: § 25.869(a), §§ 25.1303 (a), (b), and (c); §§ 25.1309 (a) thru (g); §§ 25.1321(e); § 25.1322 (a) thru (d); §§ 25.1331 (a) and (b); §§ 25.1333 (a), (b), and (c); § 25.1335, §§ 25.1355 (a) and (c); §§ 25.1359 (a) thru (d); §§ 25.1431 (a), (b), and (c); § 25.1525; § 25.1529; and § 25.1541(a).

If the administrator finds that the applicable airworthiness regulations (i.e., part 4b plus applicable part 25 requirements) do not contain adequate or appropriate safety standards for the Douglas DC-9 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after public notice, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101.

Discussion

The existing lightning protection airworthiness certification requirements are insufficient to provide an acceptable level of safety with the new technology avionic systems. There are two regulations that specifically pertain to lightning protection: One for the airframe in general (§ 25.581), and the other for fuel system protection (§ 25.954). There are, however, no regulations that deal specifically with protection of electrical and electronic systems from lightning. The loss of a critical function of these systems due to lightning could prevent continued safe flight and landing of the airplane. Although the loss of an essential function would not prevent continued safe flight and landing, it could significantly impact the safety level of the airplane.

There is also no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the McDonnell Douglas DC-9 which would require that the EFIS and Flight Director be designed and installed to

preclude component damage and interruption of function due to both the direct and indirect effects of lightning and HIRF.

Lightning

To provide a means of compliance with these special conditions, clarification of the threat definition for lightning is needed. The following "threat definition," based on FAA Advisory Circular 20–136, Protection of Aircraft Electrical/Electronic Systems Against the Indirect Effects of Lightning, dated March 5, 1990, is proposed as a basis to use in demonstrating compliance with the lightning protection special condition.

The lightning current waveforms (Components A, D, and H) defined below, along with the voltage waveforms in Advisory Circular (AC) 20–53A, will provide a consistent and reasonable standard which is acceptable for use in evaluating the effects of lightning on the airplane. These waveforms depict threats that are external to the airplane. How these threats affect the airplane and its systems depend upon their installation configuration, materials, shielding, airplane geometry, etc. Therefore, tests (including tests on the completed airplane or an adequate simulation) and/or verified analyses need to be conducted in order to obtain the resultant internal threat to the installed systems. The electronic systems may then be evaluated with this internal threat in order to determine their susceptibility to upset and/or malfunction.

To evaluate the induced effects to these systems, three considerations are required:

1. *First Return Stroke*: (Severe Strike—Component A, or Restrike—Component D). This external threat needs to be evaluated to obtain the resultant internal threat and to verify that the level of the induced currents and voltages is sufficiently below the equipment "hardness" level.

2. *Multiple Stroke Flash*: (1/2 Component D). A lightning strike is often composed of a number of successive strokes, referred to as multiple strokes. Although multiple strokes are not necessarily a salient factor in a damage assessment, they can be the primary factor in a system upset analysis. Multiple strokes can induce a sequence of transients over an extended period of time. While a single event upset of input/output signals may not affect system performance, multiple signal upsets over an extended period of time (2 seconds) may affect the systems under consideration. Repetitive pulse testing and/or analysis needs to be carried out in response to the multiple stroke environment to demonstrate that the system response meets the safety objective. This external multiple stroke environment consists of 24 pulses and is described as a single Component A followed by 23 randomly spaced restrikes of 1/2 magnitude of Component D (peak amplitude of 50,000 amps). The 23 restrikes are distributed over a period of up to 2 seconds according to the following constraints: (1) The minimum time between subsequent strokes is 10 ms, and (2) the maximum time between subsequent strokes is 200 ms. An analysis or test needs to be accomplished in order to obtain the resultant internal threat environment for the system under evaluation.

3. *Multiple Burst*: (Component H). In-flight data-gathering projects have shown bursts of multiple, low amplitude, fast rates of rise, short duration pulses accompanying the airplane lightning strike process. While insufficient energy exists in these pulses to cause physical damage, it is possible that transients resulting from this environment may cause upset to some digital processing systems.

The representation of this interference environment is a repetition of short duration, low amplitude, high peak rate of rise, double exponential pulses which represent the multiple bursts of current pulses observed in these flight data gathering projects. This component is intended for an analytical (or test) assessment of functional upset of the system. Again, it is necessary that this component be translated into an internal environmental threat in order to be used. This "Multiple Burst" consists of 24 random sets of 20 strokes each, distributed over a period of 2 seconds. Each set of 20 strokes is made up of 20 repetitive Component H waveforms distributed within a period of one millisecond. The minimum time between individual Component H pulses within a burst is 10μs, the maximum is 50μs. The 24 bursts are distributed over a period of up to 2 seconds according to the following constraints: (1) The minimum time between subsequent strokes is 10 ms, and (2) the maximum time between subsequent strokes is 200 ms. The individual "Multiple Burst" Component H waveform is defined below.

The following current waveforms constitute the "Severe Strike" (Component A), "Restrike" (Component D), "Multiple Stroke" (1/2 Component D), and the "Multiple Burst" (Component H).

These components are defined by the following double exponential equation:

$i(t) = I_o (e^{-at} - e^{-bt})$

where:

t = time in seconds,

i = current in amperes, and

	Severe strike (Component A)	Restrike (Component D)	Multiple stroke (½ Component D)	Multiple burst (Component H)
I_o, amp =	218,810	109,405	54,703	10,572
a, sec^{-1} =	11,354	22,708	22,708	187,191
b, sec^{-1} =	647,265	1,294,530	1,294,530	19,105,100

This equation produces the following characteristics;

i_{peak} = 200 KA 100 KA 50 KA 10 KA

and

$(di/dt)_{max}$ (amp/sec) =	1.4 × 10^{11} @t = 0+sec	1.4 × 10^{11} @t = 0+sec	0.7 × 10^{11} @t = 0+sec	2.0 × 10^{11} @t = 0+sec
di/dt, (amp/sec) =	1.0 × 10^{11} @t = .5μs	1.0 × 10^{11} @t = .25μs	0.5 × 10^{11} @t = .25μs	
Action Integral (amp^2 sec) =	2.0 × 10^6	0.25 × 10^6	.0625 × 10^6	

High-Intensity Radiated Fields

With the trend toward increased power levels from ground based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems, such as the EFIS and Flight Director, to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling to cockpit installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1 or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–500 KHz	80	80
500 KHz–2 MHz	80	80
2 MHz–30 MHz	200	200
30 MHz–100 MHz	33	33
100 MHz–200 MHz	33	33
200 MHz–400 MHz	150	33
400 MHz–1 GHz	8,300	2,000
1 GHz–2 GHz	9,000	1,500
2 GHz–4 GHz	17,000	1,200
4 GHz–6 GHz	14,500	800
6 GHz–8 GHz	4,000	666
8 GHz–12 GHz	9,000	2,000
12 GHz–20 GHz	4,000	509
20 GHz–40 GHz	4,000	1,000

The envelope given in paragraph 2 above is a revision to the envelope used in previously issued special conditions in other certification projects. It is based on new data and SAE AE4R subcommittee recommendations. This revised envelope includes data from Western Europe and the U.S. It will also be adopted by the European Joint Airworthiness Authorities.

Discussion of Comments

Notice No. SC–91–6–NM for the McDonnell Douglas DC–9 airplane was published in the **Federal Register** on June 24, 1991 (56 FR 28720).

Two commenters concur with the special conditions based on the fact that they are identical to special conditions that have been issued to date for other similar systems.

One commenter disagrees with the special conditions on the basis that the HIRF requirements are too stringent and not justified based on service history and the fact that the threat levels are not justified. The FAA does not agree. Even though the subjects of HIRF and lightning continue to be evaluated, the FAA considers the current requirements to be those necessary to meet the minimum safety level.

The modifier of the subject airplanes, ABX Air Inc., provided comments proposing that the FAA allow operation of their airplanes with EFIS installations utilizing non-hardended equipment, until hardware is available that meets the environmental conditions described in the notice. The FAA does not agree because at the time of approval, the intent of all applicable regulations must be met in order to issue such approval.

As a delay in issuance of these special conditions would significantly affect the applicant's installation of the system and certification of the airplane, which is imminent, the FAA has determined that good cause exists for making these special conditions effective upon issuance, as opposed to 30 days from the date of publication in the **Federal Register**.

Conclusion

This action affect only certain unusual or novel design features on one model series of airplanes. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Parts 21 and 25

Air transportation, Aircraft, Aviation safety, Safety.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2), 42 U.S.C. 1857f–10, 4321 et seq.; E.O. 11514; and 49 U.S.C. 106(g).

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for the modified McDonnell Douglas DC–9 series airplanes:

1. *Lightning Protection.* a. Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to lightning.

b. Each essential function of electrical or electronic systems or installations must be protected to ensure that the function can be recovered in a timely manner after the airplane has been exposed to lightning.

2. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated fields external to the airplane.

3. The following definitions apply with respect to these special conditions:

Critical Function. Functions whose failure could contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Essential Functions. Functions whose failure could contribute to or cause a failure condition that would significantly impact the safety of the airplane or the ability of the flightcrew to cope with adverse operating conditions.

Issued in Renton, Washington on September 12, 1991.

Darrell M. Pederson,

Acting Manager Transport Airplane Directorate Aircraft Certification Service.

[FR Doc. 91–22928 Filed 9–23–21; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 97

[Docket No. 26643; Amdt. No. 1461]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

EFFECTIVE DATE: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located; or
3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPs criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act

List of Subjects in 14 CFR Part 97

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC, on September 13, 1991.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 U.T.C. on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. App. 1348, 1354(a), 1421 and 1510; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS,

ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNVA SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective November 14, 1991*

Spencer, IA—Spencer Muni, VOR RWY 12, Amdt. 1
Spencer, IA—Spencer Muni, VOR RWY 30, Amdt. 1
Spencer, IA—Spencer Muni, VOR/DME RWY 30, Orig., CANCELLED
Lyons, KS—Lyons-Rice County Muni, NDB RWY 17R, Amdt. 5
Lyons, KS—Lyons-Rice County Muni, VOR/DME-A, Amdt. 2
Grayling, MI—Grayling AAF, VOR RWY 14, Orig.
Grayling, MI—Grayling AAF, NDB RWY 14, Amdt. 6
Lebanon, MO—Floyd W. Jones Lebanon, SDF RWY 36, Amdt. 4
Lebanon, MO—Floyd W. Jones Lebanon, NDB RWY 36, Amdt. 5
Point Lookout, MO—Graham Clark, NDB RWY 29, Amdt. 5
St. Louis, MO—Creve Coeur, VOR-A, Amdt. 3
St. Louis, MO—Spirit of St. Louis, VOR RWY 8R, Amdt. 6
St. Louis, MO—Spirit of St. Louis, VOR RWY 26L, Amdt. 4
St. Louis, MO—Spirit of St. Louis, LOC RWY 26L, Amdt. 3
St. Louis, MO—Spirit of St. Louis, NDB RWY 8R, Amdt. 10
St. Louis, MO—Spirit of St. Louis, NDB RWY 26L, Orig.
St. Louis, MO—Spirit of St. Louis, ILS RWY 8R, Amdt. 12
Hebron, NE—Hebron Muni, NDB RWY 12, Amdt. 2
Lexington, NE—Lexington Muni, VOR RWY 14, Amdt. 2
Lexington, NE—Lexington Muni, NDB RWY 14, Amdt. 1
Alice, TX—Alice Intl, VOR-A, Amdt. 12
Alice, TX—Alice Intl, VOR RWY 31, Amdt. 10
Alice, TX—Alice Intl, LOC RWY 31, Amdt. 4
El Paso, TX—West Texas, VOR/DME-A, Amdt. 3
Killeen, TX—Killeen Muni, NDB RWY 1, Amdt. 5
Port Isabel, TX—Port Isabel-Cameron County, VOR-A, Amdt. 5
Port Isabel, TX—Port Isabel-Cameron County, VOR/DME-B, Amdt. 2
Elkins, WV—Elkins-Randolph Cnty-Jennings Randolph Fld, DLA-C, Amdt. 6

** * * Effective October 17, 1991*

Austin, MN—Austin Muni, VOR/DEM-A, Amdt. 1
Shreveport, LA—Shreveport Downtown, VOR RWY 14, Amdt. 14
Shreveport, LA—Shreveport Downtown, LOC RWY 14, Amdt. 4

[FR Doc. 91-22929 Filed 9-23-91; 8:45 am]
BILLING CODE 4910-13-M

14 CFR Part 97

[Docket No. 26643 Amdt. No. 146]

Standard Instrument Approach Procedures: Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

EFFECTIVE DATE: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1. 1982.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which affected airport is located; or
3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS-420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51; and § 97.20 of the Federal Aviations Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction of charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The Provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAM for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been canceled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPs criteria were applied to only these specific conditions existing at the affected airports.

This amendment to part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC, on March 1, 1991.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instruction Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. App. 1348, 1354(a), 1421 and 1510; 49 U.S.C. 106(g) (revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

NFDC Transmittal Letter

Effective	State	City	Airport	FDC No.	SIAP
08/13/91	NM	Clovis	Clovis Muni	FDC 1/3855	VOR RWY 22, AMDT 2A *This corrects TL 91-19*
08/22/91	CA	Tracy	Tracy Muni	FDC 1/3910	VOR-A, AMDT, 4A *This corrects TL 91-19*
08/26/91	CA	El Monte	El Monte	FDC 1/3992	VOR/DME-B, AMDT 1A *This corrects TL 91-19.*
08/29/91	IA	Charles City	Charles City Muni	FDC 1/4081	NDB RWY 12, ORIG A.
08/29/91	IA	Charles City	Charles City Muni	FDC 1/4084	LOC RWY 12, ORIG A.
08/29/91	IA	Forest City	Forest City Muni	FDC 1/4088	NDB RWY 33, ORIG A.
08/29/91	IA	Hampton	Hampton Muni	FDC 1/4089	VOR/DME RWY, 35 ORIG A.
08/29/91	MO	Macon	Macon-Fower Meml	FDC 1/4079	VOR/DME RWY, 20 ORIG A.
08/29/91	NY	Plattsburgh	Clinton County	FDC 1/4078	ILS RWY 1, AMDT 1A.
08/29/91	NY	Plattsburgh	Clinton County	FDC 1/4082	VOR RWY 19, ORIG A.
08/29/91	NY	Plattsburgh	Clinton County	FDC 1/4082	VOR RWY 19, ORIG A.
08/30/91	IA	Charles City	Charles City Muni	FDC 1/4098	NDB RWY 30, AMDT 2A.
08/30/91	IA	Forest City	Forest City Muni	FDC 1/4116	VOR/DME-A, AMDT 2A.
08/30/91	IA	Hampton	Hampton Muni	FDC 1/4115	NDB RWY 17, AMDT 3A.
08/30/91	MO	Macon	Macon-Fower Meml	FDC 1/4118	VOR RWY 2, ORIG A.
09/04/91	TN	Sevierville	Gatlinburg-Pigeon Forge	FDC 1/4183	VOR/DME RWY, 10 AMDT 4A.
09/06/91	NY	Buffalo	Buffalo Airfield	FDC 1/4229	VOR RWY 24, AMDT 6 A.
09/06/91	NY	Durhamville	Kamp	FDC 1/4225	VOR RWY 28, AMDT 1A.
09/06/91	NY	Elmira	Elmira/Corning Regional	FDC 1/4231	NDB RWY 24, AMDT 13A.
09/09/91	ND	Williston	Sloulin Fld Intl	FDC 1/4270	IS RWY 29, AMDT 3A.
09/09/91	ND	Williston	Sloulin Fld Intl	FDC 1/4271	NDB RWY 29, AMDT 2A.
09/09/91	ND	Williston	Sloulin Fld Intl	FDC 1/4272	VOR/DME RWY, 29 AMDT 3A.
09/09/91	ND	Williston	Sloulin Fld Intl	FDC 1/4273	VOR RWY 11, AMDT 12A.
09/09/91	NM	Albuquerque	Albuquerque International	FDC 1/4256	VOR RWY 8, (TAC) AMDT 18A.
09/09/91	NY	Ogdensburg	Ogdensburg Intl	FDC 1/4259	LOC RWY 27, AMDT 1A.

[FR Doc 91–22930 Filed 9–23–91; 8:45 am]

BILLING CODE 4910–13–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 229 and 230

[Release Nos. 33-6910; 34-29697; File No. S7-16-89]

Registration and Reporting Requirements for Employee Benefit Plans; Technical Amendment to Rules

AGENCY: Securities and Exchange Commission.

ACTION: Technical amendment.

SUMMARY: This document corrects the language in two rules so that they appropriately cross-reference registration statement and prospectus provisions regarding undertakings.

EFFECTIVE DATE: September 17, 1991.

FOR FURTHER INFORMATION CONTACT: Elizabeth M. Murphy, Office of Disclosure Policy, Division of Corporation Finance, (202) 272-2589.

SUPPLEMENTARY INFORMATION: In the Federal Register of Wednesday, June 13, 1990 (55 FR 23909), 17 CFR 229.512 (Item 512) Undertakings, was amended by removing paragraph (f); redesignating paragraphs (g), (h), (i) and (j) as (f), (g), (h), and (i); and revising redesignated paragraph (h). In connection with the redesignation of paragraphs, two rules containing references to § 229.512 also should have been amended. They are now amended to read as follows.

List of Subjects in 17 CFR Parts 229 and 230

Reporting and recordkeeping requirements, Securities, Registration statements.

PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATIONS S-K

1. The authority citation for part 229 continues to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77jjj, 77nnn, 77sss, 78l, 78m, 78n, 78o, 78w, 80a-8, 80a-29, 80a-30, 80a-37, 80b-11, unless otherwise noted.

§ 229.510 [Amended]

2. By amending § 229.510 by removing the references to "paragraph (i)" wherever they appear and adding in their place references to "paragraph (h)."

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

3. The authority citation for part 230 continues to read as follows:

Authority: 15 U.S.C. 77b, 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78l, 78m, 78n, 78o, 78w, 79t, and 80a-37, unless otherwise noted.

4. By amending § 230.430A by revising paragraph (a)(2) to read as follows:

§ 230.430A Prospectus in a registration statement at the time of effectiveness.

(a) * * *

(2) The registrant furnishes the undertakings required by Item 512(i) of Regulation S-K (§ 229.512(i) of this chapter); and

* * * * *

Dated: September 17, 1991.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-22978 Filed 9-23-91; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committees; OTC Drugs Advisory Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment by the Commissioner of Food and Drugs of the OTC Drugs Advisory Committee in FDA's Center for Drug Evaluation and Research. Elsewhere in this issue of the Federal Register, FDA is publishing a notice requesting nominations for membership on this committee. This document adds to the agency's list of standing advisory committees.

EFFECTIVE DATE: September 24, 1991. Authority for the committee being established will end on August 27, 1993, unless the Commissioner of Food and Drugs formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA-306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463), section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394) as amended by the Food and Drug Administration Revitalization Act (Pub. L. 101-635), and 21 CFR 14.40(b), FDA is announcing the establishment by the Commissioner of Food and Drugs of the OTC Drugs Advisory Committee. The committee will review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner of Food and Drugs either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications. The committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status of these various drug products and combinations thereof. The committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

Because this is a technical amendment to 21 CFR part 14, the Commissioner of Food and Drugs finds, under 21 CFR 10.40 (c), (d), and (e), that notice and public procedure in § 10.40(b) are unnecessary and contrary to the public interest. Therefore, the agency is revising the authority citation for 21 CFR part 14 and adding new paragraph (c)(17) to 21 CFR 14.100 as set forth below.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 is revised to read as follows:

Authority: Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 21 U.S.C. 41-50, 141-149, 467f, 679, 821, 1034; secs. 2, 351, 354-306F, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b-263n, 264); secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 5 U.S.C. App. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by adding new paragraph (c)(17) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(17) *OTC Drugs Advisory Committee.*

(i) Date established: August 27, 1991.

(ii) Functions: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

* * * * *

Dated: September 16, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-22985 Filed 9-23-91; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 575

Iraqi Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Final rule; amendments to the list of specially designated nationals of the Government of Iraq.

SUMMARY: The Iraqi Sanctions Regulations, 31 CFR part 575 (56 FR 2112, Jan. 18, 1991—the "Regulations"), are being amended to remove two names from appendix A, the list of Individuals and Organizations determined to be within the term "Government of Iraq" (Specially Designated Nationals of Iraq). Appendix A contains the names of companies and individuals which the Director of the Office of Foreign Assets Control has determined are owned or controlled by or acting or purporting to act directly or indirectly for the Government of Iraq. The list may be expanded or amended at any time.

EFFECTIVE DATE: September 24, 1991.

ADDRESSES: Copies of this list are available upon request at the following location: Office of Foreign Assets Control, U.S. Department of the Treasury, Annex, 1500 Pennsylvania Avenue, NW., Washington DC 20220.

FOR FURTHER INFORMATION CONTACT: Richard J. Hollas, Chief, Enforcement Section, Office of Foreign Assets Control, Tel.: (202) 566-5021.

SUPPLEMENTARY INFORMATION: The Regulations were issued by the Treasury Department to implement Executive Orders No. 12722 and 12724 of August 2 and August 9, 1990, in which the President declared a national emergency with respect to Iraq, invoking the authority, *inter alia*, of the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and the United Nations Participation Act (22 U.S.C. 287c), and ordering specific measures against the Government of Iraq. An amendment to the Regulations (56 FR 13584, Apr. 3, 1991) added a new appendix A, the list of Individuals and Organizations Determined to be Within the Term "Government of Iraq" (Specially Designated Nationals of Iraq), and a new appendix B, the list of Merchant Vessels Registered, Owned or Controlled by the Government of Iraq or by Persons Acting Directly or Indirectly on Behalf of the Government of Iraq.

This rule removes two names from appendix A to part 575. The list consists of companies and individuals which the Director of the Office of Foreign Assets Control has determined to be owned or controlled by or to be acting or purporting to act directly or indirectly for the Government of Iraq, and which thus fall within the definition of the "Government of Iraq" contained in § 575.306 of the Regulations. The persons included in appendix A are subject to all prohibitions applicable to other components of the Government of Iraq. All unlicensed transactions with such persons, or in property in which they have an interest, are prohibited.

The list of specially designated nationals is a partial one since FAC may not be aware of all the persons that might be owned or controlled by the Government of Iraq or acting as officers, agents or front organizations for Iraq, and which thus qualify as specially designated nationals of the Government of Iraq. Therefore, persons engaging in transactions may not rely on the fact that any particular person is not on the specially designated nationals list as evidence that it is not owned or controlled by, or acting or purporting to act directly or indirectly for, the Government of Iraq. The Treasury Department regards it as incumbent upon all U.S. persons to take reasonable steps to ascertain for themselves whether persons they enter into transactions with are owned or controlled by the Government of Iraq or are acting or purporting to act on its behalf, or on behalf of other countries subject to blocking or transportation-related restrictions (at present, Cambodia, Cuba, Libya, North Korea, and Vietnam).

Pursuant to the Regulations, Arab Trans Trade Co., S.A.E. and Unimas Shipping were included in appendix A to the Regulations, published in the **Federal Register** on April 3, 1991 (56 FR 13584) as specially designated nationals of the Government of Iraq. Following a review of additional information it has been determined that Arab Trans Trade Co., S.A.E. and Unimas Shipping are not within the scope of the definition of the "Government of Iraq" as defined in § 575.306 of the Regulations; and, therefore, are removed from the list of specially designated nationals of the Government of Iraq.

Because the Regulations involve a foreign affairs function, Executive Order 12291 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, does not apply.

List of Subjects in 31 CFR Part 575

Administrative practice and procedure, Banks, Banking, Blocking of assets, Foreign trade, Iraq, Penalties, Reporting and recordkeeping requirements, Securities, Specially designated nationals, Travel restrictions.

PART 575—IRAQI SANCTIONS REGULATIONS

For the reasons set forth in the preamble, 31 CFR part 575 is amended as set forth below:

1. The "Authority" citation for part 575 continues to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; 50 U.S.C. 1601 *et seq.*; 22 U.S.C. 287c; Pub. L. 101-513, 104 Stat. 2047-55 (Nov. 5, 1990); 3 U.S.C. 301; E.O. 12722, 55 FR 31803 (Aug. 3, 1990); E.O. 12724, 55 FR 33089 (Aug. 13, 1990).

Appendix A—Individuals and Organizations Determined To Be Specially Designated Nationals of the Government of Iraq

2. Appendix A to part 575 is amended by removing the following names from the list of companies:

Arab Trans Trade Co., S.A.E., 36 Kafr Abdou Street, Rouchdy, Alexandria 481 683, Egypt;

Unimas Shipping, 183 El Geish Road, P.O. Box 44, Alexandria, Egypt.

Dated: September 6, 1991.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: September 13, 1991.

Peter K. Nunez,

Assistant Secretary (Enforcement).

[FR Doc. 91-22945 Filed 9-23-91; 8:45 am]

BILLING CODE 4810-25-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD1 91-095]

Special Local Regulation: Manhasset Bay Gold Cup Race, Hempstead Harbor, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Special local regulations are being adopted for the Manhasset Bay Gold Cup Race. The event, sponsored by the Manhasset Bay Marina, is scheduled to take place on Saturday, September 28, 1991. These regulations restrict vessel traffic in Western Long Island Sound in the vicinity of Hempstead Harbor during the event. The regulations are needed to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATES: This temporary regulation is effective from 11:30 a.m. to 3:30 p.m. on September 28, 1991. In case of inclement weather, these regulations will be effective from 11:30 a.m. to 3:30 p.m. on September 29, 1991.

FOR FURTHER INFORMATION CONTACT: Lieutenant (junior grade) C.W. Jennings, Waterways Management Officer, Coast Guard Group New York, (212) 668-7933.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rule making has not been published for these regulations and good cause exists for making them effective in less than 30 days from the date of publication. Following normal rule making procedures would have been impracticable. The application to hold the event was not received by this office until July 8th and there was not sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date.

Drafting Information

The drafters of this notice are LT(jg) C. W. JENNINGS, project officer, Coast Guard Group New York, and LT J. B. GATELY, project attorney, First Coast Guard District Legal Division.

Discussion of Regulations:

The Manhasset Bay Gold Cup Race is a high speed offshore powerboat race which will be held on the waters of Long Island Sound at the mouth of Hempstead Harbor. This event will include up to 50 powerboats competing on a triangular course at speeds approaching 100 m.p.h. The regulated area will be the race course and spectator areas, and will be patrolled by the Coast Guard, Coast Guard Auxiliary, sponsor provided patrols, and State and local law enforcement officials. The potential hazards to participants, spectators, and transiting vessels are such that in the interest of safety of life on the navigable waters of the United States, the Coast Guard District Commander is issuing special local regulations governing the conduct of the regatta.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water).

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend part 100 of title 33, Code of Federal Regulations as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35

2. A Temporary § 100.35.T1095 is added to read as follows:

§ 100.35.T1095 Manhasset Bay Gold Cup Race.

(a) Regulated Area. The regulated area includes all waters within 200 yards of the triangular course marked by racing buoys, marked by the following points:

Latitude 40 52.1 N
Longitude 073 39.9 W then Northeast to
Latitude 40 55.1 N
Longitude 073 39.0 W then Southwest to
Latitude 40 53.0 N
Longitude 073 42.85 W then Southeast to the origin

(b) Special Local Regulations.

(1) Commander, Coast Guard Group New York reserves the right to delay, modify or cancel the race as conditions or circumstances require.

(2) No person or vessel may enter, transit, or remain in the regulated area during the effective period of regulation unless participating in the event or as authorized by the sponsor or Coast Guard Patrol Commander. The Coast Guard Patrol Commander will attempt to minimize any delays for commercial vessels transiting the area and will be monitoring channel 16 VHF.

(3) Unless otherwise directed by the Coast Guard patrol commander, transiting vessels shall: Proceed at no wake speeds; remain clear of the race course area as marked by the sponsor provided buoys; and not interfere with races or make stops.

(4) Official patrol vessels include Coast Guard and Coast Guard Auxiliary vessels and other vessels so designated by the regatta sponsor or Coast Guard patrol personnel.

(5) All persons and vessels shall comply with the instructions of U.S. Coast Guard patrol personnel. Upon hearing five or more blasts from a U.S. Coast Guard vessel, the operator of a vessel shall stop immediately and proceed as directed. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard. Members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation and other applicable laws.

(6) The sponsor shall be responsible for proper marking of the course within the regulated area and adequately marking the boundaries of the spectator area. All turn and spectator area buoys shall be established in a position agreeable to the Coast Guard Patrol Commander not later than one hour prior to the start of the event. All buoys marking the course and spectator area must be removed not later than one hour after completion of the event.

(7) In the event of an emergency or as directed by the Coast Guard Patrol Commander, the sponsor shall dismantle the race course to allow the passage of any U.S. Government vessel or any other designated emergency vessel. At the discretion of the Patrol Commander, any violation of the provisions contained within this regulation shall be sufficient grounds to terminate the event.

(c) *Effective Period.* These regulations are effective between the hours of 11:30 a.m. and 3:30 p.m. on September 28, 1991. In case of inclement weather, these regulations are effective between the hours of 11:30 a.m. and 3:30 p.m. on September 29, 1991.

Dated: August 30, 1991.

J.D. Sipes,

Rear Admiral, U.S. Coast Guard,

Commander, First Coast Guard District.

[FR Doc. 91-22941 Filed 9-23-91; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Part 165

[CGD1 91-097]

Safety Zone Regulations: Upper Bay and East River, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in the Upper Bay and East River, New York. This zone is needed to protect the maritime community from the possible dangers

and hazards to navigation associated with a fireworks display. Entry into this zone, or movement within this zone, is prohibited unless authorized by the Captain of the Port, New York.

EFFECTIVE DATES: This regulation becomes effective at 7 p.m., September 25, 1991. It terminates at 8:30 p.m., September 25, 1991.

FOR FURTHER INFORMATION CONTACT: MST1 S. Whinham of Captain of the Port, New York, (212) 668–7934.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publishing an NPRM and delaying its effective date would be contrary to public interest since immediate action is needed to respond to any potential hazards.

Drafting Information

The drafters of this regulation are LTJG C.W. Jennings, project officer, Captain of the Port New York, and LT John B. Gately, project attorney, First Coast Guard District Legal Office.

Discussion of Regulation

The circumstances requiring this regulation result from the possible dangers and hazards to navigation associated with a fireworks display. This regulation is effective from 7 p.m., September 25, 1991 to 8:30 p.m., September 25, 1991. This regulation is issued pursuant to 33 U.S.C. 1225 and 1231 as set out in the authority citation for all of part 165.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Regulation

In consideration of the foregoing, part 165 of title 33, Code of Federal Regulations, is amended as follows:

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1225 and 1231; 50 U.S.C. 191; 49 CFR 1.46 and 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5.

2. A new § 165.T1097 is added to read as follows:

§ 165.T1097 Safety Zone: Upper Bay and East River, New York.

(a) *Location.* The following area is declared a Safety Zone: All waters of the East River south of the Brooklyn Bridge, north of a line drawn between the Brooklyn Battery Tunnel Ventilator on Governors Island and Pier 7 Brooklyn, and east of a line drawn between the Brooklyn Tunnel Ventilator on Governors Island and Slip 7 Manhattan.

(b) *Effective date.* This regulation becomes effective at 7 p.m., September 25, 1991. It terminates at 8:30 p.m., September 25, 1991.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part entry into or movement within this zone is prohibited unless authorized by the Captain of the Port.

Dated: August 24, 1991.

R.M. Larrabee,

Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 91–22940 Filed 9–23–91; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL–3993–7]

Ocean Dumping; Site Designation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today designates an Ocean Dredged Material Disposal Site (ODMDS) in the Gulf of Mexico offshore of Pascagoula, Mississippi, as an EPA-approved ocean dumping site for the dumping of suitable dredged material. This action is necessary to provide an acceptable ocean dumping site for consideration as a disposal option for dredged material disposal projects in the Mississippi Sound and vicinity.

DATES: Designation will be effective October 24, 1991.

ADDRESSES: Wesley B. Crum, Chief, Wetlands and Coastal Programs Section, Water Management Division, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street, NE., Atlanta, Georgia 30365.

The file supporting this designation is available for public inspection at the following locations:

EPA Public Information Reference Unit (PIRU), Room 2904 (rear), 401 M Street, SW., Washington, DC 20460.

EPA/Region IV, Water Management Division, 345 Courtland Street, NE., Atlanta, Georgia 30365.

U.S. Army Engineer District Mobile, 109 St. Joseph Street, Mobile, Alabama 36628.

FOR FURTHER INFORMATION CONTACT: Jeffrey A. Kellam, 404/347–2126.

SUPPLEMENTARY INFORMATION:

Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act (MPRSA) of 1972, as amended, 33 U.S.C. 1401 *et seq.* ("the Act"), gives the Administrator of EPA the authority to designate sites where ocean dumping may be permitted. On December 23, 1986, the Administrator delegated the authority to designate ocean dumping sites to the Regional Administrator of the Region in which the sites are located. This designation of a site offshore of Pascagoula, Mississippi, which is within Region IV, is being made pursuant to that authority.

The EPA Ocean Dumping Regulations promulgated under the Act (40 CFR ch. I, subchapter H, § 228.4) state that ocean dumping sites will be designated by promulgation in this part 228. A list of "Approved Interim and Final Ocean Dumping Sites" was published on January 11, 1977 (42 FR 2461 (January 11, 1977)). The list established the existing Pascagoula site as an interim site. The Proposed Rulemaking was published in the **Federal Register** (55 FR 30473) on July 26, 1990. Comments were incorporated into this final rulemaking.

EIS Development

Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321 *et seq.*, requires that Federal agencies prepare an EIS on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment.

The object of NEPA is to build careful consideration of all environmental aspects of proposed actions into the agency decision-making process. While NEPA does not apply to EPA activities of this type, EPA has voluntarily committed to prepare EISs in connection with ocean dumping site designations such as this (see 39 FR 16186 (May 7, 1974)). EPA, in cooperation with the Mobile District of the U.S. Army Corps of Engineers (COE), and the U.S. Naval Facilities Engineering Command, has prepared a final EIS entitled "Final Environmental Impact Statement for the Designation of an Ocean Dredged Material Disposal Site, Pascagoula, Mississippi". This Final Rule includes EIS excerpts.

This action discussed in this rule is the final designation for use and expansion of the expired interim ocean dredged material disposal site near Pascagoula, Mississippi. The purpose of the action is to provide an environmentally acceptable location for ocean disposal of dredged material. The

need for ocean disposal is determined on a case-by-case basis as part of the process of issuing permits for ocean disposal.

For the Pascagoula ODMDS, the COE and EPA would evaluate all Federal dredged material disposal projects pursuant to the EPA criteria given in the Ocean Dumping Regulations (40 CFR 220–229) and the COE regulations (33 CFR 209.120 and 335–338). The COE also issues MPRSA permits to private applicants for the transport of dredged material intended for disposal after compliance with these regulations is determined. EPA has the right to disapprove any ocean disposal project if, in its judgment, all provisions of MPRSA and the associated implementing regulations have not been met. Publication date in the **Federal Register** for the Notice of Availability of the draft EIS for public review and comment was July 27, 1990. The public comment period on the draft EIS closed on September 10, 1990. Publication date in the **Federal Register** for the Notice of Availability of the final EIS was August 16, 1991, with comment period ending September 16, 1991.

The EIS discusses the need for this site designation and examines ocean disposal site alternatives to the proposed action. The need for ocean disposal is determined on a case-by-case basis as a part of the process of permitting for ocean disposal. The EIS presents the information needed to evaluate the suitability of ocean disposal areas for final designation use and is based on one of a series of disposal site environmental studies. The environmental studies and final designation are being conducted in accordance with the requirements of the MPRSA, the Ocean Dumping Regulations, and other applicable Federal environmental legislation.

Pursuant to an Office of Water policy memorandum dated October 23, 1989, EPA has evaluated the site designation for consistency with the State of Mississippi's (the State) approved coastal management program. EPA has determined that the designation of the proposed site is consistent to the maximum extent practicable with the State coastal management program, and has submitted this determination to the State for review in accordance with EPA policy. The State subsequently provided concurrence with the EPA decision. In addition, as part of the NEPA process, EPA has consulted with the State regarding the effects of the disposal at the proposed site on the State coastal zone. EPA has taken the State's comments into account in preparing the final EIS for the site, in determining whether the proposed site should be designated, and in determining whether restrictions or limitations should be placed on the use of the site, if it is designated.

Pursuant to section 7 of the Endangered Species Act, the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS) were asked by EPA to concur with EPA's conclusion that this site designation will not affect the endangered species under their jurisdictions. The National Marine Fisheries Service concurred, on January 24, 1991, that species under their jurisdiction will not be affected by the designation. FWS deferred to NMFS in this case.

The Final Rulemaking fills the same role as a Record of Decision required under rules promulgated by the Council on Environmental Quality for agencies subject to NEPA.

Site Designation

The site is located south of Pascagoula, Mississippi, approximately 1.5 nautical miles southeast of Horn Island, and occupies an area of about 18.5 square nautical miles (nmi^2). Water depths within the area range from 39 to 53 feet, averaging about 46 feet. The coordinates of the Pascagoula site proposed for final designation are as follows:

Boundary Coordinates:
30°12'06" N 88°44'30" W
30°11'42" N 88°33'24" W
30°08'30" N 88°37'00" W
30°08'18" N 88°41'54" W
Center Coordinates:
30°10'09" N 88°39'12" W

Regulatory Requirements

Pursuant to the Ocean Dumping Regulations, 40 CFR part 228, five general criteria are used in the selection and approval for continuing use of ocean disposal sites. Sites are selected so as to minimize interference with other marine activities, to prevent any temporary perturbations associated with the dumping from causing impacts outside the disposal site, and to permit effective monitoring to detect any adverse impacts at an early stage. Where feasible, locations off the Continental Shelf and other sites that have been historically used are to be chosen. If, at any time, disposal operations at a site cause unacceptable adverse impacts, further use of the site will be restricted or terminated. The proposed site conforms to the five general criteria, except for the preference for sites located off the Continental Shelf. EPA has determined, based on the information presented in the EIS, that no environmental benefit would be obtained by selecting a site off the Continental Shelf instead of that proposed in this action.

The general criteria are given in 40 CFR 228.5 of the EPA Ocean Dumping Regulations, and 40 CFR 228.6 lists the 11 specific criteria used in evaluating a proposed disposal site to assure that the general criteria are met. Application of these 11 criteria constitutes an environmental assessment of the impact of disposal at the site. The characteristics of the proposed site are reviewed below in terms of these 11 criteria.

Geographical Position, Depth of Water, Bottom Topography, and Distance From Coast (40 CFR 228.6(a)1)

The northern boundary of the ODMDS is approximately two nautical miles south of Horn Island. The area is bounded on the east by the north-south safety fairway, on the south by the east-west safety fairway, and on the west by an imaginary line on the eastern boundary of Dog Keys Pass and is defined by the following coordinates:

Boundary Coordinates:
30°12'06" N 88°44'30" W
30°11'42" N 88°33'24" W
30°08'30" N 88°37'00" W
30°08'18" N 88°41'54" W
Center Coordinates:
30°10'09" N 88°39'12" W

This area represents approximately 18.5 nmi^2. Water depths range from 39 to 53 feet and average approximately 46 feet. Bottom topography within this site is relatively flat, sloping gently seaward.

Location in Relation to Breeding, Spawning, Nursery, Feeding, or Passage Areas of Living Resources in Adult or Juvenile Phases (40 CFR 228.6(a)2)

Many northern Gulf of Mexico fish and shellfish species are estuarine dependent, spending a portion of their life cycle in an estuary such as Mississippi Sound. In general, the species spawn in the water of the Gulf of Mexico and eggs or larvae are carried by the currents into the estuaries through the barrier island passes. After a season or more, the species migrate through the pass into the gulf where spawning occurs. Literature surveys performed during the COE Mississippi Sound and Adjacent Areas Study (USACE 1984) indicate that the Horn Island Pass area is an important migration route as are all the other barrier island passes along the northern gulf coast. The use of the migratory

routes is heavier during the spring and early summer months than during late summer and fall/winter. The preferred site is about two and one-half miles from the shallow vegetated areas on the northern sides of the barrier islands and approximately nine miles from the extensive mainland marshes of the Pascagoula Delta and Point aux Chenes Bay area. The preferred site is not known to be located near any major breeding or spawning area.

In addition, a number of commercial, sport and recreational species such as grouper, ling, red snapper are known to utilize natural and artificial reef areas for feeding and refuge areas. In the vicinity of the ODMDS, a number of identified fish havens are located to the east, south of the entrance to Mobile Bay, to the west and to the south. Significant negative impacts from use of the site are not expected to occur on these sites.

Location in Relation to Beaches and Other Amenity Areas (40 CFR 228.6(a)3)

The primary coastal amenity is the Gulf Islands National Seashore which includes Petit Bois, Horn, and Ship Islands to the north of the preferred ODMDS. The preferred ODMDS is approximately two nautical miles south of Horn Island or about 14 nautical miles south of the mainland, and about 24 nautical miles east of the Chandeleur Islands. The gulf beaches of these islands are used for recreational activities such as swimming, fishing, and sun bathing. Protection is afforded the Gulf Islands National Seashore since the predominant currents shoreward of the preferred site are parallel to the shoreline and any migration of material from the ODMDS would be alongshore rather than in an onshore direction.

Types and Quantities of Dredged Material Proposed to be Disposed of, and Proposed Methods of Release, Including Packing the Dredged Material, if Any (40 CFR 228.6(a)4)

The designated ODMDS will be used for disposal of new work and maintenance material dredged from the eastern Mississippi Sound area which meets the criteria specified in section 102 of the MPRSA. All material to be placed in the ODMDS would be fine-grained or sand-sized material. Estimated quantities of material to be placed in the ODMDS are given as follows:

New York:	
U.S. Navy	750,000–1,000,000 cubic yards.
Federal Navigation Project.	11,000,000 cubic yards.
Operation and maintenance:	
U.S. Navy	250,000 cubic yards/18 months.
Federal Navigation Project.	1,000,000 cubic yards/18 months.

The material dredged from the entrance channel meets the exclusion criteria specified in 40 CFR 227.13(b)(1), i.e. "* * * dredged material composed predominantly of sand, gravel, rock, or any other naturally occurring bottom material with particle sizes larger than silt, and the material is found in areas of high current or wave energy such as streams with large bed loads or coastal areas with shifting bars and channels * * *", therefore no testing of the material was performed. The materials to be dredged from the lower Pascagoula River and upper Mississippi Sound channels were subjected to biological and chemical testing to determine toxicity and bioaccumulation potential utilizing three representative marine organisms. The toxicity of the six sediment samples tested was minimal. Testing of material to be dredged as a part of the Navy activities has also been conducted. The toxicity of the two samples tested was also minimal.

Feasibility of Surveillance and Monitoring (40 CFR 228.6(a)5)

The location of the ODMDS presents no special problems for surveillance and monitoring. The site is 14 miles south of the mainland. Water depths range from 39 to 53 feet. These water depths are amenable to either surface sampling or diver collection and, under normal circumstances, do not require the use of a large oceanographic vessel. High turbidity may occasionally restrict diver operations and photography but is not expected to be a significant hindrance to surveillance and monitoring. Site surveillance can be accomplished by air from Jackson County Airport in Pascagoula, Mississippi or by water from numerous facilities in Mississippi Sound. A site management and monitoring plan has been developed to determine short- and long-term impacts to the marine ecosystem associated with disposal of dredged material into the ODMDS. This management and monitoring plan is included in the FEIS as an appendix.

Dispersal, Horizontal Transport, and Vertical Mixing Characteristics of the Area, Including Prevailing Current Direction and Velocity, if Any (40 CFR 228.6(a)6)

Data collected within the Gulf of Mexico between November 1980 and September 1981 indicate that the progression of the tide through Horn Island Pass segments the gulf into eastern and western areas, dominating circulation within this portion of the gulf. The eastern area is between Horn Island Pass, Mississippi, and the main pass entering Mobile Bay, Alabama. The western area is between Horn Island Pass and the Chandeleur Islands. As the tide propagates from the gulf through Horn Island Pass, a general clockwise movement of water in the eastern area is set in motion, whereas, in the western area, a general counterclockwise movement occurs. In the shallow areas of the gulf, near the barrier islands, the wind and pressure forces tend to dilute the influence of the tide on the general circulation pattern, creating a highly variable pattern. It appears that a two-layer circulation pattern exists between surface and bottom waters when stratification occurs. The stratification decouples the currents throughout the water column causing variable velocities and directions to occur.

The ODMDS occupies a small area relative to the area of the continental shelf near Pascagoula. Changes in bathymetry are small in relation to the water depths in the sites. Therefore, the discharge of dredged material into the ODMDS would have negligible impact on the circulation and mixing of the shelf waters.

The fine-grained dredged material proposed for discharge onto the ODMDS will be more easily transported than the existing bottom materials; i.e. the finer material can be moved by a lower current. Thus, the clay and silt size particles on the surface of the ODMDS can be expected to be winnowed out by the currents and the site will become armored with sand, shell, and "clay balls". The fine-grained particles should become more difficult to erode over time as the material consolidates.

The environmental consequences of the transport of this fine-grained material on the marine ecosystem will vary depending on the proximity of the area in question to the actual disposal location. Impacts within the designated ODMDS are expected to be temporary and short-term. These impacts would range from direct burial of benthic resources and increased suspended solids concentrations in areas adjacent

to the disposal location to minimal impacts near the boundaries of the site. Recovery of affected benthic populations is expected to occur in a relatively short period of time. Impacts outside the designated ODMDS will be minimal because: (1) The site is being sized to contain the majority of the fine-grained material under normal hydrographic conditions and (2) the location of the site is being chosen to be a sufficient distance from any significant resources. Under abnormal hydrographic conditions, i.e. hurricane conditions, impacts due to the movement of ambient sediment particles would mask any impacts due to movement of fine-grained materials.

Existence and Effects of Current and Previous Discharges and Dumping in the Area (Including Cumulative Effects) (40 CFR 228.6(a)7)

A portion of the preferred ODMDS has been utilized historically for the placement of dredged material from the eastern Mississippi Sound area. There have been no demonstrable adverse impacts to the marine ecosystem of this area due to this disposal.

Interference With Shipping, Fishing, Recreation, Mineral Extraction, Desalination, Fish and Shellfish Culture, Areas of Special Scientific Importance, and Other Legitimate Uses of the Ocean (40 CFR 228.6(a)8)

The ODMDS was chosen to minimize interference with the activities listed. Fish, due to their motile nature, would not be directly affected by the discharge since they can avoid the area. However, some species would be indirectly affected due to the loss of benthic organisms which serve as a food source for these species. These impacts would be localized to the immediate area of the disposal operation and would be temporary in nature. Chemical analyses and bioassays of the dredged material indicate that no significant toxic effects are expected.

There are no known areas of shellfish culture in the vicinity of the site nor are there any known areas of special scientific importance in the vicinity; therefore, no impacts to these resources would result from the proposed action.

Although the possibility of oil and gas leasing operations within the vicinity of the ODMDS exists, experience suggests that offshore oil and gas operations and dredged material disposal are not mutually exclusive. As the need arises, the management plan for the use of the ODMDS will be revised to include any ongoing or proposed oil and gas leasing activities.

There are no military restricted areas that would be affected by designation and use of the ODMDS.

The Existing Water Quality and Ecology of the Site as Determined by Available Data or by Trend Assessment or Baseline Surveys (40 CFR 228.6(a)9)

Past surveys and the baseline surveys conducted during the ODMDS siting activities show the water quality and other environmental characteristics of the ODMDS to be typical of the northern Gulf of Mexico where sand or sandy mud sediments predominate. The site does not possess unique characteristics which would preclude designation and use as an ODMDS.

Potentiality for the Development or Recruitment of Nuisance Species in the Disposal Site (40 CFR 228.6(a)10)

Some change in benthic species composition on the designated ODMDS can be expected due to a difference in grain size from the existing bottom. However, there is no evidence to suggest that benthic species which would develop would be considered nuisance species. Some fecal coliform bacteria may be contained in the dredged material; however, it is improbable that these species would become established due to the existing salinity regime of the area.

Existence at or in Close Proximity to the Site of Any Significant Natural or Cultural Features of Historical Importance (40 CFR 228.6(a)11)

Review of literature pertaining to the cultural resources of the general area of the ODMDS suggests that there are no natural or cultural features of historical importance within the site or in the vicinity. Side scan sonar transects run during the site evaluation survey did not reveal the existence of any submerged features which might be of archealogical value. Coordination, by letter dated January 25, 1989, with the Mississippi State Historic Preservation Officer, indicates that the potential for shipwrecks in open water of these depths is considered extremely low.

Site Management

Site management of the Pascagoula ODMDS is the responsibility of EPA as well as the COE. The COE issues permits to private applicants for ocean disposal; however, EPA/Region IV assumes overall responsibility for site management.

A Site Management and Monitoring Plan has been developed. This plan provides a framework for both site management and for the monitoring of effects of disposal activities. Site management may include locating and/or orienting dredged material within the site boundaries relative to predominant current patterns. Monitoring could involve sediment mapping of disposed material to determine any movement of material off of the site. Determination of the significance of any biological impacts of dredged material outside the ODMDS boundaries would then be appropriate. The Site Management and Monitoring Plan may be changed by EPA to account for additional or lesser needs to manage and monitor the site.

Action

The EIS concludes that the site may appropriately be designated for use. The site is compatible with the general criteria used for site evaluation.

The designation of the Pascagoula site as an EPA-approved ODMDS is being published as Final Rulemaking. Overall management of this site is the responsibility of the Regional Administration of EPA/Region IV.

It should be emphasized that, if an ODMDS is designated, such a site designation does not constitute EPA's approval of actual disposal of material at sea. Before ocean dumping of dredged material at the site may commence, the COE must evaluate federal projects or permit applications according to EPA's Ocean Dumping Criteria. EPA has the right to disapprove the dumping if it determines that environmental concerns under the Act have not been met.

The Pascagoula ODMDS is not restricted to disposal use by Federal Projects; private applicants may also dispose suitable dredged material at the ODMDS once relevant regulations have been satisfied. This site is restricted, however, to suitable dredged material from the Mississippi Sound and vicinity.

Regulatory Assessments

Under the Regulatory Flexibility Act, EPA is required to perform a Regulatory Flexibility Analysis for all rules that may have a significant impact on a substantial number of small entities. EPA has determined that this action will not have a significant impact on small entities since the designation will only have the effect of providing a disposal option for dredged material. Consequently, this Rule does not necessitate preparation of a Regulatory Flexibility Analysis.

Under Executive Order 12291, EPA must judge whether a regulation is

"major" and therefore subject to the requirement of a Regulatory Impact Analysis. This action will not result in an annual effect on the economy of $100 million or more or cause any of the other effects which would result in its being classified by the Executive Order as a "major" rule. Consequently, this rule does not necessitate preparation of a Regulatory Impact Analysis. This final rule does not contain any information collection requirements subject to Office Management and Budget review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Part 228

Water pollution control.

Dated: August 16, 1991.

Patrick M. Tobin,

Approved by: Patrick M. Tobin, Acting Regional Administrator.

In consideration of the foregoing, subchapter H of chapter I of title 40 is to be amended as set forth below.

PART 228—[AMENDED]

1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

2. Part 228 is amended by removing from § 228.12(a)(3) in the Approved Interim Dumping Sites, the entry for Pascagoula, MS, and adding paragraph (b)(87) as follows:

§ 228.12 Delegation of management authority for interim ocean dumping sites.

* * * * *

(b) * * *

(87) Pascagoula, Mississippi; Ocean Dredged Material Disposal Site—Region IV.

Location:
30°12'06" N 88°44'30" W
30°11'42" N 88°33'24" W
30°08'30" N 88°37'00" W
30°08'18" N 88°41'54" W

Center Coordinates:
30°10'09" N 88°39'12" W

Size: 18.5 square nautical miles.

Depth: Average 46 feet, range 38 to 53 feet.

Primary use: Dredged material.

Period of use: Continuing use.

Restriction: Disposal shall be limited to suitable dredged material from the Mississippi Sound and vicinity.

[FR Doc. 91-22870 Filed 9-23-91; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 408

[BPO-78-F]

RIN 0938-AD97

Medicare Program; Grace Period and Termination for Nonpayment of Supplementary Medical Insurance (Part B) Premiums for Insured and Uninsured Persons

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

ACTION: Final rule.

SUMMARY: This final rule changes the termination date for Supplementary Medical Insurance (SMI) (Part B) enrollees who fail to pay their Medicare Part B premiums. Presently, there is a 90 day grace period for the enrollee during which he or she may pay all overdue premiums and continue Part B coverage uninterrupted. The grace period begins at different times depending on whether the individual is or is not eligible for monthly social security, railroad retirement or civil service retirement benefits. This final rule establishes a uniform timeframe for determining the 90 day grace period which precedes the termination of SMI enrollees who fail to pay their Medicare Part B premiums.

EFFECTIVE DATE: The rules are effective October 24, 1991. Termination under these rules would begin December 31, 1991.

FOR FURTHER INFORMATION CONTACT: Paul Boerschel (301) 966-5941.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 1990, we published at 55 FR 46222 a proposed rule with a 60 day comment period that would change the termination date for Supplementary Medical Insurance (Part B) enrollees who fail to pay their Medicare Part B premiums. Under current rules there is a 90 day grace period for the enrollee during which he or she may pay all overdue premiums and continue Part B coverage uninterrupted. The grace period begins at different times depending on whether the individual is or is not eligible for monthly social security, railroad retirement or civil service retirement benefits.

In the proposed rule, we proposed changes for enrollees who are eligible for cash benefits (insured), but are not receiving their cash benefits because they are working. Under existing regulations their grace period did not begin until the taxable (calendar) year ended and another 90 days had elapsed. The change in regulations will establish their grace period for payment as the end of the third month after the initial billing month. Bills will be sent every 3 months. If payment is not received within 60 days, a second notice will be sent. If payment is not received within 90 days, a delinquent notice will be sent.

Section 1838(b) of the Act and our regulations at 42 CFR 408.8 provide for a grace period for payment of overdue premiums. This period generally may not exceed 90 days, unless good cause is established. If good cause is established, the grace period may be extended up to 180 days. As long as the enrollee pays all overdue premiums before the end of the grace period, Part B coverage continues uninterrupted.

Currently, Medicare regulations afford a 90-day grace period that begins at different times, based on receipt or nonreceipt of cash benefits. The grace period for enrollees who do not have qualifying employment to receive cash benefits ends on the last day of the third month after billing month if they are billed monthly, or the last day of each 3-month period for which the enrollee is billed if they are billed quarterly. For enrollees whose monthly cash benefits have been suspended, the grace period ends on the last day of the fourth month after the end of the enrollee's taxable year, usually April 30. For enrollees whose monthly benefit is less than their monthly premium, the grace period ends April 30 of the year following the calendar year for which the premiums are due, if the amount still overdue on the date is equal to or greater than the premium for three months (enrollees are billed at the beginning of each calendar year).

We noted that the regulation would eliminate an inequity and the potential for abuse of the system that may occur because some beneficiaries are afforded an opportunity to utilize up to 16 months of Part B protection without paying premiums before they are terminated for nonpayment of premiums.

We proposed to revise §§ 408.8 and 408.50 of our regulations to establish a uniform timeframe for determining the 90 day grace period for Medicare beneficiaries enrolled in Part B who make premium payments to HCFA, regardless of how they pay their Part B premium, that would end on the last day of the third month following the billing, with one exception. The one exception would be that those enrollees whose monthly benefits are less than the monthly premiums would not be terminated any earlier than current rules allow, viz., until April 30 of the year

following the calendar year for which unpaid premiums are due. We believe that current regulation (§ 408.63) affords the best administrative application to collect premiums while still providing for termination after a 90 day grace period. The amounts owed are small and if not paid can be recouped from current benefits payable.

Since we proposed to establish a different timeframe for determining the start of the 90-day grace period for virtually all Medicare Part B enrolless and no longer routinely would be using closed taxable years in all our calculations, we proposed to delete § 408.47.

We also proposed to make several technical revisions to §§ 408.1 and 408.10 to correct or update cross references.

II. Comments on Proposed Rule

In response to the November 2, 1990 proposed rule, we received one timely item of correspondence. The timely letter of comment was from a State committee on aging. The commenter did not specifically address the content of the proposed regulations, but recommended that we withdraw the proposed rule as written. The commenter was concerned that those elderly individuals who do not receive monthly benefits from which their premium can be deducted were frail and often depended on others to reply to correspondence or make payments, and hence, needed as much time as possible to pay their Medicare Part B premiums. However, the commenter did not address our proposal to treat all beneficiaries equally nor submit any data that our proposal was inappropriate or any alternatives to the proposed rules.

In response, we note that our intention is to treat all beneficiaries who do not have their full Part B premium deducted from a Federal benefit payment equally. We currently bill all such beneficiaries every 3 months and the majority pay promptly within the 3 month cycle. The change in the regulation would prevent potentially long periods of utilization of Medicare Part B by those who we believe intend to let their coverage expire. We believe that individuals who let Part B lapse primarily are individuals who are working or whose spouse is working and have employment related health coverage. We believe most of the population about which the commenter is concerned would be eligible for Medicaid and have their premiums routinely paid by the State Medicaid agency. For those individuals who, due to illness or other extenuating circumstances, fail to pay their premiums, we have very lenient reinstatement provisions. The change to the regulation is intended to give the insured beneficiary the same 3 month grace period that has always applied to the uninsured.

Based on our review of the comment submitted, we are making no changes to the rule as published on November 2, 1990. Therefore, we are adopting as final, the rule as proposed. In addition, for consistency in format, we are revising § 408.50(b)(3) to print the heading in italics.

III. Regulatory Impact Statement

A. Executive Order 12291

Executive order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any final rule that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in cost or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The purpose of this final rule is to establish consistent timeframes for determining when the grace period begins for Medicare beneficiaries enrolled in Part B who make full premium payments. This final rule may affect the entitlement status of approximately 344,000 individuals who are being billed premiums. If these individuals fail to take action regarding their overdue premiums within the 90 day grace period, they will lose their entitlement to Part B coverage at that time, rather than, perhaps, months later. For those who lose their Part B entitlement, the economic consequences may be significant, depending on their need for health care services and availability of other insurance. However, we are unable to determine how many individuals would fail to meet the payment deadline, and how severe the effect of failing to pay timely would be on those individuals. Savings to the Medicare program that we may achieve as a result of this final rule are expected to be insignificant.

Since we do not believe this rule would meet any of the criteria for a "major rule" specified in E.O. 12291, we have not prepared a regulatory impact analysis.

B. Regulatory Flexibility Act

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purpose of the RFA, all physicians and suppliers are treated as small entities.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

We do not believe this rule would have a significant effect on small entities as defined under RFA or on small rural hospitals. Therefore, we are not preparing either a regulatory flexibility analysis or a rural impact statement since we have determined, and the Secretary certifies that this final rule will not have a significant economic impact on small entities or on the operations of a substantial number of small rural hospitals.

IV. Paperwork Reduction Act of 1980

Section 408.50(b)(2) of this final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). A notice will be published in the **Federal Register** when approval is obtained.

List of Subjects in 42 CFR Part 408

Administrative practice and procedure, Health insurance, Medicare, Premiums.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

42 CFR part 408, subpart C is amended as follows:

1. The authority citation for part 408 continues to read as follows:

Authority: Secs. 1102, 1818, 1837–1840, 1843, 1871 and 1881(d) of the Social Security Act (42 U.S.C. 1302, 1395i–2, 1395p, 1395q, 1395r, 1395s, 1395v, 1395hh, and 1395rr(d)), and the Federal Claims Collection Act (31 U.S.C. 3711).

2–3. Section 408.8 is amended by revising paragraph (a)(1), removing paragraphs (a)(2) and (a)(3), and redesignating paragraph (a)(4) as paragraph (a)(2) and revising it to read as follows:

§ 408.8 Grace period and termination date.

(a) *Grace period.* (1) For all initial premium payments (monthly or quarterly), and subsequent monthly or quarterly payments, the grace period ends with the last day of the third month after the billing month.

(2) For payments required because the monthly benefit is less than the monthly premium, the grace period ends on April 30 of the year following the calendar year which the premiums are due.

* * * * *

§ 408.47 [Removed and Reserved]

4. Section 408.47 is removed and reserved.

5. In § 408.50, paragraphs (b)(2) and (b)(3) are revised and paragraph (c) is removed, to read as follows:

§ 408.50 When premiums are considered paid.

* * * * *

(b) *Payments within the grace period.*

* * *

(2) *Annual earnings report or other report submitted during the grace period shows a benefit is due.*

(i) Before the end of the grace period, the enrollee submits a report clearly showing that monthly cash benefits, previously withheld, are payable; and

(ii) Those benefits are sufficient to permit deduction of the full amount of the overdue premiums.

(3) *Premium arrears are paid by direct remittance.* The enrollee makes a direct remittance payment of all overdue premiums before the end of the grace period.

Technical Amendments

§ 408.1 [Amended]

6. In § 408.1(b), the reference to "45 CFR part 430" is revised to read "45 CFR part 30".

§ 408.10 [Amended]

7. In § 408.10(b)(2)(ii), the reference to "§ 408.8(a)(3)" is revised to read "§ 408.8(a)".

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: May 27, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: August 2, 1991.

Louis W. Sullivan,

Secretary.

[FR Doc. 91–22380 Filed 9–23–91; 8:45 am]

BILLING CODE 4120–01–M

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42 CFR Part 441

[MB–049–IFC]

RIN 0938–AF66

Medicaid Program; Community Supported Living Arrangements Services

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule specifies minimum protection requirements that must be met in order for a State to be eligible to provide optional community supported living arrangements services to individuals with developmental disabilities as defined in section 1930(b) of the Social Security Act (the Act).

This rule implements section 1930(h)(1)(B) of the Act, as added by section 4712 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101–508, enacted on November 5, 1990.

DATES: *Effective date:* These interim final rules are effective on October 24, 1991.

Comment date: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 25, 1991.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: MB–049–IFC P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept audio, video or facsimile (FAX) copies of comments. In commenting, please refer to file code MB–049–IFC. Written comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in room 309–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: 202–245–7890).

Organizations and individuals desiring to submit comments on the reporting requirements discussed under the section on "Collection of Information Requirements" of this preamble should direct them to the Health Care Financing Administration at one of the addresses cited above, and to the Office of Information and Regulatory Affairs, Attention: Allison Herron Eydt, Office of Management and Budget, New Executive Office Building (room 3201), Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Robert Wardwell, (301) 966–5659.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1905(a) of the Social Security Act (the Act) specifies services that States may provide as medical assistance under title XIX. Certain services listed in section 1905(a) of the Act are mandatory for certain groups specified in sections 1902(a)(10) (A) and (C) of the Act. These include services such as inpatient and outpatient hospital services, physician services, and laboratory and x-ray services. Other services listed in section 1905(a) of the Act may be provided under a Medicaid State plan at the State's option. These include such services as home health care, private duty nursing, case management, and physical therapy.

Under section 1915(c) of the Act, States may obtain waivers to provide certain home and community-based services beyond those included under its State plan listed in section 1905(a) of the Act to individuals who, except for the provision of such services, would require institutionalization. The section 1915(c) waivers include such services as personal care services, adult day health services, habilitation services, and respite care services.

Prior to the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101–508, enacted November 5, 1990, community supported living arrangements (CSLA) services were not available under title XIX, except to the extent that some of the services may have been provided under section 1915(c) home and community-based services waivers. CSLA services represent a new approach in service

systems for individuals with developmental disabilities. CSLA services programs offer highly personalized services that assist individuals with disabilities to live their lives in homes they choose for themselves and are based on the concepts of consumer empowerment and non-facility-based services for individuals with various levels of disabilities.

II. Legislative Changes

Section 4712 of OBRA '90 amended section 1905(a) of the Act by adding CSLA services as an optional Medicaid service, to the extent allowed and as defined in section 1930 of the Act. Section 1930, as added by section 4712 of OBRA '90, places limits on the extent to which States may offer CSLA services as an optional Medicaid service. Specifically, section 1930(c) provides that, during the first five years that CSLA services are allowed as an optional Medicaid service, the Secretary must select a minimum of two and a maximum of eight States that would be eligible to provide one or more CSLA services to developmentally disabled individuals and receive Federal financial participation (FFP). Section 1930(a) defines CSLA services to mean one or more of the following services that are furnished in a community supported living arrangement setting and are designed to assist a developmentally disabled individual in activities of daily living necessary to permit the individual to live in his or her own home, apartment, family home, or rental unit:

- Personal assistance;
- Training and habilitation services necessary to assist the individual in achieving increased integration, independence, and productivity;
- 24-hour emergency assistance (as defined by the Secretary);
- Assistive technology;
- Adaptive equipment;
- Support services necessary to aid an individual to participate in community activities; and
- Other nonexcluded services as approved by the Secretary (excluded services are room and board, and the cost of prevocational, vocational, and supported employment services).

Section 1930(b) of the Act defines the term "developmentally disabled individuals" to mean individuals, as defined by the Secretary, who are residing in their own home, apartment or rental unit or their family's home in which no more than three other individuals receiving CSLA services reside, without regard to whether or not they are at risk of institutionalization.

To implement the provisions in section 4712 of OBRA '90, section 1930(g) of the Act specifies that States may request waivers of such provisions of title XIX as necessary, including but not limited to the requirements of comparability of amount, duration and scope of services under section 1902(a)(10)(B) of the Act, and the statewideness requirements under section 1902(a)(1).

Section 1930(d) specifies that to be eligible to provide CSLA services and to receive Federal financial participation (FFP) for such services, States must establish and maintain a quality assurance program that includes requirements for:

- Provider survey and certification (such surveys to be unannounced and average at least one a year);
- Standards for survey and certification that include minimum qualifications and training requirements for provider staff, financial operating standards, and a consumer grievance process;
- A system that allows for monitoring boards;
- Ongoing monitoring of the well-being of each recipient;
- Reporting procedures to make available information to the public;
- Development of individual support plans (as defined by the Secretary in regulations); and
- Review of a State plan amendment.

Additionally, section 1930(h)(1)(B) of the Act specifies that, in addition to the quality assurance programs specified in section 1930(d) of the Act and State licensure processes, States selected to provide CSLA services must also meet minimum requirements to, among other things, protect individuals receiving CSLA services from neglect, physical and sexual abuse and financial exploitation.

Section 4712(c)(1) of OBRA '90 specifies that the implementing amendments of section 4712 apply to CSLA services furnished on or after the later of July 1, 1991 or 30 days after publication of interim regulations implementing the minimum protection requirements under section 1930(h)(1)(B) of the Act.

III. Provisions of the Regulation

This interim final rule deals exclusively with the minimum protection requirements under section 1930(h)(1)(B) of the Act. Separate regulations dealing with the remaining provisions of section 4712 of OBRA '90 will be published at a later date. Until that time, States selected to provide CSLA services will be bound by the requirements of the statute and the terms of a HCFA-approved application and HCFA-approved State plan amendment in providing the services.

To implement the provisions under section 1930(h)(1)(B) of the Act, we are adding a new subpart I to 42 CFR part 441 that consists of three sections. New § 441.400, Basis and purpose, specifies the statutory authority for the provision of CSLA services and the minimum protection requirements. New § 441.402, State plan requirements, provides that any State eligible to provide CSLA services must specify that it complies with the minimum protection requirements in new § 441.404, Minimum protection requirements. New § 441.404 implements the minimum protection requirements described in section 1930(h)(1)(B) of the Act.

Specifically, § 441.404 provides that, to be eligible to provide CSLA services to developmentally disabled individuals, a State must assure, through methods other than reliance on State licensure processes or the State quality assurance programs described under section 1930(d) of the Act, that:

- Individuals receiving CSLA services are protected from neglect, physical and sexual abuse, and financial exploitation;
- Providers of CSLA services do not use individuals who have been convicted of child or client abuse, neglect, or mistreatment or of a felony involving physical harm to an individual;
- Providers of CSLA services take all reasonable steps to determine whether applicants for employment by the provider have histories indicating involvement in child or client abuse, neglect, or mistreatment or a criminal record involving physical harm to an individual;
- Individuals or entities delivering CSLA services are not unjustly enriched as a result of abusive financial arrangements (such as owner lease-backs); and
- Individuals or entities delivering CSLA services to developmentally disabled individuals, or the relatives of such individuals, are not named beneficiaries of life insurance policies purchased by or on behalf of developmentally disabled clients.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking for a regulation in the **Federal Register** to provide a period for public comment prior to publication of a final rule. Section 4207(j) of OBRA '90 provides specific authority for the issuance of interim final rules as necessary to implement provisions of OBRA '90. We are exercising our

discretion under section 4207(j) in this instance by issuing this rule as an interim final rule. However, we are providing a 30-day comment period for public comments on this interim final rule as indicated at the beginning of this document.

Section 4712(c)(1) of OBRA '90 further specifies that the implementing amendments of section 4712 apply to CSLA services furnished on or after the later of July 1, 1991 or 30 days after publication of interim regulations dealing with the minimum protection requirements under section 1930(h)(1)(B) of the Act. The promulgation of interim final regulations results in the earlier availability of this optional Medicaid service than if we were to issue a proposed rule.

VI. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any final rule that meets one of the E.O. 12291 criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we do not consider States or individuals to be small entities.

This interim final rule conforms the Medicaid regulations to certain provisions in OBRA '90. The FFP available for CSLA services provided in fiscal years 1991 through 1995 is explicitly limited to the amounts specified in section 1930(j) of the Act. Sums for subsequent fiscal years will be as specifically provided by Congress. We do not believe that this rule produces an effect that meets the criteria of E.O. 12291 or will have a significant effect on a substantial number of small entities. Therefore, we have not prepared a final regulatory impact statement under E.O. 12291 or a regulatory flexibility analysis under the RFA.

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

We have determined, and the Secretary certifies, that these interim final rules with comment period will not have a significant economic impact on the operations of a substantial number of small rural hospitals, and therefore have not prepared a rural hospital impact statement.

VII. Collection of Information Requirements

The new regulation at § 441.402 contains information collection or recordkeeping requirements, or both, that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). The information collection requirements concern the development of State plan amendment material concerning the provision of CSLA services. The respondents who will provide the information include State Medicaid agencies. Public reporting burden for this collection of information is estimated to be less than one hour per amendment. The Office of Management and Budget has approved this information collection under approval number 0938–0585. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct the comments to HCFA and to the OMB official whose name appears in the "**ADDRESSES**" section of this preamble.

VIII. Response to Public Comments

Because of the large volume of public comments that we usually receive on rules, we cannot acknowledge or respond to them individually. However, we will address all public comments that we receive by the date specified in the "**DATES**" section of this preamble and respond to them in the preamble to the subsequent final rule that we issue.

List of Subjects in 42 CFR Part 441

Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

42 CFR part 441 is amended as set forth below:

1. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. The table of contents is amended by adding a new Subpart I, Community Supported Living Arrangements Services, and new §§ 441.400 through 441.404 to read as follows:

Sec.

* * * * *

Subpart I—Community Supported Living Arrangements Services

441.400 Basis and purpose.
441.402 State plan requirements.
441.404 Required minimum protections.

3. A new subpart I is added to read as follows:

Subpart I—Community Supported Living Arrangements Services

§ 441.400 Basis and purpose.

This subpart implements section 1905(a)(24) of the Act, which adds community supported living arrangements services to the list of services that States may provide as medical assistance under title XIX (to the extent and as defined in section 1930 of the Act), and section 1930(h)(1)(B) of the Act, which specifies minimum protection requirements that a State which provides community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals must meet to ensure the health, safety and welfare of those individuals.

§ 441.402 State plan requirements.

If a State that is eligible to provide community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals provides such services, the State plan must specify that it complies with the minimum protection requirements in § 441.404.

§ 441.404 Minimum protection requirements.

To be eligible to provide community supported living arrangements services to developmentally disabled individuals, a State must assure, through methods other than reliance on State licensure processes or the State quality assurance programs described under section 1930(d) of the Act, that:

(a) Individuals receiving community supported living arrangements services are protected from neglect, physical and sexual abuse, and financial exploitation;

(b) Providers of community supported living arrangements services—

(1) Do not use individuals who have been convicted of child or client abuse, neglect, or mistreatment, or of a felony involving physical harm to an individual; and

(2) Take all reasonable steps to determine whether applicants for employment by the provider have histories indicating involvement in child or client abuse, neglect, or mistreatment, or a criminal record involving physical harm to an individual;

(c) Providers of community supported living arrangements services are not unjustly enriched as a result of abusive financial arrangements (such as owner lease-backs) with developmentally disabled clients; and

(4) Providers of community supported living arrangements services, or the relatives of such providers, are not named beneficiaries of life insurance policies purchased by or on behalf of developmentally disabled clients.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medical Assistance Program.)

Dated: August 7, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: August 30, 1991.

Louis W. Sullivan,

Secretary.

[FR Doc. 91-22598 Filed 9-23-91; 8:45 am]

BILLING CODE 4120-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 901231-1203]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of finding of non-conformance; correction.

SUMMARY: This action corrects a notice of finding of non-conformance announcing that the Republic of Vanuatu and the Republic of Venezuela submitted documentary evidence establishing that the average rates of incidental taking of marine mammals by their vessels are not comparable to the average rate of incidental taking of marine mammals by U.S. vessels in the course of harvesting yellowfin tuna by purse seine in the eastern tropical Pacific Ocean (ETP). This correction is necessary to clarify that, as a result of the court order of March 26, 1991, only the importation of yellowfin tuna, or products derived from yellowfin tuna, harvested in the ETP by Venezuelan or Vanuatuan purse seine vessels is prohibited.

SUPPLEMENTARY INFORMATION: In rule document 91-19887 beginning on page 41308 in the issue of Tuesday, August 20, 1991, make the following corrections:

1. On page 41308, the last sentence of the **SUMMARY** paragraph should read: "As a result of these findings, yellowfin tuna and yellowfin tuna products harvested by purse seine vessels from Vanuatu and Venezuela operating in the ETP may not be imported into the United States until the Assistant Administrator determines otherwise."

2. On page 41309, in the first column, the last sentence of the first full paragraph should read: "Nevertheless, as a result of the finding of the average incidental taking of marine mammals, yellowfin tuna and yellowfin tuna products harvested by purse seine vessels from Vanuatu or Venezuela operating in the ETP may not be imported into the United States until the Assistant Administrator makes a positive finding to allow such importation."

Dated: September 17, 1991.

Samuel W. McKeen,

Program Management Officer.

[FR Doc. 91-22894 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 56, No. 185
Tuesday, September 24, 1991

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1980

Agricultural Resource Conservation Demonstration Program (Farms for the Future Act of 1990)

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: Farmers Home Administration (FmHA) is issuing regulations to implement section 1465 of the Agriculture, Conservation, and Trade Act of 1990, Public Law 101–624. A national farmland preservation effort is needed to preserve farmland for future generations. The intended effect of this action is to assist states in financing farmland preservation.

DATES: Comments must be submitted on or before October 24, 1991.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Regulations Analysis and Control Branch, Farmers Home Administration, U.S. Department of Agriculture, room 6348, South Agriculture Building, 14th Street and Independence Avenue SW., Washington, DC 20250–0700. All written comments made pursuant to this notice will be available for public inspection during regular working hours at the above address. The reporting and recordkeeping requirements contained in this regulation have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980. Public reporting burden for this collection of information is estimated to vary from 5 minutes to 10 hours per response, with an average of 4.2 hours per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Department of Agriculture, Clearance Officer, OIRM, room 404–W, Washington, DC 20250; and the Office of Management and Budget, Attention: Desk Officer for Farmers Home Administration, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Rick Bonnet, Senior Loan Specialist, Community Facilities Division, Farmers Home Administration, U.S. Department of Agriculture, room 6310, South Agriculture Building, 14th Street and Independence Avenue SW., Washington, DC 20250–0700, telephone (202) 382–1495.

SUPPLEMENTARY INFORMATION:

Classification

This action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291, and has been determined to be significant but nonmajor. The annual effect on the economy is likely to be less than $100 million and will not likely increase costs or prices for consumers, individual industries, organizations, governmental agencies, or geographic regions. In addition, there will likely be no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This action is not expected to substantially affect budget outlay, to affect more than one Agency, or to be controversial. The expected net result is to provide a new service within a State operating under this program. Currently, Vermont appears to be the only State for which funds may be available. Prior to any other State becoming eligible for assistance, there must be provisions therefore made in an appropriations act In order to determine the potential impact if such an appropriation act is passed, FmHA will complete a Regulatory Impact Analysis in accordance with the requirements of Executive Order 12291 and consistent with the guidelines in appendix V of the 1990 Regulatory Program of the United States prior to publication of a final rule for all eligible States other than Vermont. A final rule, effective for Vermont only, may be adopted prior to completion of the Regulatory Impact Analysis.

Intergovernmental Review

This program is not listed in the Catalog of Federal Domestic Assistance. The program is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. FmHA conducts intergovernmental consultation in the manner delineated in FmHA Instructions 1901–H and 1940–J.

Environmental Impact

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." FmHA has determined this action does not constitute a major Federal action significantly affecting the quality of human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

Background

It is perceived that a national farmland protection effort is needed to preserve our national farmland resources for future generations. FmHA was authorized by the Food, Agriculture, Conservation, and Trade Act of 1990 to guarantee loans to assist States in financing such an effort. The program provides for Federal guarantees of timely payments of principal and interest due and substantial interest assistance on 10-year loans made to States and other entities created by States. A number of States currently have programs in which the State purchases development rights from farmers so that the farmland is not subdivided or otherwise developed in perpetuity. The proposed program was fashioned, to some extent, after several of these programs. States are required to share in this effort by contributing an amount equal to at least half the amount of the loan guaranteed by FmHA. Each eligible State may receive up to $10 million in loan guarantees per fiscal year. Loan funds may be invested by the borrower to increase the capital available for farmland preservation.

This proposal defines this new loan guarantee program and establishes procedures for the public and lending institutions to use in applying for loan

guarantees and for FmHA to follow in administering the program.

The Agency is requesting comments on the proposed regulation. Specific comments are also requested on existing programs and alternate methods for protecting farmland through means other than implementation of this program. In addition, comments are specifically requested concerning criteria in the proposed regulation pertaining to eligible loan purposes.

List of Subjects in 7 CFR Part 1980

Agriculture, Loan programs—Agriculture, Rural areas.

Therefore, chapter XVIII, title 7, Code of Federal Regulations is proposed to be amended as follows:

PART 1980—GENERAL

1. The authority citation for part 1980 is revised to read as follows:

Authority: 7 U.S.C. 1989; 7 U.S.C. 4201 note; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart J—Agricultural Resource Conservation Demonstration Program

2. Subpart J of part 1980, consisting of §§ 1980.901 through 1980.1000 and appendices A through D are added as follows:

Subpart J—Agricultural Resource Conservation Demonstration Program

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Appendix A—Form FmHA 1980–75, "Conditional Commitment for Guarantee (Agricultural Resource Conservation Demonstration Program.)"
Appendix B—Form FmHA 1980–76, "Lender's Agreement (Agricultural Resource Conservation Demonstration Program)"
Appendix C—Form FmHA 1980–77, "Loan Note Guarantee (Agricultural Resource Conservation Demonstration Program)"
Appendix D—Form FmHA 1980–78, "Interest Assistance Agreement (Agricultural Resource Conservation Demonstration Program)"

Subpart J—Agricultural Resource Conservation Demonstration Program

§ 1980.901 Introduction.

(a) This subpart contains the regulations for Agricultural Resource Conservation Demonstration Program (ARCDP) loans guaranteed by the Farmers Home Administration (FmHA) and applies to lenders, borrowers, and other parties involved in making, guaranteeing, servicing, or liquidating such loans. This program is commonly referred to as Farms for the Future.

(b) The purpose of the ARCDP is to assist States in financing a farmland protection effort to preserve our vital farmland resources for future generations. This purpose is achieved through the guaranteeing of prompt payments and interest assistance on loans used to purchase development rights easements and other types of easements on farmland, the purchase of farmland in fee simple, and related activities.

(c) The ARCDP is administered by the Administrator through a State Director serving each State. The State Director or his/her designee is the focal point for the program and the local contact person for processing and servicing activities.

§ 1980.902 Definitions.

The following general definitions are applicable to the terms used in this subpart.

Appraisal or Appraisal Report. A written statement independently and impartially prepared by a qualified appraiser setting forth an opinion of defined value of an adequately described property, as of a specific date, supported by the presentation and analysis of relevant market information.

Conditional Commitment for Guarantee. Form FmHA 1980–75, "Conditional Commitment for Guarantee (Agricultural Resource Conservation Demonstration Program)." FmHA's notification to the lender that the material submitted is approved subject to the completion of all conditions and requirements set forth in the Conditional Commitment for Guarantee.

Development rights. The rights of the fee simple owner of farmland to develop, construct on, or otherwise improve agricultural land for uses that result in rendering such land no longer farmland. For purposes of this subpart, mineral rights are considered development rights if their development would render the agriculture land no longer farmland.

Easement. The vehicle by which development rights or other rights are passed from the fee simple owner of farmland to the borrower.

Easement property. The real estate described in the easement.

Farmland. Land which is used, or is suitable for use, in the production of livestock or crops to include prime and unique farmland and additional farmland of Statewide and local importance as defined in appendix A to subpart G of part 1940 of this chapter.

Guaranteed loan. A loan made and serviced by a lender for which FmHA has entered into a Lender's Agreement and issued a Loan Note Guarantee.

Lender. The organization making and servicing the loan which is guaranteed under the provisions of this subpart.

Lender's Agreement. Form FmHA 1980–76, "Lender's Agreement (Agricultural Resource Conservation Demonstration Program)." The signed agreement between FmHA and the lender setting forth the lender's responsibilities when the Loan Note Guarantee is issued.

Loan classification system. The process by which loans are examined and categorized by degree of potential for loss in the event of default.

Loan Note Guarantee. Form FmHA 1980–77, "Loan Note Guarantee (Agricultural Resource Conservation Demonstration Program)." The signed commitment to the lender issued by FmHA setting forth the terms and conditions of the guarantee.

Market Value. The most probable price which a property should bring in a competitive and open market under all conditions requisite to a fair sale. The market value of an easement is the difference in the value of a property with the easement and its value without it. (If a non-profit organization has acquired an easement and wishes to sell it to the borrower, the borrower may elect to reimburse the non-profit organization for the purchase price and actual, reasonable, and customary expenses incidental to the easement's purchase by the non-profit organization.)

Problem loan. A loan which is not performing according to its original terms and conditions or which is not expected to perform according to those terms and conditions in the future.

Proposed Borrower. The entity requesting the loan to be guaranteed under provisions of this subpart.

Protective advance. An advance made by the lender for the purpose of preserving and protecting the collateral where the debtor has failed to, and will not or cannot, meet obligations to protect or preserve collateral Ordinarily, protective advances are made when liquidation is contemplated or in progress. A protective advance will become an indebtedness of the borrower.

Seller. The fee simple owner of farmland who sells development rights and other rights to the borrower for monetary compensation under provisions of this subpart.

State. Any of the fifty States, the Commonwealth of Puerto Rico, and the Virgin Islands of the United States.

State trust fund. A trust fund or account established by a borrower into which guaranteed loan funds and State matching funds are deposited and disbursed for farmland preservation.

§§ 1980.903–1980.909 [Reserved]

§ 1980.910 Eligible loan purposes.

Guaranteed loan funds may be used for the following purposes when in accordance with the State Farmland Preservation Plan prepared by the borrower and approved by FmHA. (See § 1980.918 of this subpart.)

(a) The purchase of development rights easements, conservation easements, other types of easements, and farmland in fee simple. The borrower will pay no more than the market value of the easement or real estate as defined in § 1980.902 of this subpart.

(b) Reasonable and customary real estate appraisal fees, survey fees, and legal costs associated with purchasing and enforcing easements owned by the borrower.

(c) Other uses described by the borrower in the State Farmland Preservation Plan that directly promote a farmland protection effort to preserve farmland for agriculture purposes.

§ 1980.911 Ineligible loan purposes.

Loan funds will not be used to pay administrative costs of the borrower such as salaries, office equipment and supplies, or office lease payments.

§ 1980.912 [Reserved]

§ 1980.913 Transactions which will not be guaranteed.

(a) FmHA will not guarantee any loan on which the interest is excludable from income under section 103 of the Internal Revenue Code of 1954, as amended. FmHA guaranteed loans may not serve as collateral for tax-exempt issues.

(b) A note which provides for payment of interest on interest shall not be guaranteed. Any Loan Note Guarantee attached to, or relating to, a note which provides for payment of interest on interest is void.

§ 1980.914 Availability of credit from other sources.

The inability to obtain credit from other sources is not a requirement for assistance under this subpart.

§§ 1980.915–1980.916 [Reserved]

§ 1980.917 Guarantee fee.

Guarantee fee rates are specified in exhibit K of FmHA Instruction 440.1 (available in any FmHA Office). The fee will be the applicable rate multiplied by the principal loan amount, paid one time only at the time the Loan Note Guarantee is issued. The fee will be paid to FmHA by the lender and is nonrefundable. The fee may be passed on to the borrower.

§ 1980.918 State Farmland Preservation Plan.

Each proposed borrower for each proposed loan must prepare a State Farmland Preservation Plan (Plan) that describes in detail the intended uses of the guaranteed loan funds and State matching funds, as well as the policies and procedures the proposed borrower intends to use in implementing the program. After reviewing the plan for compliance with the regulations, the State Director will ensure that needed changes are made and concur in the Plan. The Plan will be referenced in the Conditional Commitment for Guarantee.

(a) The plan must describe how the proposed borrower will insure that properties selected will have the following characteristics to contribute most to the preservation of the agriculture potential of the area. The borrower should attempt to select properties that:

(1) Contain the largest tracts of farmland available or, are contiguous to other easement properties or fee simple properties owned by the borrower;

(2) Have significant urban pressure; and

(3) Contain the highest percentage of available important farmland as determined by the USDA Soil Conservation Service.

(b) The Plan must describe in detail the restrictions to be imposed by the easements. No proposed activity should result in a material decrease in the acreage or productivity of arable land. If development rights easements are purchased, they:

(1) Must prohibit the subdivision of the property and severely limit the number of dwellings or other structures that can be built on the property;

(2) May require the notification of the borrower prior to the sale of land on which the borrower owns development rights;

(3) May prohibit the dumping of trash, rubbish, or other material on the easement property;

(4) May restrict the use of signs, billboards, or other outdoor advertising structures;

(5) Must address restrictions on the development of mineral rights;

(6) May require the notification and approval of the borrower prior to construction, replacement, or substantial addition to any residence or farm building, in an effort to restrict the formation of "country estates;" and

(7) May impose additional similar restrictions or requirements.

(c) In accordance with exhibit M of subpart G of part 1940 of this chapter, when the easement property contains highly erodible land as identified by the Soil Conservation Service (SCS), a conservation plan of the easement property must be completed by the SCS, followed by the farm operator, and enforced by the borrower. Sellers of easements should be advised that they are considered to be recipients of Federal Assistance, and as such, they are required to comply with the conservation plan and other environmental requirements. If they do not, they may be determined ineligible for other benefits offered by the U.S. Department of Agriculture.

(d) A preliminary hazardous waste site survey must be performed by a qualified firm or individual for each property being considered.

(e) It is intended that all easements will be perpetual. However, the Plan must describe the conditions when the trade or sale and release of an easement will be considered. All sale proceeds must be returned to the State trust fund to be subsequently used for purposes consistent with the Plan.

(f) The Plan must include the method of advising potential sellers of the rights they would be selling and other restrictions that would be imposed. A copy of the proposed agreement or other proposed form of notification must be included.

(g) The Plan must include the procedures for processing applications from prospective sellers of easements of farmland.

(h) The deed of easement will thoroughly describe the restrictions and other requirements being imposed. A copy of the proposed deed of easement must be included as part of the State's plan.

(i) The restrictions and other requirements imposed by the easements must be monitored and enforced. The plan must describe how this will be accomplished including the penalties that will be imposed on violators of provisions of the easements.

(j) The easement must give the borrower and other appropriate parties the right to enter the easement property for inspections and enforcement of the easement provisions.

(k) All appropriate documents must include nondiscrimination language. (See § 1980.943 of this subpart.)

(l) The easement may state that the easement is not intended to grant public access or use of the property.

§ 1980.919 Eligible borrower.

A State or an entity created by a State that:

(a) Operates or administers a land preservation fund that invests funds in the protection or preservation of farmland for agricultural purposes on or before August 1, 1991; and

(b) Works in conjunction with the State, municipalities, counties, districts, or other political subdivisions of a State; private nonprofit corporations or public organizations in the preservation of farmland for agricultural purposes.

§ 1980.920 Legal authority.

The proposed borrower must have or will obtain the legal authority necessary to:

(a) Obtain, pledge security for, and repay the proposed loan;

(b) Acquire development rights easements, other types of easements, and land in fee simple if part of the State Farmland Preservation Plan, and to enforce the restrictions and other conditions imposed by easements in perpetuity.

(c) Perform all other activities described in the State Farmland Preservation Plan.

§ 1980.921 State matching funds requirements.

Each State and/or borrower must contribute an amount equal to at least half the amount of the loan guaranteed by FmHA. Such funds must be in the form of cash and available for use at the time the loan is guaranteed.

(a) The source of the State matching funds must not be an obligation on which the interest is excludable from income under section 103 of the Internal Revenue Code of 1954, as amended.

(b) Funds expended by the borrower and/or State prior to loan closing for purposes consistent with this subpart, and in the same fiscal year, may be considered State matching funds.

(c) Investment earnings of the State trust fund may be considered State matching funds.

§§ 1980.922–1980.925 [Reserved]

§ 1980.926 Eligible lenders.

Eligible lenders, as defined in this section, may participate in loans guaranteed under this subpart. These lenders must be subject to credit examination and supervision by either an Agency of the United States or a State. Only those lenders identified in this section are eligible to make and service guaranteed loans made under this subpart. Such lenders must be in good standing with their licensing authority and have met licensing, loanmaking, loan servicing, and other requirements of the State in which the collateral will be located. A lender must have the capability to adequately service loans for which a guarantee is requested. Eligible lenders include:

(a) Any Federal or State chartered bank or savings and loan association;

(b) Any mortgage company that is a part of a bank holding company;

(c) A Bank of Cooperatives or other Farm Credit System Institution with direct lending authority authorized to make loans of the type guaranteed by this subpart;

(d) An insurance company regulated by a State or National insurance regulatory agency; and

(e) Other lenders that possess the legal powers necessary and incidental to making and servicing guaranteed loans authorized by this regulation that meet the requirements in this section. These types of lenders must be approved by the FmHA Administrator prior to the issuance of the Loan Note Guarantee.

§ 1980.927 Participation of other lenders.

Other eligible lenders may participate in loans made under this subpart. One lender will be the lead lender and will be responsible for servicing and liquidating, if necessary, the entire loan. The lender may use agents, correspondents, branches, financial experts, or other institutions or persons to provide expertise to assist in carrying out its responsibilities. FmHA will use the lead lender as the point of contact.

§§ 1980.928–1980.932 [Reserved]

§ 1980.933 Full faith and credit.

The Loan Note Guarantee constitutes an obligation supported by the full faith and credit of the United States and its incontestable except for fraud or misrepresentation of which the lender has actual knowledge at the time it becomes such lender or which the lender participates in or condones, and the following:

(a) The Loan Note Guarantee will not be honored by FmHA to the extent that

any delinquency or loss is occasioned by violation of usury laws, negligent servicing, or failure to obtain the required security, regardless of the time FmHA acquires knowledge of the foregoing. Negligent servicing is defined as the failure to perform those services which a reasonably prudent lender would perform in servicing its own portfolio of loans that are not guaranteed. The term includes not only the concept of a failure to act, but also not acting in a timely manner contrary to the manner in which a reasonably prudent lender would act; and

(b) The Loan Note Guarantee will not be honored by FmHA to the extent that loan funds are used for purposes other than those specifically approved by FmHA in the Conditional Commitment for Guarantee.

§ 1980.934 Loan limits.

Each State may receive no more than $10 million in loans guaranteed under this subpart per Federal fiscal year.

§ 1980.935 Interest rates.

The interest rate will be a fixed rate set by FmHA. Each loan will bear interest at the rate prescribed in FmHA Instruction 440.1, Exhibit B (available in any FmHA Office). The interest rate will be based on the taxable 10-year treasury rate as published in the Schedule of Certified Interest Rates. The exhibit will be adjusted periodically. All interest rates will be rounded to the nearest one-eighth of 1 percent.

§§ 1980.936–1980.939 [Reserved]

§ 1980.940 Terms of loan repayment.

Principal and interest on the loan will be due and payable as provided in the debt instrument.

(a) All loans made under this subpart will mature ten years from the date of the note.

(b) Accrued interest will be due annually on the anniversary date of the note. The payment of principal will be deferred until the maturity date of the note.

§ 1980.941 Interest assistance.

Form FmHA 1980–78, "Interest Assistance Agreement (Agricultural Resource Conservation Demonstration Program)," will fully document the interest assistance to be provided by FmHA. The lender will advise FmHA of the accrued interest by completing Form FmHA 1980–24, "Request Interest Rate Buydown/Subsidy Payment to Guaranteed Lender." Such subsidy shall be deposited into the trust fund and shall be used solely to pay interest on the loan as it becomes due.

(a) In each of the first 5 years, FmHA will pay to the borrower an amount equal to the annual interest payment due that year.

(b) In each of the sixth through tenth year, FmHA will pay to the borrower a portion of the annual interest payments due that year. This portion will be the greater of:

(1) An amount equal to 3 percentage points of the interest due; or

(2) An amount equal to the difference between the interest due as prescribed in the debt instrument and that charged by FmHA to its Limited Resource Operating Loan borrowers (as prescribed in Exhibit B of FmHA Instruction 440.1, available in any FmHA Office).

§ 1980.942 Environmental requirements.

(a) *Environmental assessment.* FmHA is responsible for assuring that the requirements of subpart G of part 1940 of this chapter are met. FmHA will review the complete application and initiate a Class II environmental assessment. This assessment will focus on the potential cumulative impacts of the easements, and other practices authorized by this subpart that can be identified at the time the assessment is completed.

(b) *Highly erodible land wetlands.* Farmland owners who have sold easements under provisions of this subpart are considered recipients of Federal assistance, and as such, must comply with the provisions of exhibit M of subpart G of part 1940 of this chapter concerning farming highly erodible land and converting wetlands to make possible the production of an agriculture commodity. Compliance with exhibit M by the farmland owners must be established prior to the sale of the easement. FmHA and the lender will be required to monitor compliance and enforce these provisions.

(c) *National Historic Preservation Act of 1966.* The borrower will provide a written statement from the State Historic Preservation Officer (SHPO) to the lender of any effect that can be identified at the time the loan application is submitted, that the practices authorized by this subpart will have on any district, site, structure, or object that has been or is eligible to be included in the National Register of Historic places. (See subpart F of part 1901 of this chapter.) The SHPO will be afforded the opportunity to establish a process with the borrower by which the SHPO will be able to review individual properties for National Register purposes as properties are selected by the borrower.

§ 1980.943 Equal opportunity and nondiscrimination requirements.

In accordance with the Equal Credit Opportunity Act, title V of Public Law 93–495, with respect to any aspect of a credit transaction, neither the lender nor FmHA will discriminate against any borrower or proposed borrower, and the borrower will not discriminate against a proposed seller of rights or property on the basis of race, color, religion, national origin, age, sex, marital status, or physical/mental handicap, providing the person can execute a legal document. The lender will comply with the requirements of this act as set forth in the Federal Reserve Board's Regulation implementing this act. (See 12 CFR part 202). Such compliance will be accomplished prior to loan closing.

§ 1980.944 Other Federal, State, and local requirements.

(a) In addition to the specific requirements of this subpart, proposals will be coordinated with all appropriate Federal, State, and local agencies.

(b) Effective with the issuance of the Loan Note Guarantee, borrowers and lenders are required to comply with all applicable Federal, State, or local laws; regulatory commission rules; ordinances; and regulations which are presently in existence or may be later adopted, including, but not limited to, those governing the following:

(1) Borrowing money, pledging security, and raising revenues for loan repayment;

(2) Land use zoning; and

(3) Protection of the environment.

§§ 1980.945–1980.947 [Reserved]

§ 1980.948 Economic feasibility requirements.

All loans made under the provisions of this subpart must be based on taxes, assessments, or other satisfactory sources of revenue in an amount sufficient to provide for operating expenses and debt repayment.

§ 1980.949 [Reserved]

§ 1980.950 Security requirements.

(a) The lender is responsible for seeing that proper and adequate security is obtained and maintained in existence and of record to protect the interests of the lender and FmHA.

(b) Security must be of such a nature that repayment of the loan is reasonably assured. The security may include, but is not limited to, general obligation bonds, pledge of taxes or assessments, real estate, and cash and other accounts.

(c) Easements and agriculture land purchased with loan funds may not be pledged as security.

§ 1980.951 Appraisal reports.

Appraisal reports prepared in accordance with industry standards and the Fee Appraisers Foundation by independent third party fee appraisers will be required for all real estate related transactions.

(a) The State Director may modify this requirement by permitting the appraisal to be made by a qualified appraiser on the lender's or borrower's staff, as appropriate, with experience appraising the type of property involved when:

(1) The value of an easement or tract of farmland to be purchased with loan funds is $250,000 or less; or

(2) Real estate is offered for security and its value is $1 million or less.

(b) The lender will be responsible for assuring that appropriate appraisals are made and the fees are reasonable.

(c) The lender will require the borrower to forward copies of all appraisals to the lender. All appraisals will become a permanent part of the lender's file.

§ 1980.952 Fees and charges by the lender.

(a) *Routine charges and fees.* The lender may establish the charges and fees for the loan provided they are the same as those charged other applicants for similar types of transactions. "Similar types of transactions" include similar non-guaranteed loans.

(b) *Late payment charges.* Late payment charges will not be covered by the guarantee and will not be added to the principal and interest due. Late payment charges may be assessed only if:

(1) They are routinely made by the lender in all types of loan transactions;

(2) The payment in cash, check, money order, wire transfer, or similar medium has not been received by the lender at its main office, branch office, or other designated place of payment; and

(3) The lender agrees with the borrower in writing that late payment charges will not be increased while the Loan Note Guarantee is in effect.

§§ 1980.953–1980.955 [Reserved]

§ 1980.956 Preapplication processing.

The State Office will assist proposed borrowers, as needed, in completing Standard Form (SF) 424.1, "Preapplication for Federal Assistance" and in filing written notice of intent and request for priority recommendation with the approprite clearinghouse.

(a) *Contents of preapplication package:*

(1) Copy of SF–424.1, "Preapplication for Federal Assistance";

(2) Supporting documentation necessary to make an eligibility determination, including at a minimum:

(i) Copies of the proposed borrower's last five year's financial statements or audits, when available;

(ii) Copies of the proposed borrower's organizational documents;

(iii) Evidence that a farmland preservation program was being operated or administered on August 1, 1991;

(iv) Any credit reports on the proposed borrower obtained by the lender or FmHA;

(v) State Historic Preservation Officer Comments; and

(vi) Copy of a certification from the proposed borrower certifying whether it is in default or delinquent on Federal debt.

(3) Eligibility determination and recommendations.

(b) *Delinquency on Federal debt.*

(1) If the proposed borrower is in default or delinquent on Federal debt, the application for guarantee will be rejected and the proposed borrower will be notified in accordance with § 1980.990 of this subpart and § 1900.55 of subpart B of part 1900 of this chapter.

(2) If the delinquency or default has been resolved, it must be verified by the Federal Agency owed the debt. If the delinquency has not been resolved, the Administrator of FmHA, or designee, may waive the nondelinquent requirement upon specific determination that it is in the best interest of the Government to do so.

(c) *Request for complete application.* If preapplication information indicates the proposal is ineligible, does not have sufficient priority or guarantee authority, or funds are not available, FmHA will inform the lender and proposed borrower in writing in accordance with § 1980.990 of this subpart and § 1900.55 of subpart B of part 1900 of this chapter. If it appears the proposal is eligible, has sufficient priority, is economically feasible, and funds and loan guarantee authority are available, FmHA will inform the lender and proposed borrower in writing and request that they complete the application. The lender must be informed that an environmental review has not been conducted and no major commitment should be made that could affect the consideration of alternatives.

§ 1980.957 Application processing.

(a) *Application conference.* When a lender is notified to proceed with an application, the State Director will arrange for a conference with the lender and proposed borrower to provide copies of appropriate appendices and forms and furnish guidance necessary for orderly application processing. FmHA will confirm decisions made at this conference by letter to the lender and proposed borrower. The State Director will arrange for additional conferences as needed.

(b) *Contents of application package.*—(1) Form FmHA 1980–74, "Application for Loan and Guarantee (Agricultural Resource Conservation Program)."

(2) Proposed loan agreement containing at least the following:

(i) Proposed security;

(ii) Proposed borrower's financial projections including the plan for loan repayment;

(iii) Requirements for accounting and recordkeeping and periodic financial reporting.

(3) State Farmland Preservation Plan (see § 1980.918 of this subpart).

(4) Appraisal reports (as appropriate).

(5) Evidence that the required State matching funds will be available when needed.

(6) Complete environmental assessment including supporting documentation.

(7) Form FmHA 1910–11, "Applicant Certification Federal Collection Policies for Consumer or Commercial Debts."

(8) Copies of any necessary certifications and recommendations of appropriate regulatory or other agencies having jurisdiction.

(9) SHPO/borrower agreement for review of individual properties for National Register purposes, if applicable.

(10) Any additional information as may be required by the State Director.

(c) *Review of decision.* (1) FmHA will complete Form FmHA 1942–43, "Project Summary Community Facilities (Other Than Utility-type Projects)." A determination will be made as to whether the proposed borrower is eligible, the proposed loan is for eligible purposes, there is reasonable assurance of repayment ability, security is sufficient, the proposed loan complies with all applicable statutes and regulations, and adequate funds are available. If FmHA decides to conditionally commit to guaranteeing the loan, it will provide the lender and proposed borrower with the Conditional Commitment for Guarantee, listing all conditions for the guarantee and a full description of the approved uses of guaranteed loan funds as described in the State Farmland Preservation Plan. This may be by reference to the Plan.

(2) If at any time prior to issuance of the Conditional Commitment for Guarantee, FmHA decides that favorable action will not be taken, the State Director will notify the lender in writing of the reasons why the request was not favorably considered. The notification will state that a review of this decision by FmHA may be requested by the lender under § 1980.990 of this subpart and subpart B of part 1900 of this chapter. The Federal Agency that administers compliance with this law is the Federal Trade Commission, Equal Credit Opportunity, Washington, DC 20580.

(3) All loan guarantee applications must be approved or disapproved, and the lender notified in writing, within 60 days of receipt of a completed application.

(i) If an application is not complete, FmHA will provide the lender with a written listing of the items missing, within 20 days of receipt of the application.

(ii) When a decision to disapprove an application is reversed or revised by an appeal, FmHA will notify the lender or the action within 15 days after the reversal/revision decision is made.

(4) The State Director will send copies of the following documents to the National Office Community Facilities Division within 30 days after the Conditional Commitment for Guarantee has been accepted:

(i) Project Summary, Form FmHA 1942–43;

(ii) Executed Lender's Agreement, Form FmHA 1980–76;

(iii) Executed Conditional Commitment for Guarantee (with attachments) accepted by the lender and proposed borrower, Form FmHA 1980–75;

(iv) Proposed loan agreement between the lender and proposed borrower;

(v) Application for Loan and Guarantee, Form FmHA 1980–74; and

(vi) Lender Certification required by § 1980.966(a) of this subpart, if the Loan Note Guarantee has been issued. If it has not been issued, provide a proposed date for its issuance in the cover memorandum.

§ 1980.958 Case and identification numbers.

(a) *Case Number.* The case number will be the proposed borrower's Internal Revenue Service Taxpayer Identification (Tax ID) Number, preceded by the State and county code numbers. FmHA will provide the lender with these numbers. Only one case number will be assigned to each borrower regardless of the number of loans it has, unless an exception is granted by the National Office.

(b) *Temporary ID numbers.* When a proposed borrower has not received a Tax ID Number, FmHA will assign a temporary ID number. See the Forms Manual Insert (FMI) for Form FmHA 1940–3, "Request for Obligation of Funds (Guaranteed Loans), " for specific instructions. Any temporary ID number assigned by FmHA must be replaced with the Tax ID Number prior to issuing the Loan Note Guarantee, unless prior approval of the National Office is received.

(c) *ID number of lender.* The lender's Tax ID Number will be used as its ID number in correspondence and FmHA forms relating to the guarantee.

§ 1980.959 Loan approval, issuing the Conditional Commitment for Guarantee, and obligating funds.

(a) The State Director's loan approval authority (including the conditions cited in Exhibit B of FmHA Instruction 1901–A, available in any FmHA Office) is the same as for Guaranteed Domestic Water Loans.

(b) The State Director will prepare an original and two copies of Form FmHA 1940–3 for each loan to be obligated. The State Director will sign the original and one copy and conform the second copy. The form will not be mailed to the Finance Office. FmHA will prepare and execute Form FmHA 1980–75, and notify the lender of the approval by forwarding signed copies of Form FmHA 1940–3 and the Conditional Commitment for Guarantee to the lender on the obligation date, unless the Administrator has given the Finance Office prior authorization to obligate before the 6-day reservation period, and directs the State Director to forward Form FmHA 1940–3 to the lender prior to issuing of the Conditional Commitment for Guarantee. The State Director will record the actual date of lender notification on the original Form FmHA 1940–3 and retain the original and remaining conformed copy. The State Office terminal will be used to request the reservation/obligation of funds. When the State Office terminal is inoperative and will be for a significant period of time or during emergency situations, the State Office will request the Finance Office to reserve/obligate the funds. Any specific security, processing, or reporting requirements will be addresses at the time of the telephone call.

§§ 1980.960–1980.962 [Reserved]

§ 1980.963 Funding applications.

In order to ensure the equitable distribution of funds available for loan guarantees under this subpart, the National Office will retain the entire appropriation in the National Office. All complete applications received from eligible borrowers by July 1 of each fiscal year will be evaluated and funded subject to the availability of funds.

§ 1980.964 Projects Requiring National Office review.

The following will be submitted to the National Office when the loan guarantee exceeds the State Director's approval authority:

(a) Transmittal memorandum including:

(1) State Director's recommendation;

(2) Date of expected obligation; and

(3) Any unusual circumstances;

(b) Preapplication package;

(c) Items 1 through 6 and 10 of the application package; and

(d) Project Summary (Form FmHA 1942–45).

§ 1980.965 Review of requirements of the Conditional Commitment for Guarantee.

(a) Immediately after reviewing the conditions and requirements in the Conditional Commitment for Guarantee, the lender and proposed borrower should complete and sign the "Acceptance of Conditions" section of the form and return a copy to FmHA. If certain conditions cannot be met, the lender and proposed borrower may propose alternate conditions to FmHA.

(b) If the lender subsequently decides that it no longer wants a guarantee, the lender will immediately advise FmHA.

§ 1980.966 Conditions precedent to issuing the Loan Note Guarantee

(a) *Lender certification.* The lender must certify that:

(1) No major changes have been made in the lender's loan conditions and requirements since the issuance of the Conditional Commitment for Guarantee, except those approved in the interim by FmHA in writing;

(2) Truth in lending requirements, if applicable, have been met;

(3) All equal employment opportunity and nondiscrimination requirements have been or will be met at the appropriate time.

(4) The loan has been properly closed, and the required security instruments have been obtained;

(5) The borrower has marketable title to the collateral, subject only to the instrument securing the guaranteed loan and other exceptions approved in writing by FmHA;

(6) Lien priorities are consistent with requirements of the Conditional Commitment for Guarantee;

(7) All other requirements of the Conditional Commitment for Guarantee have been met;

(8) If any advances have occurred, they were made for purposes consistent with the Conditional Commitment for Guarantee and as specified in the Form FmHA 1980–74, "Application for Loan and Guarantee." A copy of a detailed loan settlement statement of the lender will be attached to support this certification; and

(9) There has been no adverse change(s) in the proposed borrower's financial condition nor any other adverse change in the proposed borrower during the period of time from FmHA's issuance of the Conditional Commitment for Guarantee to issuance of the Loan Note Guarantee. The lender's certification must address all adverse changes of the proposed borrower and its guarantors not more than 60 days old at time of certification.

(b) *Execution of Lender's Agreement.* The lender has executed and delivered the Lender's Agreement, Form FmHA 1980–76, to FmHA.

(c) *Changes in Conditional Commitment for Guarantee.* Once the Conditional Commitment for Guarantee is issued and accepted by the lender and proposed borrower, only minor changes will be considered unless otherwise provided for in this subpart.

(d) Preguarantee review. Conincident with, or immediately after, loan closing the lender will contact FmHA and provide those documents and certifications required in § 1980.966(a) of this subpart. For any loans involving bonds, the opinion of a recognized bond counsel will be reviewed to determine the adequacy of the bonds issued or to be issued. Only when the State Director is satisfied that all conditions for the guarantee have been met will the Loan Note Guarantee be executed.

(e) *Title for land, rights-of-way, and easements.* When real estate is offered for security and when applicable, the lender must certify that the borrower has obtained:

(1) A legal opinion that ensures that the borrower has obtained valid, continuous, and adequate rights-of-way and easements; and

(2) A title opinion by the borrower's attorney showing ownership of the land and all mortgages or other lien defects, restrictions, or encumbrances, if any. It is the lender's responsibility to obtain and record any releases, consents, or subordinations, etc., as may be necessary. All title opinions will be come a part of the file.

(f) *Review by OGC.* The State Director will forward the loan docket to the Office of the General Counsel (OGC) for review prior to issuing the Loan Note Guarantee, but after the Conditional Commitment for Guarantee has been issued and after the lender's proposed closing documents with lender's legal counsel's opinion have been received by FmHA. The State Director will include with the docket a letter identifying any items, documents, or problems that may have a significant impact on the loan or guarantee or may be contrary to the regulations and need to be specifically addressed. Copies of the following documents should be submitted to OGC for review:

(1) National Office letter concurring in the loan guarantee (if applicable);

(2) Form FmHA 1980–85, "Conditional Commitment for Guarantee," including any amendments;

(3) Loan agreement;

(4) Proposed promissory notes and/or bond transcripts;

(5) Proposed security instruments;

(6) Proposed Form FmHA 1980–76, "Lender's Agreement";

(7) Proposed lender certifications as required by § 1980.966(a) of this subpart; and

(8) Opinion of lender's counsel in form prescribed by OGC.

(g) *OGC advice.* OGC will review the docket and furnish advice to FmHA on whether it should issue the Loan Note Guarantee once the loan is closed. Such advice is for the benefit of FmHA only and does not relieve the lender of any of its responsibilities under FmHA regulations. Any deficiencies noted by OGC will be corrected prior to issuing the Loan Note Guarantee.

(h) *Loan closing.* The lender will notify FmHA when the date for loan closing has been established.

(i) *Substitution of borrower.* FmHA will not issue a Loan Note Guarantee to a lender who is in receipt of a Conditional Commitment for Guarantee with an obligation in a previous fiscal year, if the originally approved proposed borrower (including changes in legal entity) is changed. All requests for exceptions must be approved by the FmHA National Office.

(j) *Inspections.* The lender will notify FmHA of any scheduled field inspections. FmHA may attend such field inspections. Any inspections or review conducted by FmHA, including those with the lender, are for the sole benefit of FmHA. FmHA inspections do not relieve any parties of interest of their responsibilities to conduct necessary inspections, nor can these parties rely on FmHA's inspections in any manner whatsoever.

§ 1980.967 Substitution of lender.

With prior written concurrence of the FmHA Administrator, the State Director may approve the substitution of a new eligible lender in place of a lender who holds an outstanding Conditional Commitment for Guarantee (where Loan Note Guarantee has not yet been issued), provided there are no changes in the proposed borrower, State Farmland Preservation Plan, loan conditions, and loan agreements. To effect such a substitution, the former lender will provide FmHA with a letter stating the reasons it no longer desires to be a lender. The substituted lender will execute a new part "B" of the Application for Loan and Guarantee. If approved by FmHA, the Administrator will issue a letter of amendment to the original Conditional Commitment for Guarantee, reflecting the new lender who will acknowledge acceptance of the letter or amendment in writing. The State Director will complete Form FmHA 1980–42, "Notice of Substitution of Lender."

§ 1980.968 Issuance of Lender's Agreement, Loan Note Guarantee, and Interest Assistance Agreement.

(a) *Lender's Agreement.* If FmHA finds that all requirements have been met, the lender and FmHA will execute Form FmHA 1980–76. The original will be delivered to FmHA and a signed duplicate original retained by the lender. There will be a Lender's Agreement executed for all loans guaranteed by FmHA.

(b) *Loan Note Guarantee.*

(1) Upon receipt of the executed Lender's Agreement and after all requirements have been met, FmHA will execute the Loan Note Guarantee, Form FmHA1980–77. The original will be retained by the lender and attached to the original note. A conformed copy with a conformed copy of the note attached will be retained by FmHA.

(2) If the lender has selected the multi-note system as provided in the Lender's Agreement, a Loan Note Guarantee will be prepared and attached to each note the borrower issues. All the notes will be listed on each Loan Note Guarantee.

(3) If the lender requests a series of new notes to replace previously issued guaranteed notes as provided in the Lender's Agreement, the State Director may reissue new Loan Note Guarantees in exchange for the original Loan Note Guarantees.

(c) *Interest Assistance Agreement.* Form FmHA 1980–78, will be executed concurrently with the Loan Note Guarantee.

(d) *FmHA's refusal to execute the Loan Note Guarantee.* If FmHA determines that it cannot execute the Loan Note Guarantee because all requirements have not been met, it will promptly inform the lender of the reasons, giving a reasonable period within which to satisfy FmHA objections. If the lender writes FmHA within the period allowed requesting additional time to satisfy the objections. FmHA may, in writing, grant any additional time it considers necessary and reasonable. If the lender is unable to satisfy FmHA objections, the lender will be informed of its appeal rights as set out in § 1980.990 of this subpart and subpart B of part 1900 of this chapter.

(e) *Cancellation of obligation.* If the conditions for the loan are rejected or cannot be met after completion of any appeal, FmHA will cancel the obligation using Form FmHA 1940–10, "Cancellation of U.S. Treasury Check and/or Obligation."

(f) *Payment of guarantee fee.* The lender will prepare a Form FmHA 1980–19, "Guaranteed Loan Closing Report," for each loan to be guaranteed, and deliver with the guarantee fee to the FmHA representative who concurrently delivers the Loan Note Guarantee. The State Office will enter guarantee fees received on Form FmHA 541–2, "Schedule of Remittances," and process in accordance with subpart B of part 1951 of this chapter.

(g) *FmHA representatives authorized to execute forms.* State Directors and, if delegated by the State Director, Community Programs and Community and Business Programs Chiefs are authorized to execute the Lender's Agreement, Loan Note Guarantee, and Interest Assistance Agreement.

§§ 1980.969–1980.971 [Reserved]

§ 1980.972 Closing requirements for easements and farmland in fee simple.

To assist the lender in monitoring the use of funds, at a minimum, the borrower will submit the following to the lender, as appropriate:

(a) A final title opinion prepared by an attorney certifying the following within 30 days following the closing, as appropriate:

(1) The easement is valid, perpetual, and enforceable;

(2) The owner of the easement has continuous and adequate rights-of-way to the easement property so that restrictions and other requirements can be monitored;

(3) Any releases and consents have been obtained from lienholders and others necessary to certify the title; and

(4) If the owner of the easement or property is not a State, in the event of dissolution of the owner's organization or for other reason the owner is unable or unwilling to enforce the provisions of the easement, the easement or property will pass to the State or other entity selected by the State that is involved in the preservation of farmland for agricultural purposes. FmHA must concur in any change of ownership.

(b) A copy of the settlement statement;

(c) A copy of the appraisal of the property completed in accordance with § 1980.951 of this subpart;

(d) A copy of a plat of the property including a location map. A survey is required if a plat of the easement property is not available;

(e) A copy of a United States Department of Agriculture SCS conservation plan completed prior to closing when the property contains highly erodible land as identified by the SCS.

(f) A certification by the landowner that he will remain in compliance with the environmental requirements in Exhibit M of subpart G of part 1940 of this chapter and, as applicable, the SCS conservation plan; and

(g) In accordance with the agreement between the borrower and the SHPO, as appropriate, comments of the SHPO.

§ 1980.973 Disbursement of funds.

The lender is responsible for assuring that guaranteed loan funds are disbursed properly.

(a) Guarantee loan funds will be disbursed by the lender only as needed.

(1) The borrower will request funds as easements or property is optioned.

(2) The lender will advance the Federal share of the option price after verifying that the required State matching funds are on deposit in the State trust fund. The lender will advance funds no more than 180 days prior to the proposed closing date of the easement.

(b) In some instances, prior to closing the guaranteed loan, the State may expend funds for easements and related uses consistent with this subpart. The lender may consider such expenditures that are within the same fiscal year as State matching funds and advance the Federal share as properties are optioned.

(c) Guaranteed loan funds advanced by the lender may be invested by the borrower for up to 180 days to accumulate additional capital to be subsequently used to promote a farmland preservation effort consistent with the approved State Farmland Preservation Plan. This investment income will become a part of the State Trust Fund and may be used as State matching funds.

(d) When the borrower and seller agree to the paying of the selling price being spread out over time, the lender may advance guaranteed loan funds as if the full selling price were fully advanced to the seller at closing.

(e) When subsequent draws of loan funds are requested by the borrower, the lender will consider previous advances when either of the following situations exist and reduce the borrower's request by the Federal share of these options.

(1) Cancelled and expired option for which funds have been advanced;

(2) More than 180 days have elapsed since the lender advanced funds for an option and the easement or property has not closed

(f) Prior to closing a subsequent loan in a subsequent year, the borrower will provide evidence that all funds of any outstanding guaranteed loan made under this subpart, plus required State matching funds, have been utilized for purposes consistent with this subpart.

§ 1980.974 [Reserved]

§ 1980.975 Loan servicing.

In accordance with the lender's loan agreement, the lender will be responsible for servicing the entire loan, including any advances made to the lender by FmHA under its guarantee of timely payments in accordance with the Loan Note Guarantee. The lender will notify FmHA of any violations of the lender's loan agreement.

(a) The lender will require, at a minimum, annual audited financial statements which will be reviewed by the lender and a copy forwarded to the FmHA State Office with a summary evaluation by the lender. After receipt of the evaluation, the State Director will determine if a joint FmHA, lender, and borrower visit will be necessary. Lender visits to the borrower will be conducted at least once every 3 years but may be scheduled more frequently if conditions warrant. Borrowers with problem loans will be visited by the lender at least annually.

(b) The lender will make an initial visit to the borrower within the first 6 months following the initial loan closing to review the borrower's accounts and procedures.

(c) The State Director will meet annually with each lender or his/her agent with whom a loan guarantee is outstanding to review the lender's performance and determine if any future actions are needed. FmHA will document the meeting in the running

record of each borrower serviced by the lender and followed with a letter to the lender.

§ 1980.976 Lender reports.

In addition to other lender requirements, the lender will furnish the following to the State Director on an annual basis.

(a) Listing of easements and properties closed including:

(1) Purchase price of each easement or property and the amount of guaranteed and State matching funds used;

(2) Numbers of acres under each easement or property;

(3) Location of each easement or property; and

(4) Date of each option and date of each advance of guaranteed loan funds.

(b) Copy of the option for each easement or property that has not yet closed but for which guaranteed loan funds have been advanced to the borrower.

(c) If available to the lender, copies of appropriate ledgers and other financial statements of the borrower.

§ 1980.977 Access to lender's records.

The lender will permit representatives of FmHA and other agencies of the USDA authorized by that Department to inspect and make copies of any of the records of the lender pertaining to loans guaranteed by FmHA. Such inspection and copying may be made during the regular office hours of the lender, or any other time the lender and FmHA find convenient.

§ 1980.978 [Reserved]

§ 1980.979 Loan classification.

All guaranteed loans made under this subpart will be classified by FmHA at loan closing and again whenever there is a change in the loan which would impact on the original classification. The loans will be classified as set out at § FmHA Instruction 1904–C (available in any FmHA Office).

§ 1980.980 Sale or assignment of guaranteed loan.

Loans guaranteed under provisions of this subpart may not be sold or assigned by the lender to any other lender or investor except to FmHA at FmHA's request.

§ 1980.981 Defaults by borrower.

FmHA will 100 percent guarantee the timely payment of principal and interest due on loans guaranteed under provisions of this subpart.

(a) In case of monetary default or significant non-monetary default, the lender will negotiate with the borrower in good faith in an attempt to resolve the problem and cure the default. If unsuccessful, the lender will arrange a meeting with FmHA and the borrower. A memorandum of the meeting, listing the individuals in attendance and summarizing the problem and proposed solution will be prepared by FmHA and retained in the FmHA loan file. When a solution to a delinquency cannot be reached within 60 days of the payment due date, and when requested by the lender in writing using Form FmHA 449–30, "Loan Note Guarantee Report of Loss," FmHA will request funds from the Finance Office to pay the delinquency. Any late payment charges will not be paid by FmHA. The check will be made payable to the lender.

(1) Such advance must be considered an indebtedness of the borrower and will accrue interest at the note rate.

(2) Any such advance is immediately due and payable. It is the lender's responsibility to collect advances from the borrower and promptly remit to FmHA.

(3) The loan will be considered a problem loan until the advance and accrued interest on such advance are fully repaid by the borrower.

(b) The State Director will report all delinquent and problem loans quarterly to the National Office Community Facilities Division by the 20th day of January, April, July, and October.

§ 1980.982 Liquidation.

Liquidation will be conducted in accordance with the Lender's Agreement.

(a) When either the lender or FmHA determines that liquidation is necessary, the lender will prepare a liquidation plan. The State Director will forward the lender's liquidation plan, along with appropriate recommendations and exceptions to the plan, to the National Office Community Facilities Division. Guidance will be provided by the National Office.

(b) Within delegated authorities, the State Director may approve a written partial liquidation plan submitted by the lender covering collateral that must be immediately protected or cared for to preserve or maintain its value. Approval of the partial liquidation plan must be in the best interest of the government. The approved partial liquidation plan is only good for those actions necessary to immediately preserve and protect the collateral and must be followed by a complete liquidation plan prepared by the lender.

(c) FmHA will exercise its option to liquidate only when there is reason to believe the lender is not likely to initiate liquidation efforts that will result in maximum recovery. The State Director has no authority to exercise this option without National Office approval.

§ 1980.983 Protective advances.

Protective advances may be made in accordance with the Lender's Agreement.

(a) Within delegated authorities, the State Director may approve protective advances in writing. Advances must be reasonable when associated with the value of collateral being preserved.

(b) When considering protective advances, sound judgment must be exercised in determining that the additional funds advanced will actually preserve collateral interests and recovery is actually enhanced by making the advance.

§§ 1980.984–1980.986 [Reserved]

§ 1980.987 Transfers and assumptions.

(a) *General.* It is the policy of FmHA to approve transfers and assumptions of loans to transferees who will continue the original purpose of the guaranteed loan. All transfers and assumptions will be approved in writing by FmHA. Transfers and assumptions may be approved subject to the following:

(1) The present borrower is unable or unwilling to accomplish the objectives of the guaranteed loan.

(2) The entire unpaid balance on the guaranteed loan is assumed by the new borrower.

(3) All funds in the State Trust Fund are transferred to the new borrower.

(b) *Eligible borrowers.* (1) The total indebtedness must be transferred to an eligible borrower on the same terms.

(2) A guaranteed loan for which the transferee is eligible may be made in connection with a transfer.

(c) *Transfer fees.* Transfer fees are a one-time nonrefundable cost to be collected by the lender at the time of application or proposal.

(1) *Amount.* The transfer fees will be a standard fee plus the cost of the appraisal, as applicable. This fee will be established by the FmHA National Office and issued annually to all FmHA State Offices for further distribution.

(2) *Remittance.* The lender will collect and submit the fee to the FmHA State Office. The FmHA State Office will submit the fee to the Finance Office identified as a transfer fee using Form FmHA 451–2, "Schedule of Remittance."

(3) *Waiver.* When the State Director determines waiving the transfer fee is in the best interest of the Government, the file will be submitted to the National Office with appropriate recommendations for the request.

(d) *Processing transfers and assumptions.* (1) In any transfer and

assumption case, the transferor, may be released from liability by the lender with FmHA written concurrence, only when the value of the collateral being transferred is at least equal to the amount of the loan or part of the loan being assumed.

(2) The lender will issue a statement to FmHA that the transaction can be properly transferred and the conveyance instruments will be filed, registered, or recorded as appropriate and legally permissible.

(3) The State Director may approve all transfer and assumption provisions, including the transferor's release from liability, if the guaranteed loan debt balance is within his/her loan approval authority.

Note: The assumption will be reviewed as if it were a new loan. The Loan Note Guarantee(s) will be endorsed in the space provided on the form(s).

(4) A copy of the Assumption Agreement will be retained in the FmHA file. The State Director will notify the Finance Office of all approved transfer and assumption cases on Form FmHA 1980–7, "Notification of Transfer and Assumption of a Guaranteed Loan," and submit Form FmHA 1980–50, "Add, Delete, or Change Guaranteed Loan Borrower Information," for all new borrowers and Form FmHA 1980–51, "Add, Change, or Delete Guaranteed Loan Record," in order that Finance Office records may be adjusted accordingly.

(5) If the guaranteed loan debt balance is in excess of the State Director's loan approval authority, the State Director will forward the file, together with his/her recommendations, to the National Office Community Facilities Division for approval.

(6) The assumption will be made on the lender's form of assumption agreement and will contain the FmHA case number of the transferor and transferee.

(7) Loan terms cannot be changed.

(8) In the case of a transfer and assumption, it is the lender's responsibility to see that all such transfers and assumptions will be noted on all originals of the Loan Note Guarantee(s). The lender will provide FmHA a copy of the transfer and assumption agreement. Notice must be given by the lender to FmHA before any borrower or guarantor is released from liability.

(e) *Submission to National Office.* (1) All proposed transfers or assumptions will be forwarded to the National Office for prior review and approval before making any commitments.

(i) Transfer case file;

(ii) OGC comments on the proposed transfer or assumption;

(iii) Appropriate forms to complete the transfer prepared by the transferee;

(iv) Completed environmental review; and

(v) Any other necessary supporting information.

§ 1980.988 Bankruptcy.

(a) It is the lender's responsibility to protect the guaranteed loan and all the collateral securing it in bankruptcy proceedings. These responsibilities include, but are not limited to, the following

(1) The lender will file a proof of claim, when necessary, and all the necessary papers and pleadings concerning the case.

(2) The lender will attend and, when necessary, participate in meetings of the creditors and all court proceedings.

(3) The lender, whose collateral is subject to being used by the trustee in bankruptcy, will immediately seek adequate protection of the collateral.

(4) When appropriate, the lender should seek dismissal of the proceedings.

(5) FmHA will be kept adequately and regularly informed, in writing, of all aspects of the proceedings.

(b) Activities related to bankruptcy proceedings are considered loan servicing. The related expenses are the responsibility of the lender.

(c) In bankruptcy, if an independent appraisal is necessary in FmHA's opinion, FmHA and the lender will share such appraisal fee equally.

(d) The State Director should report all bankruptcy cases immediately to the National Office by forwarding a copy of Form FmHA 1980–44, Guaranteed Loan Borrower Default Status. The State Director must keep OGC informed of the proceedings.

§ 1980.989 State Director's additional authorizations and guidance.

Any proposed servicing actions which the State Director or lender is not authorized by this subpart to approve, will be referred to the Administrator, Attention: Community Facilities Division.

§ 1980.990 Appeals.

Only the borrower or proposed borrower and lender can appeal FmHA decisions. The borrower and lender must jointly execute the written request for review of the decision made by FmHA, and both parties must participate in the appeal. A decision by the lender which may be adverse to the interest of the borrower or proposed borrower is not a decision by FmHA, even when concurred in by FmHA. Appeals will be handled in accordance with subpart B of part 1900 of this chapter.

§§ 1980.991–1980.994 [Reserved]

§ 1980.995 Replacement of loss, theft, destruction, mutilation, or defacement of Form FmHA 1980–77, Loan Note Guarantee.

Except where the evidence of debt was or is a bearer instrument, the FmHA State Director is authorized, on behalf of FmHA, to issue a replacement Loan Note Guarantee(s) to the lender upon receipt of an acceptable certificate of loss and an indemnity bond. After the required documentation has been received, the State Director will review all documents presented by the lender to assure all requirements are met and consult with OGC to assure that all documents are of legal sufficiency before the reissuance of the Loan Note Guarantee(s).

(a) A certificate of loss properly notarized should include:

(1) Legal name and present address of the owner who is requesting the replacement forms;

(2) Legal name and address of lender of record;

(3) Capacity of person certifying;

(4) Full identification of the Loan Note Guarantee including the name of the borrower, FmHA case number, date of the Loan Note Guarantee, face amount of the evidence of debt purchased, date of evidence of debt, present balance of the loan, and percentage of guarantee. Any existing parts of the document to be replaced should be attached to the certificate; and

(5) A full statement of circumstances of the loss, theft, or destruction of the Loan Note Guarantee.

(b) An indemnity bond acceptable to FmHA shall accompany the request for replacement except when the holder is the United States, a Federal Reserve Bank, a Federal Government Corporation, a State or Territory, or the District of Columbia. The bond shall be with surety except when the outstanding principal balance and accrued interest due the present holder is less than $1,000,000 verified by the lender in writing in a Letter of Certification of balance due. The surety shall be a qualified surety company holding a certificate of authority from the Secretary of the Treasury and listed in Treasury Department Circular 580.

(c) All indemnity bonds must be issued and/or payable to the United States of America acting through the FmHA. The bond shall be in an amount not less than the unpaid principal and interest. The bond shall save FmHA

harmless against any claim or demand which might arise or against any damage, loss, costs, or expenses which might be sustained or incurred by reasons of the loss or replacement of the instruments.

(d) In those cases where the guaranteed loan was closed under the "Multi-Note System" provisions of Lender's Agreement, FmHA will not attempt to or participate in the obtaining of replacement notes from the borrower. Should such note be replaced, the terms of the note cannot be changed. The Lender's Agreement describes general conditions for reissuing notes. If the evidence of debt has been lost, stolen, destroyed, mutilated or defaced, such evidence of debt must be replaced before FmHA will replace any instruments.

(e) If the decision is to reissue Loan Note Guarantee(s), the following procedure will be followed:

(1) Multi-note system. A new Form FmHA 1980–77 will be prepared using the original face amounts and amounts guaranteed (not outstanding loan balance). At the top of the form type "This Loan Note Guarantee is issued to replace the original dated _____ which was (insert "lost, stolen, destroyed, defaced or mutilated"). Only execute an original for the holder. Copies may be conformed for the lender and FmHA file. If borrower notes are needed, they must be obtained by the holder from the borrower. The indemnity bond must be kept in safekeeping;

(2) The lender must execute the replacement forms prior to FmHA execution of the same; and

(3) Certificates of Incumbency may be provided.

§ 1980.996 Lender's request to terminate Loan Note Guarantee.

If the Loan Note Guarantee has not automatically terminated, the lender may request FmHA to terminate the Loan Note Guarantee for any reason. The lender will provide the State Director with a written notice that the Loan Note Guarantee is paid in full and/or terminated. Within 30 days, the State Director will forward a memorandum to the Finance Office indicating that the loan is paid in full and/or the Loan Note Guarantee is cancelled at the lender's request.

§§ 1980.997–1980.998 [Reserved].

§ 1980.999 FmHA Forms.

(a) Forms FmHA 1980–75, "Conditional Commitment for Guarantee (Agricultural Resource Conservation Demonstration Program)"; FmHA 1980–76, "Lender's Agreement (Agricultural Resource Conservation Demonstration Program)"; FmHA 1980–77, "Loan Note Guarantee (Agricultural Resource Conservation Demonstration Program)"; and FmHA 1980–78, "Interest Assistance Agreement (Agricultural Resource Conservation Demonstration Program)"; are incorporated into and made a part of this subpart, and appear as appendices, A, B, C, and D.

(b) The following FmHA forms will be used in the processing and servicing of loans made under this subpart. Refer to the forms manual inserts and directions printed on the form for specific details concerning completion of the forms, number of copies, and distributions. Copies of forms may be obtained from any FmHA State office.

FmHA form No.	Title of form	Purpose and code[1]
1980–77	Loan Note Guarantee (Agricultural Resource Conservation Demonstration Program).	Used to document FmHA's guarantee and related responsibilities. (1)
1980–76	Lender's Agreement (Agriculture Resource Conservation Demonstration Program).	used to document lender's responsibilities. (2)
1980–78	Interest Assistance Agreement (Agricultural Resource Conservation Demonstration Program).	Used to document FmHA's agreement to subsidize borrower's interest. (1)
1980–74	Application for Loan and Guarantee (Agricultural Resource Conservation Demonstration Program).	Used to ducment lender's guarantee request. (3)
1980–75	Conditional Commitment for Guarantee (Agricultural Resource Conservation Demonstration Program).	Used to document FmHA's conditions to issue Loan Note Guarantee. (2)
1940–3	Request for Obligation of Funds (Guaranteed Loans)	Used to approve loan and establish account. (1)
1980–19	Guaranteed Loan Closing Report	Used to pay guarantee fee and establish guarantee loan account. (2)
1980–24	Request Interest Rate Buydown/Subsidy Payment to Guaranteed Lender	Used by lender to request interest assistance
449–30	Loan Note Guarantee Report of Loss	Used to request delinquent payments. (3)
1980–41	Guaranteed Loan Status Report	Used to update FmHA's records of outstanding balance of loan. (3)
1980–42	Notice of Substitution of Lender	Used to change FmHA record of lender. (1)
1980–43	Lender's Guaranteed Loan Payment	Used by lender to transmit payments due FmHA as a holder. (3)
1980–44	Guaranteed Loan Borrower Default Status	Used by lender to inform FmHA of borrower default. (3)
1980–45	Notice of Liquidation Responsibility	Used by FmHA to indicate to Finance Office liquidation responsibility. (1)
1980–46	Report of Liquidation Expense	Used by FmHA to pay liquidation costs or appraisal fees. (1)
1980–47	Guaranteed Loan Borrower Adjustments	Used by FmHA to adjust borrower loan account. (1)
1980–49	Guaranteed Loan Status Update Adjustment	Used by FmHA to update status elements on loans. (1)
1980–51	Add, Change, or Delete Guaranteed Loan Record	Used by FmHA to update borrower information. (1)
1980–52	Report Request	Used by FmHA to request reports on guaranteed loans. (1)
449–30	Loan Note Guarantee Report of Loss	Used to claim reimbursement for losses. (2)
1980–40	Reverse a Report of Liquidation Expense	Used by FmHA to collect appraisal fees recovered from the liquidation of loan assets (2)
Exhibit H, subpart G of part 1940.	Environmental Assessment for Class II Actions	Format for Class II Environmental Assessment (1)

[1] (1) FmHA use only; (2) FmHA and lender use; (3) Lender use only.

§ 1980.1000 OMB control number.

Appendix A—Form FmHA 1980–75, Conditional Commitment for Guarantee—Agricultural Resource Conservation Demonstration Program

Form Approved
OMB No.
7 CFR Part 1980

Subpart J
To: Lender

Lender's Address

Borrower

Case No.

State

Principal Amount of Loan $—

From an examination of information supplied by the lender on the above proposed loan, and other relevant information deemed necessary, it appears that the transaction can properly be completed.

Therefore, the United States of America acting through the Farmers Home Administration (FmHA) hereby agrees that, in accordance with applicable provisions of the FmHA regulations published in the Federal Register and related forms, it will execute Form(s) FmHA 1980–77, "Loan Note Guarantee (Agricultural Resource Conservation Demonstration Program)" subject to the conditions and requirements specified in said regulations and below.

The Loan Note Guarantee fee payable by the lender to FmHA will be the amount as specified in the regulations on the date of this Conditional Commitment for Guarantee. The annual interest rate for the loan will be ____%. The annual interest assistance rate will be ____% for years 1 through 5 and for years 6 through 10 a rate equal to the difference between the note interest rate and that charged by FmHA to its Limited Resource Operating Loan borrowers but not less than 3 percent per annum.[1]

A Loan Note Guarantee will not be issued until the lender certifies as required in 7 CFR 1980.966 there have been no adverse changes in the borrower's financial condition, or any other adverse change in the borrower's condition during the period of time from FmHA's issuance of the Conditional Commitment for Guarantee to issuance of the Loan Note Guarantee. The lender's certification must address all adverse changes and be supported by financial statements of the borrower and its guarantors not more than 60 days old at the time of certification.

This agreement becomes null and void unless the conditions are accepted by the lender and borrower within 60 days from the date of issuance by FmHA. Any negotiations concerning these conditions must be completed by that time.

Except as set out below, the purposes for which the loan funds will be used and the amounts to be used for such purposes in Form FmHA 1980–74, "Application for Loan and Guarantee" and State Farmland Preservation Plan. Once this instrument is executed and returned to FmHA, no major change in conditions or approved loan purpose as listed on these forms will be considered. Additional conditions and requirements including the source and use of funds: [2]

Acceptance of Conditions

This conditional commitment will expire on _____[3] unless the time is extended in writing by FmHA, or upon the lender's earlier notification to FmHA that it does not desire to obtain an FmHA guarantee.

United States of America

Date: _____

To: Farmers Home Administration (FmHA) [4]

By: _____

FmHA: (Title) _____

The conditions of this Conditional Commitment for Guarantee, including attachments, are acceptable and the undersigned intend to proceed with the loan transaction and request issuance of a Loan Note Guarantee within ____ days.

_____

(Name of Lender)

_____

(Date)

By: _____

(Signature of Lender)

_____

(Date)

_____

(Signature of Borrower)

Appendix B—Form FmHA 1980–76, Lender's Agreement Agricultural Resource Conservation Demonstration Program

Form Approved

OMB No.

7 CFR Part 1980

Subpart J

FmHA Loan ID No.

(Lender) of _____ has made a loan(s) to _____ (Borrower) _____ in the principal amount of $_____ as evidenced by _____ note(s) (include Bond as appropriate) described as follows: _____

_____

_____

_____

_____

The United States of America, acting through Farmers Home Administration (FmHA), has entered into a "Loan Note Guarantee (Agricultural Resource Conservation Conservation Program)" (Form FmHA 1980–77) or has issued a "Conditional Commitment for Guarantee (Agricultural Resource Conservation Conservation Program)" (Form FmHA 1980–75) to enter into a Loan Note Guarantee with the lender applicable to such. The terms of the Loan Note Guarantee are controlling.

THE PARTIES AGREE:

I. FmHA will 100 percent guarantee the timely payment of principal and interest payments due.

II. *Full Faith and Credit.* The Loan Note Guarantee constitutes an obligation supported by the full faith and credit of the United States and is incontestable except for fraud or misrepresentation of which the lender has actual knowledge at the time it became such lender or which the lender participates in or condones and the following:

The Loan Note Guarantee will not be honored by FmHA to the extent that any delinquency or loss is occasioned by violation of usury laws, negligent servicing, or failure to obtain the required security regardless of the time at which FmHA acquires knowledge of the foregoing. Negligent servicing is defined as the failure to perform those services which a reasonably prudent lender would perform in servicing its own portfolio of loans that are not guaranteed. The term includes not only the concept of a failure to act but also not acting in a timely manner contrary to the manner in which a reasonably prudent lender would act. The Loan Note Guarantee will not be honored by FmHA to the extent that loan funds are used for purposes other than those specifically approved by FmHA in the Conditional Commitment for Guarantee.

III. The lender agrees loan funds will be used for the purposes authorized in subpart J of title 7 CFR part 1980 and in accordance with the terms of Form FmHA 1980–75.

IV. The lender certifies that none of its officers or directors, stockholders or other owners (except stockholders in a Bank of Cooperatives or other Farm Credit System (FCS) institution with direct lending authority that have normal stock share requirements for participation) have a substantial financial interest in the borrower. The lender certifies that neither the borrower nor its officers or directors, stockholders or other owners have a substantial financial interest in the lender. If the borrower is a member of the board of directors or an officer of a Bank of Cooperatives or other FCS institution with direct lending authority, the lender certifies that an FCS institution on the next highest level will independently process the loan request and will act as the lender's agent in servicing the account.

V. The lender certifies that it has no knowledge of any material adverse change, financial or otherwise, in the borrower, borrower's business, or any parent subsidiaries, or affiliates since it requested a Loan Note Guarantee.

VI. The lender certifies that a loan agreement and/or loan instruments concurred in by FmHA has been or will be signed with the Borrower.

VII. The lender certifies that it has paid the required guarantee fee.

VIII. *Servicing.*

A. The lender will service the entire loan and will remain mortgagee and/or secured party of record, notwithstanding the fact that another may hold a portion of the loan. The entire loan will be secured by the same security with equal lien priority.

B. The lender's servicing responsibilities include, but are not limited to:

1. Obtaining compliance with the covenants and provisions in the note, loan agreement, security instruments, and any supplemental agreements and notifying in writing FmHA and the borrower of any violations. None of these instruments will be altered without FmHA's prior written concurrence. The lender must service the loan in a reasonable and prudent manner.

2. Receiving all payments on principal and interest (including interest assistance) on the loan as they fall due.

3. Inspecting the collateral (when appropriate) as often as necessary to properly service the loan.

4. Monitoring the State Farmland Preservation Plan.

5. Assuring that adequate insurance is maintained. This includes hazard insurance obtained and maintained on security property with a loss payable clause in favor of the lender as secured party.

6. Assuring that taxes, assessment or ground rents against or affecting collateral are paid; the loan and collateral are protected in foreclosure, bankruptcy, receivership, insolvency, condemnation, or other litigation, insurance loss payments, condemnation

[1] Insert the fixed interest rate and the appropriate interest assistance rate.

[2] Insert any additional conditions or requirement in this space or on an attachment referred to in this space.

[3] FmHA will determine the expiration date of this contract. Consideration will be given to the date indicated by the lender in the Acceptance of Conditions.

[4] Return completed and signed copy of this form to issuing FmHA State Office.

awards, or similar proceeds are applied on debts in accordance with lien priorities on which the guarantee was based, or to rebuilding or otherwise acquiring needed replacement collateral with the written approval of FmHA; proceeds from the sale or other disposition of collateral are applied in accordance with the lien priorities on which the guarantee is based; the borrower complies with all laws and ordinances applicable to the loan, the collateral and/or operating of the program.

7. In the case of guarantees secured by collateral, assuring the security is properly maintained.

8. Obtaining the lien coverage and lien priorities specified by the lender and agreed to by FmHA, properly recording or filing lien or notice instruments to obtain or maintain such lien priorities during the existence of the guarantee by FmHA.

9. Assuring that the borrower obtains marketable title to the collateral and easements or properties in fee simple acquired with loan funds.

10. Assuring that the borrower obtains marketable title to the easements or properties in fee simple acquired with loan funds.

11. Assuring that the borrower (any party liable) is not released from liability for all or any part of the loan, except in accordance with FmHA regulations.

12. Providing FmHA Finance Office with loan status reports semiannully as of June 30 and December 31 on Form FmHA 1980–41, "Guaranteed Loan Status Report."

13. Obtaining from the borrower periodic financial statements under the following schedule:

—The lender is responsible for analyzing the financial statements, taking any servicing actions and providing copies of statements and record of actions to the FmHA State Office responsible for the loan. ———————

14. Monitoring the use of loan funds to ensure they will not be used for any purpose that will contribute to excessive erosion of highly erodible land or to the conversion of wetlands to produce an agricultural commodity, as further explained in 7 CFR part 1940, subpart G, exhibit M.

X. *Default.* In case of any monetary default, the lender will negotiate with the borrower in good faith in an attempt to resolve any problem to permit the borrower to cure the default. When a loan becomes 60 days or more past due, the lender will arrange a meeting with FmHA and the borrower to resolve the problem. When an immediate solution to the delinquency cannot be reached, and upon demand by the lender, FmHA will make funds available to pay the delinquent payment. FmHA will not pay any late payment charges to the lender. All such advances are immediately due and payable and it is the responsibility of the lender to collect them from the borrower. The loan will be considered a problem loan until the advance and accured interest on such advance is fully repaid to FmHA through the lender.

XI. *Liquidation.* If the lender concludes that liquidation of a guaranteed loan account is necessary because of one or more defaults or third party actions that the borrower cannot, or will not, cure or eliminate within a reasonable period of time, a meeting will be arranged by the lender with FmHA. When FmHA concurs with the lender's conclusion or at any time concludes independently that liquidation is necessary, it will notify the lender. The lender will liquidate the loan unless FmHA, at its option, decides to carry out liquidation.

A. *The lender's proposed method of liquidation.* Within 30 days after the decision to liquidate, the lender will advise FmHA in writing of its proposed detailed method of liqudation called a liquidation plan and will provide FmHA with:

1. Such proof as FmHA requires to establish the Lender's ownership of the guaranteed loan debt instrument(s) and related security instruments.

2. Information lists concerning the borrower's assets including real and personal property, fixtures, claims, contracts, inventory (including perishables), accounts receivable, and other existing and contingent assets, advice as to whether or not each item is serving as collateral for the guaranteed loan.

3. A proposed method of making the maximum collection possible on the indebtedness.

4. If the outstanding principal loan balance, including accrued interest, is less than $200,000, the lender will obtain an estimate of the market and potential liquidated value of the collateral. On loan balances in excess of $200,000, the lender will obtain an independent appraisal report on all collateral securing the loan, which will reflect the current market value and potential liquidation value. The appraisal report is for the purpose of permitting the lender and FmHA to determine the appropriate liquidation actions.

B. *FmHA's response to the lender's liquidation plan.* FmHA will inform the lender in writing whether it concurs in the lender's liquidation plan. Should FmHA and the Lender not agree on the lender's liquidation plan, negotiations will take place between FmHA and the lender to resolve the disagreement. The lender will ordinarily conduct the liquidation; however, should FmHA opt to conduct the liquidation, FmHA will proceed as follows:

1. The lender will transfer to FmHA all rights and interest necessary to allow FmHA to liquidate the loan.

2. FmHA will attempt to obtain the maximum amount of proceeds from liquidation.

3. Options available to FmHA include any one or combination of the usual commercial methods of liquidation.

C. *Acceleration.* The lender or FmHA, if it liquidates, will proceed as expeditiously as possible when acceleration of the indebtedness is necessary, including giving any notices and taking any other legal action required by the security instruments. A copy of the acceleration notice or other acceleration document will be sent to FmHA or the lender, as the case may be.

D. *Liquidation: Accounting and Reports.* When the lender conducts the liquidation, it will account for funds during the period of liquidation and will provide FmHA with periodic reports on the progress of liquidation, disposition of collateral, resulting costs, and additional procedures necessary for successful completion of liquidation. The lender will transmit to FmHA any payment received from the borrower from liquidation or other proceeds, etc., using Form FmHA 1980–43, "Lender's Guaranteed Loan Payment to FmHA." When FmHA liquidates, the lender will be provided with similar reports on request.

E. *Income from collateral.* Any net rental or other income that has been received by the lender from the collateral will be applied on the guaranteed loan debt.

XII. *Protective Advances.*

Protective advances must constitute an indebtedness of the borrower to the lender and be secured by the security instrument(s). FmHA written authorization is required on all protective advances in excess of $500. Protective advances include, but are not limited to, advances made for taxes, annual assessments, ground rent, hazard or flood insurance premiums affecting the collateral, and other expenses necessary to preserve or protect the security. Attorney fees are not a protective advance.

XIII. *Future Recovery.*

After a loan has been liquidated, any future funds which may be recovered by the lender will be forwarded to FmHA.

XIV. *Bankruptcy.*

The lender is responsible for protecting the guaranteed loan debt and all collateral securing the loan in bankruptcy proceedings.

XV. *Other Requirements.*

This agreement is subject to all the requirements of subpart J of title 7 CFR part 1980, and any future amendments of these regulations not inconsistent with this agreement. Interested parties may agree to abide by future FmHA regulations not inconsistent with the agreement.

XVI. *Execution of Agreements.*

If this agreement is executed prior to the execution of the Loan Note Guarantee, this agreement does not impose any obligation upon FmHA with respect to the execution of such contract. FmHA in no way warrants that such a contract has been, or will be, executed.

XVIII. *Notices.*

All notices and actions will be initiated through FmHA.

XVIII. *Environmental Requirements.*

The lender will ensure that the borrower complies with the measure identified in the Government's environmental impact analysis for the program for the purpose of avoiding or reducing the adverse environmental impacts of the program's operation.

Dated this ____ day of _____, 19____.

ATTEST:_____ (Seal)
Lender:
By: _____
Title:_____

United States of America
Farmers Home Administration
By: _____
Title:_____

Appendix C— Form FmHA 1980–77, Loan Note Guarantee—Agricultural Resource Conservation Demonstration Program

Form Approved OMB No.
7 CFR Part 1980
Subpart J

Borrower

Lender

Lender's Address

State

Date of Note

FmHA Loan ID Number

Lender's IRS Tax ID Number

Principal Amount of Loan $—

The principal amount of loan evidenced by _____ note(s) (includes bonds as appropriate) is described below. This instrument is attached to note _____ in the face amount of $_____ and is number _____ of _____.

Lender's note No.	Face amount	Percent of total face amount
Total	$	100

In consideration of the making of the subject loan by the above-named lender, the United States of America, acting through the Farmers Home Administration, of the United States Department of Agriculture (called "FmHA"), pursuant to the Farms for the Future Act of 1990 (7 U.S.C. 4201 note), does hereby agree that in accordance with, and subject to, the conditions and requirements in this instrument, will:

(a) at the lender's request, advance to the lender the unpaid portion of any principal and/or interest payment, 60 days or more past due as evidenced by said note(s). Such advance will accrue interest at the note rate and must be an indebtedness of the borrower.

(b) pay to the lender, any principal and interest indebtedness on secured protective advances for protection and preservation of collateral made with FmHA's authorization, including, but not limited to, advances for taxes, annual assessments, any ground rents, and insurance premiums affecting the collateral.

Definition of Lender

The lender is the person or organization making and servicing the loan which is guaranteed under the provisions of subpart J, 7 CFR of part 1980. The lender is also the party requesting a loan guarantee.

Conditions of Guarantee

1. *Loan Servicing.* The lender will remain mortgagee and/or secured party of record not withstanding the fact that another party may hold a portion of the loan. When multiple notes are used to evidence a loan, the lender will structure repayments as provided in the loan agreement. The lender will be responsible for servicing the entire loan, including any advances made by FmHA to the lender under its guarantee of timely payments.

2. *Full Faith and Credit.* The Loan Note Guarantee constitutes an obligation supported by the full faith and credit of the United States and is incontestable except for fraud or misrepresentation of which the lender has actual knowledge at the time it became such a lender or which the lender participates in or condones and the following:

(a) The Loan Note Guarantee will not be honored by FmHA to the extent that any delinquency or loss is occasioned by violation of usury laws, negligent servicing, or failure to obtain the required security regardless of the time at which FmHA acquires knowledge of the foregoing. Negligent servicing is defined as the failure to perform those services which a reasonably prudent lender would perform in servicing its own portfolio of loans that are not guaranteed. The term includes not only the concept of a failure to act but also not acting in a timely manner contrary to the manner in which a reasonably prudent lender would act.

(b) The Loan Note Guarantee will not be honored by FmHA to the extent that loan funds are used for purposes other than those specifically approved by FmHA in its Form FmHA 1980–75, "Conditional Commitment for Guarantee (Agricultural Resource Conservation Demonstration Program)."

(c) The Loan Note Guarantee is void if the note to which this is attached or relates provides for payment of interest on interest.

3. *Protective Advances.* Protective advances made by the lender pursuant to the regulations will be guaranteed to the same extent as provided in the Loan Note Guarantee.

4. *Lender's Obligations.* The lender will promptly remit to FmHA any payment or portion of a payment, including accrued interest thereon, previously advanced by FmHA to the lender under its guarantee of timely payments and subsequently received from the borrower.

5. *When Guarantee Terminates.* This Loan Note Guarantee will terminate automatically ten years from the date of the note or upon full payment of the guaranteed loan.

6. *Settlement.* The amount due under this instrument will be determined and paid as provided in the subpart J of part 1980 of title 7 CFR in effect on the date of this instrument.

7. *Interest Assistance.* In addition to FmHA's guarantee of timely payments of principal and interest, FmHA will pay a portion of the interest to the borrower as provided in the executed Form FmHA 1980–78, "Interest Assistance Agreement (Agricultural Resource Conservation Demonstration Program)."

9. *Notices.*

All notice and actions will be initiated through the FmHA _____ for _____ (State) with mailing address at the date of this instrument

United States of America
Farmers Home Administration
By: _____
Title: _____
(Date) _____

Form Approved
OMB No.
7 CFR Part 1980
Subpart J

Appendix D—Form FmHA 1980–78, Interest Assistance Agreement; Agricultural Resource Conservation Demonstration Program

Borrower

Lender

Lender's Address

State

Date of Note

FmHA Loan ID No.

Lender's IRS Tax ID No.

Principal Amount of Loan $—

The principal amount of loan is evidenced by _____ note(s) described below.

Lender's note No.	Amount of Note	Note interest rate
	$	%

This agreement is effective beginning _____ and expires on _____. The United States of America, acting through the Farmers Home Administration of the United States Department of Agriculture (called FmHA), pursuant to the Farms for the Future Act of 1990 (7 U.S.C. 4201 note), agrees that in accordance with and subject to the conditions and requirements in this agreement, to assist the borrower in making its interest payments, will pay the borrower as follows:

In each of the initial 5 years of the loan beginning _____ and ending _____, FmHA agrees to pay the borrower an amount equal to the interest accruing on the loan each of the first 5 years.

In each of the sixth through tenth years of the loan beginning _____ and ending _____, FmHA agrees to pay the borrower an amount equal to the difference between the note interest rate and the rate of interest then being charged FmHA Limited Resource Operating Loan borrowers but not less than 3 percent per annum.

Payments will be made to the borrower 10 days prior to an interest payment due date. The payment shall be by wire transfer into the Trust Fund Account identified as follows:

Bank _____
Account # _____

Wire Transfer Information _____

Conditionss of Interest Assistance

1. *Interest Assistance Payments.* FmHA payments made in connection with interest assistance will be calculated using a 360 or 365 day year method on a declining balance. The lender will indicate on Form FmHA 1980–19 "Guaranteed Loan Closing Report," the preferred method which may not change once established. The lender will notify FmHA of the interest due using Form FmHA 1980–24, "Request Interest Rate Buydown/Subsidy Payment to Guaranteed Lender," 30 days prior to the payment due date.

2. *When Interest Assistance Payments Cease.* Interest assistance payments will cease upon termination of the Loan Note Guarantee reaching the expiration date set forth in this agreement or upon cancellation by the Government.

3. *Cancellation of Interest.* The lender certifies that the amount of interest reduction on the subject borrower's account will be permanently cancelled as it becomes due and no attempt will be made to collect that portion of the debt which will be paid by FmHA.

4. *Regulatory Changes.* This Agreement is subject to the present regulations of the FmHA and its future regulations not inconsistent with any provision of this Agreement.

5. *Cancellation.* The Interest Assistance Agreement is incontestable except for fraud or misrepresentation of which the lender has actual knowledge at the time this Agreement is executed or for which the lender participates in or condones.

6. *Access to Lender's Files.* Upon request by FmHA, the lender will permit representatives of FmHA (or other agencies of the U.S. Department of Agriculture authorized by that Department) to inspect and make copies of any of the records of the lender pertaining to FmHA guaranteed loans. Such inspection and copying may be made during regular office hours of the lender or any other time the lender and FmHA find convenient.

7. Borrower shall use the interest assistance solely to promptly pay interest as it becomes due on the loan.

To the extent permitted by law and the supervisory agency, the lender agrees to allow FmHA access to audit findings by the lender's supervising agency when examining interest assistance claims.

Address: _____

_____

By: _____

Title: _____

United States of America
Farmers Home Administration
Acknowledged
Borrower:
Attest: _____ (Seal)
By: _____
Title: _____
Lender:
Attest: _____ (Seal)
By: _____
Title: _____

_____

Date: July 18, 1991.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 91–22972 Filed 9–23–91; 8:45 am]

BILLING CODE 3410–07–M

Food Safety and Inspection Service

9 CFR Parts 318 and 381

[Docket No. 88–033P]

RIN 0583–AA95

Finished Product Inspection

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations to allow canning establishments more flexibility in complying with the regulatory requirements concerning finished product inspection of thermally-processed shelf stable canned product. The existing regulations allow establishments to use quality control programs to ensure compliance with the regulations. However, an association of processors expressed, in two petitions, that they have little flexibility in developing different, yet equally effective quality control procedures for finished product inspections, because the scope of quality control programs now permitted is limited by the regulations.

DATES: Comments must be received on or before November 25, 1991.

ADDRESSES: Written comments to: Policy Office, Attn: Linda Carey, FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. (See also "Comments" under Supplementary Information.)

FOR FURTHER INFORMATION CONTACT: Mr. William C. Smith, Director, Processed Products Inspection Division, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, Area Code (202) 447–3840.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Agency has determined that this proposed rule is not a "major rule" within the scope of Executive Order 12291. It will not result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Effect on Small Entities

The Administrator has made an initial determination that this proposed rule will not have a significant economic impact upon a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). Finished product inspections are conducted in accordance with §§ 318.309 and 381.309 of the Federal meat and poultry products inspection regulations. All canners of thermally-processed shelf stable meat and poultry products, therefore, have operating costs related to the requirements of these sections of the regulations. The proposed changes would permit increased flexibility in developing effective quality control procedures for finished product inspections. Establishments choosing to continue complying with the existing regulations will not be affected by this proposal. Establishments voluntarily choosing to create different quality control programs would have to provide for at least the same level of assurance as that of the requirements in §§ 318.309(d) and 381.309(d) of the meat and poultry products inspection regulations. However, it is expected that such a voluntary quality control program would not be considered unless the establishment determines it is a more cost-effective procedure than previously existed.

Paperwork Requirements

Under this proposal, quality control programs may differ from the specific regulatory requirements if they are determined to be equivalent to the requirements or meet the intent of the requirements which is to provide assurance of the safety and stability of canned products. Currently, quality control programs must comply with the requirements of §§ 318.309 and 381.309 of the Federal meat and poultry products inspection regulations. The proposed rule would require establishments voluntarily choosing to develop a quality control program that is different from, but equivalent to, the requirements for finished product inspection, to submit quality control program plans to the Administrator for approval in accordance with §§ 318.4(c)

and (d) and 381.145(c) and (d) of the regulations. Establishments may develop a quality control program to address all or some of the requirements of §§ 318.309 and 381.309 of the current finished product inspection regulations. The information collection requirements contained in this rule have been submitted to the Office of Management and Budget for approval.

Comments

Interested persons are invited to submit written comments concerning this proposal. Written comments should be sent to the Policy Office and should refer to Docket Number 88–033P. Any person desiring an opportunity for an oral presentation of views as provided under the Poultry Products Inspection Act should make such request to Mr. William C. Smith so that arrangements can be made for such views to be presented. A record will be made of all views orally presented. All comments submitted in response to the proposal will be available for public inspection in the Policy Office during the hours of 9 a.m. and 12:30 p.m. and 1:30 p.m. and 4 p.m., Monday through Friday.

Background

The Agency has received two petitions from the National Food Processors Association (NFPA) to amend the Federal meat and poultry products inspection regulations to allow canning establishments more latitude in complying with the specific requirements contained in §§ 318.309 and 381.309 (9 CFR 318.309, 381.309) of the Federal meat and poultry products inspection regulations. Sections 318.309 and 381.309 of the regulations allow establishments to control all or part of finished product inspection operations with a quality control program or, in lieu of a quality control program, to follow all of the current requirements covering incubation procedures, monitoring container condition, and shipping. Currently, all establishments, whether or not they have quality control programs, must comply with all of the following requirements.

Establishments must sample at least one container for incubation from batch-type thermal processing systems and one container per 1,000 from continuous systems. Sample containers must be incubated for not less than 10 days (240 hours) at 95±5°F (35±2.8°C.) The finding of abnormal containers among incubation samples is cause to officially retain at least the code lot involved. Likewise, when abnormal containers are detected by means other than incubation, the affected lots cannot be shipped until the Program has determined that the product is safe and stable, meaning that the product was not contaminated or adulterated during processing and the product remains wholesome. Moreover, establishments cannot ship canned product before the end of the required incubation period unless the establishment has approval from the FSIS area supervisor of written procedures for preventing the shipped product from reaching the retail level of distribution before sample incubation is completed. The procedures must assure that the product could be returned to the establishment promptly should such action be deemed necessary due to the incubation results.

One of two petitions from the NFPA requested revisions to the regulations that would permit establishments to ship product to retail outlets before the completion of incubation, provided they operate under an approved quality control program that exceeds certain elements of existing regulations. As an example, it suggested an augmented incubation program and development of a program for evaluating process deviations and the significance of abnormal containers found during incubation. The second petition from the NFPA requested that §§ 318.309(d)(1)(iv)(*b*) and 381.309(d)(1)(iv)(*b*) of the meat and poultry products inspection regulations (incubation sampling frequency for continuous-type thermal processing systems) be revised "* * * to provide greater equality with the required minimum sampling rates for batch-type processing systems." The petitioner suggested that at least one container be drawn for incubation sampling at time intervals not to exceed the process time for the product. For example, if a particular product/container has a process schedule of 25 minutes at 250°F, then at least one incubation sample would be selected every 25 minutes. However, because some systems operate at a very high volume (e.g., several hundred containers/minute), the NFPA suggested a minimum sampling rate of at least one container for every 20,000 processed.

Both of the above-mentioned petitions are being addressed in this proposal. However, rather than amend current requirements for finished product inspection concerning sampling frequency and developing quality control requirements specifically for shipment of product before the end of the 10-day incubation period as requested by the petitioner, the Agency is proposing to provide establishments the option to develop quality control programs containing provisions that are different, but no less effective, than current requirements. For example, the shipment of products before the end of incubation and decreasing the sampling incubation rate, as discussed in the above-referenced petitions, may be addressed in such quality control programs. Quality control programs would be required to provide for at least the same level of assurance as the existing requirements of §§ 318.309 and 381.309 which are designed to ensure that thermally-processed canned product is wholesome and unadulterated. Therefore, FSIS is proposing that the regulations be amended to permit the use of FSIS-approved quality control programs that vary from the specific requirements in §§ 318.309(d) and 381.309(d) of the regulations. Establishments currently operating quality control programs which comply with finished product inspection requirements in accordance with §§ 318.309(a) and 381.309(a) would be able to continue to do so. The regulations in paragraph (d) of §§ 318.309 and 381.309 would still be applicable in the absence of an approved quality control program.

Variations from the regulatory requirements would be allowed only as long as a particular proposal provides at least the same level of assurance as that of the requirements in §§ 318.309(d) and 381.309(d). For example, a quality control program proposing a reduction in the incubation sampling rate for a continuous system from the required incubation sampling rate 1/1,000 to 1/10,000, would have to provide for at least the same level of assurance as that of the existing requirements in §§ 318.309 and 381.309. An example would be to incubate the samples for more than 10 days at no less than 95°F. Similarly, a processor wishing to ship product at any time after processing may be expected to exceed current incubation sampling requirements by increasing the number of incubation samples. Moreover, a quality control program would have to contain a provision that would invoke tightened criteria compared to those regularly employed in the establishment's quality control program in cases where unwholesome product, abnormal containers, or other irregularities, which may compromise product wholesomeness, occur. Such tightened criteria could include, for example, increasing the incubation sampling rate, lengthening the incubation period, delaying product shipment until after the incubation period has ended, intensifying container condition examinations prior to shipment, or other

actions depending upon the quality control program. An establishment would use these tightened criteria until the cause of the irregularities is identified and resolved and the Program has determined that the corrective action taken by the establishment is sufficient to produce wholesome and unadulterated product with the routine provisions contained in the approved quality control program.

Proposed Rule

For the reasons discussed in the preamble, FSIS is proposing to amend parts 318 and 381 of the Federal meat and poultry products inspection regulations as set forth below.

List of Subjects

9 CFR Part 318

Meat inspection; canned products; quality control.

9 CFR Part 381

Poultry products inspection; canned product; quality control; packaging and containers.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–195; 7 CFR 2.17, 2.55.

2. Section 318.309 would be amended by revising paragraphs (b), (c), and (d)(1)(viii) to read as follows:

§ 318.309 Finished product inspection.

* * * * *

(b) Any partial quality control program for finished product inspection shall be prepared and submitted to the Administrator for approval in accordance with § 318.4 of this part.

(c) That portion of a total quality control system for finished product inspection shall be prepared and submitted to the Administrator for approval in accordance with § 318.4 of this part.

(d) * * *

(1) * * *

(viii) *Shipping.* No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451–470, 7 CFR 2.17, 2.55.

2. Section 381.309 would be amended by revising paragraphs (b), (c), and (d)(1)(viii) to read as follows:

§ 381.309 Finished product inspection.

* * * * *

(b) Any partial quality control program for finished product inspection shall be prepared and submitted to the Administrator for approval in accordance with § 381.145 of this part.

(c) That portion of a total quality control system for finished product inspection shall be prepared and submitted to the Administrator for approval in accordance with § 381.145 of this part.

(d) * * *

(1) * * *

(viii) *Shipping.* No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section.

* * * * *

Done at Washington, DC on September 18, 1991.

R. J. Prucha,

Acting Administrator, Food Safety and Inspection Service.

[FR Doc. 91–22968 Filed 9–23–91; 8:45 am]

BILLING CODE 3410–DM–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket S–026]

RIN 1218–AB20

Process Safety Management of Highly Hazardous Chemicals

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule; notice of availability of the John Gray Institute report on contractors and peer reviews of the report; reopening of the record to reexamine the issue of contractors in light of the study; and request for comments.

SUMMARY: This document announces the availability of a study conducted by the John Gray Institute of Lamar University (John Gray report) concerning the use of contractors in the petrochemical industry and invites the public to reexamine, in light of this study, the contractor provisions contained in the proposed standard for Process Safety Management of Highly Hazardous Chemicals (Process Safety Management standard), published on July 17, 1990 (55 FR 29150). OSHA wants to assure that safety issues surrounding contractor employees how are exposed or may expose site employees to potentially catastrophic events are thoroughly addressed in the final Process Safety Management standard. The John Gray report addresses various aspects of this issue and may be pertinent to the proposed standard.

DATES: Comments must be postmarked by October 24, 1991.

ADDRESSES: John Gray Report. The John Gray report, "Managing Worker Safety and Health: The Case of Contract Labor in the U.S. Petrochemical Industry," as well as the peer reviews of the report, are available upon request from the Docket Office, U.S. Department of Labor, Occupational Safety and Health Administration, N2625, 200 Constitution Avenue, NW., Washington, DC 20210 telephone (202) 523–7894.

Comments. Comments on the John Gray report and the contractor provisions contained in the proposed Process Safety Management standard should be submitted in quadruplicate to the Docket Office, Docket S–026, U.S. Department of Labor, Occupational Safety and Health Administration, N2625, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, U.S. Department of Labor, Occupational Safety and Health Administration, room N3637, 200 Constitution Avenue, NW., Washington, DC 20210, (202)523–8151.

SUPPLEMENTARY INFORMATION:

I. Background

On October 23, 1989, catastrophic explosions and fires occurred at the Phillips 66 Company's Houston Chemical Complex resulting in 23 deaths and more than 130 injuries. The issue of contractors at the workplace surfaced since a contractor had been working in the vicinity of the release.

OSHA's growing experience with the petrochemical industry indicated that a significant number of companies in this industry were using contractors to perform regular maintenance, repairs, construction, and renovation. The Agency determined that more information was needed about the extent to which contract work might affect workplace safety.

OSHA asked the John Gray Institute to conduct a study of safety and health issues as they relate to contract work in the petrochemical industry. The Institute

was guided on the methodology and approach for the study by a Steering Committee made up of representatives from labor, management and academia.

The John Gray Institute report examined such factors as the extent of industry reliance upon contract employees; the nature of work performed by contractors; the role of safety records in contractor selection; the training provided to employees and the supervision accorded to safety and health compliance for contract operations as compared with that for company operations; and injury/illness recordkeeping.

On July 17, 1990, OSHA published in the **Federal Register** (55 FR 29150) its notice of proposed rulemaking concerning Process Safety Management. The proposed standard contained specific provisions concerning contractors. The text reads as follows:

(h) *Contractors.* (1) The employer shall inform contractors performing work on, or near, a process of the known potential fire, explosion or toxic release hazards related to the contractor's work and the process, and ensure that contract employees are trained in the work practices necessary to safely perform their job. The employer shall also inform contractors of any applicable safety rules of the facility.

(2) The employer shall explain to contractors the applicable provisions of the emergency action plan required by paragraph (n) of this section.

(3) Contract employers shall assure that each of their employees follow all applicable work practices and safety rules of the facility. (55 FR 29164–29165)

OSHA has received significant input on these contractor provisions during the rulemaking on the Process Safety Management standard and this information will be thoroughly considered in the development of the final provisions.

II. Agency Action

Since the John Gray report contains information that may be relevant to the contractor provisions of the proposal, the Agency is reopening the record to receive the report and to allow the public an opportunity to comment on the report. Therefore, OSHA invites interested persons to comment on the John Gray report particularly focusing comments on how the report should influence the Process Safety Management proposal.

Also, because this study may be an important factor in the development of safety requirements for contractors, OSHA believed that it was appropriate for the study to undergo a peer review to ensure the reliability of the study and its findings. These peer reviews are also available in the Docket Office.

Public Participation

Interested persons are invited to submit written data, views, and arguments on the John Gray report and how it should affect the July 17, 1990, PSM proposal. Comments must be postmarked by October 24, 1991. Four copies of comments must be submitted to the OSHA Docket Office, Docket S–026, U.S. Department of Labor, Occupational Safety and Health Administration, N2625, 200 Constitution Avenue, NW., Washington, DC 20210. The telephone number of the Docket Office is (202) 523–7894, and its hours of operation are 10 a.m. to 4 p.m., Monday through Friday. Comments limited to 10 pages or less may also be transmitted by facsimile to (202) 523–5046, provided that the original and four copies of the comment are subsequently sent to the Docket Office.

All materials submitted will be available for inspection and copying at this address. All submissions will become a part of the record developed for the process safety management of highly hazardous chemicals rulemaking.

The contractor provisions will be reviewed in light of all submissions received. Decisions on the contractor provisions will be made by the Assistant Secretary based on the entire record of the proceeding.

Authority

This document has been prepared under the direction of Gerard F. Scannell, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

It is issued under section 6(b) of the Occupational Safety and health Act of 1970 (20 U.S.C. 655); Secretary of Labor's Order No. 1–90 (55 FR 9033); and 29 CFR part 1911.

Signed at Washington, DC, on this 19th day of September, 1991.

Gerard F. Scannell,

Assistant Secretary of Labor.

[FR Doc. 91–22944 Filed 9–23–91; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8–R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Basic Program

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule removes the existing CHAMPUS benefit exclusion of certain diagnostic or treatment procedures which involve electronic transmission of data.

The intention of this change is to allow coverage, in addition to the current coverage of remote cardiac pacemaker monitoring, of otherwise allowable procedures when they employ electronic transfer of data to improve the quality and efficiency of the management of a clinical condition.

DATES: Comments must be submitted on, or before, October 24, 1991.

ADDRESSES: Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Office of Program Development, Aurora, CO 80045–6900.

FOR FURTHER INFORMATION CONTACT: Joseph W. Baker, Office of Program Development, OCHAMPUS, telephone (303) 361–4019.

SUPPLEMENTARY INFORMATION: In FR Doc. 77–7834, appearing in the **Federal Register** on April 4, 1977 (42 FR 17972), the Office of the Secretary of Defense published its regulation, DoD 6010.8–R, "Implementation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)" (32 CFR part 199). DoD 6010.8–R "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)" was revised in the **Federal Register** on July 1, 1986 (51 FR 24008).

The CHAMPUS Basic Program currently excludes payment for "services or advice rendered by telephone or other telephonic device, including remote monitoring, except for transtelephonic monitoring of cardiac pacemakers." This exclusion promotes the quality of care standard that a substantive service of a diagnostic or treatment nature requires a face-to-face contact between provider and patient. The transtelephonic monitoring exception for cardiac pacemakers, added in 1984 (84 FR 24000), recognized that remote monitoring can be an efficient alternative to certain outpatient visits to a physician's office or hospital.

This proposed rule facilitates timely access to distant clinical experts and efficient management of certain medical conditions in the home environment. This is especially important for CHAMPUS beneficiaries who reside in locations which have limited specialized medical resources.

The intention of this change is to allow coverage, in addition to the current coverage of remote cardiac pacemaker monitoring, of otherwise allowable procedures when they employ

electronic transfer of data to improve the quality and efficiency of the management of a clinical condition.

Executive Order 12291

Requires that a regulatory analysis be prepared for major rules, which are defined to include any rule that has an annual effect on the economy of $100 million or more, or certain other specified effects. The Office of CHAMPUS has determined that this proposed regulation amendment is not a major rule under Executive Order 12291 because this change will not add clinical conditions which would not otherwise be allowable. Consequently this proposed change is not expected to change benefit costs because it is not expected to increase the volume of covered procedures relative to the volume anticipated to have been acceptably performed in a different manner in the absence of this change. Coverage of a procedure subsequent to the promulgation of this proposed rule as a final rule requires that both clinical and fiscal advantages be demonstrated compared to the procedure without the electronic data transfer element

The Regulatory Flexibility Act of 1980

Requires that a federal agency prepare an analysis when the agency issues regulations which would have significant impact upon a substantial number of small entities. We certify that this proposed rule, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act because this proposed rule, if otherwise issued as a final rule, does not add or remove requirements for providers of services to CHAMPUS beneficiaries or substantially alter the scope of services which providers have found to be covered by the CHAMPUS.

Paperwork Reduction Act of 1980

Requires all Departments to submit to the Office of Management and Budget (OMB) for review and approval any reporting or record keeping requirements in a proposed or final rule. This notice of proposed rule making adds no new paperwork requirements.

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health Insurance, and Military personnel.

PART 199—[AMENDED]

Accordingly, 32 CFR part 199 is amended as follows:

1. The authority citation for part 199 continues to read as follows:

Authority: 10 U.S.C. 1079, 1086, and 5 U.S.C. 301.

2. Section 199.4 is proposed to be amended by revising paragraph (g)(52) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(g) * * *

(52) *Telephonic services.* Services or advice rendered by telephone are excluded, except that a diagnostic or monitoring procedure which incorporates electronic transmission of data or remote detection and measurement of a condition, activity, or function (biotelemetry) is not excluded when:

(i) The procedure without electronic transmission of data or biotelemetry is otherwise an explicit or derived benefit of § 199.4 of this part, and

(ii) The addition of electronic transmission of data or biotelemetry to the procedure is found by the Director, OCHAMPUS, or designee, to be medically necessary and appropriate medical care which usually improves the efficiency of the management of a clinical condition in defined circumstances, and

(iii) That each data transmission or biotelemetry device incorporated into a procedure that is otherwise an explicit or derived benefit of § 199.4 of this part, has been classified by the U.S. Food and Drug Administration, either separately or as a part of a system, for use consistent with the defined circumstances in § 199.4(g)(52)(ii) of this part.

* * * * *

Dated: September 18, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-22825 Filed 9-23-91; 8:45 am]

BILLING CODE 3810-01-M

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32 CFR Part 199

[DoD 6010.8-R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Eligibility of Former Spouses and Widows or Widowers Whose Remarriage Ends in Annulment; Effect of Medicare Entitlement of Former Spouses; and Federal Claims Collection

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses three changes to DoD 6010.8-R (32 CFR part 199) relevant to CHAMPUS. These changes will update the Regulation to stipulate that annulled remarriages of former spouses or widows or widowers will be regarded as if the remarriage had never taken place and will reinstate their eligibility effective 12:01 a.m. of the day following the annulment; will clarify the effect of Medicare entitlement on former spouses; and will adopt the Federal Claims Collection Act and the Federal Claims Collection Standards by reference.

DATES: Written comments, whether from the general public, or from other governmental agencies must be received on or before October 24, 1991.

ADDRESSES: Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Office of Program Development, Aurora, CO 80045-6900.

FOR FURTHER INFORMATION CONTACT: Mr. A. Chris Armijo, Office of Program Development, OCHAMPUS, telephone (303) 361-3630.

SUPPLEMENTARY INFORMATION: In FR Doc. 77-7834, appearing in the **Federal Register** on April 4, 1977 (42 FR 17972), the Office of the Secretary of Defense published its regulation, DoD 6010.8-R, Part 199—Implementation of the Civilian Health and Medical Program of the Uniformed Services.

The first part of this proposed regulation addresses the remarriage of former spouses, and previously eligible widows or widowers to an individual whose dependents are not eligible for CHAMPUS. Under the terms of the existing regulation, previously eligible former spouses or widows or widowers who remarry an individual whose dependents are not eligible under CHAMPUS lose their eligibility as of 12:01 a.m. of the day following the day of the remarriage. In the event of termination of the subsequent remarriage, such individuals remain ineligible for CHAMPUS regardless of the reason for termination. This has had the effect of excluding from further coverage even those individuals whose subsequent marriage terminates by annulment. Since an annulment voids the marriage, the need exists for a provision that CHAMPUS eligibility for such individuals can be reinstated effective 12:01 a.m. of the day following the annulment. This proposed rule will correct the inadvertent discrepancy.

The second part of this proposed rule addresses the fact that, when Medicare part A is concerned, former spouses cannot be considered dependents of active duty members and, therefore, lose CHAMPUS eligibility upon becoming eligible for part A of Medicare.

The third part of this proposed rule is required to comply with a recent amendment to the Federal Claims Collection Act and the Federal Claims Collection Standards which changed the manner in which claims in favor of the United States Government will be handled. The amendment to both the Federal Claims Collection Act, 31 U.S.C. 3711(a)(2) and the Federal Claims Collection Standards, 4 CFR 103.1 and 104.1, allows Federal Agencies to compromise, suspend, or terminate collection actions on claims when the amount, exclusive of interest costs, does not exceed $100,000. The proposed rule adopts, by reference, the language of the Federal Claims Collection Act and the Federal Claims Collection Standards so that future amendments to the Act and the Regulation will not necessitate corresponding amendment to DoD 6010.8–R. The proposed rule will reduce the number of claims which must be referred to the Department of Justice, facilitate more timely resolution of CHAMPUS claims, diminish the size of the backlog of claims which, under the old system, only the Department of Justice was authorized to review, and enhance the timeliness of reviews.

Regulatory Procedures

Executive Order 12291 requires that a regulatory impact analysis be performed on any major rule. A *major rule* is defined as one which would result in an annual effect on the national economy of $100 million or more or have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities.

This proposed rule is not a major rule under Order 12291. The changes set forth in this proposed rule are minor revisions to the existing regulation. In addition, this proposed rule does not impose information collection requirements. It does not, therefore, need to be reviewed by the Executive Office of Management and Budget under authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3511).

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health Insurance, and Military personnel.

PART 199—[AMENDED]

Accordingly. 32 CFR, part 199, is proposed to be amended as follows:

1. The authority citation for part 199 continues to read as follows:

Authority: 10 U.S.C. 1079, 1086, and 5 U.S.C. 301.

2. Section 199.3, paragraphs (b)(2)(ii)(A), (e)(3)(v), and (e)(3)(vi) are revised to read as follows:

§ 199.3 Eligibility.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(A) *Must be unremarried.* (A former spouse who remarries, but whose remarriage is legally annulled, is considered to be unremarried as of 12:01 a.m. of the day following the day of the annulment).

* * * * *

(e) * * *

(3) * * *

(v) *Marriage of Widow or Widower.* The remarriage of a widow or widower of an active duty member or retiree to a person whose dependents are not eligible for CHAMPUS terminates his or her CHAMPUS eligibility as of 12:01 a.m. of the day following the day of the marriage. Even if such marriage should terminate for any reason, CHAMPUS benefits cannot be reinstated. The only exception is in the case of a widow or widower who remarries and whose remarriage is subsequently voided by annulment. In such a case of annulment, eligibility can be reinstated as of 12:01 a.m. of the day following the annulment.

(vi) *Attainment of entitlement to hospital insurance benefits (Part A under Medicare).* Retirees, and all other CHAMPUS eligible persons except dependents of active duty members lose their eligibility for CHAMPUS if they become eligible for hospital insurance benefits (Part A) of Medicare. This is true even though the persons attaining such status live outside the United States where benefits are not available. (For the purpose of this paragraph (e)(13)(vi), a former spouse cannot be considered a dependent of an active duty member).

* * * * *

3. Section 199.11 is amended by removing paragraphs (g)(1)(i), (ii), and (iii) and by revising paragraph (g)(1) as follows:

§ 199.11 Overpayments recovery.

* * * * *

(g) * * *

(1) *Basic Considerations.* Federal claims against the debtor and in favor of the United States arising out of the administration of the CHAMPUS may be compromised or collection action taken thereon may be suspended or terminated in compliance with the Federal Claims Collection Act, 31 U.S.C. 3711(a)(2) as implemented by the Federal Claims Collection Standards, 4 CFR 103.1 and 104.1.

* * * * *

Dated: September 18, 1991.

Linda M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91–22824 Filed 9–23–91; 8:45 am]

BILLING CODE 3810–01–M

Corps of Engineers, Department of the Army

33 CFR Part 330

Proposed Rule for Nationwide Permit Program Regulations

AGENCY: U.S. Army Corps of Engineers, DOD.

ACTION: Proposed rule.

SUMMARY: The Corps of Engineers proposes to amend its nationwide permit program regulations to clarify the expiration date of the nationwide permits.

DATES: Comments must be received on or before October 9, 1991.

ADDRESSES: Comments should be submitted in writing to: The Chief of Engineers, U.S. Army Corps of Engineers, ATTN: CECW–OR, Washington, DC 20314–1000. Comments will be available for examination at the Office of the Chief of Engineers, room 6225, Pulaski Building, 20 Massachusetts Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Sam Collinson or Mr. John Studt at (202) 272–1782.

SUPPLEMENTARY INFORMATION: Nationwide permits (NWPs) are a type of general permit issued by the Chief of engineers and are designed to regulate with little, if any, delay or paperwork certain activities having minimal impacts. Section 404(e)(2) of the Clean Water Act provides that general permits may not be effective for more than five years. Consequently, an NWP must be reissued at least every five years to continue to be in effect.

On November 13, 1986, we published in the **Federal Register** a final rule regarding NWPs. The NWPs contained in the rule became effective on January 12, 1987. It was our intent that the NWPs be in effect for five years from their effective date unless modified or revoked earlier. Thus, the preamble noted that the NWPs "will be in effect for 5 years beginning with the effective

date of this regulation, unless sooner revised or modified." Our position regarding the NWPs expiration date was further discussed in Regulatory Guidance Letter 90–1, which stated that the NWPs "will expire on 13 January 1992 unless they are modified or reissued." In contrast, the text of the November 13, 1986, final rule, codified at 33 CFR 330.12, provides that if an NWP "is not modified or reissued within five years of publication in the **Federal Register**, it automatically expires and becomes null and void." Today we propose to correct that discrepancy and amend 33 CFR 330.12 to reflect more accurately our original intentions.

This proposed rule is not intended to affect the ongoing rulemaking process involving NWPs that was published for public notice and comment on April 10, 1991.

List of Subjects in 33 CFR Part 330

Navigation, Water pollution control, Waterways.

Nancy P. Dorn,

Assistant Secretary of the Army (Civil Works).

Accordingly, 33 CFR part 330 is proposed to be amended as follows:

PART 330—NATIONWIDE PERMITS

1. The authority citation for part 330 continues to read as follows:

Authority: 33 U.S.C. 401 *et seq.*; 33 U.S.C. 1344; 33 U.S.C. 1413.

2. Section 330.12 is proposed to be amended by revising the second sentence to read as follows:

§ 330.12 Expiration of nationwide permits.

* * * If a nationwide permit is not modified or reissued within five years of its effective date, it automatically expires and becomes null and void. * * *

[FR Doc. 91–22898 Filed 9–23–91; 8:45 am]

BILLING CODE 3710–92–M

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. RM 91–5]

Registration of Claims to Copyright—Architectural Works

AGENCY: Library of Congress, Copyright Office.

ACTION: Proposed regulation.

SUMMARY: This notice of proposed rulemaking is issued to inform the public that the Copyright Office of the Library of Congress is considering adoption of new regulations governing the registration and deposit of architectural works. The Judicial Improvements Act of 1990, Public Law 101–650, amended the Copyright Act, title 17 of the U.S. Code and established "architectural works" as a new category of copyrightable subject matter. These proposed regulations are intended to implement copyright registration of this new category of copyrightable authorship and to establish the nature of the required deposit for mandatory deposit purposes.

DATES: Comments should be received on or before October 24, 1991.

ADDRESSES: Ten copies of written comments should be addressed, if sent by mail to: Library of Congress, Department 100, Washington, DC 20540. If delivered by hand, copies should be brought to: Office of the General Counsel, James Madison Memorial Building, room 407, First and Independence Avenue, SE., Washington, DC 20559, (202) 707–8380.

FOR FURTHER INFORMATION CONTACT: Dorothy Schrader, General Counsel, U.S. Copyright Office, Library of Congress, Washington, DC 20559, (202) 707–8380.

SUPPLEMENTARY INFORMATION: On December 1, 1990, the President signed into law the Judicial Improvements Act of 1990, which contained provisions modifying portions of the federal copyright law, the Copyright Act of 1976, title 17 of the United States Code. One of the most significant amendments established "architectural works" as copyrightable subject matter. The amendment defined "architectural work" as "the design of a building as embodied in any tangible medium of expression, including a building, architectural plans or drawings * * *."

The issue of protecting architectural works became a prominent copyright concern as a result of United States adherence to the Berne Convention, which was effective on March 1, 1989. Article 2(1) of the Berne Convention requires member countries to provide copyright for "works of architecture," that is, for the original design of buildings. The U.S. copyright law before December 1990 provided protection for "diagrams, models, and technical drawings, including architectural plans" as a species of protected "pictorial, graphic, and sculptural work." However, no protection was provided for original designs of buildings. In 1989, the Copyright Office conducted a study of issues relating to works of architecture and concluded that the U.S. law was deficient in its protection of architectural works. The amendment passed in December 1990 cures that deficiency.

Because protection covering architectural works became immediately effective upon the President's signature, the Copyright Office was unable to institute a rulemaking proceeding before making preliminary decisions as to implementation. Written practices were developed instead in order to guide the staff and the public as to registration procedures, and a preliminary decision has been made to register claims in architectural works on Form VA, the form used to register claims in "pictorial, graphic, or sculptural works." These preliminary decisions, however, can be restudied and possibly improved through this public proceeding. The written practices will govern registration of architectural works, pending issuance of final regulations.

In general, copyright principles, regulations, and practices applying to other categories of copyrightable authorship will apply in a similar fashion to architectural works, except as modified by specific written practices or any final regulations. The proposed regulations on architectural works cover issues unique to this new category of copyrightable authorship. Prominent issues addressed in the proposed regulations are as follows:

1. Subject Matter

While the definition of "architectural work" limits subject matter coverage to embodiments of "buildings," no definition of "building" is provided by the statute. The legislative history indicates that the term "building" is intended to mean habitable structures and structures used by humans.[1]

The regulation's specified exclusions closely track the statute. Structures other than buildings are outside of the definition of "architectural work." Standard features of buildings are likewise specified by the definition as being outside the scope of coverage. The law is mainly prospective in its effect. The provision concerning the effective date of the amendment excludes most pre-December 1, 1990 building designs.

2. Application Form

The proposed regulation designates Form VA as appropriate for registering claims in architectural works. Ultimately, the Copyright Office may decide to create a new form specifically tailored to architectural works rather than continue to register architectural

[1] H.R. Rep. No. 101–735, 101st Cong. 2d Sess. p.20 (1990).

works on Form VA. The copyright Office is interested in receiving public comments on the issue.

The advantage in using existing Form VA is largely administrative simplicity. Development of a new form costs money. A separate form may not be wanted for only a few hundred or few thousand registrations annually. In the first six months under the new law, the copyright office has received fewer than 100 applications to register architectural works.

On the other hand, if a new form were developed, the instructions and requested information could be tailored specifically to fit architectural works. For example, information about construction of the building could be explicitly requested on the form. In addition, possibly less confusion would occur concerning whether the registered work is an "architectural work" (embodiment of a building design), or a "technical drawing" (a species of pictorial, graphic, or sculptural works).

3. Publication

The Copyright Office interprets the Copyright Act to provide that publication of architectural plans also publishes the architectural work embodied in the plans. The proposed regulation adopts this interpretation of the Act. Since the definition of architectural work provides that an architectural work may be embodied in the plans, the Copyright Office believes it would be inconsistent to treat architectural works embodied in published plans as unpublished works. Clearly, the plans are copies of the architectural work for infringement purposes, and distribution of copies constitutes publication.

4. Relationship With Technical Drawings

Frequently, dual copyright claims exist in technical drawings and the architectural work depicted in the technical drawing. In such circumstances, the proposed regulation provides that separate registrations covering each category of authorship must be made, if both forms of authorship are to be placed on public record. Registration, as always, is permissive except as a jurisdictional prerequisite to an infringement suit in the case of non-Berne Convention works.

The Copyright Office considered allowing a unitary registration and decided that such a practice would not produce a clear public record. In most instances, different information is required to register a technical drawing from that required to register an architectural work. For example, it would be possible for the architectural work to be published by virtue of a distribution of models, or the public offering to sell copies of the building design, while the underlying technical drawings might remain unpublished. In a unitary registration, there would be no way to reflect this diverse information.

5. Deposit

The definition of architectural work provides that authorship "includes the overall form as well as the arrangement and composition of spaces and elements in the design * * *." The deposit provision governing copyright registration requires disclosure of the interior space if this is part of the claim. In general, architectural plans or drawings are required for unpublished, unconstructed works; for constructed works, photographs are also required.

Materials deposited for registration are considered for inclusion in the collections of the Library of Congress. The quality and longevity of the submitted copies is an important factor in the determination of their suitability for selection. The Copyright Office considered adoption of high archival quality standards for all deposits submitted for registration of architectural works. On further reflection, the Library of Congress and the Copyright Office decided to follow a unique approach to the deposit requirements in which we specify minimum mandatory deposits for purposes of registration, but also express a preference for receiving higher archival quality deposits. While the Copyright Office will not insist upon compliance with the archival quality standards in order to make registration, we encourage architects and other registrants to prepare deposits in accordance with the archival quality standards. The Library of Congress is a "treasure house" for the nation. It seeks to acquire the highest quality architectural works to reflect our national heritage. The Library must of course be selective regarding its permanent acquisitions, and will be more inclined to select an architect's work for the collections if the deposit meets archival quality standards.

Accordingly, the proposed regulations first prescribe the minimum deposit and then express preferences for archival quality deposits. Depositing high quality copies will both ensure a clearer public record of the authorship being registered and enhance the possibility that the deposit will be retained in the permanent collections of the Library.

Finally, published architectural works are subject to mandatory deposit for the benefit of the Library of Congress under section 407 of the Copyright Act. The Library seeks to acquire high quality, archival deposits of architectural works for the collections on a selective basis.

Regulatory Flexibility Act

With respect to the Regulatory Flexibility Act, the Copyright Office takes the position that this Act does not apply to Copyright Office rulemaking. The Copyright Office is a department of the Library of Congress, and is a part of the legislative branch. Neither the Library of Congress nor the Copyright Office is an "agency" within the meaning of the Administrative Procedure Act of June 11, 1946, as amended (Title 5, chapter 5 of the U.S. Code, subchapter II and chapter 7). The Regulatory Flexibility Act consequently does not apply to the Copyright Office since that Act affects only those entities of the Federal Government that are agencies as defined in the Administrative Procedure Act.[2]

Alternatively, if it is later determined by a court of competent jurisdiction that the Copyright Office is an "agency" subject to the Regulatory Flexibility Act, the Register of Copyrights has determined and hereby certifies that this regulation will have no significant impact on small business.

List of Subjects in 37 CFR Part 202

Copyright, Copyright registration; Architectural works.

Proposed Regulations

In consideration of the foregoing, the Copyright Office proposes to amend part 202 of 37 CFR, chapter II.

1. The authority citation for part 202 would continue to read as follows:

Authority: Sec. 702 90 Stat. 2541 17 U.S.C. 702; §§ 202.19, 202.20 and 202.21 are also issued under 17 U.S.C. 407 and 408.

2. New section 202.11 would be added as follows:

§ 202.11 Architectural works.

(a) *General.* This section prescribes rules pertaining to the registration of architectural works, as provided for in the amendment of title 17 of the United States Code by the Judicial

[2] The Copyright Office was not subject to the Administrative Procedure Act before 1976, and it is now subject to it only in areas specified by section 701(d) of the Copyright Act (i.e. "all actions taken by the Register of Copyrights under this title (17)," except with respect to the making of copies of copyright deposits). (17 U.S.C. 706(b)). The Copyright Act does not make the Office an "agency" as defined in the Administrative Procedure Act. For example, personnel actions taken by the Office are not subject to APA–FOIA requirements.

Improvements Act of 1990, Public Law 101–650.

(b) *Definitions.*

(1) For the purposes of this section, the term "architectural work" has the same meaning as set forth in section 101 of title 17, as amended.

(2) The term *building* means habitable structures, such as houses and office buildings, and structures that are used by human beings, such as churches, gazebos, and garden pavilions.

(c) *Registration.*

(1) *Original Design.* In general, an original design of a building embodied in any tangible medium of expression, including a building, architectural plans, or drawings, may be registered as an architectural work.

(2) *Application form.* Registration should be sought on Form VA. Line one of the form should give the title of the building. The date of construction of the building, if any, should also be designated. If the building has not yet been constructed, the notation "not yet constructed" should be given following the title.

(3) *Separate registration for plans.* Where dual copyright claims exist in technical drawings and the architectural work depicted in the drawings, any claims with respect to the technical drawings and architectural work must be registered separately.

(4) *Publication.* Publication of an architectural work occurs when underlying plans or drawings of the building or other copies of the building design are distributed to the general public by sale or other transfer of ownership, or by rental, lease, or lending. The offering to distribute copies to a group of persons for further distribution or public display also constitutes publication. Construction of a building does not itself constitute publication.

(d) *Works excluded.* The following structures, features, or works cannot be registered:

(1) *Certain functional structures.* Purely functional structures other than buildings, such as bridges, cloverleafs, dams, or walkways.

(2) *Standard features.* Individual standard features, such as windows, doors, and other staple building components.

(3) *Pre-December 1, 1990 building designs.* The designs of buildings where the plans or drawings of the building were published before December 1, 1990, or the buildings were constructed or otherwise published before December 1, 1990.

3. Section 202.19 would be amended by revising paragraph (b)(3), by removing paragraph (b)(4), and by adding new paragraph (d)(2)(viii) as follows:

§ 202.19 Deposit of published copies or phonorecords for the Library of Congress.

* * * * *

(b) *Definitions.* * * *

(3) The terms "architectural work," "copies," "collective work," "device," "fixed," "literary work," "machine," "motion picture," "phonorecord," "publication," "sound recording," "useful article," and their variant forms, have the meanings given to them in section 101 of title 17.

* * * * *

(d) *Nature of required deposit.* * * *

(2) * * *

(viii) In the case of published architectural works, the deposit shall consist of the most finished form of presentation drawings in the following descending order of preference:

(A) Original format, or best quality form of reproduction, including offset or silk screen printing;

(B) Xerographic or photographic copies of good quality paper;

(C) Positive photostat or photodirect positive;

(D) Blue line copies (diazo or ozalid process). If photographs are submitted, they should be 8 x 10 inch and should clearly show several exterior and interior views. The deposit should disclose the name(s) of the architect(s) and draftsperson(s) and the building site.

* * * * *

4. Section 202.20 would be amended by revising paragraph (b)(3) and by adding new paragraph (c)(2)(xvii) as follows:

§ 202.20 Deposit of copies of phonorecords for copyright registration.

* * * * *

(b) *Definitions.* * * *

(3) The terms "architectural works," "copy," "collective work," "device," "fixed," "literary work," "machine," "motion picture," "phonorecord," "publication," "sound recording," "transmission program," and "useful article," and their variant forms, have the meanings given to them in section 101 of title 17.

* * * * *

(c) *Nature of required deposit.* * * *

(2) * * *

(xviii) *Architectural works.*

(A) For designs of unconstructed buildings, the deposit must consist of one complete copy of an architectural drawing or blueprint in visually perceptible form showing the overall form of the building and any interior arrangements of spaces and/or design elements in which copyright is claimed. For archival purposes, the Copyright Office prefers that the drawing submissions consist of the following in descending order of preference:

(*1*) Original format, or best quality form of reproduction, including offset or silk screen printing;

(*2*) Xerographic or photographic copies on good quality paper;

(*3*) Positive photostat or photodirect positive;

(*4*) Blue line copies (diazo or ozalid process).

The Copyright Office prefers that the deposit disclose the name(s) of the architect(s) and draftsperson(s) and the building site, if known.

(B) For designs of constructed buildings, the deposit must consist of one complete copy of an architectural drawing or blueprint in visually perceptible form showing the overall form of the building and any interior arrangement of spaces and/or design elements in which copyright is claimed. In addition, the deposit must also include identifying material in the form of photographs complying with § 202.21 of these regulations, which clearly discloses the architectural works being registered. For archival purposes, the Copyright Office prefers that the drawing submissions constitute the most finished form of presentation drawings and consist of the following in descending order or preference:

(*1*) Original format, or best quality form of reproduction, including offset or silk screen printing;

(*2*) Xerographic or photographic copies on good quality paper;

(*3*) Positive photostat or photodirect positive;

(*4*) Blue line copies (diazo or ozalid process).

With respect to the accompanying photographs, the Copyright Office prefers 8 x 10 inch, good quality photographs, which clearly show several exterior and interior views. The Copyright Office prefers that the deposit disclose the name(s) of the architect(s) and draftsperson(s) and the building site.

* * * * *

Dated: September 12, 1991.

Ralph Oman,

Register of Copyrights.

Approved:

James H. Billington,

The Librarian of Congress.

[FR Doc. 91-22790 Filed 9-23-91; 8:45 am]

BILLING CODE 1410-07-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 80, 86, and 600

[FRL-4011-7]

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Refueling Emission Regulations for Gasoline-Fueled Light-Duty Vehicles and Trucks and Heavy-Duty Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of extension of public hearing.

SUMMARY: This notice announces a one day extension of a previously announced public hearing. On September 3, 1991 (56 FR 43682), EPA announced that a public hearing would be held regarding safety issues associated with onboard refueling control systems. The public hearing was previously scheduled to last one day, September 26, 1991. Due to the high level of interest and the amount of time requested for testimony by those planning to participate, the hearing has been extended to September 27, 1991

DATES: The public hearing will be held on both September 26, 1991, and September 27, 1991. Both sessions will start at 9 a.m. The second day of the hearing will continue throughout the day as long as necessary to complete testimony. Participants are welcome to testify on either day.

ADDRESSES: Both sessions of the public hearing will be held at the Royce Hotel (formerly the Airport Hilton), 31500 Wickham Road, Romulus, Michigan 48174 (telephone: 313-292-3400).

FOR FURTHER INFORMATION CONTACT: Mr. Don Kopinski, U.S. EPA (SDSB), Emission Control Technology Division, 2565 Plymouth Road, Ann Arbor, MI 48105, Telephone: (313) 668-4264.

Dated: September 17, 1991.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 91-22966 Filed 9-23-91; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 90-05; Notice 3]

RIN 2127-AD51

Federal Motor Vehicle Safety Standards; School Bus Passenger Seating and Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice solicits comments on a proposal to amend Standard No. 222, *School Bus Passenger Seating and Crash Protection*. School buses designed (on a voluntary basis or pursuant to a legal requirement other than one issued by this agency) to transport persons in wheelchairs would be required to have wheelchair securement devices and occupant restraint systems meeting specified performance requirements. The proposed amendments include establishing minimum strength and location requirements for the anchorages for securement and restraint devices, and establishing minimum strength requirements for the securement and restraint devices themselves. Currently, Standard No. 222 specifies occupant protection requirements for school bus passenger seating and restraining barriers. This proposal would provide a level of occupant protection for students in wheelchairs comparable to that currently provided to persons able to use standard bench seats. In addition, this proposal is intended to prevent potential injuries to all occupants caused by a wheelchair which is not adequately secured.

DATES: Comments must be received by November 25, 1991. If adopted, the proposed amendments would become effective one year following the publication of the final rule.

ADDRESSES: Comments should refer to the docket and notice number of this notice and be submitted to: Docket Section, room 5109, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. (Docket Room hours are 9:30 a.m.-4 p.m., Monday through Friday)

FOR FURTHER INFORMATION CONTACT: Mr. Charles Gauthier, NRM-10, Office of Vehicle Safety Standards, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC, 20590, Telephone: (202) 366-4799.

SUPPLEMENTARY INFORMATION:

Background

Federal motor vehicle safety standard No. 222, *School Bus Passenger Seating and Crash Protection*, specifies occupant protection requirements for school bus passenger seating and restraining barriers. The requirements, which apply to each "school bus passenger seat," include limits on the fore and aft spacing between adjacent rows of seats in order to keep students compartmentalized or contained within their immediate seating area during a crash. The term "school bus passenger seat" is defined in S4 of the standard as "a seat in a school bus, other than the driver's seat or a seat installed to accommodate handicapped or convalescent passengers as evidenced by orientation of the seat in a direction that is more than 45 degrees to the left or right of the longitudinal centerline of the vehicle." While recognizing that occupant protection is as important for students with disabilities as for others, the agency included this exception because the technical requirements for forward-facing seats are not relevant to or suitable for side-facing seats designed for disabled or convalescent students. The agency did not want to delay realizing the safety benefits from issuing standards for other students while attempting to develop suitable methods for providing students with disabilities with crash protection. The agency announced that it intended to establish requirements for these specialized seating arrangements in the future (41 FR 28506, July 12, 1976).

In July 1989, Mr. Lyle Stephens and Ms. Debra Simms filed a discrimination complaint with the U.S. Department of Transportation concerning seating for students with disabilities on school buses. They alleged that the Department had violated Section 504 of the Rehabilitation Act of 1973, as amended, by failing to establish "school bus passenger seating or crash protection requirements for handicapped students who use wheelchairs or require devices other than the traditional school bus passenger seat while being transported." Since the plaintiffs indicated that the relief they sought was rulemaking, the agency treated the Stephens/Simms complaint as a petition for rulemaking and published a **Federal Register** notice granting their petition to establish Standard No. 222 requirements for students with disabilities (55 FR 7346, March 1, 1990).

Shortly thereafter, the agency published a notice (55 FR 21891; May 30, 1990) announcing the availability of a study ("Wheelchair and Occupant

Restraint on School Buses," DOT–HS–807–570, May 1990) on the state-of-the-art in wheelchair securement and occupant restraints on school buses. The study was initiated in order to gather data on current wheelchair securement and occupant restraint devices on school buses to support possible future rulemakings.

The tentative conclusions of the study were:

(1) Persons transported in wheelchairs on school buses should ride in a forward-facing position.

(2) Means of securement to the vehicle for the occupant and for the wheelchair should be independent of each other.

(3) Lap and shoulder belt systems are one means of effective occupant restraint.

(4) The most universally adaptable, currently available securement systems for wheelchairs rely upon tying down the wheelchair to the floor of the vehicle with straps anchored at four points.

The May 30 notice requested comments on this report, as well as any other comments relating to the pending rulemaking to amend Standard No. 222 to establish requirements for school bus seating for students with disabilities.

Comments were received from school districts, state organizations, national and state associations, and one individual, in response to the **Federal Register** notice. All of the 12 commenters supported establishing "standards" for wheelchair securement/occupant protection. Three commenters (Arizona Department of Transportation, Indiana University School of Medicine, and the Eleventh National Conference on School Transportation) provided detailed specifications for wheelchair securement and occupant restraint systems in school buses. Three other issues were raised by commenters: Consistent safety belt use policies (Connecticut Department of Health Services); potential loss of bus capacity (Connecticut Department of Motor Vehicles and the Cupertino Union School District); and wheelchair crashworthiness (Minnesota School Bus Safety Committee). These comments are addressed in greater detail below.

Agency's Proposal

NHTSA is proposing that school buses designated (on a voluntary basis or pursuant to a legal requirement other than one issued by this agency) to transport persons in wheelchairs be required to be equipped with wheelchair securement devices and occupant restraint systems meeting specified performance requirements.

Specifically, the agency has tentatively concluded that every wheelchair securement location on a school bus must be equipped with devices which would secure a wheelchair at a minimum of four points in a forward-facing position. In addition, the wheelchair securement location must be equipped with lap and upper torso belts to restrain the wheelchair occupant. The proposed standard would also include strength requirements for the wheelchair securement device, for the belts used in the occupant restraint device, and for the anchorages used for wheelchair securement devices and occupant restraint devices.

Finally, the agency believes that if this proposal is adopted, the manufacturers and purchasers of the wheelchair securement and occupant restraint systems should endeavor to design and select systems which can be operated by the wheelchair user. User-friendly systems would enhance the independence and protect the privacy of the wheelchair user. The agency recognizes, as is noted in the state-of-the-art study, that nearly all current wheelchair securement systems require assistance to operate. However, this is not necessarily the case with occupant restraint systems, some of which can be connected by the occupant of the wheelchair if the student has adequate ability and/or strength to do so.

The specific issues considered by the agency in developing this proposal are discussed below.

1. Whether To Propose Requiring Each School Bus To Have a Wheelchair Securement Location

The agency is not proposing that all school buses be designed to transport at least one person in a wheelchair. The agency believes that decisions on how many school buses should be configured to carry students in wheelchairs are most easily and accurately made by local school districts based on the particular number of children with disabilities whom they have the responsibility to transport.

2. System Versus Component Test Requirements

A major aspect of developing any regulation dealing with occupant crash protection is determining the appropriate means of measuring performance. Two approaches can be taken. First, the agency can take a full system approach which measures the forces experienced by a human surrogate in a simulated crash to determine the occupant protection performance of the entire system. Such an approach would require that many steps be taken by the agency, including the development of an appropriate test dummy, the identification of human injury tolerance levels appropriate for students whose disabilities may make them more susceptible to injury than able-bodied students, the establishment of test conditions, the selection and use of a "standard" or surrogate wheelchair, the establishment of test procedures for placing the wheelchair and the dummy in an effective test configuration, and the development and building of an appropriate test buck, i.e., a structure that would simulate a portion of a representative school bus body and to which securement and restraint devices and anchorages could be attached for the purpose of conducting a sled crash test.

All of the parties active in national and international efforts to establish standards for wheelchair securement and occupant restraint are attempting to establish standards based on dynamic tests. However, the agency is unaware of any activities that are underway which would enable it to take all the previously mentioned steps. Therefore, at this time, NHTSA is unable to propose a dynamic test of wheelchair securement and occupant restraint systems.

Second, the agency can take an approach in which it specifies performance criteria for individual components of a wheelchair securement system and an occupant restraint system. Such an approach would require the specification of the location and strength of anchorages and securement and restraint devices.

While the first approach is preferred, the agency does not believe that it is reasonable to delay the entire process of providing crash protection to wheelchair occupants while major research programs are developed, initiated and completed. For that reasons, NHTSA is proposing performance requirements for the equipment that would be used to secure wheelchairs and provide occupant restraint for occupants of wheelchairs on school buses. Requirements for the major components of wheelchair securement and occupant restraint systems have also been adopted by the various "standards" organizations that are attempting to develop a dynamic test. A review of the requirements of these organizations is summarized in Chart 1.

In addition to the requirements of various organizations, NHTSA has reviewed the specifications of various manufacturers of wheelchair securement and occupant restraint systems to determine the strength of devices currently being manufactured. Chart 2 provides data from several

manufacturers. After reviewing these specifications and the requirements of the "standards" organizations, the agency has concluded that current wheelchair securement and occupant restraint systems meet or exceed the "standards" established by these organizations in most instances.

CHART 1.—WHEELCHAIR SECUREMENT/OCCUPANT RESTRAINT COMPONENT REQUIREMENTS

Organization	Anchorage strength	Securement/restraint strength
Architectural and Transportation Barrier Compliance Board	GVWR>30,000#: 2,000# GVWR<30,000#: 2,500#	GVWR>30,000#: 2,000# for each component of the system. GVWR<30,000#: 2,500# for each component of the system.
Canadian Standards Association	1,500#-Upper Torso 2,500#-Pelvic 3,000#-Combined	2,500# for each component of the system. 6,000# total for a Type 1 belt system. 5,000# total for a Type 2 belt system.
Sweden		2,000# for each component.
Great Britain		2,000# for each component.
Eleventh National Conference on School Transportation	2,500# per anchorage; and Comply wth FMVSS 210	2,500# for each component of the system; and Comply with FMVSS 209.
Indiana	Wheelchair anchorage: Comply with FMVSS 207 Restraint anchorage: Comply with FMVSS 210 If securement device and restraint share common anchorages: 6,000# per anchor point (2) 12,000# per single anchor point	Comply with FMVSS 209

CHART 2.—WHEELCHAIR SECUREMENT/OCCUPANT RESTRAINT MANUFACTURERS' SPECIFICATIONS

Company	Anchorage strength	Securement/restraint strength
Kinedyne Corporation (formerly Aeroquip)	Floor track: 5,000# Sidewall anchor: FMVSS 210	
Q-Straint	Floor anchor: 6,000#	Rear securement belt: 6,000# Front securement belt and lap belt: 2,000# Shoulder belt: 2,500#
Tie Tech, Inc.	Floor anchor: 5,000#	Front & rear securement belt: 3,000# Lap belt: 6,000# Shoulder belt: 6,000#

3. Performance Criteria

Based on its review of the standards and manufacturing practices outlined above, NHTSA believes that a fairly consistent pattern of requirements exists. In particular, they provide for forward-facing wheelchair securement positions, separate securement and restraint devices, four-point securement of wheelchairs through the use of belt systems, and the strength requirements for the anchorage and securement/restraint systems. The agency has used these standards and practices as the basis for the minimum Federal requirements proposed in this notice.

The performance requirements for the wheelchair securement/occupant restraint devices reference Standard No. 209, *Seat Belt Assemblies*. These requirements are consistent with existing systems in the marketplace and "standards" of other organizations.

With regard to anchorages, the agency has tentatively concluded that the appropriate floor strength requirement for each anchorage is 3,000 pounds (6,000 pounds if the securement and restraint systems share a common anchorage). This requirement is based on S4.2(a) of Standard No. 207, *Seating Systems*. That section specifies the force level applied to a seat anchorage as 20 times the weight of a seat. Therefore, for a 200 pound wheelchair, the force level would be 4,000 pounds. However, crash conditions do not always produce force directions that would result in the 4,000 pounds being evenly distributed between two anchorage locations. Crash directions and the complicated angles of securement and restraint systems suggest that adequate strength potential be included in the requirements. For this reason, the agency has tentatively concluded that the floor strength requirement for each anchorage should be 75 percent of the figure derived from Standard No. 207. As seen in charts 1 and 2, the proposed requirements are consistent with existing systems in the marketplace and "standards" of other organizations.

In addition to anchorage and securement/restraint device strengths, the other critical component is the location of the anchorage points. NHTSA has reviewed the requirements of the various national and international organizations on anchorage location and found that the requirements are fairly consistent in the ranges they allow for the locations of the securement and restraint device anchorages and for the angles for applying forces to those anchorages. These ranges are necessary in order to accommodate various sizes and configurations of wheelchairs, different sizes of individuals with varying degrees of disability, and design differences among restraint devices. Because of the wide variety of wheelchair sizes and configurations, wheelchair securement anchorage locations are not defined in terms of their physical location, but rather in terms of the installed angles of the securement device relative to the wheelchair. The requirements of other national and international organizations universally require angles not less than 30 degrees and not more than 60 degrees as measured from either the horizontal or vertical position in the longitudinal direction. The agency is proposing to require a narrower range of angles (40 degrees to 50 degrees) in Standard No. 222.

4. Wheelchair Orientation

As noted in the state-of-the-art report on wheelchair securement devices, a number of wheelchair securement devices are designed for side-facing

wheelchairs. The conclusions section of the report noted that in order to provide for maximum occupant protection, wheelchairs on school buses should be in a forward-facing position because wheelchairs are inherently stronger in this direction and because human injury tolerance levels are higher in the forward versus side direction. Additionally, a review of the Fatal Accident Reporting System for 1989 indicates that approximately 68 percent of school bus crash fatalities are frontal crashes.

Various other organizations working on wheelchair securement and occupant restraint occur with the forward-facing orientation, including the Society of Automotive Engineers (SAE), the International Standards Organization (ISO), and the Canadian Standards Association (CSA). Additionally, the existing standards of several countries, e.g., Australia, Canada, and Great Britain, allow only forward or rearward-facing wheelchair orientations.

Comments in response to the May 1990 notice were primarily positive with regard to this issue. However, two commenters, the Connecticut Department of Motor Vehicles and the Cupertino Union School District, voiced concern about mandating forward-facing wheelchair locations. The basis for their concern was an estimated ⅓ reduction in wheelchair capacity resulting from using forward-facing locations instead of side-facing ones in buses configured wholly or mostly for transporting students in wheelchairs. NHTSA acknowledges this reduction would occur in cases in which the entire bus is configured for transporting children in wheelchairs, but believes that the additional level of safety provided in the forward-facing position more than offsets the loss in capacity. In addition, as the agency has already noted, not all school buses need to be equipped for transporting children with disabilities to and from school and school-related activities. Decisions on the number of buses that should be designed to carry persons in wheelchairs, and the number of wheelchair locations on those buses, should be made by local school districts based on the number of children with disabilities they have the responsibility to transport. Therefore, the loss of capacity would not be so great as the commenters suggest.

Additionally, the agency has reviewed the requirements of several states and determined that requirements for forward-facing wheelchair locations either already exist or are being proposed in most of the states. These actions are consistent with the recommendation from the Eleventh National Conference on School Transportation. For these reasons, the agency is proposing that wheelchair locations must be forward-facing.

5. Separate Restraint Systems for Wheelchair Securement and Occupant Restraint

Existing wheelchair securement standards of various groups and countries use three approaches to the securement of wheelchairs and the restraint of wheelchair occupants. The first utilizes completely independent securement and restraint devices which are independently secured directly to anchorage points. The second approach utilizes a main belt which secures the wheelchair to the floor and an occupant restraint system which has the lap belt portion attached to the main belt. The third approach utilizes a wheelchair securement device that attaches to the bus and an occupant restraint system that attaches to the wheelchair.

The state-of-the-art study tentatively concluded that "(t)he wheelchair and its occupant should be restrained to the vehicle independently." Comments responding to the May 1990 notice supported that finding. Further, the detailed "standards" provided by the Eleventh National Conference on School Transportation and the Indiana University School of Medicine require separate restraint systems for the wheelchair and its occupant.

Even though existing standards require separate securement and restraint systems, the agency is proposing a component test approach which would allow any of the above mentioned systems. The agency is concerned about the potential for the secured wheelchair to place a load on the restrained wheelchair occupant in certain high-speed crashes, for example, a small child riding in a heavy electric wheelchair, if separate securement and restraint systems are required. In a crash, the heavier wheelchair would tend to move forward further than the much lighter wheelchair occupant who does not stretch the restraint belts as much as the wheelchair stretches the securement belts. The wheelchair could push against the back of the occupant and cause the occupant to be compressed between the wheelchair and the occupant restraint safety belts. In this situation, the child could be exposed to a higher injury potential because the wheelchair could be applying a force on his or her back. This problem is commonly referred to as "phasing," the result of different masses reacting to the same deceleration forces.

However, the agency does not believe that the "phasing" problem warrants prohibiting separate wheelchair securement and occupant restraint systems. First, it is possible to control or lessen the problem by requiring less elongation for wheelchair securement belts relative to those for the occupant restraint belts. The proposed regulatory language includes comparable belt strengths for the wheelchair securement belts (2,500 pounds) than for the occupant restraint belts (2,500 pounds for a pelvic restraint, 1,500 pounds for a torso restraint, and 3,000 pounds for combination pelvic and torso restraints). Additionally, the belt elongation limits of Standard No. 209 for Type 1 belts (wheelchair securement) and Type 2 belts (occupant restraint) are included in the proposed regulatory requirement.

Second, NHTSA believes that the occurrence of phasing problems is relatively rare, based on the fact that the agency has no information indicating that fatalities or serious injuries have occurred to wheelchair occupants in buses. Third, the agency does not believe that phasing is a significant problem when compared to the benefits of secured wheelchairs and restrained occupants in low-speed crashes and sudden driving maneuvers which constitute the majority of situations resulting in injuries to wheelchair occupants in school buses.

The proposed rule allows for, but does not mandate, the use of systems which either reduce or eliminate the potential phasing problem. Clearly, an occupant restraint system which has the lap belt portion attached to the wheelchair would not have a phasing problem since it allows the wheelchair and its occupant to move forward as a unit. However, this system cannot be mandated because there are not many wheelchairs in the marketplace which are capable of withstanding the forces that would be generated by anchoring an occupant restraint system to them.

6. Safety Belt Implications

The Connecticut Department of Health Services believes that providing safety belts for children in wheelchairs in school buses would give other children a mixed message about the importance of safety belts, and believes that safety belts should be installed in all seating positions on school buses.

With regard to requiring safety belts on all school buses, NHTSA believes that the conclusions of the National Academy of Sciences in their May 1989 report, "Improving School Bus Safety," are still valid. This report concludes, "(t)he overall potential benefits of

requiring seat belts on large school buses are insufficient to justify a federal requirement for mandatory installation. The funds used to purchase and maintain seat belts might better be spent on other school bus safety programs and devices that could save more lives and reduce more injuries."

With regard to providing safety belts for children in wheelchairs on school buses, the agency believes that a significant number of school buses used to transport children with disabilities have gross vehicle weight ratings of 10,000 pounds or less, and are, therefore, required under Standard No. 222 to be equipped with lap belts at all passenger seating positions. When Standard No. 222 was initially established, the agency determined that passengers in school buses in this lower weight category are better protected through the installation of safety belts and not just compartmentalization. Thus, there is regulatory symmetry for school buses with gross vehicle weight ratings of 10,000 pounds or less.

For school buses with gross vehicle weight ratings over 10,000 pounds, requiring safety belts for children in wheelchairs is one part of creating a "safe environment". For able-bodied children, a "safe environment" is provided by Standard No. 222 by "compartmentalization." Since the seat-spacing required by Standard No. 222 cannot be obtained with wheelchairs, full "compartmentalization" cannot be obtained. Additionally, the agency believes that a significant number of students with disabilities may be more susceptible to injury than able-bodied students. For both "safe environments", it is the responsibility of the school district and/or school bus operator to ensure that the "safe environment" is properly used. In the case of a compartmentalized seat, students must be directed to sit correctly (for example, not kneeling on the seats or sitting backwards) in order to benefit from the "compartmentalization." In the case of the children in wheelchairs, they and their wheelchairs must be restrained in order to be protected from crash forces.

Finally, student education programs on safety belts and their use are currently included in most school curricula, and these programs could be expanded to include a section on school bus safety.

For the above reasons, NHTSA does not agree with the Connecticut Department of Health Services that safety belts should be installed in all school buses.

7. Wheelchair Crashworthiness

When commenting on the May 1990 notice, the Minnesota School Bus Safety Committee questioned the ability of various wheelchair designs to withstand crash forces and also noted the lack of information on securement locations on wheelchairs and other mobile seating devices. NHTSA agrees that these are legitimate concerns. NHTSA notes that other organizations, e.g., CSA, are actively involved in establishing standards for wheelchairs, and that some wheelchair manufacturers are actively involved with these organizations and the development of "transport" wheelchairs, i.e., wheelchairs that can withstand a 30 mph/20 g crash test with an integral occupant restraint system. However, the agency expects that such concerns as development of appropriate levels of structural integrity for wheelchairs and other mobile seating devices, as well as the development of objective tests to ensure such integrity, will take an extremely long time.

At the present, almost any type of wheelchair or mobile seating device can be used on school buses. The agency believes this proposed rule would improve on these situations by mandating adequate securement and restraint devices, even though requirements for a "transport-certified" wheelchair are not proposed.

8. Definition of "School Bus Passenger Seat"

NHTSA is also proposing to delete the phrase "or a seat installed to accommodate handicapped or convalescent passengers as evidenced by orientation of the seat in a direction that is more than 45 degrees to the left or right of the longitudinal centerline of the vehicle" from the definition of a "school bus passenger seat." The agency believes that the only side-facing seating currently in school buses are wheelchair locations oriented in a side-facing direction. The agency is not aware that there is any need for seating beyond regular school bus bench seating or wheelchair securement locations. Deleting this phrase would ensure that all students transported in a school bus are offered a high level of crash protection.

The agency requests comments on any existing need to retain the exception for side-facing seats in the definition.

9. School Bus Capacity

The Eleventh National Conference on School Transportation's standard requires that any vehicle which would have been a school bus if equipped with regular bench seats (i.e., which has a capacity of 11 or more), and which is classified as a multipurpose passenger vehicle when wheelchair restraints are installed in place of bench seats (i.e., has a capacity of 10 or less), must comply with all the standards applicable to school buses. The agency believes that the majority of vehicles used to transport persons in wheelchairs are vehicles which, when equipped with regular, forward-facing bench seating, have a sufficient number of seating positions to be classified as school buses. When these vehicles are equipped with wheelchair positions instead of bench seats, their passenger capacity is reduced. The agency is concerned that, especially for vehicles with multiple wheelchair locations, the capacity could be lowered to the point that the vehicle is classified as a multipurpose passenger vehicle (MPV) instead of a school bus. As an MPV, the vehicle would not be subject to the proposal, or to any of the existing school bus standards.

The agency requests comments on the size and capacity of vehicles which are equipped to transport students in wheelchairs. The agency also requests comments on extending the performance requirements for wheelchair securement/occupant restraints to systems installed in multipurpose passenger vehicles. Specifically, the agency requests comments on the impact such an extension would have on non-school uses of multipurpose passenger vehicles, such as para-transit vans, to transport persons in wheelchairs.

Benefits

The agency's review of various crash data reveals only one fatality involving a wheelchair occupant in a school bus crash. However, the potential for a fatality is always present, particularly given the wide diversity of devices and techniques used in school buses to secure wheelchairs and provide some form of occupant restraint to the occupants of those wheelchairs. Additionally, larger numbers of children with disabilities are being "mainstreamed" into the public school systems each year, and these students require safe transportation. Developing minimum Federal performance standards for wheelchair securement and occupant restraint devices would provide assurance that equipment would be available which could provide an environment which gives persons in wheelchairs a level of occupant protection comparable to that provided to able-bodied school bus passengers.

Wheelchair securement and occupant restraint systems provide an environment for the safe transportation of students in wheelchairs. Likewise, strong, well-anchored, evenly-spaced, and padded school bus seats provide an environment for the safe transportation of able-bodied students. Both of these environments are effective only when properly used.

While benefits cannot be measured in terms of numbers of fatalities prevented, the agency believes that the largest potential benefit of this rulemaking would be in reducing injuries in low-speed crashes and sudden driving maneuvers. This is particularly important when considering the issue of separate wheelchair securement and occupant restraint systems. As previously discussed, in a high-speed, high-energy level crash, the light-weight occupant of a heavy wheelchair could be exposed to a dangerous environment created by securement and restraint systems which anchor separately to the floor. In low-speed crashes and sudden driving maneuvers, separate securement and restraint devices are not potentially harmful for the light-weight occupant of a heavy wheelchair. Accordingly, large numbers of injuries to the occupants of wheelchairs would be averted.

The agency reviewed the 1986–1990 nonfatal crash data from the National Electronic Injury Surveillance System (NEISS) and estimates that approximately 300 occupants of wheelchairs in all types of buses were injured over that 5-year period as a result of a wheelchair securement problem, e.g., no securement device. Nearly all of these injuries were of a nature that the persons were either treated and released by the hospital, or examined and released without treatment. A few of the injuries were of moderate severity.

While the agency has no data specifically on school buses, it is believed that most of the above mentioned injuries occurred on non-school buses. The agency requests commenters to supply any data they have on the number of injuries that occur each year to children with disabilities on school buses that involve a wheelchair securement device.

While the agency has not quantified the benefits of this standard, it has quantified the potential population of people who would benefit from this rulemaking action. In the state-of-the-art study, it was estimated that of the 46 million students enrolled in public and private schools in 1990 (grades K through 12), approximately 50,000 to 80,000 students are transported in wheelchairs. As mentioned previously, this number is expected to increase in the future. While this is a small percentage of the total school population, these students are at least as likely as other students to be injured in a crash or sudden driving maneuver. It has been argued that because of their particular disability, some children are even more susceptible to injury. Additionally, a wheelchair that is not adequately secured becomes a potential cause of injury to all occupants of a school bus.

Costs

The decision to install wheelchair securement/occupant restraint devices in school buses would result from local preferences and other considerations, and not this agency's adoption of the proposed requirements. Therefore, equipment and installation costs can only be attributed to this rulemaking if the cost of a device certified to meet this standard, and associated installation costs, would exceed the cost of devices currently being installed. However, since many of the current securement and restraint devices appear to be capable of meeting the proposed requirements, it is estimated that the additional cost to equip a school bus with restraints that are certified to meet these requirements would be minimal.

Another potential source of costs associated with this rulemaking would arise from the need of any school district or contract carrier to buy additional buses to offset the loss of seating capacity resulting from the switch from side-facing seats to forward-facing positions for children in wheelchairs. However, the agency expects that these costs would also be minimal.

The agency believes that the loss of wheelchair positions due to switching to a forward-facing orientation can be offset, by some school districts (e.g. large metropolitan fleets), by utilizing excess school bus fleet capacity. School districts typically have extra buses in their fleets to augment maintenance/repair schedules, to accommodate fluctuations in enrollment, as well as to support extracurricular school activities. In addition, NHTSA believes that many local school districts may opt to reconfigure their existing fleet of buses (e.g. remove conventional seats, add wheelchair positions to buses already equipped with wheelchair lifts) and/or redesign bus routes to better utilize available equipment and manpower. However, there may be local cost impacts (e.g. adding wheelchair lifts to a limited number of conventional school buses), but these costs are not anticipated to be national in scope. NHTSA does not expect that more school buses will have to be purchased to accommodate the forward-facing wheelchair requirement. Several state Directors of Pupil Transportation contacted by the agency have indicated that they have adopted or in the process of adopting the Eleventh National Conference on School Transportation recommendation and are ordering new school buses with forward-facing wheelchair positions.

Questions

NHTSA requests that commenters specifically address the following questions:

1. The agency seeks comment on all aspects of the proposed requirements, particularly with respect to the forces and angles specified under the test conditions.

2. Is there room in a bus to pull on the securement and restraint anchorages with the forces and at the angles specified in the regulatory language?

3. Would different angles, such as 10 degrees (rather than 45 degrees) above the floor plane for the wheelchair securement devices, create more severe test conditions? Would these test conditions be more representative of real-world situations? What are the most appropriate angles for testing?

4. As an alternative to separately testing securement and restraint anchorage locations and the securement and restraint systems themselves, should the agency test everything in a systems test by pulling the securement and restraint system with blocks of material that represent a wheelchair and a person? The body blocks specified in FMVSS No. 210 could be used to test both the securement and restraint systems. The test could be conducted using a 3,000 lb. force on the occupant restraint and a 5,000 lb. force on the wheelchair securement under the general test conditions of Standard No. 210.

5. What data, particularly sled test data, exist on the issue of potential phasing problems related to small, light-weight students in heavy wheelchairs where separate wheelchair securement and occupant restraint devices are utilized?

6. Will the belt elongation requirements specified in Standard No. 209 (Type 1 belts = 20% elongation; Type 2 belts = 30–40% elongation) be sufficient to eliminate the "phasing" problem? If not, what elongation requirements would be effective?

7. Is there any existing information which indicates that conducting dynamic tests using wheelchairs and

test dummies, as opposed to the proposed component tests, would result in safer wheelchair securement and occupant restraint devices?

8. What types of wheelchairs or other mobile seating devices are being transported on school buses currently? Are the proposed requirements suitable for the full range of wheelchair types currently available or anticipated in the marketplace, e.g., conventional 4-wheel, motorized 4-wheel, 3-wheel scooters, orthopedic, etc.?

9. What types of wheelchair securement and occupant restraint systems are individual states, school districts and contract carriers currently using on school buses? What number and percentage of the wheelchair securement and occupant restraint systems are forward-facing? What number and percentage are side-facing?

10. What have been the school bus crash and injury experiences involving persons seated in wheelchairs? What types of crashes or sudden driving maneuvers resulted in injuries? What is the type and severity of the resulting injuries? What types of wheelchair securement and/or occupant restraint systems were being used?

11. How often are school buses retrofitted with wheelchair securement and occupant restraint devices? Are school buses retrofitted with these types of equipment or are the systems installed on new school buses by the school bus manufacturer?

12. Is the selection of the securement and restraint systems based on the physical or medical needs of the individual or the characteristics of the wheelchair? When multiple wheelchair locations are provided on a school bus, are all the securement and restraint systems the same and can they accommodate the needs of different wheelchairs and students being transported?

13. Would the requirement for only forward-facing wheelchair orientations in school buses produced after the effective date of the proposed requirements affect the number of school buses that would be necessary to transport students with disabilities? If the amount of space devoted to wheelchair locations in a school bus was held constant, what loss in the number of such locations would occur in switching from side-facing locations to front-facing locations? If the number of wheelchair locations in a school bus equipped also with bench seats was held constant in switching from side-facing locations to front-facing ones, what loss in bench seat positions would occur? Would there be any practical or policy problems created by operating older school buses with side-facing wheelchair locations and new buses with forward-facing wheelchair locations in the same school district?

14. The agency is concerned about the storage and cleanliness aspects of wheelchair securement and occupant restraint belts because of the potential effects of these aspects on the usage rates of those devices. NHTSA therefore seeks comments on requiring that these belts be retractable. Do any systems currently use retractors? Would retractors render securement and/or restraint systems more difficult to use because of the need to have the belt go through or around parts of the wheelchair?

15. While the regulatory text in this notice is limited to wheelchair securement and occupant restraint on school buses, the agency is interested in information on the appropriateness of these requirements for other buses and vehicles used to transport individuals in wheelchairs. In considering this question, the agency is concerned about how local regulations governing the permissibility of the bus driver leaving his seat to assist in the securing and restraining of a person in a wheelchair affects the appropriateness of this proposal for non-school buses.

16. Of the school buses used to transport students in wheelchairs, what number and percentage have gross vehicle weight ratings of 10,000 pounds or less? What number and percentage are Type A, B, C or D school buses?

17. What is the average number of wheelchairs accommodated by school buses currently in use? What is the distribution of school buses with 1 wheelchair location, 2, 3, 4, 5, and 6 or more?

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has examined the impacts of this rulemaking action and determined that the notice is not major within the meaning of E.O. 12291. However, it is "significant" within the meaning of E.O. 12291. However, it is "significant" within the meaning of the Department of Transportation's regulatory policies and procedures because of the public interest associated with this proposed rulemaking action. The agency has prepared a Preliminary Regulatory Evaluation (PRE) for this proposal, and placed a copy of the PRE in the public docket for this rulemaking action. A copy of the PRE may be obtained by writing to: Docket Section, NHTSA, room 5109, 400 Seventh Street, SW., Washington, DC 20590.

NHTSA is not mandating the use of wheelchair securements/occupant restraints in school buses. School districts must install wheelchair securements/occupant restraints in order to comply with State and local ordinances/regulations governing the transport of handicapped students. School districts order the appropriate wheelchair tie-down/restraint anchorage points as optional equipment from the school bus manufacturers or they retrofit the anchorage points (e.g., install the anchors themselves). Most school buses have side-facing wheelchair positions. The consumers, in this case, are the state and local school districts as well as private school bus contractors.

Incremental consumer costs are potentially associated with three aspects of this proposal; (1) the switch to forward-facing wheelchair positions, (2) the cost for the bus manufacturers to design, develop, test, certify and build school buses with the proposed anchorage strength levels and (3) securement/restraint equipment manufacturers certification that their hardware complies with the agency's requirements. The agency does not anticipate any significant increase in consumer costs due to any of the requirements of the subject proposal. For this rule to be *major* the incremental consumer costs would have to exceed $100 million. Interested persons are invited to examine the PRE for more detailed discussion.

Regulatory Flexibility Act

NHTSA has also considered the impacts of this rulemaking action under the Regulatory Flexibility Act. This analysis appears in the PRE. Based on this evaluation, I certify that the proposed amendments would not have a significant economic impact on a substantial number of small entities.

The Regulatory Flexibility Act is concerned with the adverse economic impact of rules and regulations on small entities, namely—small businesses, small organizations and small governmental jurisdictions. A small business is defined by either the number of employees or the annual sales volume in dollars, a small organization is defined as being non-profit and not dominant in its field, and a small governmental jurisdiction (e.g. a local school district) consists of 50,000 or less constituents. The proposed rule will affect small businesses (SB), small organizations (SO) and small governmental jurisdictions (SGJ) which

exist in the following categories: Public and contractor school bus transportation operations (SGJ/SB), city and county public school systems (SGJ), private schools (SB/SO), manufacturers of side-facing wheelchair securement/occupant restraint equipment (SB), forward-facing wheelchair securement/occupant restraint equipment manufacturers/distributors (SB), school bus manufacturers (SB), and dealers and distributors of school buses (SB).

School bus transportation operators (public and contracted) which transport both public and private school students must periodically purchase new school buses to replace worn-out equipment or expand operations. Lift equipped school bus purchase decisions and the types of wheelchair securement/occupant restraints employed, are made, in many cases, by small governmental jurisdictions (e.g. local public school districts) and/or small business/organizations (e.g. local public school districts) and/or small business/organizations (e.g. private schools). The agency believes that the cost (consumer or retail cost) of purchasing a new school bus will not increase due to NHTSA's proposal because bus manufacturing costs will not increase. In addition, because the consumer cost of a new school bus will not increase, sales will not be influenced and school bus dealers and distributors will not be affected by the proposed rule. Many of the school bus manufacturers are small businesses and all of the school bus dealers are believed to be small businesses.

NHTSA believes that many of the forward-facing wheelchair securement/occupant restraint manufacturers are small business entities. The agency does not expect a significant cost impact on these manufacturers because most, if not all, already comply with the proposed requirements. Additionally, focusing national attention on restraints for students in wheelchairs should increase business opportunities.

The manufacturers of side-facing wheelchair securement hardware will lose their school bus business, and if the proposed requirements are extended to non-school buses, this line of business may be completely lost. The agency believes that most of these manufacturers are small businesses, however, NHTSA does not believe these manufacturers will be put out-of-business because, (1) they can re-tool for forward-facing hardware and use their existing marketing infrastructure and (2) the agency believes that these companies have many other product lines to sustain them in business.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. No. 96–511), there are no requirements for information collection associated with this proposed amendent.

National Environmental Policy Act

NHTSA has also analyzed this rulemaking action for the purpose of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

Executive Order 12612 (Federalism)

Finally, NHTSA has analyzed this proposal in accordance with the principles and criteria contained in E.O. 12612, and the agency has determined that this proposal does not have significant federalism implications to warrant the preparation of a Federalism Assessment.

Submission of Comments

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted.

All comments must not exceed 15 pages in length. (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the enveloped with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, it is proposed that 49 CFR 571.222 be amended as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

1. The authority citation for part 571 would continue to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.222 [Amended]

2. S4 would be amended by revising the definition of "school bus passenger seat" as follows:

School bus passenger seat means a seat in a school bus, other than the driver's seat.

3. S4 would be revised to add the following new definitions:

Wheelchair means a wheeled seat frame for the support and conveyance of a physically disabled person, comprised of at least a frame, seat, and wheels.

Wheelchair occupant restraint anchorage means the provision for transferring wheelchair occupant restraint system loads to the vehicle structure.

Wheelchair securement anchorage means the provision for transferring wheelchair securement device loads to the vehicle structure.

Wheelchair securement device means a strap, webbing or other device used for securing a wheelchair in place in a school bus during normal travel as well as during a crash, including all necessary buckles and other fasteners.

4. A new section 5.4 would be added as follows:

S5.4 Each school bus having one or more locations designed for carrying a person seated in a wheelchair shall comply with S5.4.1 through S5.4.4 at each such wheelchair location.

S5.4.1 *Wheelchair securement anchorages.* Each wheelchair location shall have not less than four wheelchair

securement anchorages complying with S5.4.1.1 through S5.4.1.2.

S5.4.1.1 Each wheelchair securement anchorage shall have a wheelchair securement device complying with S5.4.2 attached to it.

S5.4.1.2 The wheelchair securement anchorages at each location shall be located so that—

(a) The wheelchair is secured in a forward-facing position.

(b) The wheelchair can be anchored by a wheelchair securement device at two locations in the front and two locations in the rear.

(c) The front wheel of a three-wheeled mobile seating device can be secured.

S5.4.1.3 Each wheelchair securement anchorage shall be capable of withstanding a force of 3,000 pounds applied as specified in paragraphs (a) through (e) of this section.

(a) The initial application force shall be applied at an angle of not less than 40 degrees, but not more than 50 degrees, measured from the horizontal. (See Figure 1.)

(b) The horizontal projection of the force direction shall be within a horizontal arc of ±45 degrees relative to a longitudinal line which has its origin at the anchorage location and projects rearward for an anchorage whose wheelchair securement device is intended to secure the front of the wheelchair and forward for an anchorage whose wheelchair securement device is intended to secure the rear of the wheelchair. (See Figure 1.)

(c) The force shall be applied at the onset rate of not more than 30,000 pounds per second.

(d) The 3,000 pound force shall be attained in not more than 30 seconds, and shall be maintained for 10 seconds.

BILLING CODE 4910-59-M

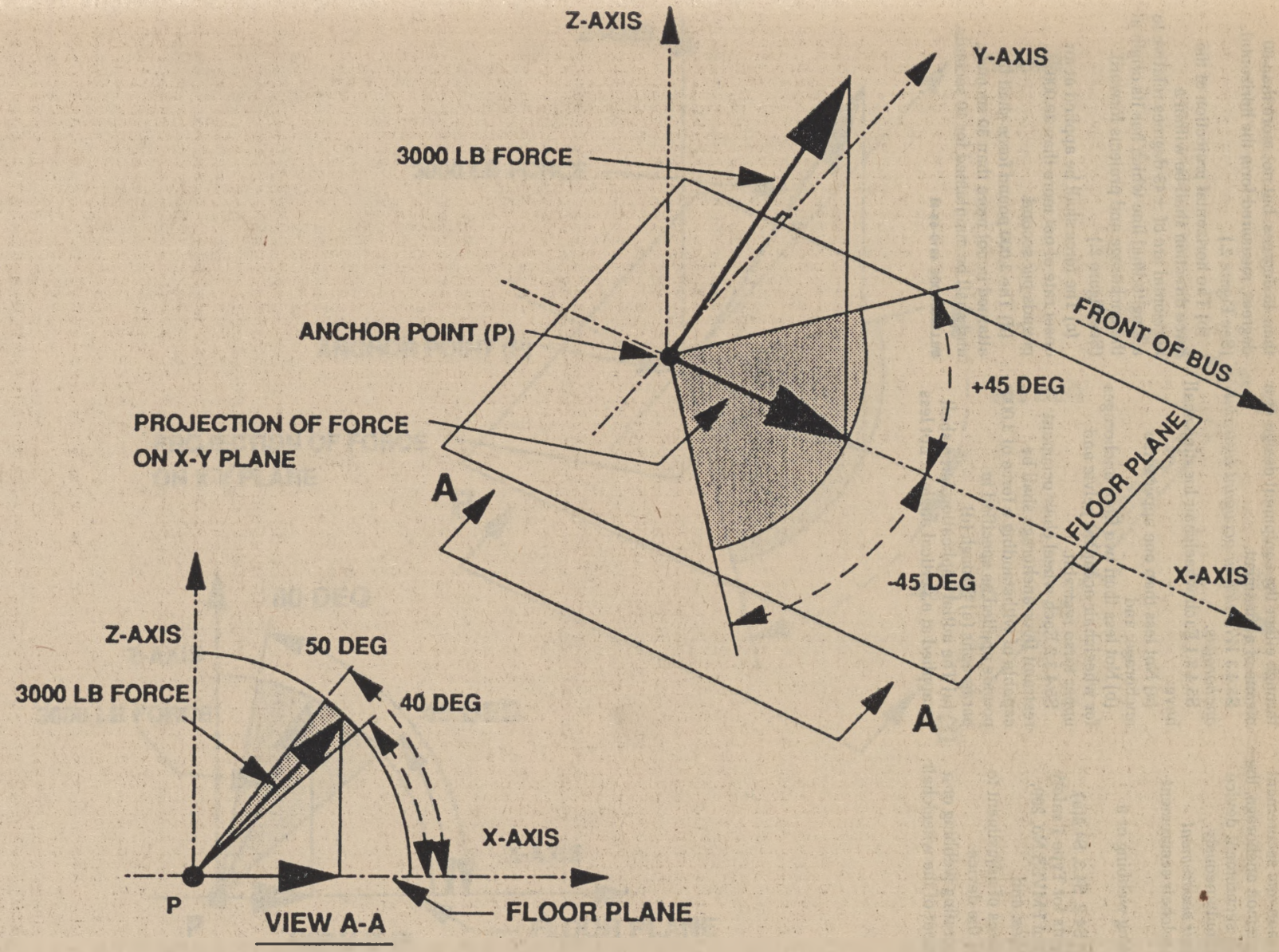


Figure 1. Wheelchair Securement Anchorage Loading Direction (Rear Anchorage Shown)

BILLING CODE 4910-59-C

(e) When more than one securement device shares a common anchorage, the loads through each securement device shall be applied simultaneously.

S5.4.2 *Wheelchair securement devices.* Each wheelchair securement device shall—

(a) If incorporating webbing or a strap—

(1) Comply with S4.2, S4.3, S4.4(a), and the requirements for Type 1 safety belt systems in S5 of FMVSS No. 209, *Seat Belt Assemblies*; and

(2) Provide a means of adjustment to remove slack from the device.

(b) If not incorporating webbing or a strap, limit movement of the wheelchair through either the equipment design or a means of adjustment.

S5.4.3 *Wheelchair occupant restraint anchorages.*

S5.4.3.1 Each wheelchair location shall have:

(a) Not less than one upper torso anchorage; and

(b) Not less than two floor anchorages for wheelchair occupant pelvic and upper torso restraint.

S5.4.3.2 Each wheel chair occupant restraint floor anchorage shall be capable of withstanding a force of 3,000 pounds applied as specified in paragraphs (a) through (d).

(a) The initial application force shall be applied at a vertical angle of not less than 45 degrees, but not more than 80 degrees, measured form the horizontal. (See Figure 2.)

(b) The horizontal projection of the force direction shall be within a horizontal arc of ±45 degrees relative to a longitudinal line which has its origin at the anchorage and projects forward. (See Figure 2.)

(c) The force shall be applied at an onset rate of not more than 30,000 pounds per second.

(d) The 3,000 pound force shall be attained in not more than 30 seconds, and shall be maintained for 10 seconds.

BILLING CODE 4910-59-M



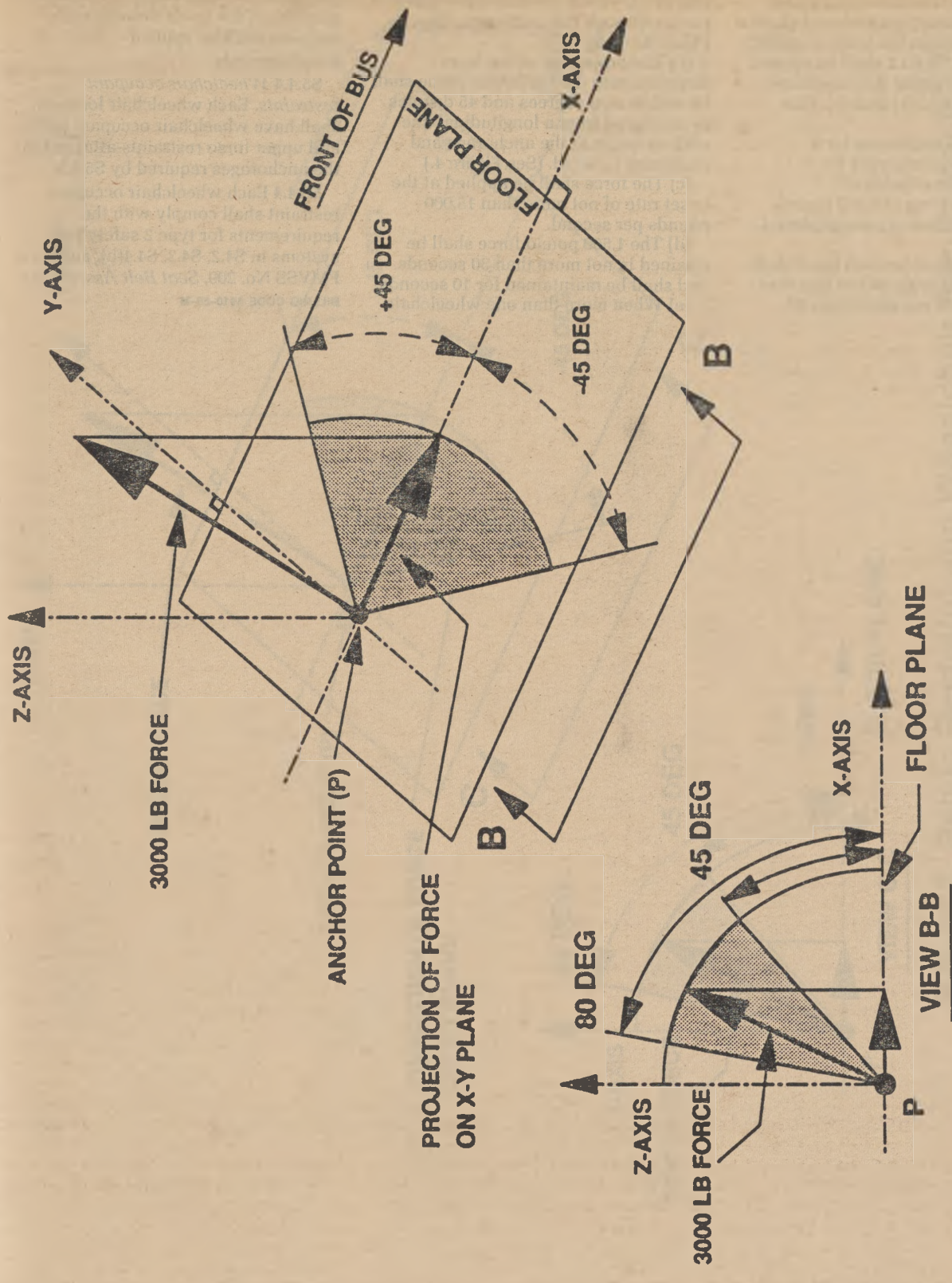


Figure 2. Pelvic Restraint Anchorage Loading Direction

BILLING CODE 4910-59-C

(e) When a wheelchair securement device and an occupant restraint share a common anchorage, the loads required by S5.4.1.3 and S5.4.3.2 shall be applied simultaneously, under the conditions specified in S5.4.3.2(a) and (b). (See Figure 3.)

S5.4.3.3. Each anchorage for a wheelchair occupant upper torso restraint shall be capable of withstanding a force of 1,500 pounds applied as specified in paragraphs (a) through (e).

(a) The initial application force shall be applied at an angle of not less than zero degrees, but not more than 40 degrees, below a horizontal plane which passes through the anchorage. (See Figure 4.)

(b) The projection of the force direction onto the horizontal plane shall be within zero degrees and 45 degrees as measured from a longitudinal line with its origin at the anchorage and projecting forward. (See Figure 4.)

(c) The force shall be applied at the onset rate of not more than 15,000 pounds per second.

(d) The 1,500 pound force shall be attained in not more than 30 seconds, and shall be maintained for 10 seconds.

(e) When more than one wheelchair occupant restraint shares a common anchorage, the loads through each restraint shall be applied simultaneously.

S5.4.4 *Wheelchair occupant restraints.* Each wheelchair location shall have wheelchair occupant pelvic and upper torso restraints attached to the anchorages required by S5.4.3.

S5.4.4 Each wheelchair occupant restraint shall comply with the requirements for type 2 safety belt systems in S4.2, S4.3, S4.4(b), and S5 of FMVSS No. 209, *Seat Belt Assemblies.*

BILLING CODE 4910-59-M



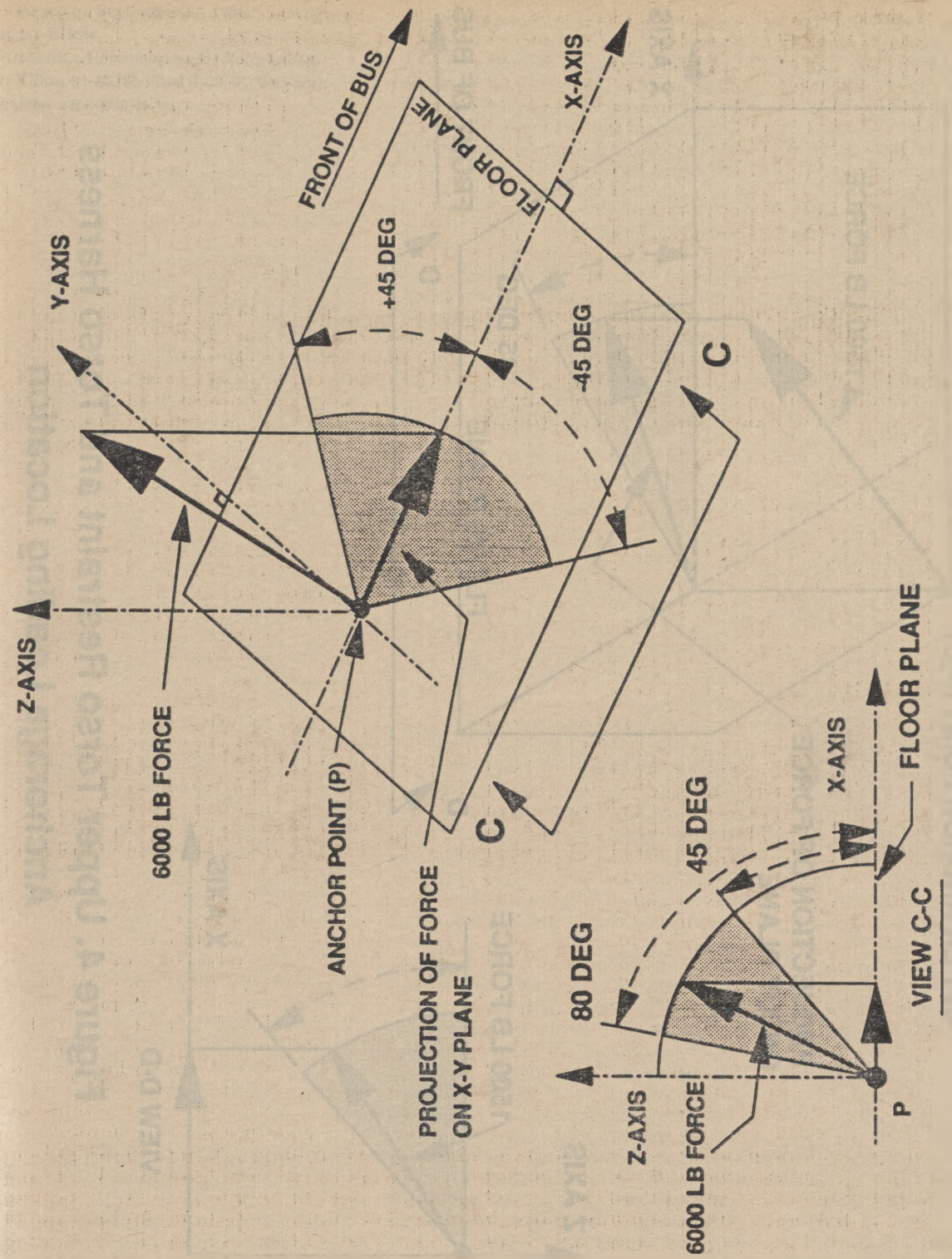


Figure 3. Pelvic Restraint and Wheelchair Securement Common Anchorage Loading Direction (Rear Direction Only)

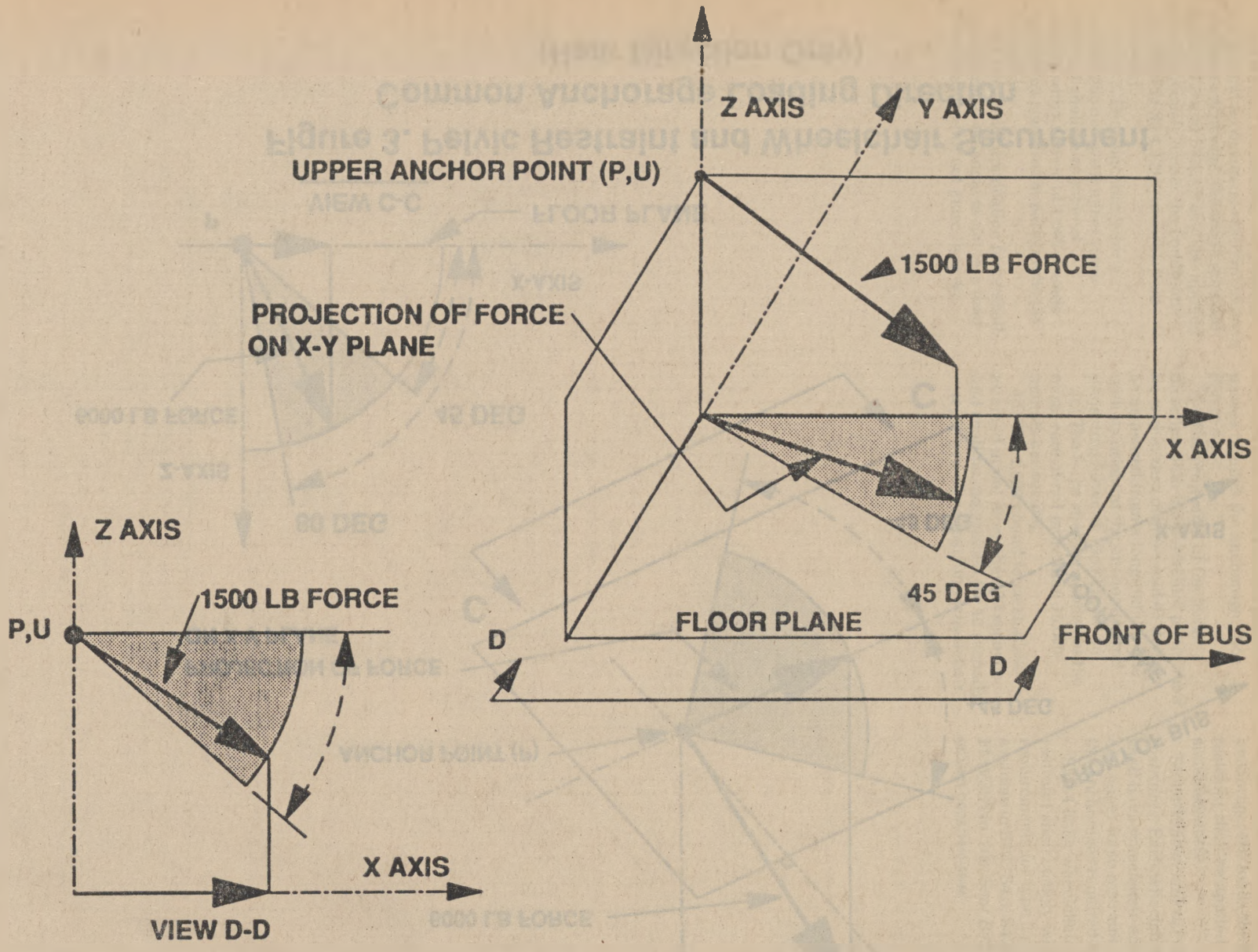


Figure 4. Upper Torso Restraint and Torso Harness Anchorage Loading Location

BILLING CODE 4910-59-C

Issued on September 17, 1991.

Barry Felrite,

Associate Administrator for Rulemaking.

[FR Doc. 91–22766 Filed 9–23–91; 8:45 am]

BILLING CODE 4910–59–M

Notices

Federal Register
Vol. 56, No. 185
Tuesday, September 24, 1991

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.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Select Committee on the Future of the Administrative Conference, Committee on Regulation, and Committee on Adjudication; Public Meetings

Pursuant to the Federal Advisory Committee Act (Pub. L. No. 92–463), notice is hereby given of meetings of the Select Committee on the Future of the Administrative Conference, the Committee on Regulation, and the Committee on Administration of the Administrative Conference of the United States.

Selection Committee on the Future of the Administrative Conference

Date: Wednesday, September 25, 1991.
Time: 2:30 p.m.
Location: Administrative Conference of the United States Library, 2120 L Street NW., suite 500, Washington, DC.

Agenda: This is the first meeting the committee which has been established to review the Administrative Conference's organization and activities and to suggest changes for the future.

Contact: Michael W. Bowers, 202–254–7020.

Committee on Regulation

Date: Friday, October 4, 1991.
Time: 9:30 a.m.–12:30 p.m.
Location: Administrative Conference of the United States Library, 2120 L Street NW., suite 500, Washington, DC.

Agenda: The Committee will meet to discuss a draft report and possible recommendations concerning federal noise abatement regulation. The draft report was prepared for the Administrative Conference by Professor Sidey A. Shapiro, University of Kansas School of Law, and Dr. Alice Suter, Alice Suter and Associates, Cincinnati, Ohio. The committee may also discuss the status of other pending projects.

Contact: David M. Pritzker, 202–254–7020.

Committee on Adjudication

Date: Monday, October 7, 1991.
Time: 1:30 p.m.
Location: Administrative Conference of the United States Library, 2120 L Street NW., Suite 500, Washington, DC.

Agenda: The committee has scheduled this meeting to discuss a study of enforcement under the Fair Housing Act, prepared by Professor Leland Ware of St. Louis University School of Law.

Contact: Nancy Miller, 202–254–7020.

Committee on Adjudication

Date: Tueday, October 29, 1991.
Time: 9:30 a.m.
Date: Thursday, November 7, 1991.
Time: 1:30 p.m.
Location: Administrative Conference of the United States Library, 2120 L Street NW., suite 500, Washington, DC.

Agenda: The committee has scheduled these meeting to discuss a study of whether jurisdiction of adjudication under the Federal Aviation Act should be at the Federal Aviation Administration or the National Transportation Safety Board, prepared by Professor Henry H. Perritt, Jr. of Villanova University School of Law.

Contact: Nancy Miller, 202–254–7020.

Public Participation

Attendance at the committee meetings is open to the public, but limited to the space available. Persons wishing to attend should notify the contact person at least one day in advance of the meeting. The committee chairmen may permit members of the public to present oral statements at meetings. Any member of the public may file a written statement with a committee before, during, or after a meeting. Minutes of the meetings will be available on request to the contact persons. The contact persons' mailing address is: Administrative Conference of the United States, 2120 L Street NW., suite 500, Washington, DC 20037.

Dated: September 20, 1991.

Jeffrey S. Lubbers,

Research Director.

[FR Doc. 91–23164 Filed 9–23–91 8:45 am]

BILLING CODE 6110–01–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 52–91]

Foreign-Trade Zone 112—Colorado Springs, Colorado; Application for Subzone: Apple Computer, Fountain, Colorado

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Colorado Springs Foreign-Trade Zone, Inc., grantee of FTZ 112, requesting special-purpose subzone status for the electronic data processing and communications equipment manufacturing plant of Apple Computer, Inc. (Apple), located in the City of Fountain, El Paso County, Colorado, some 12 miles south of Colorado Springs. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on September 12, 1991.

Apple is an international producer of personal computers and related products with annual sales of over $5 billion. It has plants in the U.S., the U.K., and Singapore.

The new Apple plant (340,000 sq. ft. bldg. on 125-acre site) is located at 702 Frontage Road in Fountain, Colorado. The company purchased the facility from Data General in 1991 and is currently renovating it. Full production is scheduled to begin in early 1992. The facility will employ 1000 persons and will be used to produce electronic data processing and communication products including computers, word processors, printers, displays, telecommunications equipment, instruments, and other related products and components.

Some of the components are purchased from abroad including computer processing units, keyboards, disc drives, monitors, flat panel displays, printers, power supplies, motors, batteries, transformers, circuit boards, diodes, integrated circuits, resistors, capacitors, switches, optical fibers, recording media, plastic and rubber parts, glass envelopes, springs, fasteners, cable and other related computer components and supplies.

Zone procedures would exempt Apple from Customs duty payments on the foreign components used in products made for export. On domestic sales, the

company wishes to be able to choose the duty rates that apply to the finished products (0.0–10.0 percent). The rates on components range from 0.0 to 15.0 percent, and there is currently an antidumping duty order in effect on certain flat panel display units. The application indicates that zone savings will help improve the international competitiveness of Apple's Colorado plant.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: Dennis Puccinelli (Chairman), Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington, DC 20230; Donald W. Myhra, District director, U.S. Customs Service, North Central Region, 300 Second Avenue South, Great Falls, Montana 59401; and Lt. Colonel Michael J. Debow, District Engineer, U.S. Army Engineer District Albuquerque, 517 Gold Avenue, SW., Albuquerque, NM 87103–1580.

Comments concerning the proposed subzone are invited in writing from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before October 31, 1991.

A copy of the application is available for public inspection at each of the following locations:

Office of the District Director, U.S. Department of Commerce, suite 680, 1625 Broadway, Denver, CO 80202.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, 14th & Pennsylvania Avenue, NW., room 3716, Washington, DC 20230.

Dated: September 18, 1991.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 91–22892 Filed 9–23–91; 8:45 am]

BILLING CODE 3510-DS-M

[Docket 53-91]

Foreign-Trade Zone 22—Chicago, IL; Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Illinois International Port District (IIPD), grantee for FTZ 22, requesting authority to expand its zone in the Chicago, Illinois, area. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR part 400). It was formally filed on September 16, 1991.

FTZ 22 was approved on October 29, 1975 (Board Order 108, 40 FR 51242, 11/4/75), and expanded on April 9, 1987 (Board Order 353, 52 FR 12217, 4/15/87). It currently consists of four sites in the Chicago area: Site 1 (19 acres) within the Port's 2,250-acre Lake Calumet Harbor terminal facility; *Site 2* (578 acres) at One Diversatech Drive in Manteno, Illinois; *Site 3* (5 acres) at 2525 Busse Avenue, in Elk Grove Village (expires 6/9/92); *Site 4* (1 acre) at 1351 Mark Street, Elk Grove Village (expires 12/31/92).

The grantee requests authority to expand the zone to add a permanent site (8 acres) at Gerry Drive and Hansen Court in Wood Dale, Illinois, 6 miles west of O'Hare International Airport. The site is owned and operated by Meiko America, Inc., which currently operates Site 4 (a temporary site) in the airport area. Meiko plans to shift its public warehousing zone activity from the Elk Grove to the Wood Dale site, and zone authority would expire at the former site during mid-1992. No manufacturing requests are being made at this time. Such approvals would be requested from the Board on a case-by-case basis.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: Dennis Puccinelli (Chairman), Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington, DC 20230; Richard Roster, District Director, U.S. Customs Service, North Central Region, 610 South Canal Street, Chicago, IL 60607; and LTC Randall R. Inouye, District Engineer, U.S. Army Engineer District Chicago, 111 North Canal Street, Chicago, IL 60606-7206.

Comments concerning the proposed expansion are invited in writing from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before November 8, 1991.

A copy of the application is available for public inspection at each of the following locations:

U.S. Department of Commerce , District Office, room 1406, Mid-Continental Plaza Building, 55 E. Monroe Street, Chicago, Illinois 60603.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, 14th and Pennsylvania Avenue, NW., room 3716, Washington, DC 20230.

Dated: September 18, 1991.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 91-22971 Filed 9-23-91; 8:45am]

BILLING CODE 3510-DS-M

International Trade Administration

[A-588-035]

Cadmium From Japan; Determination Not To Revoke Antidumping Finding

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of determination not to revoke antidumping finding.

SUMMARY: The Department of Commerce is notifying the public of its determination not to revoke the antidumping finding on cadmium from Japan.

EFFECTIVE DATE: September 24, 1991.

FOR FURTHER INFORMATION CONTACT: Dennis U. Askey or John R. Kugelman, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 377–3601.

SUPPLEMENTARY INFORMATION: On August 1, 1991, the Department of Commerce (the Department) published in the **Federal Register** (56 FR 36764) its intent to revoke the antidumping finding on cadmium from Japan (37 FR 14700, August 4, 1972). The Department may revoke a finding if the Secretary concludes that the finding is no longer of interest to interested parties. We had not received a request for an adminstrative review of this finding for the last four consecutive annual anniversary months and, therefore, published a notice of intent to revoke pursuant to 19 CFR 353.25(d)(4).

On August 30, 1991, the Big River Zinc Corporation, an interested party, objected to our intent to revoke this finding. Therefore, we no longer intend to revoke this finding.

Dated: September 16, 1991.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 91–22889 Filed 9–23–91; 8:45 am]

BILLING CODE 3510–DS–M

[A-557-805]

Initiation of Antidumping Duty Investigation: Extruded Rubber Thread from Malaysia

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 24, 1991.

FOR FURTHER INFORMATION CONTACT: Vincent Kane or Carole Showers, Office of Countervailing Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, room B099, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 377–2815 or 377–3217.

Initiation

The Petition

On August 29, 1991, the North American Rubber Thread Company, Inc., filed with the Department of Commerce (the Department) an antidumping duty petition on behalf of the United States industry producing extruded rubber thread. In accordance with 19 CFR 353.12, the petitioner alleges that imports of extruded rubber thread from Malaysia 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 Tariff Act of 1930, as amended (the Act), and that these imports are materially injuring, or threaten material injury to, domestic producers of extruded rubber thread. Petitioner also alleges that critical circumstances exist with respect to imports of extruded rubber thread from Malaysia.

The Petitioner has stated that it has standing to file the petition because it is an interested party, as defined in 19 CFR 353.2(k), and because it has filed the petition on behalf of the U.S. industry producing extruded rubber thread. If any interested party, as described in 19 CFR 353.2(k)(3), (4), (5), or (6), wishes to register support for, or opposition to, this investigation, please file written notification with the Assistant Secretary for Import Administration, room B099, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

United States Price and Foreign Market Value

Petitioner based U.S. price (USP) on documented prices from U.S. subsidiaries of the Malaysian exporters to unrelated U.S. buyers. Petitioner calculated USP pursuant to the exporter's sales price (ESP) methodology (19 CFR 353.41(c)), because petitioner asserts that sales are made in the United States after the date of importation by companies related to the exporters. Adjustments were made, where appropriate, for indirect selling expenses, credit expenses, U.S. inland freight, port handling charges, and ocean freight. These adjustments were based on petitioner's own experience in selling extruded rubber thread in the U.S. market and in importing it from Malaysia, petitioner's knowledge of the distribution practices of the Malaysian subsidiaries in the United States, and information form U.S. purchasers of Malaysian extruded rubber thread.

Petitioner's estimate of foreign market value (FMV) is based on constructed value (19 CFR 353.50). Petitioner based the cost of natural rubber latex on information from sources in Malaysia and the Untied States. Chemical costs were based on petitioner's own costs, unadjusted for possible differences between the markets, since petitioner asserts that chemical prices in developing country markets are normally at a premium. Labor and energy costs were based on information from the Malaysian Industrial Development Authority. Petitioner added the statutory ten and eight percent for general expenses and profit in accordance with section 773(e)(1)(b) of the Act.

In accordance with our ESP methodology, we have recalculated credit expense as a circumstance of sale adjustment to FMV. Based on a comparison of FMV to USP, the alleged margins range from 18 percent to 32 percent.

Initiation of Investigation

Under 19 CFR 353.13(a), the Department must determine, within 20 days after a petition is filed, whether the petition properly alleges the basis on which an antidumping duty may be imposed under section 731 of the Act, and whether the petition contains information reasonably available to the petitioner supporting the allegations. We have examined the petition on extruded rubber thread from Malaysia and find that it meets the requirements of 19 CFR 353.13(a). Therefore, we are initiating an antidumping duty investigation to determine whether imports of extruded rubber thread from Malaysia are being or are likely to be, sold in the United States at less than fair value.

In accordance with 19 CFR 353.13(b) we are notifying the International Trade Commission of this action.

Any producer or reseller seeking exclusion from a potential antidumping duty order must submit its request for exclusion within 30 days of the date of the publication of this notice. The procedures and requirements regarding the filing of such requests are contained in 19 CFR 353.14.

Scope of Investigation

The product covered by this investigation is extruded rubber thread from Malaysia. Extruded rubber thread is defined as vulcanized rubber thread obtained by extrusion of stable or concentrated natural rubber latex of any cross sectional shape, measuring from 0.18 mm, which is 0.007 inch or 140 gauge, to 1.42 mm, which is 0.056 inch or 18 gauge, in diameter. Extruded rubber thread is currently classifiable under subheading 4007.00.00 of the Harmonized Tariff Schedule (HTS). Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Preliminary Determination by ITC

The ITC will determine by October 13, 1991, whether there is a reasonable indication that imports of extruded rubber thread from Malaysia are materially injuring, or threaten material injury to, a U.S. industry. If its determination is negative, the investigation will be terminated. If affirmative, the department will make its preliminary determination on or before February 5, 1992, unless the investigation is terminated pursuant to 19 CFR 353.17 or the preliminary determination is extended pursuant to 19 CFR 353.15.

This notice is published pursuant to section 732(c)(2) of the Act and 19 CFR 353.13(b).

Dated: September 18, 1991.

Francis J. Sailer,

Acting Assistant Secretary for Import Administration.

[FR Doc. 91–22969 Filed 9–23–91; 8:45 am]

BILLING CODE 3510-DS-M

[C-517-501]

Carbon Steel Wire Rod From Saudi Arabia; Final Results of Countervailing Duty Administrative Reviews

AGENCY: International Trade Administration/Import Administration Department or Commerce.

ACTION: Notice of final results of countervailing duty administrative reviews.

SUMMARY: On June 25, 1991, the Department of Commerce published the preliminary results of its administrative reviews of the countervailing duty order

on carbon steel wire rod from Saudi Arabia (56 FR 28866). We have now completed these reviews and determine the total bounty or grant to be 0.13 percent *ad valorem* for the period January 1, 1988 through December 31, 1988 and 0.49 percent *ad valorem* for the period January 1, 1989 through December 31, 1989. In accordance with 19 CFR 355.7, any rate less than 0.50 percent *ad valorem* is *de minimis*.

EFFECTIVE DATE: September 24, 1991.

FOR FURTHER INFORMATION CONTACT: Philip Pia or Kelly Parkhill, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377–2786.

SUPPLEMENTARY INFORMATION:

Background

On June 25, 1991, the Department of Commerce (the Department) published in the **Federal Register** (56 FR 28866) the preliminary results of its administrative reviews of the countervailing duty order on carbon steel wire rod from Saudi Arabia (February 3, 1986; 51 FR 4206). The Department has now completed these administrative reviews in accordance with section 751 of the Tariff Act of 1930, as amended (the Tariff Act).

Scope of Review

Imports covered by these reviews are shipments of Saudi carbon steel wire rod. Carbon steel wire rod is a coiled, semi-finished, hot-rolled carbon steel product of approximately round solid cross section, not under 0.20 inch nor over 0.74 inch in diameter, tempered or not tempered, treated or not treated, not manufactured or partly manufactured, and valued over or under 4 cents per pound. During the 1989 review period, such merchandise was classifiable under item numbers 607.1400, 607.1710, 607.1720, 607.1730, 607.2200 and 607.2300 of the Tariff Schedules of the United States Annotated (TSUSA). Such merchandise is currently classifiable under item numbers 7213.20.00, 7213.31.30, 7213.31.60, 7213.39.00, 7213.41.30, 7213.41.60, 7213.49.00 and 7213.50.00 of the Harmonized Tariff Schedule (HTS). The TSUSA and HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

The reviews cover the periods January 1, 1988 through December 31, 1988, and January 1, 1989 through December 31, 1989 and eight programs: (1) Public Investment Fund loan to HADEED, (2) SABIC's transfer of SULB shares to HADEED, (3) preferential provision of equipment to HADEED, (4) income tax holiday for joint venture projects in Saudi Arabia, (5) SABIC loan guarantees, (6) preferential provision of services by SABIC, (7) government procurement preferences, and (8) issuance of preferential government bonds. The Saudi Iron and Steel Company (HADEED) was the sole producer and exporter of carbon steel wire rod to the United States during the review periods.

Analysis of Comments Received

We gave interested parties an opportunity to comment on the preliminary results. We received comments from the respondent (HADEED), and the petitioners.

Comment 1: The respondent argues that the Public Investment Fund (PIF) loan program and the Saudi Industrial Development Fund (SIDF) loan program are "integrally linked" as defined in § 355.43(b)(6) of the Department's proposed regulations; see, Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments, 54 FR 23366, (May 31, 1989). Since PIF and SIDF are integrally linked, they should be considered together in determining whether loans provided by these two entities are limited to a specific enterprise or industry, or group of enterprises or industries. SIDF and PIF qualify for linkage under each factor identified in the Department's proposed regulations. These factors are (1) Evidence of a government policy to treat industries equally, (2) the purposes of the programs as stated in their enabling legislation, (3) the administration of the programs, (4) the manner of funding the programs, and (5) "other factors."

The information on the record shows a Saudi government policy to treat industries equally. PIF and SIDF provide identical benefits—low-cost, long-term construction loans—on identical terms to a wide variety of industries. PIF and SIDF are two of five Specialized Credit Institutions that the Saudi government created to develop and diversify the Saudi economy. The PIF and SIDF share a common purpose as the only sources of low-cost financing for the industrial and manufacturing sector. PIF loans are available to companies with some government equity, and are suited for the types of large projects that the Saudi government would be most likely to undertake. SIDF loans, on the other hand, are available to companies with some private Saudi ownership and are best suited for small and medium-sized projects. Between them, the two programs address the borrowing needs of the entire range of Saudi industries.

PIF and SIDF share a common purpose, based on statements in each entity's enabling legislation. PIF was created "to finance investment in the productive projects of a commercial nature." Similarly, SIDF was created "to support industrial development in the private sector of the Kingdom's economy." Both programs are aimed at financing development in the Saudi industrial and manufacturing sector.

PIF and SIDF are administered in a comparable manner through SAMA (the Saudi Central Bank) and the Ministry of Finance and National Economy. Both PIF and SIDF are administered by boards of directors with a common chairman, the Minister of Finance and National Economy, with the remaining members drawn from SAMA and other Saudi government agencies.

PIF and SIDF were originally funded through the Ministry of Finance and National Economy. Currently, both programs are self-sufficient. SAMA produces a consolidated balance sheet showing assets and liabilities of PIF and SIDF jointly. All information regarding budget allocations, disbursements and repayments of PIF and SIDF are published as consolidated statements.

Other factors integrally linking PIF and SIDF include the fact that there are no *de jure* limitations on the types of industries eligible to receive loans under either fund. The lending practices and histories of both funds is similar. The maximum loan amount is SR 500 million for PIF and SR 400 million for SIDF. The maximum loan period for both PIF and SIDF is 15 years. The PIF requires Saudi government equity participation in a project in order to obtain funds. Similarly, SIDF requires at least 25 percent equity contribution from private Saudi sources in order to obtain funds. PIF and SIDF each accounted for 25.5 percent of the total outstanding loans and advances held by Saudi Specialized Credit Institutions in 1988.

Thus, in light of the factors described above, respondent argues that the Department has compelling case for finding integral linkage between PIF and SIDF. The programs are part of the same overall government lending policy, they are intended to be complementary and to achieve the same purpose, they are administered and funded through the same governmental agency, and they provide similar benefits to the same sector of the Saudi economy. Based on a finding of integral linkage, the Department should consider PIF and SIDF programs together and find that neither is specifically provided and therefore countervailable.

The petitioner argues that the Department has rejected respondent's argument regarding integral linkage in

the previous review (see, Final Results of Countervailing Duty Administrative Review; Carbon Steel Wire Rod from Saudi Arabia, 56 FR 26652, June 10, 1991). The unique aspects of the PIF program cannot be hidden by lumping it together with other Saudi government financing programs such as SIDF, which were established for other reasons. Nothing the Saudi government does in providing other loans through separate programs detracts from PIF's specificity.

Department's Position: Although the respondent has demonstrated that a number of similarities may exist between PIF and SIDF, any argument for integral linkage between the two programs must include a description of how the programs, at their inception(s), were directly related to an overall government policy or national development plan. See, Final Affirmative Countervailing Duty Determination: Certain Fresh Cut Flowers from the Netherlands, 52 FR 3301, 3309 (February 3, 1987).

PIF was established in 1971, SIDF was established three years later in 1974. It may be that, in principle and practice, the respective roles of PIF and SIDF have evolved to complement and overlap each other. However, the fact that these programs were founded separately, three years apart, suggests (without other documented information) that the programs were not conceived as parts of a single program. Any conclusion regarding the roles of PIF and SIDF in a broader Saudi governmental policy initiative could only be reached by considering the historical and practical development of each program in its entirely. Documented information on the inception of the programs that explicitly ties PIF and SIDF as complementary parts of an overarching governmental policy directive has not been presented by the respondent. Therefore, since there is insufficient factual information on the record relevant to the establishment and development of PIF and SIDF, we will continue to consider each program separately.

Comment 2: The respondent argues that, contrary to the Department's preliminary results, PIF loans are not limited to a specific group of enterprises, and therefore, they are not countervailable. HADEED contends that the Department's preliminary determination that the Saudi government, through PIF, provides loans to "a specific enterprise or industry or group of enterprises or industries" within the meaning of section 1677(5)(B), is incorrect. The basis for the Department's determination is the erroneous assumption that only six companies have effectively benefitted from the program. In reality, 24 companies in a wide variety of industries have received PIF financing. The 18 companies that are at least 50 percent-owned by either SABIC or PETROMIN should be treated as separate entities. The Department has, in effect, found that there is an intercorporate transfer of benefits based solely on corporate relationships with SABIC or PETROMIN. Such an application of the specificity test based on a commonality of shareholders is without precedent and contravenes the Department's established policy not to assume automatic transfer of benefits based on related party status. Respondents cite the following cases in defense of their argument: Carbon Steel Wire Rod from Malaysia, 53 FR 13303 (April 22, 1988); Industrial Phosphoric Acid from Israel, 52 FR 25447 (July 7, 1987); Operators for Jalousie and Awning Windows from El Salvador, 51 FR 41516 (November 17, 1986); Low-Fuming Brazing Copper Rod and Wire from New Zealand, 50 FR 31638 (August 5, 1985); and Carbon Steel Structural Shapes from Luxembourg, 47 FR 39364 (September 7, 1982).

The petitioner contends that PIF provides benefits almost exclusively to the projects undertaken by a few companies with controlling government ownership and therefore constitute a specific group of enterprises in Saudi Arabia.

Department's Position: As we stated in our preliminary results, the application of the government equity participation requirement limited benefits under this program to a small number of enterprises. The cases cited by respondent are not relevant because they deal with the question of collapsing related corporate bodies into a single entity for the purpose of determining the transfer of countervailable benefits. The issue here is the correctness of the Department's determination that PIF benefits are limited to a specific group of enterprises. As in the original investigation, the number of actual recipients was lower than the number of named recipients (because of majority ownership considerations). The Court of International Trade found that the record in the original investigation contained substantial evidence to support Commerce's determination that the operations of other named recipients of PIF loans were projects of three enterprises, Saudia Airlines, SABIC, and PETROMIN. That determination was based in large part upon evidence of majority ownership interest in the companies named as recipients of PIF loans. The Court decision states, in part, that "Commerce determined, as a matter of fact, that the Saudi government provides PIF benefits to a specific group of enterprises, based on a finding that all PIF loans since 1978 and most PIF loans since 1973 have been provided to only three companies and their projects. The Court finds Commerce reasonably applied the specificity test and holds Commerce's determination that the Saudi government provides PIF loans to a specific group of enterprises is in accordance with law." See, *Saudi Iron and Steel Co.* v. *United States*, 675 F. Supp. 1362 (C.I.T. 1987).

Comment 3: The respondent argues that the Department incorrectly determined that the income tax holiday is limited to a specific group of enterprises, and is therefore countervailable. Respondent claims that there is no evidence in the record to support the allegation that the income tax holiday is anything more than a program designed to encourage foreign investors to share their technical expertise with Saudi Arabia through Saudi joint ventures in a wide variety of industries. In the absence of such evidence, the income tax holiday should be considered a valid component of Saudi Arabia's domestic policy of industrial development and not subject to countervailing duties. Contrary to the Department's preliminary finding, there is no evidence that suggests that the 25 percent ownership requirement substantially limits the number of licensed foreign investors who qualify for the income tax holiday or that the ownership requirement has a more restrictive effect when supplied to the income tax holiday than when applied to SIDF loans. Rather than limit the pool of eligible recipients, the 25 percent Saudi ownership requirement has the long-term goal of ensuring that Saudi industrial diversification is accompanied by significant Saudi participation in new industries.

Petitioner contends that the record clearly demonstrates that the income tax holiday is restricted to companies meeting the following criteria: (1) Saudi participation amounts to at least 25 percent of total capital; (2) the foreign capital is invested in projects other than petroleum related and mineral extraction ventures; and (3) the investment is accompanied by the provision of foreign technical know-how and expertise. Therefore, the Department correctly determined this tax holiday to be specific and countervailable.

Department's Position: We disagree with respondent. We have considered and rejected respondent's argument in previous reviews of this countervailing duty order. (See, the Comment 6 in Final Results of Countervailing Duty Administrative Review; Carbon Steel Wire Rod from Saudi Arabia, 56 FR 26652, June 10, 1991). The respondent has not presented new evidence that gives us reason to reconsider this argument.

Comment 4: The respondent claims that the Department erroneously included a short-term interest rate in its calculation of a long-term interest rate benchmark for measuring the subsidy attributable to HADEED's PIF loan. In previous reviews, the Department has used the interest rates on HADEED's other commercial borrowings to construct a benchmark. However, in this review HADEED had no other outstanding liabilities. Thus, the respondent claims that the absence of a borrowing alternative justifies dropping that component from the benchmark. Respondent claims that there are a number of alternatives that HADEED would have exercised in order to obtain financing in lieu of a PIF loan. Such alternatives are far more rational and likely than the Department's assumption that HADEED would have borrowed the capital directly from a Saudi commercial bank. Furthermore, the Department's Proposed Regulations direct it to use a short-term benchmark rate for measuring the subsidy attributable to a preferential long-term loan as a last resort. (See, § 355.44(b)(4)(iv), (b)(5)(v) of Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments, 54 FR 23366, (May 31, 1989). The inclusion of a short-term loan component in the construction of a long-term composite benchmark is inconsistent with Department practice and precedent.

Petitioners contend that the Department's use of a composite benchmark incorporating a short-term interest rate is correct and that it accurately reflects what HADEED otherwise would have had to pay in Saudi Arabia absent PIF lending.

Department's Position: We disagree with the respondent. The loan in question is a long-term loan. We requested information on average long-term commercial lending rates from respondent and were told that such information was not available in Saudi Arabia. Therefore, we have used short-to medium-term private bank commercial rates and the only long-term lending rates for which we have information, SIDF rates, to construct composite interest rate benchmarks for each review period. Since the PIF loan covered 60 percent of HADEED's total project costs, for our benchmark we assumed that HADEED could have financed 50 percent of its total project costs with a SIDF loan (the maximum eligibility for a company with at least 50 percent Saudi ownership) and the remaining 10 percent of project costs with a Saudi commercial bank loan. The commercial bank portion of the benchmark was based on the average Jeddah Interbank Offering Rate (JIBOR) for 1988 and 1989, plus the normal one percent spread that is common in short-to medium-term commercial borrowings from private Saudi banks. We agree with respondent that Proposed Regulations § 355.44(b)(4)(vi) permits the Department to use a short-term benchmark rate in the case of a fixed rate, long-term loan provided by a government only as a sixth and last resort.

However, because we have no information on the other five alternatives, we have resorted to the JIBOR rate. Any factual information regarding this issue submitted by HADEED after publication of our preliminary results is untimely and has not been used to recalculate our benchmark for the final results.

Comment 5: The respondent claims that the Department used the incorrect profit figure in its calculation of the benefit from the income tax holiday. Rather than use the net income amount stated in HADEED's financial report, the Department should recalculate an adjusted profit or loss figure according to the methodology required by Saudi government guidelines.

Department's Position: We disagree. The respondent has not provided sufficient factual information that would give us a basis to consider its argument.

Final Results of Review

After reviewing all of the comments received, we determine the total bounty or grant to be 0.13 percent *ad valorem* for the period January 1, 1988 through December 31, 1988, and 0.49 percent *ad valorem* for the period January 1, 1989 through December 31, 1989. In accordance with 19 CFR 355.7, any rate less than 0.50 percent *ad valorem* is *de minimis*.

Therefore, the Department will instruct the Customs Service to liquidate, without regard to countervailing duties, all shipments of this merchandise exported on or after January 1, 1988 and exported on or before December 31, 1989.

The Department will also instruct the Customs Service to waive cash deposits of estimated countervailing duties on all shipments of this merchandise entered, or withdrawn from warehouse, for consumption, on or after the date of publication of these final results of administrative review. The waiving of cash deposits of estimated countervailing duties shall remain in effect until publication of the final results of the next administrative review.

These administrative reviews and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: September 17, 1991.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

[FR Doc. 91-22891 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-DS-M

[C-557-806]

Initiation of Countervailing Duty Investigation: Extruded Rubber Thread From Malaysia

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 24, 1991.

FOR FURTHER INFORMATION CONTACT: Vincent Kane or Carole Showers, Office of Countervailing Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, room B099, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-2815 and (202) 377-3217, respectively.

Initiation

The Petition

On August 29, 1991, the North American Rubber Thread Company filed with the Department of Commerce (the Department) a countervailing duty petition on behalf of the United States industry producing extruded rubber thread. In accordance with 19 CFR 355.12, the petitioner alleges that producers and exporters of extruded rubber thread in Malaysia receive bounties or grants within the meaning of section 303 of the tariff Act of 1930, as amended (the Act). Petitioner also alleges that critical circumstances exist with respect to imports of extruded rubber thread from Malaysia.

Although Malaysia is not a "country under the Agreement" within the meaning of section 701(b) of the Act, extruded rubber thread from Malaysia is nondutiable under the Generalized System of Preferences and Malaysia is a

contracting party to the General Agreement on Tariffs and Trade. Therefore, the U.S. International Trade Commission (ITC) is required to determine whether imports of the subject merchandise from Malaysia materially injure, or threaten material injury to, the U.S. industry.

The petitioner has stated that it has standing to file the petition because it is an interested party as defined in 19 CFR 355.2(i), and because it has filed the petition on behalf of the U.S. industry producing extruded rubber thread. If any interested party, as described in 19 CFR 355.2(i)(3), (4), (5), or (6), wishes to register support for, or opposition to, this petition, please file written notification with the Assistant Secretary for Import Administration, room B099, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Allegations of Subsidies

Petitioner lists a number of practices by the Government of Malaysia which allegedly confer subsidies on producers or exporters of extruded rubber thread in Malaysia. We are initiating an investigation of the following programs:

1. Free Trade Zones.
2. Export Credit Refinancing Scheme.
3. Tax Abatement of Adjusted Income for Exports.
4. Tax Abatement of Five Percent of Indigenous Malaysian Materials for Exports.
5. Five Percent Export Allowance.
6. Double Deduction of Export Credit Insurance Premiums.
7. Double Deduction for Promotion of Exports.
8. Industrial Building Allowance.
9. Rubber Discount Scheme.
10. Investment Tax Allowance.
11. Abatement of Five Percent of Adjusted Income for Firms in Promoted Industrial Areas.
12. Abatement of Five Percent of Adjusted Income for Certain Capital Participation and Employment Practices.
13. Accelerated Depreciation Allowance.
14. Reinvestment Allowance.

We are not initiating an investigation on the following programs alleged in the petition:

1. Development and Planting Cess

The Government of Malaysia assesses a development and planting cess on purchases of natural rubber latex to promote the development of the rubber industry. Petitioner has alleged that the government provides an exemption from the cess on imports of natural rubber latex used in the production of rubber goods for export. Since the rubber cess is an indirect tax assessed on an input which is physically incorporate into the export product, the non-excessive rebate of this tax upon export or the exemption from the tax initially is a permissible rebate or exemption. Therefore, we are not initiating an investigation on this program.

2. Export Duty on Natural Rubber Latex

The Government of Malaysia imposes a duty on exports of natural rubber latex. When purchasing natural rubber latex from Malaysian suppliers, U.S. extruded rubber thread producers must pay this duty as a part of their overall cost. The duty is not imposed on domestic sales. Therefore, Malaysian extruded rubber thread producers would appear to enjoy a cost advantage on purchases of their major input. Petitioner, however, has not demonstrated that a cost advantage does, in fact, exist.

In Final Affirmative Countervailing Duty Investigation and Countervailing Duty Order: Leather Products from Argentina (55 FR 40212, October 2, 1990), the Department stated that it investigated an allegation of an export embargo on cattle hides only after petitioner had supplied considerable pricing data demonstrating that the embargo had a measurably downward effect on Argentine prices for cattle hides, the major imput into the product under investigation in that case. Such information has not been supplied by the petitioner in the case. Therefore, we are not initiating an investigation on the export duty on natural rubber latex.

3. Pioneer Status

Under the Promotion of Investments Act of 1986, pioneer status is available to companies producing a product (1) not currently produced in Malaysia, (2) favorable to further development and/or export, and (3) suitable to the public interest or economic development of Malaysia. Benefits of pioneer status include income tax and other tax exemptions. In Final Results of Countervailing Duty Administrative Review: Carbon Steel Wire Rod from Malaysia (56 FR 41649, August 22, 1991), the Department found the pioneer status program to be not countervailable because it was not limited to a specific industry or group of industries. Petitioner has provided no evidence of changed circumstances with regard to this program; therefore, we are not initiating on it.

Initiation of Investigation

Under 19 CFR 355.13(a), the Department must determine, within 20 days after a petition is filed, whether the petition properly alleges the bases on which a countervailing duty may be imposed under section 705 of the Act, and whether the petition contains information reasonably available to the petitioner supporting the allegations. We have examined the petition on extruded rubber thread from Malaysia and find that it meets the requirements of 19 CFR 355.13(a). Therefore, we are initiating a countervailing duty investigation to determine whether Malaysian producers or exporters of extruded rubber thread receive bounties or grants.

Any producer or reseller seeking exclusion from a potential countervailing duty order must submit its request for exclusion within 30 days of the date of publication of this notice. The procedures and requirements regarding the filing of such requests are contained in 19 CFR 355.14.

Scope of Investigation

The product covered by this investigation is extruded rubber thread from Malaysia. Extruded rubber thread is defined as vulcanized rubber thread obtained by extrusion of stable or concentrated natural rubber latex of any cross sectional shape, measuring from 0.18 mm, which is 0.007 inch or 140 gauge, to 1.42 mm, which is 0.056 inch or 18 gauge, in diameter. Extruded rubber thread is currently classified under subheading 4007.00.00 of the Harmonized Tariff Schedule (HTS). Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

ITC Notification

Section 702(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it all non-privileged and non-proprietary information. We will also allow the ITC access to all privileged and business proprietary information in the Department's files, provided the ITC confirms in writing that it will not disclose such information, either publicly or under administrative protective order, without the written consent of the Deputy Assistant Secretary for Investigations, Import Administration.

Preliminary Determination by the ITC

The ITC will determine by October 13, 1991, whether there is a reasonable indication that imports of extruded rubber thread from Malaysia are materially injuring, or threaten material

injury to, a U.S. industry. If its determination is negative, the investigation will be terminated. If affirmative, the Department will make its preliminary determination on or before November 22, 1991, unless the investigation is terminated pursuant to 19 CFR 355.17 or the preliminary determination is extended pursuant to 19 CFR 355.15.

This notice is published pursuant to section 702(c)(2) of the Act

Dated: September 18, 1991.

Francis J. Sailer,

Acting Assistant Secretary for Import Administration.

[FR Doc. 91-22970 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-DS-M

[C-201-505]

Porcelain-on-Steel Cookingware From Mexico; Preliminary Results of Countervailing Duty Administrative Review

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce has conducted an administrative review of the countervailing duty order on porcelain-on-steel cookingware from Mexico for the period January 1, 1990 through December 31, 1990. We preliminarily determine the net subsidy to be 2.47 percent *ad valorem* for all firms. We invite interested parties to comment on these preliminary results.

EFFECTIVE DATE: September 24, 1991.

FOR FURTHER INFORMATION CONTACT: Dana Mermelstein or Barbara Tillman, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2786.

SUPPLEMENTARY INFORMATION:

Background

On December 12, 1990, the Department of Commerce (the Department) published a notice of "Opportunity to Request Administrative Review" (55 FR 51139) for the countervailing duty order on porcelain-on-steel cookingware from Mexico. On December 26, 1990, the respondents, Acero Porcelanizado, S.A. (APSA) (formerly Troqueles Y Esmaltes, S.A.) and CINSA, S.A. requested an administrative review of the order. We initiated the review, covering the period January 1, 1990 through December 31, 1990, on January 30, 1991 (56 FR 3445). The Department has now conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). The final results of the last administrative review of this order were published in the **Federal Register** on June 6, 1991 (56 FR 26064).

Scope of Review

Imports covered by this review are shipments of porcelain-on-steel cookingware from Mexico. The products are porcelain-on steel cookingware (except teakettles), which do not have self-contained electric heating elements. All of the foregoing are constructed of steel, and are enameled or glazed with vitreous glasses. During the review period, such merchandise was classifiable under item number 7323.94.0020 of the Harmonized Tariff Schedule (HTS). The HTS item number is provided for convenience and Customs purposes.The written description remains dispositive.

The review covers the period January 1, 1990 through December 31, 1990, two companies, and eleven programs.

Analysis of Programs

(1) *FOMEX*

The Fund for the Promotion of Exports of Mexican Manufactured Products (FOMEX) is a trust of the Mexican Treasury Department, with the National Bank of Foreign Trade acting as trustee for the program. Until the program was eliminated by decree on December 30, 1989, the National Bank of Foreign Trade, through financial institutions, made FOMEX loans available at preferential rates to Mexican manufacturers and exporters for pre-export financing and export financing. Although the Government of Mexico eliminated the program prior to this review period, there were outstanding FOMEX loans that matured during the review period. We consider pre-export and export loans granted under the FOMEX program to be countervailable subsidies since they were given at preferential rates only on merchandise destined for export.

We consider the benefit from loans to occur when the interest is paid. Because interest on FOMEX export loans is pre-paid, we normally calculate benefits based on FOMEX export loans received during the review period. However, because the FOMEX program was eliminated by decree published in the *Diario Oficial* on December 30, 1989, no exporters of porcelain-on-steel cookingware received FOMEX export loans during the review period.

Because interest on FOMEX pre-export loans is paid at maturity, we calculated benefits based on loans that matured during the review period; these were obtained between November 1989 and December 1989, prior to the government's elimination of the program. We found that the annual interest rate that financial institutions charged borrowers for FOMEX pre-export loans outstanding during the review period were lower than commercial rates. To determine the effective interest rate benchmark for FOMEX pre-export dollar loans granted in 1989, we used the quarterly weighted-average effective interest rates published in the Federal Reserve Bulletin, which resulted in an annual average benchmark of 11.99 percent in 1989, when the loans subject to this review were granted. We preliminarily determine the benefit to be the difference between the interest the companies would have paid at the benchmark interest rate and the interest they actually paid.

Both exporters of the subject merchandise had FOMEX pre-export loans that matured during the review period. Because we found that the exporters were able to tie their FOMEX loans to exports to specific countries, we measured the benefit only from FOMEX loans tied to shipments to the United States. We divided the firm's FOMEX benefit by the value of its total exports of the subject merchandise to the United States during the review period. We then weight-averaged the resulting benefits by the firm's proportion of exports of the subject merchandise to the United States during the review period. On this basis, we preliminarily determine the benefit from FOMEX pre-export loans to be 0.03 percent *ad valorem*.

Because the FOMEX program was terminated on December 30, 1989, and there are no longer any FOMEX loans outstanding (export or pre-export), we preliminarily determine the benefit from this program to be zero for purposes of the cash deposit of estimated countervailing duties.

(2) BANCOMEXT Financing for Exporters

Effective January 1, 1990, the Mexican Treasury Department transferred the FOMEX trust to the Banco Nacional de Comercio Exterior, S.N.C. (BANCOMEXT) upon the elimination of the FOMEX loan program. BANCOMEXT offers financing to producers or trading companies engaged in export; any company which generates foreign currency through exporting is

eligible for financing under this program. The BANCOMEXT program operates much like its predecessor, FOMEX. BANCOMEXT provides financing in dollars to exporters for two purposes: Working capital loans (pre-export loans), and loans for export sales (export loans). In addition, BANCOMEXT may provide financing to foreign buyers of Mexican goods and services. We consider this new loan program to provide countervailable export subsidies because the loans are given at preferential rates only on merchandise which will earn foreign currency, *i.e.*, destined for export.

We consider the benefits from loans to occur when the interest is paid. Because interest on BANCOMEXT pre-export loans is paid at maturity, we calculated benefits based on loans that matured during the review period; these were obtained between January and October, 1990. Interest on BANCOMEXT loans for export sales is paid in advance; we therefore calculated benefits based on BANCOMEXT loans received during the review period.

We found that the annual interest rate that BANCOMEXT charged to borrowers for loans on which interest payments were due during the review period were lower than commercial rates. To determine the effective interest rate benchmark for BANCOMEXT pre-export and export loans granted in 1990, we used the quarterly weighted-average effective interest rates published in the Federal Reserve Bulletin, which resulted in an annual average benchmark of 10.88 percent in 1990.

We found that both exporters of porcelain-on-steel cookingware used BANCOMEXT pre-export and export sales financing. Because we found that the exporters were able to tie their BANCOMEXT loans to specific countries and merchandise, we measured the benefit only from the BANCOMEXT loans tied to sales of the subject merchandise to the United States. To determine the benefit in dollars for each exporter, we subtracted the actual interest payment, as reported by the exporters, from the interest payment that would have been made at the benchmark interest rate. We then allocated each company's BANCOMEXT benefit over the value of its total exports of subject merchandise to the United States during the review period. We then weight-averaged the resulting benefits by each company's proportion of total exports to the United States. On this basis, we preliminarily determine the benefit from this program to be 0.56 percent *ad valorem* for all companies.

(3) FONEI

The Fund for Industrial Development (FONEI), administered by the Banco de Mexico, is a specialized financial development fund that provides long-term loans at below-market rates. FONEI loans are available under various provisions having different eligibility requirements. The plant expansion provision is designed for the creation, expansion, or modernization of enterprises in order to promote the efficient production of goods capable of competing in the international market or to meet the objectives of the National Development Plan (NDP), which include industrial decentralization. The studies and counsel provision provides loans to finance studies of the international competitiveness of companies. We consider these FONEI loan provisions to confer a subsidy because they provide loans on terms inconsistent with commercial considerations, and the availability of these loans is restricted to enterprises located outside Zone IIIA (Mexico City and designated areas around Mexico City).

One firm had a FONEI loan for a feasibility study outstanding during the review period. This loan had a variable rate and was denominated in pesos. We treated this variable-rate loan as a series of short-term loans.

The Banco de Mexico stopped publishing data on nominal and effective commercial lending rates in Mexico after 1984. Therefore, as the basis for our benchmark, we have relied in part on the rates for the years 1981 through 1984, as published in the Banco de Mexico's Indicadores Economicos y Moneda (I.E.). We calculated the average difference between the I.E. effective interest rates and the Costo Porcentual Promedio (CPP) rates, the average cost of short-term funds to banks, for the years 1981 through 1984. We added this average difference to the 1990 CPP rates. For peso-denominated loans on which interest was due during 1990, we calculated an average monthly benchmark of 3.73 percent.

To calculate the benefit, we compared this benchmark with the preferential interest rate in effect for each FONEI loan payment made during the review period. We divided the benefits by the firm's total sales to all markets during the review period. We then weight-averaged the resulting benefit by the company's proportion of exports of subject merchandise to the United States during the review period. On this basis, we preliminarily determine the benefit from this program to be 0.01 percent *ad valorem* for all companies.

(4) *PITEX*

The Program for Temporary Importation of Products used in the Production of Exports (PITEX) was established by a decree published in the Diario Oficial on May 9, 1985, and amended in the Diario Oficial on September 19, 1986, and May 3, 1990. The program is jointly administered by the Ministry of Commerce and Industrial Development (SECOFI) and the Customs Administration. Under PITEX, exporters with a proven export record may receive authorization to temporarily import products to be used in the production of exports for up to five years without having to pay the import duties normally imposed on those imports. PITEX allows for the exemption of import duties for the following categories of merchandise used in export production: raw materials, packing materials, fuels and lubricants, machinery used to manufacture products for export, and spare parts and other machinery. The importer must post a bond or other security to guarantee the reexportation of the imports. Because it is only available to exporters, we preliminarily determine that PITEX provides countervailable benefits to the extent that it provides duty exemptions on temporary imports of merchandise not physically incorporated into exported products.

One firm used the PITEX program during the review period, for temporary imports of machinery and spare parts which are not physically incorporated into exported products. To calculate the benefit from this program, we first calculated the duties that should have been paid on the non-physically incorporated items that were imported under the PITEX program during the review period. We then divided that amount by the company's total exports. We then weight-averaged the resulting benefit by the company's proportion of exports of subject merchandise to the United States during the review period. On this basis, we preliminarily determine the benefit from this program to be 1.87 percent *ad valorem* for all companies.

(5) *Other Programs*

We also examined the following programs and preliminarily determine that exporters of the subject merchandise did not use them during the review period;

(A) Certificates of Fiscal Promotion (CEPROFI);

(B) Guarantee and Development Fund for Medium and Small Industries (FOGAIN);

(C) Other BANCOMEXT preferential financing;

(D) Import duty reductions and exemptions;

(E) State tax incentives;

(F) NAFINSA FONEI-type financing; and

(G) NAFINSA FOGAIN-type financing.

Preliminary Results of Review

As a result of our review, we preliminarily determine the net subsidy to be 2.47 percent *ad valorem* for all companies during the period January 1, 1990 through December 31, 1990.

Upon completion of this review, the Department intends to instruct the Customs Service to assess countervailing duties of 2.47 percent of the f.o.b. invoice price on all shipments of this merchandise exported on or after January 1, 1990 and on or before December 31, 1990.

Due to the elimination of the FOMEX export financing program on December 30, 1989, the total estimated duty deposit rate is lower than the above assessment rate by 0.3% *ad valorem*, the rate attributable to FOMEX. Therefore, the Department intends to instruct the Customs Service to collect a cash deposit of estimated countervailing duties of 2.44 percent of the f.o.b. invoice price on all shipments of this merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

Parties to the proceeding may request disclosure of the calculation methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with 19 CFR 355.38(e).

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under 19 CFR 355.38(c), are due.

The Department will publish the final results of this administrative review including the results of its analysis of issues raised in any case or rebuttal brief or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: September 16, 1991.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

[FR Doc. 91-22890 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-DS-M

Export Trade Certificate of Review

ACTION: Notice of application for an amendment to an Export Trade Certificate of Review.

SUMMARY: The Office of Export Trading Company Affairs (OETCA), International Trade Administration, Department of Commerce, has received an application for an amendment to an Export Trade Certificate of Review. This notice summarizes the amendment and requests comments relevant to whether the Certificate should be amended.

FOR FURTHER INFORMATION CONTACT: George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration, 202/377-5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001-21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. A Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private, treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Act and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination of whether the Certificate should be amended. An original and five (5) copies should be submitted not later than 20 days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, room 1800H, Washington, DC 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). Comments should refer to this application as "Export Trade Certificate of Review, application number 87-7A004."

OETCA has received the following application for an amendment to Export Trade Certificate of Review #87-00004, which was issued on May 19, 1987 (52 FR 19371, May 22, 1987) and previously amended on December 11, 1987 (52 FR 48454, December 22, 1987), January 3, 1989 (54 FR 837, January 10, 1989), April 20, 1989 (54 FR 19427, May 5, 1989), May 31, 1989 (54 FR 24931, June 12, 1989), May 29, 1990 (55 FR 23576, June 11, 1990), and June 7, 1991 (56 28140, June 19, 1991).

Summary of the Application

Applicant: National Machine Tool Builders' Association, ("NMTBA") a.k.a. NMTBA—The Association for Manufacturing Technology, 7901 Westpark Drive, McLean, Virginia 22102-4269.

Contact: Richard G. Slattery, Legal Counsel, Telephone: (202) 662-6000.

Application No.: 87-7A004.

Date Deemed Submitted: September 16, 1991.

Request For Amended Conduct: NMTBA seeks to amend its Certificate to:

1. Add each of the following companies as a new "Member" of the Certificate: Cone Blanchard Machine Company, Windsor, VT; Jones & Lamson-Vermont Corp., Springfield, VT (controlling entity: Vermont-USA Machine Tool Group); and Motch Corporation, Cleveland, OH (controlling entity: Pittler AG); and

2. Delete each of the following companies as a "Member" of the Certificate: Anocut, Inc.; CHEMTOOL, Incorporated; DeVlieg-Sundstrand; Empire Abrasive Equipment Corporation; ETTCO Tool & Machine Co., Inc.; L&F Industries; Lenawee Industrial Machine, Inc.; Lyon Machine Builders; MHP Machines Inc.; The Pratt & Whitney Company, Inc.; and Vapor Blast Manufacturing Company.

Dated: September 16, 1991.

George Muller,

Director, Office of Export Trading Company Affairs.

[FR Doc. 91-22887 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-DR-M

Export Trade Certificate of Review

ACTION: Notice of application for an amendment to an Export Trade Certificate of Review.

SUMMARY: The Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, has received an application for an amendment to an Export Trade Certificate of Review. This notice summarizes the amendment and requests comments relevant to whether the amended Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration, 202/377–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. A Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private, treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Act and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether the Certificate should be amended. An original and five (5) copies should be submitted not later than 20 days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, room 1800H, Washington, DC 20230. Information submitted by any person is exempted from disclosure under the Freedom of Information Act (5 U.S.C. 552). Comments should refer to this application as "Export Trade Certificate of Review, application number 88–4A017."

OETCA has received the following application for an amendment to Export Trade Certificate of Review No. 88–00017, which was issued on May 26, 1989 (54 FR 24932, June 12, 1989). The Certificate was previously amended April 4, 1990 (55 FR 14100 April 16, 1990) and January 3, 1991 (56 FR 843 January 9, 1991).

Summary of the Application

Applicant: Construction Industry Manufacturers Association ("CIMA"), 111 East Wisconsin Avenue, suite 940, Milwaukee, Wisconsin 53202, *Contact:* J. William Peterson, Director of Government Affairs, *Telephone:* 202/479–2666.

Application No.: 88–4A017.

Dated Deemed Submitted: September 12, 1991.

Request For Amended Certificate: CIMA seeks to amend its Certificate to:

1. And Sioux Steam Cleaner Corporation of Beresford. South Dakota as a "Member" within the meaning of § 325.2(1) of the Regulations (15 CFR 325.2(1));

2. Add (a) General Industrial Machinery and Equipment, Not Elsewhere Classified (SIC code 3569) and (b) Service Industry Machinery, Not Elsewhere Classified (SIC code 3589) as products to be covered by the Certificate; and

3. Delete CMI Corporation as a "Member" of the Certificate.

Dated: September 16, 1991.

George Muller,

Director, Office of Export Trading Company Affairs.

[FR Doc. 91–22888 Filed 9–23–91; 8:45 am]

BILLING CODE 3510–DR–M

National Institute of Standards and Technology

[Docket No. 910921–1221]

Opportunity To Join a Cooperative Research and Development Consortium for Rheological and Temperature Sensors for On-Line Monitoring of Polymer Processing

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) seeks industrial parties interested in entering into a cooperative industrial/NIST research consortium on the development of new measurement technology to monitor polymer processing. This technology is based on optical measurement methods. The program will be undertaken within the scope and confines of The Federal Technology Transfer Act of 1986 (15 U.S.C. 3710a), which provides federal laboratories including NIST, with the authority to enter into cooperative research agreements with qualified parties. Under this law, NIST may contribute personnel, equipment and facilities—but no funds—to the cooperative research program. For this consortium, participants will be required to contribute $10,000 annually for the four-year program (a total of $40,000). This is not a grant program.

DATES: Interested parties should contact NIST at the address or telephone number shown below but no later than October 24, 1991.

ADDRESSES: Dr. H. Thomas Yolken, Office of Intelligent Processing of Materials, National Institute of Standards and Technology, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Dr. H. Thomas Yolken, (301) 975–5727.

SUPPLEMENTARY INFORMATION: NIST seeks qualified industrial parties interested in entering into a cooperative consortium research program on the development of new measurement technology to monitor important polymer processing parameters in real time. NIST has been engaged in research using optical and fluorescence measurement methods to develop sensors which can be used with polymer processing machinery. Previous work has involved the instrumentation of processing machinery using optical fibers to probe at specific sites in the process line. Real-time measurements of the quality-of-mix of ingredients, solids concentration and residence time distribution have been made. The primary focus of future work is rheological and temperature measurements. The goal is to develop the necessary technology to measure, in real-time, viscosity, strain rate, stress, velocity and temperature of molten polymers undergoing flow. The measurements are based on optical and fluorescence science and the use of optical fibers as the sensing vehicle.

NIST would like to enter into a cooperative consortium research and development program with industrial companies in order to develop measurement concepts into usable technology for polymer processing. NIST would like to work with materials/polymer processors or instrumentation companies that have significant expertise in the measurement of materials processing and/or in the processing of polymers. Companies should be prepared to invest adequate resources in the collaboration and be firmly committed to the goal of developing new measurement technology.

This program is being undertaken within the scope and confines of the Federal Technology Transfer Act of 1986 (Pub. L. 99–502, 15 U.S.C. 3710a), which authorizes government owned and operated federal laboratories, including NIST, to enter into cooperative research and development agreements (CRDAs) with qualified parties. Under the law, a CRDA may provide for contributions

from the federal laboratory of personnel, facilities and equipment, but not direct funding. Participants will be required to contribute $10,000 per year for the four-year program (a total of $40,000).

Dated: September 17, 1991.

John W. Lyons,

Director.

[FR Doc. 91-22901 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-13-M

National Oceanic and Atmospheric Administration

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Application for Permit; Oregon Coast Aquarium, Inc. (P491).

SUMMARY: Notice is hereby given that an applicant has applied in due form for a Public Display Permit to obtain the care and custody of marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

1. Applicant: Oregon Coast Aquarium, Inc., 2820 SE Ferry Slip Road, P.O. Box 2000, Newport, Oregon 97365.

2. Type of Permit Requested: Public Display.

3. Number and Name of Marine Mammals: Six California sea lions (*Zalophus californiaus*) and six harbor seals (*Phoca vituliana*).

4. The applicant requests permission to maintain six California sea lions and six harbor seals. The animals will be obtained from captive or stranded stock being held at other institutions in the United States and Canada. The themes of the education program associated with the seal exhibits will include conservation, natural history and behavior.

The arrangements and facilities for transporting and maintaining the marine mammals requested in this application will be concluded consistent with requirements established by the U.S. Department of Agriculture under the Animal Welfare Act. The animals will be under the care of a licensed veterinarian at the Oregon Coast Aquarium.

Concurrent with the publication of this notice in the **Federal Register**, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, 1335 East-West Highway, Silver Spring, Maryland 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review by interested persons in the following offices:

Office of Protected Resources and Habitat Programs, National Marine Fisheries Service, 1335 East West Highway, room 7330, Silver Spring, Maryland 20910, (301) 427-2289; and

Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NE, BIN C15700—Bldg. 1, Seattle, WA 98115-0070, (206) 526-6150.

Dated: September 18, 1991.

Nancy Foster,

Director, Office of Protected Resources.

[FR Doc. 91-22893 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-22-M

COMMISSION ON INTERSTATE CHILD SUPPORT

Public Hearing

The U.S. Commission on Interstate Child Support will hold a public hearing in Washington, DC, September 30, 1991 from 10 a.m. to 12 noon in room 216 of the Hart Senate Office Building.

The Commission will hear testimony from national groups invited to review tenative recommendations. Recommendations cover a wide number of reforms to the interstate establishment and enforcement of child support obligations.

For more information contact Joyce Moore at 202-254-8093.

Margaret Campbell Haynes,

Chair.

[FR Doc. 91-22906 Filed 9-23-91; 8:45 am]

BILLING CODE 6820-64-M

Commission Meeting

The U.S. Commission on Interstate Child Support will meet on September 29, 1991 from 1 p.m. to 6 p.m. and September 30, 1991 from 12 noon to 6 p.m. All meetings will be held in room 211 of the Hall of States, 444 North Capitol Street NW., Washington, DC.

The Commission will review recommendations made by its committees. Recommendations cover a wide number of reforms to the interstate establishment and enforcement of child support obligations.

For more information contact Joyce Moore at 202-254-8093.

Margaret Campbell Haynes,

Chair.

[FR Doc. 91-22905 Filed 9-23-91; 8:45 am]

BILLING CODE 6820-64-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Man-made Fiber Textile Products Produced or Manufactured in Egypt

September 18, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: September 18, 1991.

FOR FURTHER INFORMATION CONTACT: Kim-Bang Nguyen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 566-5810. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limit for Categories 300/301 is being increased by application of swing and carryover. The Group I limit is being reduced to account for the swing being applied.

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 55 FR 50756, published on December 10, 1990). Also see 55 FR 49936, published on December 3, 1990.

The letter to the Commissioner of Customs and the actions taken pursuant

to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 18, 1991.

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 November 27, 1990, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton and man-made fiber textile products, produced or manufactured in Egypt and exported during the twelve-month period which began on January 1, 1991 and extends through December 31, 1991.

Effective on September 18, 1991, you are directed to amend the directive dated November 27, 1990 to adjust the limits for the following categories, as provided under the terms of the current bilateral agreement between the Governments of the United States and the Arab Republic of Egypt:

Category	Adjusted twelve-month limit [1]
Group I	
218-220, 224-227, 313-317 and 326, as a group.	62,123,436 square meters equivalent.
Sublevel in Group I	
227	12,272,957 square meters.
Level not in a group	
300/301	7,012,120 kilograms of which not more than 908,072 kilograms shall be in Category 301.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1990.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-22886 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-DR-F

Adjustment of Import Limits for Certain Cotton, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in India

September 18, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: September 25, 1991.

FOR FURTHER INFORMATION CONTACT: Jennifer Tallarico, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 343-6494. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limits for certain categories are being reduced for carryforward used during the previous agreement period.

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 55 FR 50756, published on December 10, 1990). Also see 55 FR 51144, published on December 12, 1990.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 18, 1991.

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 7, 1990, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in India and exported during the twelve-month period which began on January 1, 1991 and extends through December 31, 1991.

Effective on September 25, 1991, you are directed to amend further the directive dated December 7, 1990 to reduce the limits for the following categories, as provided under the terms of the current bilateral agreement between the Governments of the United States and India:

Category	Adjusted twelve-month limit [1]
Levels in Group I	
336/339/340	1,335,177 dozen.
347/348	357,559 dozen.
369pt. [2]	8,473,266 kilograms of which not more than 822,926 kilograms shall be in Category 369-D [3] and not more than 426,787 kilograms shall be in Category 369-S [4].
Sublevels in Group II	
640	149,652 dozen.
641	912,046 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1990.

[2] Category 369pt.: all HTS numbers except 5702.10.9020, 5702.49.1010 and 5702.99.1010.

[3] Category 369-D: only HTS numbers 6302.60.0010, 6302.91.0005 and 6302.91.0045.

[4] Category 369-S: only HTS number 6307.10.2005.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-22885 Filed 9-23-91; 8:45 am]

BILLING CODE 3510-DR-F

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Policy Board Advisory Committee Task Force on Soviet Military

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: The location of the Defense Policy Board Advisory Committee Task Force on Soviet Military meeting announced in the **Federal Register** on Thursday, 12 September, 1991 (FR 46414) has been changed to 4001 North Fairfax Drive, suite 500, Fairfax, Virginia from 0845 until 1200. All other information remains the same.

Dated: September 18, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-22953 Filed 9-23-91; 8:45 am]

BILLING CODE 3810-01-M

Department of the Army

Privacy Act of 1974; Amend Record Systems

AGENCY: Department of the Army, DoD.

ACTION: Amend Privacy Act Record Systems.

SUMMARY: The Department of the Army proposes to amend 23 record systems in its inventory of record system notices subject to the Privacy Act of 1974, as amended, (5 U.S.C. 552a).

DATES: The proposed action will be effective without further notice on October 24, 1991, unless comments are received that would result in a contrary determination.

ADDRESSES: Contact Ms. Alma Lopez, Office of Systems Management Branch (ASOP-MP), Ft. Huachuca, AZ 85613–5000.

SUPPLEMENTARY INFORMATION: The Department of the Army record system notices subject to the Privacy Act of 1974, as amended, have been published in the **Federal Register** as follows:

50 FR 22090, May 29, 1985 (DoD Compilation, changes follow)
51 FR 23576, Jun. 30, 1986
51 FR 30900, Aug. 29, 1986
51 FR 40479, Nov. 7, 1986
51 FR 44361, Dec. 9, 1986
52 FR 11847, Apr. 13, 1987
52 FR 18798, May 19, 1987
52 FR 25905, Jul. 9, 1987
52 FR 32329, Aug. 27, 1987
52 FR 43932, Nov. 17, 1987
53 FR 12971, Apr. 20, 1988
53 FR 16575, May 10, 1988
53 FR 21509, Jun. 8, 1988
53 FR 28247, Jul. 27, 1988
53 FR 28249, Jul. 27, 1988
53 FR 28430, Jul. 28, 1988
53 FR 34576, Sep. 7, 1988
53 FR 49586, Dec. 8, 1988
53 FR 51580, Dec. 22, 1988
54 FR 10034, Mar. 9, 1989
54 FR 11790, Mar. 22, 1989
54 FR 14835, Apr. 13, 1989
54 FR 46965, Nov. 8, 1989
54 FR 50268, Dec. 5, 1989
55 FR 13935, Apr. 13, 1990
55 FR 21897, May 30, 1990 (Army Address Directory)
55 FR 41743, Oct. 15, 1990
55 FR 46707, Nov. 6, 1990
55 FR 46708, Nov. 6, 1990
55 FR 48671, Nov. 21, 1990 (Army System ID Changes)
55 FR 48678, Nov. 21, 1990
56 FR 7018, Feb. 21, 1991
56 FR 15593, Apr. 17, 1991
56 FR 21134, May 7, 1991
56 FR 27949, Jun. 18, 1991

The amendments are not within the purview of subsection (r) of the Privacy Act, as amended, (5 U.S.C. 552a) which requires the submission of an altered system report. The specific changes to the record systems are set forth below followed by the record system notices published in their entirety, as amended.

Dated: September 18, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0037–104–3DASG

System name:

Health Professions Scholarship Program (52 FR 18798, May 19, 1987).

Changes:

* * * * *

System location:

Delete the fifth and sixth lines and replace with "5109 Leesburg Pike, Falls Church, VA 22041–3258".

Categories of records in the system:

In line 13, after "telephone number", add "Social Security Number".

* * * * *

Retention and disposal:

Delete entry and replace with "Upon completion of the program, records for members entering active duty are forwarded to the Commander, U.S. Total Army Personnel Center, ATTN: TAPC–MSR, 200 Stovall Street, Alexandria, VA 22332–0400.

Records for members on continued educational delay are forwarded to Commander, U.S. Army Reserve Personnel Center, 9700 Page Boulevard, ATTN: DARP–DPL, St. Louis, MO 63132–5200.".

System manager(s) and address:

Delete entire entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Finance and Accounting Office, Fitzsimons Army Medical Center, Aurora, CO 80045–5001, so long as reservist is enrolled in the Scholarship Program. Thereafter, information may be obtained from either the Commander, U.S. Total Army Personnel Command, 200 Stovall Street, Alexandria, VA 22332–0400 or the Commander, U.S. Army Reserve Personnel Center, 9700 Page Boulevard, St. Louis, MO 63132–5200 as appropriate.

For verification purposes, the individual should provide the full name, present address and telephone number."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Finance and Accounting Office, Fitzsimons Army Medical Center, Aurora, CO 80045–5001, so long as reservist is enrolled in the Scholarship Program. Thereafter, information may be obtained from either the Commander, U.S. Total Army Personnel Command, 200 Stovall Street, Alexandria, VA 22332–0400 or the Commander, U.S. Army Reserve Personnel Center, 9700 Page Boulevard, St. Louis, MO 63132–5200 as appropriate.

For verification purposes, the individual should provide the full name, present address and telephone number."

* * * * *

A0037–104–3DASG

SYSTEM NAME:

Health Professions Scholarship Program.

SYSTEM LOCATION:

Fitzsimons Army Medical Center, Aurora, CO 80045–5001. A segment of this system exists at the U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Members of the U.S. Army Reserve who are enrolled in the Army-Health Professions Scholarship Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contract records between the Army and the University participating in the Health Professions Scholarship Program, tuition payments, individual's military pay records, cost data worksheets, active duty military pay vouchers, personal financial history records, monthly payroll listings of current members showing entitlements and deductions, bank identification data for deposit of pay, member's permanent home address, current mailing address and telephone number, Social Security Number, orders to active duty, student's elective to defer entry on active duty, and similar relevant documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. chapter 104, et. seq.: Public Law 94–426; and Executive Order 9397.

PURPOSE(S):

To establish the pay account of students accepted into the Health Professions Scholarship Program; to determine appropriate pay, deductions, reimbursable expenses, taxes and disbursements.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information may be disclosed to the Department of the Treasury to record check issue data, taxable earnings and taxes withheld.

To states and cities/counties which have an agreement with the Department of the Army to verify tax liability against member's state and city/county tax returns.

To the Social Security Administration to record earned wages by member under the Federal Insurance Contributions Act.

The "Blanket Routine Uses" set forth at the beginning of the Army's compilation of record systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders; magnetic tapes; computer printouts; microfilm; ledger cards.

RETRIEVABILITY:

By member's name and Social Security Number.

SAFEGUARDS:

Information is accessible only to authorized personnel having official need therefor. Records are stored in secured buildings protected by military police/security guards.

RETENTION AND DISPOSAL:

Upon completion of the program, records for members entering active duty are forwarded to the Commander, U.S. Total Army Personnel Center, ATTN: TAPC-MSR, 200 Stovall Street, Alexandria, VA 22332–0400.

Records for members on continued educational delay are forwarded to Commander, U.S. Army Reserve Personnel Center, ATTN: DARP-DPL, 9700 Page Boulevard, St. Louis, MO 63132–5200.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Finance and Accounting Office, Fitzsimons Army Medical Center, Aurora, CO 80045–5001, so long as reservist is enrolled in the Scholarship Program. Thereafter, information may be obtained from either the Commander, U.S. Total Army Personnel Command, 200 Stovall Street, Alexandria, VA 22332–0400 or the Commander, U.S. Army Reserve Personnel Center, 9700 Page Boulevard, St. Louis, MO 63132–5200 as appropriate.

For verification purposes, the individual should provide the full name, present address and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Finance and Accounting Office, Fitzsimons Army Medical Center, Aurora, CO 80045–5001, so long as reservist is enrolled in the Scholarship Program. Thereafter, information may be obtained from either the Commander, U.S. Total Army Personnel Command, 200 Stovall Street, Alexandria, VA 22332–0400 or the Commander, U.S. Army Reserve Personnel Center, 9700 Page Boulevard, St. Louis, MO 63132–5200 as appropriate.

For verification purposes, the individual should provide the full name, present address and telephone number.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual; university/college in which student is enrolled; Army records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040DASG

System name:

Medical Facility Administration Records (50 FR 22214, May 29, 1985).

Changes:

* * * * *

Categories of records in the system:

In line 7, after "records", add "individual's surname, Social Security Number".

Authority for maintenance of the system:

Add at the end "and Executive Order 9397."

* * * * *

Storage:

Add at the end "or other computerized or machine readable media."

Safeguards:

Add at the end "Automated segments are protected by controlled system passwords governing access to data".

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this records system should address written inquiries to the Patient Administrator at the medical facility where service/care was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, individual should provide the full name, Social Security Number, details which will assist in locating record, and signature.

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Patient Administrator at the medical facility where service/care was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, individual should provide the full name, Social Security Number, details which will assist in locating record, and signature."

* * * * *

A0040DASG

SYSTEM NAME:

Medical Facility Administration Records.

SYSTEM LOCATION:

Medical centers, hospitals, and health clinics. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are authorized to use services of an Army medical facility.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information in this system generally relates to administration at a medical facility, as opposed to an individual's health/care. Typically, records comprise

scheduling of appointments, medical history data used to locate medical records, individual's name, Social Security Number, birth, death, accountability of patients (e.g., bad charts; transfer, leave requests, etc.); receipts for patients' personal property, prescriptions for medications, eyeglasses, hearing aids, prosthetic devices, diet/special nourishment plans, blood donor records, charges, receipts and accounting, documents of payments for medical/dental services; register number assigned; Social Security Number, and similar records/reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 10 U.S.C. 3013 and Executive Order 9397.

PURPOSE(S):

To locate medical records and personnel, schedule appointments; provide research and statistical data.

To enhance efficient management practices and effective patient administration.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Birth records are disclosed to states' Bureau of Vital Statistics and overseas birth records are disclosed to the Department of State to provide the official certificates of birth. Birth records may also be used for statistical purposes.

Death records are disclosed to federal, state and private sector authorities to provide the official certificates of death. Death records may also be used for statistical purposes.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Cards; paper records in file holders or other computerized or machine readable media.

RETRIEVABILITY:

By individual's surname or Social Security Number

SAFEGUARDS:

Records are maintained within secured buildings in areas accessible only to persons having official need therefor who are properly trained and screened. Automated segments are protected by controlled system passwords governing access to data.

RETENTION AND DISPOSAL:

Nominal index files, including register numbers assigned, are destroyed after 20 years. Records of transient value (e.g., issuance of spectacles/prosthetics, diet/food plan, etc.) are destroyed within 3 months of patient's release. Other records have varying periods of retention: Record of birth/death—2 years; patient accountability (admission/discharge)—5 years; blood donor—5 years or when no longer needed for medical/legal reasons whichever is longer; record of patient's personal property—3 years.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this records system should address written inquiries to the Patient Administrator at the medical facility where service/care was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, individual should provide the full name, Social Security Number, details which will assist in locating record, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Patient Administrator at the medical facility where service/care was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, individual should provide the full name, Social Security Number, details which will assist in locating record, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual; medical facility records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–1DASG

System name:

Professional Consultant Control Files (50 FR 22217, May 29, 1985).

Changes:

* * * * *

System location:

Add at the end "U.S. Army Medical Command, Korea". Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

Categories of records in the system:

Delete entry and replace with "Documents containing name, curriculum vitae of professional qualifications and experience, appointment, utilization, duties, responsibilities, and compensation of appointed consultants."

* * * * *

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

Delete entry and replace with "Information on individuals may be provided to civilian and military medical facilities, Federation of State Medical boards of the United States, State Licensure Authorities and other appropriate professional regulating bodies for use in considering and selecting individuals for panels or boards or for speaking engagements."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, "5109 Leesburg Pike, Falls Church VA 22041–3258".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS-CP, Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, current address and telephone number, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS-CP, Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name,

current address and telephone number, and signature.

* * * * *

A0040-1DASG

SYSTEM NAME:

Professional Consultant Control Files.

SYSTEM LOCATION:

Office of the Surgeon General, Headquarters, Department of the Army; U.S. Army Health Services Command; U.S. Army Medical Command, Europe; U.S. Army Medical Command, Korea. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual who has been used or appointed as a professional consultant in the professional medical services.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents containing name, curriculum vitae of professional qualifications and experience, appointment, utilization, duties, responsibilities, and compensation of appointed consultants.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 10 U.S.C. 1071–1086.

PURPOSE(S):

To appoint and monitor utilization of designated consultants.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information on individuals may be provided to civilian and military medical facilities, Federation of State Medical boards of the United States, State Licensure Authorities and other appropriate professional regulating bodies for use in considering and selecting individuals for panels or boards or for speaking engagements.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM.

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

By last name of consultant.

SAFEGUARDS:

Records are maintained in secured areas accessible only to authorized individuals having official need therefor in the performance of assigned duties.

RETENTION AND DISPOSAL:

Records are destroyed 1 year after termination of consultant's appointment.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS-CP, Leesburg Pike, Falls Church, VA 2204l–3258. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, current address and telephone number, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the office of the Surgeon General Headquarters, Department of the Army, ATTN: SGPS-CP, Leesburg Pike, Falls Church, VA 22041–3258. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, current address and telephone number, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual; Army records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–1HSC

System name:

Professional Personnel Information (50 FR 22218, May 29, 1985).

Changes:

* * * * *

System location:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Categories of individuals covered by the system:

Replace "Health Services Command" with "Army Medical Department".

Categories of records in the system:

Replace "Health Services Command" with "Department of the Army Surgeon General". In line five, delete "command".

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church VA 22041–3258".

Notification procedure:

Delete entry and replace with Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, current address and telephone number, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themseves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, current address and telephone number, and signature."

* * * * *

A0040–1HSC

SYSTEM NAME:

Professional Personnel Information File.

SYSTEM LOCATION:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Practicing physicians, residents, psychologists, social workers, and pharmacists assigned or employed in medical treatment facilities operated by the Army Medical Department.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files contain personal information provided to the various professional staff officers assigned to Department of the Army Surgeon General by practitioners assigned to medical treatment facilities. This includes personal data questionnaires, curricula, vitae, assignment preferences, personal correspondence, and other records pertaining to the professional qualifications and experience of personnel being monitored by the consultant.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013.

PURPOSE(S):

To establish and maintain familiarity with the locations, assignments, utilization, marital and family status, professional and military experience and qualifications, and assignment preferences of professional staff in medical treatment activities, and as an aid in monitoring the utilization of professional personnel and to assist in career management and assignment activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Clinical privileged information may be provided to civilian and military medical facilities, Federation of State Medical Boards of the United States, State Licensure Authorities and other appropriate professional regulating bodies.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM: STORAGE:

Paper records in file folders and on index cards.

RETRIEVABILITY:

By last name of professional person.

SAFEGUARDS:

Records are stored in buildings protected by security guards; access to records is restricted to designated individuals having need therefor in the performance of official duties.

RETENTION AND DISPOSAL:

Records are destroyed within 1 year following termination of practitioner's assignment or employment.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, current address and telephone number, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, current address and telephone number, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial agency determinations by the individual concerned are published in Department of the Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Official Personnel Rosters, registers, and Army records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–3aDASG

System name:

Medical Review Files (50 FR 22215, May 29, 1985).

Changes:

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedure:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, place and date of medical examination, additional details that will facilitate locating the record, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, place and date of medical examination, additional details that will facilitate locating the record, and signature."

* * * * *

A0040–3aDASG

SYSTEM NAME:

Medical Review Files.

SYSTEM LOCATION:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants and registrants who are being considered for Army service and whose medical fitness is questionable; Army members being considered for continuance in service, promotion, special assignment, or separation whose medical fitness is questioned either by the medical evaluating authority or by the individual.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files contain documents relating to medical fitness of individuals for appointment, enlistment, retention in service, promotion, special assignment, or separation. Included are reports of medical examination and evaluation, psychological evaluation reports, and similar or related documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 10 U.S.C. 1071.

PURPOSE(S):

To evaluate medical fitness of marginally qualified personnel for Army program with strict regard to established medical standards.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OR SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

By individual's name.

SAFEGUARDS:

Records are maintained in secured areas accessible only to designated personnel having official need therefor in the performance of assigned duties.

RETENTION AND DISPOSAL:

Destroyed after 3 years.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, place and date of medical examination, additional details that will facilitate locating the record, and signature.

RECORD ACCESS PROCEDURES

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, place and date of medical examination, additional details that will facilitate locating the record, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From clinical records, health records, medical boards, civilian physicians, consultation reports, other Army records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM.

None.

A0040–3bDASG

System name:

Medical Evaluation Files (50 FR 22216, May 29, 1985).

Changes:

Authority for maintenance of the system:

Add at the end "and Executive Order 9397".

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, any details which will assist locating pertinent records, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, any details which will assist locating pertinent records, and signature."

* * * * *

A0040–3bDASG

SYSTEM NAME:

Medical Evaluation Files.

SYSTEM LOCATION:

Primary system is located at Army Medical Department medical facilities convening a medical board. A segment exists at the U.S. Army Physical Evaluation Board and the U.S. Army Physical Disability Agency (USAPDA).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Army members whose medical fitness for continued service has been questioned either by the member or his/her commander.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personal information concerning the member; certain codes of specific types of injuries for research study purposes; Department of Veteran Affairs Schedule for Rating Disability Diagnostic Codes; documents reflecting determination by an Army board of medical fitness for continued Army active service; board proceedings and related documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; l0 U.S.C. 1071 and 1201; and Executive Order 9397.

PURPOSE(S):

Records are used by Medical Boards to determine medical fitness for continued Army active service. They are used by the Physical Evaluation Board to review board findings when required and to determine if the individual should be discharged, temporarily or permanently retired for disability, or retained for active service. The U.S. Physical Disability Agency reviews determinations and dispositions, and responds to inquiries.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING,AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders; magnetic diskettes.

RETRIEVABILITY:

By individual's name.

SAFEGUARDS:

Records are maintained in areas accessible only to authorized personnel who are properly screened and trained. Operation of data processing equipment and magnetic tapes are limited strictly to authorized personnel. Computer has key lock and key is controlled. Magnetic diskettes are stored and controlled to ensure they do not result in unauthorized disclosure of personal information.

RETENTION AND DISPOSAL:

Records of Medical Boards are retained for 5 years and then destroyed. Records of the U.S. Army Physical Evaluation Boards are retained for 2 years or until discontinued, whichever occurs first. Records at the U.S. Army Physical Disability Agency are retained

for 5 years and then destroyed. Destruction of all records is by shredding.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, details which will assist in locating pertinent records, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, details which will assist in locating pertinent records, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual; medical records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–3cDASG

System name:

Medical Regulating Files (50 FR 22217, May 29, 1985).

Changes:

* * * * *

System location:

Delete "Office of the Surgeon General, Headquarters, Department of the Army, The Pentagon, Washington, DC 20310" and replace with "U.S. Air Force Medical Center, Scott Air Force Base, IL 62225–6300".

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258 or to the Patient Administrator at the medical treatment facility where service was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, rank or status and parent service, approximate date of transfer, medical treatment facility from which transferred, and current address and telephone number."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258 or to the Patient Administrator at the medical treatment facility where service was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, rank or status and parent service, approximate date of transfer, medical treatment facility from which transferred, and current address and telephone number."

* * * * *

A0040–3cDASG

SYSTEM NAME:

Medical Regulating Files.

SYSTEM LOCATION:

Primary location is at the U.S. Air Force Medical Center, Scott Air Force Base, IL 62225–6300. Segments exist at Army medical treatment facilities, evacuation units and medical regulating offices. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any patient requiring transfer to another medical treatment facility who is reported to the Armed Services Medical Regulating Office by the U.S. Government medical treatment facilities for designation of the receiving medical facility.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains information reported by the transferring medical treatment facility and includes, but is not limited to, patient identity, service affiliation and grade or status, sex, medical diagnosis, medical condition, special procedures or requirements needed, medical specialties required, administrative considerations, personal considerations, the patient's home town and/or duty station and other information having an impact on the transfer.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301.

PURPOSE(S):

To properly determine the appropriate medical treatment facility to which the reported patient will be transferred; to notify the reporting U.S. Government medical treatment facility of the transfer destination; to notify the receiving medical treatment facility of the transfer, to notify evacuation units, medical regulating offices and other government offices for official reasons; to evaluate the effectiveness of reported information; to establish further the specific needs of the reported patient; for statistical purposes; and when required by law and official purposes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

Note: Record of the identity, diagnosis, prognosis, or treatment of any client/patient, irrespective of whether or when he ceases to be a client/patient, maintained in connection with the performance of any alcohol or drug abuse prevention and treatment function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States, shall, except as provided therein, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized in Title 42 U.S.C. 290dd–3 and 290ee–3. These statutes take precedence over the Privacy Act of 1974, in regard to accessibility of such records except to the individual to whom the record pertains.

The "Blanket Routine Uses" do not apply to these records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM.

STORAGE:

Paper records in file folders; index cards.

RETRIEVABILITY:

By individual's name.

SAFEGUARDS:

Records are maintained in secured areas accessible only to authorized personnel who are properly screened and trained.

RETENTION AND DISPOSAL:

Destroyed 1 year following the end of the calendar year in which the patient was reported to the Armed Services Medical Regulating Office.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258 or to the Patient Administrator at the medical treatment facility where service was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, rank or status and parent service, approximate date of transfer, medical treatment facility from which transferred, and current address and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–AOI, 5109 Leesburg Pike, Falls Church, VA 22041–3258 or to the Patient Administrator at the medical treatment facility where service was provided. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, rank or status and parent service, approximate date of transfer, medical treatment facility from which transferred, and current address and telephone number.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From transferring and receiving medical treatment facilities, medical regulating offices, evacuation offices, and other U.S. Government offices, agencies and commands relevant to the patient transfer.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–5DASG

System name:

Occupational Health Records (50 FR 22224, May 29, 1985).

Changes:

Authority for maintenance of the system:

Add at the end "and Executive Order 9397."

* * * * *

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

Delete entry and replace with "Information may be disclosed to the Department of Labor, Department of Health and Human Services, Office of Safety and Health Affairs, Center for Disease Control, and the National Institute of Occupational Safety and Health for use in disease and injury prevention efforts."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedure:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Patient Administrator at the appropriate medical treatment facility, or to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, Social Security Number, current address and telephone number, details which will assist in locating records, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Patient Administrator at the appropriate medical treatment facility, or to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, Social Security Number, current address and telephone number, details which will assist in locating records, and signature."

* * * * *

A0040–5DASG

SYSTEM NAME:

Occupational Health Records.

SYSTEM LOCATION:

Army medical treatment facilities. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Department of the Army employees; active duty military personnel and their dependents who are treated on an outpatient basis by medical treatment facilities for whom specific occupational health examinations have been requested.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, date and place of birth, marital status, dates of medical surveillance tests and their results; documents reflecting the training, experience and certification to work within hazardous environments; external exposures to chemicals; radiation, physical stress, non-human primates, including personnel monitoring results, work area monitoring readings, and similar and related documents; personnel protective equipment and medical programs

required to limit exposure to environmental safety and health hazards.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 CFR chapter XVII, Occupational Safety and Health Standards; 5 U.S.C. 150; Executive Orders 11612, 11807 and 9397.

PURPOSE(S):

To determine medical fitness and evaluate health of Department of the Army employees and activity duty military personnel and their dependents pursuant to appropriate preventive medicine programs; to ensure that employees are qualified to perform duties under environmental stress and that such stress is limited to lowest level practical.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information may be disclosed to the Department of Labor, Department of Health and Human Services, Office of Safety and Health Affairs, Center for Disease Control, and the National Institute of Occupational Safety and Health for use in disease and injury prevention efforts.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records; magnetic tapes, discs, and printouts.

RETRIEVABILITY:

By individual's name and/or Social Security Number.

SAFEGUARDS:

Access to all records is restricted to designated individuals whose official duties dictate need therefor. Information in automated media are further protected by storage in locked rooms. All individuals afforded access are given periodic orientations concerning sensitivity of personal information and requirement to prevent unauthorized disclosure.

RETENTION AND DISPOSAL:

Personnel exposure files/monitoring data are retained 5 years after evaluation and recorded on permanent medical records. Records relating to individual's health are incorporated in the individual's medical record.

SYSTEMS MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Patient Administrator at the appropriate medical treatment facility, or to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, Social Security Number, current address and telephone number, details which will assist in locating records, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Patient Administrator at the appropriate medical treatment facility, or to the Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Official mailing addresses are published as an appendix to the Army's compilation of system of records notices.

For verification purposes, the individual should provide the full name, Social Security Number, current address and telephone number, details which will assist in locating records, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determination are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From Army Medical records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–14DASG

System name:

Radiation Exposure Records (50 FR 22166, May 29, 1985).

Changes:

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Authority for maintenance of the system:

Add at the end "and Executive Order 9397".

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258."

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS-PSP-E, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, dates and locations at which exposed to radiation or radioactive materials, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS-PSP-E, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, dates and locations at which exposed to radiation or radioactive materials, and signature."

* * * * *

A0040–14DASG

SYSTEM NAME:

Radiation Exposure Records.

SYSTEM LOCATION:

Army installations, activities, laboratories, etc., which use or store radiation producing devices or radioactive materials or equipment. An automated segment exists at Lexington Blue Grass Depot, KY 40141–5520. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons employed by the Army, including employees of contractors, who are occupationally exposed to radiation or radioactive materials.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents reflecting individual's training, experience, and certification to work within hazardous environments which require the handling of or exposure to radioactive materials or equipment. Records may include DD

Form 1852 (Dosimeter Application and Record of Occupational Radiation Exposure), DD 1141 (Dosimetry Record), DA Form 3484 (Photodosimetry Report), SF 11–206, exposed dosimetry film, investigative reports of harmful chemical, biological, and radiological exposures, relevant management reports.

Automated records contain data elements such as individual's name, Social Security Number, date of birth, film badge number, coded cross-reference to place of assignment at time of exposure, dates of exposure and radiation dose, cumulative exposure, type of measuring device, and coded cross-reference to qualifying data regarding exposure readings.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

U.S. Nuclear Regulatory Commission Regulation (10 CFR part 19), Department of Labor Regulation (29 CFR part 1910), and Executive Order 9397.

PURPOSE(S):

To ensure individual qualifications to handle radioactive materials and/or to work under management identified stressful conditions.

To monitor, evaluate, and control the risks of individual exposure to ionizing radiation or radioactive materials by comparison of short and long term exposures.

To conduct investigations of occupational health hazards and relevant management studies and to determine safety standards.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information from this system of records may be disclosed to Federal agencies, academic institutions, and nongovernmental agencies such as the National Council on Radiation Protection and Measurement, and the National Research Council for research, evaluation, and monitorship of exposure.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Papers in file folders, film packets, magnetic tapes/discs.

RETRIEVABILITY:

By individual's name and/or Social Security Number.

SAFEGUARDS:

Access to all records is restricted to designated individuals having official need for them in the performance of assigned duties. In addition, access to automated records is controlled by Card Key System, which requires positive identification and authorization.

RETENTION AND DISPOSAL:

Personnel dosimetry and bioassay records are permanent. Investigative reports of harmful chemical, biological, and radiological exposures are retained for 30 years. Processed film showing individual exposure is retained 5 years after evaluation and recorded on permanent records. Medical test results are transferred to military members' medical records or, in the case of civilians, to their civilian personnel records on reassignments, transfer, or separation.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–PSP–E, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, dates and locations at which exposed to radiation or radioactive materials, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS–PSP–E, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, dates and locations at which exposed to radiation or radioactive materials, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, dosimetry film, Army and/or Department of Defense records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–31aDASG

System name:

Pathology Consultation Record Files (50 FR 22219, May 29, 1985).

Changes:

* * * * *

Categories of individuals covered by the system:

Add at the end "Individuals involved in aircraft crashes, other similar mishaps, or death investigations undertaken by the Office of the Armed Forces Medical Examiner."

Categories of records in the system:

Insert the words "wet tissue" after the words "tissue blocks".

Authority for maintenance of the system:

Add at the end "and Executive Order 9397".

* * * * *

Purpose(s):

Add at the end "and to provide information to investigative, legal, and law enforcement personnel."

* * * * *

Storage:

Insert the words "tissue in formalin solution" after "appropriate storage containers".

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Chief, Records Repository and Information Release Division, Walter Reed Army Medical Center, Washington, DC 20306–6000.

For verification purposes, the individual should provide the full name, Social Security Number or service number of military sponsor and branch of military service, if applicable, or accession number assigned by the Army Forces Institute of Pathology, if known.

For requests made in person, identification such as military

identification card or valid driver's license is required.

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Chief, Records Repository and Information Release Division, Walter Reed Army Medical Center, Washington, DC 20306–6000.

For verification purposes, the individual should provide the full name, Social Security Number or service number of military sponsor and branch of military service, if applicable, or accession number assigned by the Army Forces Institute of Pathology, if known.

For requests made in person, identification such as military identification card or valid driver's license is required."

* * * * *

A0040–31aDASG

SYSTEM NAME:

Pathology Consultation Record Files.

SYSTEM LOCATION:

Armed Forces Institute of Pathology, Walter Reed Army Medical Center, Washington, DC 20306–6000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals treated in military or civilian medical facilities whose cases were reviewed on a consultative basis by members of the staff of the Armed Forces Institute of Pathology. Individuals involved in aircraft crashes, other similar mishaps, or death investigations undertaken by the Office of the Armed Forces Medical Examiner."

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents, tissue blocks, wet tissue microscopic slides, X-rays and photographs reflecting outpatient or inpatient treatment or observation of all individuals on whose cases consultation has been requested.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and Executive Order 9397.

PURPOSE(S):

To ensure complete medical data are available to pathologist providing consultative diagnosis to requesting physician in order to improve quality of care provided to individuals; to provide a data base for education of medical personnel; to provide a data base for medical research and statistical purposes when required by law or for official purposes; and to provide information to investigative, legal, and law enforcement personnel.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Individual records may be released to referring physician, to physicians treating the individual, to qualified medical researchers and students, and to other Federal agencies and law enforcement personnel when requested for official purposes involving criminal prosecution, civil court action or regulatory orders.

The "Blanket Routine Uses" set forth at the beginning of the Army's compilation of record system notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records, x-rays, photographs in paper file folders, microfiche, magnetic tape, printout; tissue blocks in appropriate storage containers; tissue in formalin solution and microscopic slides in cardboard file folders.

RETRIEVABILITY:

By last name or terminal digit number (Social Security Number) or accession number assigned when case is received for consultation.

SAFEGUARDS:

Access to the Armed Forces Institute of Pathology is controlled. Records are maintained in areas accessible only to authorized personnel who are properly screened and trained.

RETENTION AND DISPOSAL:

Retained as long as case material has value for medical research or education. Individual cases are reviewed periodically and materials no longer of value to the Institute are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Chief, Records Repository and Information Release Division, Walter Reed Army Medical Center, Washington, DC 20306–6000.

For verification purposes, the individual should provide the full name, Social Security Number or service number of military sponsor and branch of military service, if applicable, or accession number assigned by the Army Forces institute of Pathology, if known.

For requests made in person, identification such as military identification card or valid driver's license is required.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Chief, Records Repository and Information Release Division, Walter Reed Army Medical Center, Washington, DC 20306–6000.

For verification purposes, the individual should provide the full name, Social Security Number or service number of military sponsor and branch of military service, if applicable, or accession number assigned by the Army Forces Institute of Pathology, if known.

For requests made in person, identification such as military identification card or valid driver's license is required.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Interview, diagnostic test, other available administrative or medical records obtained from civilian or military sources.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–31bDASG

System name:

Research and Experimental Case Files (50 FR 22219, May 29, 1985).

Changes:

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System location:

Delete "DASG-PSA" in the third paragraph, lines six and seven, and replace with "SGPS-PSA". Delete "Washington, DC 20310" in the third paragraph and replace with "5109 Leesburg Pike, Falls Church, VA 22041–3258".

* * * * *

Authority for maintenance of the system:

Add at the end "Executive Order 9397".

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD 21010–5425.

Individuals should provide the full name, Social Security Number, current address and telephone number of the requester.

For personal visits, the individual should be able to provide acceptable identification such as valid driver's license, employer or other individually identifying number, building pass, etc."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD 21010–5425.

Individuals should provide the full name, Social Security Number, current address and telephone number of the requester.

For personal visits, the individual should be able to provide acceptable identification such as valid driver's license, employer or other individually identifying number, building pass, etc."

* * * * *

A0040–31bDASG

SYSTEM NAME:

Research and Experimental Case Files.

SYSTEM LOCATION:

U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD 21010–5425. Individual research/test/medical documents (paper records) are contained in individual's health record which, for reserve and retired military members, is at the U.S. Army Reserve Components Personnel and Administration Center, St. Louis, MO; for other separated military members, is at the National Personnel Records Center, St. Louis, MO 63132–5200; for military members on active duty, is at the servicing medical facility/center, for civilians (both Federal employees and prisoners) is in a special file at the National Personnel Records Center. As paper records are converted to microfiche, the original (silver halide) and 1 copy of the microfiche will be located at the Washington National Records Center; 1 copy will be located at the Office of the Surgeon General, ATTN: SGPS-PSA, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258; 1 copy will reside with the Army contractor—the National Academy of Sciences; and 1 copy retained at the U.S. Army Medical Research Institute of Chemical Defense. Historical 16mm film and audio visual tapes are at Norton Air Force Base, CA 92409–5000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Volunteers (military members, Federal civilian employees, state prisoners) who participated in Army tests of potential chemical agents and/or antidotes from the early 1950's until the program ended in 1975.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual pre-test physical examination records and test records of performance and biomedical parameters measured during and after test exposure.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013e and 4503 and Executive Order 9397.

PURPOSE(S):

To follow up on individuals who voluntarily participated in Army chemical/biological agent research projects for the purpose of assessing risks/hazards to them, and for retrospective medical/scientific evaluation and future scientific and legal significance.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information may be disclosed to the Department of Veteran Affairs in connection with benefits determinations.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in individual's medical file folders; microfiche, computer magnetic tapes and paper printouts, video tapes and 16mm film.

RETRIEVABILITY:

Paper records in individual's health record are retrieved by surname and/or service number/Social Security Number. Microfiche are retrieved by individual's surname. Film/video tape is accessed by case number and/or volunteer's number. Automated records are accessed by number assigned to volunteer or by case number.

SAFEGUARDS:

Paper records and microfiche are kept in locked rooms/compartments with access limited to authorized personnel. Access to computerized data is by use of a valid site ID number assigned to the individual terminal and by a valid user ID and password code assigned to authorized user, changed periodically to avoid compromise. Data entry is on-line using a dial-up terminal. Computer files are controlled by keys known only to U.S. Army Medical Research Institute of Chemical Defense personnel assigned to work on the data base. Data base output is available only to designated computer operators at the Institute. Computer facility has double barrier physical protection. The remote terminal is in a room which is locked when vacated and the building is secured when unoccupied. The contractor (National Academy of Sciences) employs equal safeguards which meet Army standards for Privacy Act data.

RETENTION AND DISPOSAL:

Records stored in the computer and on microfiche are retained indefinitely. Paper medical records in an individual's health records are retained permanently.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system, should address written inquiries to the Commander, U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD 21010–5425.

Individuals should provide the full name, Social Security Number, current address and telephone number of the requester.

For personal visits, the individual should be able to provide acceptable identification such as valid driver's

license, employer or other individually identifying number, building pass.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD 21010–5425.

Individuals should provide the full name, Social Security Number, current address and telephone number of the requester.

For personal visits, the individual should be able to provide acceptable identification such as valid driver's license, employer or other individually identifying number, building pass.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual through test/questionnaire forms completed at test location; from medical authorities/sources by evaluation of data collected previous to, during, and following tests while individual was participating in this research program.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–66aDASG

System name:

Medical Staff Credentials File (50 FR 22218, May 29, 1985).

Changes.

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Authority for maintenance of the system:

Add at the end "and Executive Order 9397".

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedure:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the commander of the medical treatment where practitioner provided clinical service. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the commander of the medical treatment where practitioner provided clinical service. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, and signature."

* * * * *

A0040–66aDASG

SYSTEM NAME:

Medical Staff Credentials File.

SYSTEM LOCATION:

Medical treatment facilities at Army commands, installations and activities. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals performing clinical practice in medical treatment facilities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents reflecting delineation of clinical privileges and clinical performance.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 10 U.S.C. 1071 and Executive Order 9397.

PURPOSE(S):

To determine and assess capability of practitioner's clinical practice.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In specific instances, clinical privileged information from this system of records may be provided to civilian and military medical facilities, Federation of State Medical Boards of the United States, State Licensure Authorities and other appropriate professional regulating bodies for use in assuring high quality health care.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM.

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

By individual's surname.

SAFEGUARDS:

Records are maintained in areas accessible only to the medical treatment facility commander and credentials committee members.

RETENTION AND DISPOSAL:

Records are retained in medical treatment facility of individual's last assignment. Records of military members are transferred to individual's Military Personnel Records Jacket upon separation or retirement. Records on civilian personnel are destroyed 5 years after employment terminates.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the commander of the medical treatment where practitioner provided clinical service. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the commander of the medical treatment where practitioner provided clinical service. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Interviewer, individual's application, medical audit results, other administrative or investigative records obtained from civilian or military sources.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–66bDASG

System name:

Health Care and Medical Treatment Record System (50 FR 22220, May 29, 1985).

Changes:

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Authority for maintenance of the system:

Add at the end "and Executive Order 9397."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedure:

Delete entry and replace with "Military and civilian individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the medical facility where treatment was provided. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices. Red Cross employees may write to the Medical Officer, American National Red Cross, 1730 E Street, NW., Washington, DC 20006.

For verification purposes, the individual should provide the full name, Social Security Number, and current address and telephone number. Inquiry should include name of the hospital, year of treatment and any details which will assist in locating the records."

Record access procedures:

Delete entry and replace with "Military and civilian individuals seeking access to records about themselves contained in this record system should address written inquiries to the medical facility where treatment was provided. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices. Red Cross employees may write to the Medical Officer, American National Red Cross, 1730 E Street, NW., Washington, DC 20006.

For verification purposes, the individual should provide the full name, Social Security Number, and current address and telephone number. Inquiry should include name of the hospital, year of treatment and any details which will assist in locating the records."

* * * * *

A0040–66bDASG

SYSTEM NAME:

Health Care and Medical Treatment Record System.

SYSTEM LOCATION:

Army Medical Department facilities and activities. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military members of the Armed Forces (both active and inactive); dependents; civilian employees of the Department of Defense; members of the U.S. Coast Guard, Public Health Service, and Coast and Geodetic Survey; cadets and midshipmen of the military academies; employees of the American National Red Cross; and other categories of individuals who receive medical treatment at Army Medical Department facilities/activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, medical records (of a permanent nature) used to document health; psychological and mental hygiene consultation and evaluation; medical/dental care and treatment for any health or medical condition provided an eligible individual on an inpatient and/or outpatient status to include but not limited to: Health; clinical (inpatient); outpatient; dental; consultation; and procurement and separation x-ray record files. Subsidiary medical records (of a temporary nature) are also maintained to support records relating to treatment/observation of individuals. Such records include but are not limited to: Social work case files, inquiries/complaints about medical treatment or services rendered by the medical treatment facility, and patient treatment x-ray and index files.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 10 U.S.C. 1071–1085; 50 U.S.C. Supplement IV, appendix 454, as amended and Executive Order 9397.

PURPOSE(S):

To provide health care and medical treatment of individuals; to establish tuberculosis/tumor/cancer registries; for research studies; compilation of statistical data and management reports; to implement preventive medicine, dentistry, and communicable disease control programs; to adjudicate claims and determining benefits; to evaluate care rendered; determine professional certification and hospital accreditation; and determine suitability of persons for service or assignment.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information may be disclosed to the Department of Veterans Affairs to adjudicate veterans' claims and provide medical care to Army members.

National Research Council, National Academy of Sciences, National Institute of Health, and similar institutions for authorized health research in the interest of the Federal Government and the public. When not essential for longitudinal studies, patient identification data shall be eliminated from records used for research studies. Facilities/activities releasing such records shall maintain a list of all such research organizations and an accounting disclosure of records released thereto.

Local and state government and agencies for compliance with local laws and regulations governing control of communicable diseases, preventive medicine and safety, child abuse, and other public health and welfare programs.

Note: Records of identity, diagnosis, prognosis, or treatment of any client/patient, irrespective of whether or when he/she ceases to be a client/patient, maintained in connection with the performance of any alcohol or drug abuse prevention and treatment function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States, shall, except as provided therein, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized in title 42 U.S.C. 290dd–3 and 290ee–3. These statutes take precedence over the Privacy Act of 1974 in regard to accessibility of such records except to the individual to whom the record pertains.

The "Blanket Routine Uses" do not apply to these records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders; visible card files; microfiche; cassettes; punched cards; magnetic tapes/discs; computer printouts; x-ray film preservers.

RETRIEVABILITY:

By patient or sponsor's surname or Social Security Number.

SAFEGUARDS:

Records are maintained in buildings which employ security guards and are accessed only by authorized personnel

having an official need-to-know. Automated segments are protected by controlled system passwords governing access to data.

RETENTION AND DISPOSAL:

Military health/dental and procurement/separation x-ray records are permanent. Clinical (inpatient), outpatient, dental and consultation record files for years; records pertaining to U.S. Military Academy cadets are withdrawn and retired to the Surgeon, U.S. Military Academy, West Point, NY 10996–1797. Records on civilians and foreign nationals are destroyed after 25 years. Records on American Red Cross personnel are withdrawn and forwarded to the American National Red Cross.

All medical records (except the Military Health/Dental records which are active while individual is on active duty, then retired with individual's Military Personnel Records Jacket and the procurement/separation x-ray records which are forwarded to the National Personnel Records Center on an accumulation basis) are retained in an active file while treatment is provided and subsequently held for a period of 1 to 5 years following treatment before being retired to the National Personnel Records Center.

Subsidiary medical records, of a temporary nature, are normally not retained long beyond termination of treatment; however, supporting documents determined to have significant documentation value to patient care and treatment are incorporated into the appropriate permanent record file.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Military and civilian individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the medical facility where treatment was provided. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices. Red Cross employees may write to the Medical Officer, American National Red Cross, 1730 E Street, NW., Washington, DC 20006.

For verification purposes, the individual should provide the full name, Social Security Number, and current address and telephone number. Inquiry should include name of the hospital, year of treatment and any details which will assist in locating the records.

RECORD ACCESS PROCEDURES:

Military and civilian individuals seeking access to records about themselves contained in this record system should address written inquiries to the medical facility where treatment was provided. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices. Red Cross employees may write to the Medical Officer, American National Red Cross, 1730 E Street, NW., Washington, DC 20006.

For verification purposes, the individual should provide the full name, Social Security Number, and current address and telephone number. Inquiry should include name of the hospital, year of treatment and any details which will assist in locating the records.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Personal interviews and history statements from the individuals; abstracts or copies of pertinent medical records; examination records of intelligence, personality, achievement, and aptitude; reports from attending and previous physicians and other medical personnel regarding results of physical, dental, and mental examinations, treatment, evaluation, consultation, laboratory, x-ray and special studies and research conducted to provide health care and medical treatment; and similar or related documents.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–400DASG

System name:

Entrance Medical Examination Files (50 FR 22215, May 29, 1985).

Changes:

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Authority for maintenance of the system:

Add at the end "and Executive Order 9397."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedure:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the commander of the medical examining facility where physical examination was given. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, home address, approximate date of the examination, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the commander of the medical examining facility where physical examination was given. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, home address, approximate date of the examination, and signature."

A0040–400DASG

SYSTEM NAME:

Entrance Medical Examination Files.

SYSTEM LOCATION:

Army medical examining facilities; Military Enlistment Processing Stations (for enlistees); Department of Defense Medical Review Board, U.S. Academy, CO 80840 (except for reservists). Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who enroll in the Reserve Officers Training Corps program, enlist or are appointed in the U.S. Army or U.S. Army Reserves, or are appointed as a cadet to the U.S. Military Academy.

CATEGORIES OF RECORDS IN THE SYSTEM:

Entrance medical examination and resulting documentation such as SF 88, Report of Medical Examination, and SF 93, Report of Medical History, together with relevant and supporting documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and Executive Order 9397.

PURPOSE(S):

To determine medical acceptance of applicant for military service and thereafter to properly assign and use individual. Management data are derived and used by Health Services Command to evaluate effectiveness of procurement medical standards.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders; selected management data are stored on word processing or magnetic discs and tapes.

RETRIEVABILITY:

By individual's surname.

SAFEGUARDS:

Records are maintained in buildings using security guards, accessible only to authorized personnel having official need for the information who are properly screened and trained.

RETENTION AND DISPOSAL:

Original SF 88 and 93 become permanent documents in individual's Health Record; 1 copy of these forms and supporting documentation is retained by the Army or Military Enlistment Processing Station examining Facility for 1 year; 1 copy is forwarded to the Department of Defense Medical Review Board where it is retained for 5 years. Records of individuals rejected for military service are retained for statistical analyses, but for no longer than 2 years, after which they are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon Genera1, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the commander of the medical examining facility where physical examination was given. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, home address, approximate date of the examination, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themse1ves contained in this record system should address written inquiries to the commander of the medical examining facility where physical examination was given. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, home address, approximate date of the examination, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual; from the physician and other medical personnel.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–407DASG

System name:

Army Community Health Nursing Records—Family Records (50 FR 22224, May 29, 1985).

Changes:

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Authority for maintenance of the system:

Add at the end "Executive Order 9397."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedure:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Patient Administrator of the Army medical treatment facility which provided the health nursing care. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should furnish the full name, Social Security Number, name and Social Security Number of sponsor, if applicable, relationship to military member, current address and telephone number, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Patient Administrator of the Army medical treatment facility which provided the health nursing care. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should furnish the full name, Social Security Number, name and Social Security Number of sponsor, if applicable, relationship to military member, current address and telephone number, and signature."

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A0040–407DASG

SYSTEM NAME:

Army Community Health Nursing Records—Family Records

SYSTEM LOCATION:

Army Medical Centers and hospitals. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals eligible for Army military medical care.

CATEGORIES OF RECORDS IN THE SYSTEM:

Family Record Form (DA Form 3762) Case Referral Form (DA Form 3763); Medical diagnosis, observations, socioeconomic plans and goals for nursing care, summarization of consultations, and similar relevant documents and reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 10 U.S.C. 3013 and Executive Order 9397.

PURPOSE(S):

To identify family members who receive Army community health nursing care.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The "Blanket Routine Uses" set forth at the beginning of the Army's compilation of record systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders retained in the Army Community Health Nursing Office; copy of DA Forms 3762 and 3763 is filed in individual's outpatient medical record.

RETRIEVABILITY:

By surname of eligible military member or sponsor.

SAFEGUARDS:

Records are maintained in areas accessible only to authorized personnel having official need therefor. Facilities are locked during non-duty hours.

RETENTION AND DISPOSAL:

Records are destroyed 3 years after case is closed.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Patient Administrator of the Army medical treatment facility which provided the health nursing care. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should furnish the full name, Social Security Number, name and Social Security Number of sponsor, if applicable, relationship to military member, current address and telephone number, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Patient Administrator of the Army medical treatment facility which provided the health nursing care. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should furnish the full name, Social Security Number, name and Social Security Number of sponsor, if applicable, relationship to military member, current address and telephone number, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, family members, other persons having information relevant to health of family members; educational institutions; civilian health, welfare, and recreational agencies; civilian law enforcement agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–905DASG

System name:

Privately Owned Animal Record Files (50 FR 22225, May 29, 1985).

Changes:

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System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258".

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized. Official mailing addresses are published in the Army's compilation of record systems notices.

Animal owner should provide the full name, home address and telephone number and the animal's rabies vaccination number."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized. Official mailing addresses are published in the Army's compilation of record systems notices.

Animal owner should provide the full name, home address and telephone number and the animal's rabies vaccination number.

Personal visits may be made to the veterinary facility where animal was treated. Owner must provide personal identification such as a valid military identification card or driver's license."

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A0040–905DASG

SYSTEM NAME:

Privately Owned Animal Record Files.

SYSTEM LOCATION:

Veterinary service at medical facilities on Army installations and activities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons whose privately owned animals receive veterinary care.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, home address and telephone number of animal's owner; record of treatment of animal; and related information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 133, 1071 through 1087, 5031 and 8012.

PURPOSE(S):

To record registration, vaccination, and/or treatment of animals; to compile statistical data; and to identify animals registered with the Veterinary Animal Disease Preventive and Control Facility in connection with the Veterinary Preventive Medicine and Zoonotic Disease Control Program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

By name of the animal's owner.

SAFEGUARDS:

Records are maintained in buildings which are locked when unattended and are accessed only by authorized personnel having an official need-to-know.

RETENTION AND DISPOSAL:

Destroyed within 6 months of death of the animal, expiration of rabies vaccination, or transfer of owner.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is

contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized. Official mailing addresses are published in the Army's compilation of record systems notices.

Animal owner should provide the full name, home address and telephone number and the animal's rabies vaccination number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized. Official mailing addresses are published in the Army's compilation of record systems notices.

Animal owner should provide the full name, home address and telephone number and the animal's rabies vaccination number. Personal visits may be made to the veterinary facility where animal was treated. Owner must provide personal identification such as a valid military identification card or driver's license.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the animal owner, veterinarian reports, and similar or related documents.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0070–16DASG

System name:

Immunity Booster Files (50 FR 22242, May 29, 1985).

Changes:

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Storage:

Delete entry and replace with "Random access disc files and backup on magnetic tape."

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System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-UIA, 5109 Leesburg Pike, Falls Church, AA 22041–3258."

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701–5011.

For verification purposes, the individual should be specific concerning type of information sought."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701–5011.

For verification purposes, the individual should be specific concerning type of information sought."

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A0070–16DASG

SYSTEM NAME:

Immunity Booster Files

SYSTEM LOCATION:

U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701–5011.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military and civilian employees of Fort Detrick engaged in research who have been immunized with a biological product or who fall under the Occupational Health and Safety Act or Radiologic Safety Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains name of biological agents, individual's name, Social Security Numbers, age, race, date of birth, occupation, titers, immunization schedules, known allergies, amount of dosage, reaction to immunization, radiologic agents, exposure level, health screening test results, health test schedule, similar relevant documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. § 301.

PURPOSE(S):

To create a large data base of immunological data for research purposes, and to manage the scheduling of all health screening tests, immunizations, physicals, and other special procedures required by the U.S. Army Medical Research Institute of Infectious Diseases biosurveillance program, radiologic safety program, and occupational health and safety program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Random access disc files and backup on magnetic tape.

RETRIEVABILITY:

For research purposes, the data are usually retrieved and analyzed with respect to relative times, vaccine lots, titers, demographic values, etc. Data are seldom retrieved by name, by test to be taken, and by month of scheduled examinations.

SAFEGUARDS:

Records are maintained in controlled areas; access is restricted to authorized persons having need therefor in the performance of official duties.

RETENTION AND DISPOSAL:

Records are permanent.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-UIAs, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701–5011.

For verification purposes, the individual should be specific concerning type of information sought.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detricks, Frederick, MD 21701–5011.

For verification purposes, the individual should be specific concerning type of information sought.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32

CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From medical persons, their interview with individual concerned, laboratory results, immunization results, and other relevant test results.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0070–25DASG

System name:

Medical Research Volunteer Registry (53 FR 16575, May 10, 1988).

Changes:

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Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-HR, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide full names, Social Security Number, military status or other information verifiable from the record itself."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-HR, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide full name, Social Security Number, military status or other information verifiable from the record itself."

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A0070–25DASG

SYSTEM NAME:

Medical Research Volunteer Registry

SYSTEM LOCATION:

Primary locations are U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, MD 21701–5012;

U.S. Army Chemical Research, Development, and Engineering Center, Aberdeen Proving Ground, MD 21010–5423;

Secondary locations are Letterman Army Institute of Research, Presidio of San Francisco, CA 94129–6800;

Walter Reed Army Institute of Research, Washington, DC 20307–51004;

U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL 36362–5000;

U.S. Army Institute of Dental Research, Washington, DC 20307–5300;

U.S. Army Institute of Dental Research, Fort Sam Houston, TX 78234–6200;

U.S. Army Medical Bioengineering Research and Development Laboratory, Fort Detrick, Frederick, MD 21701–5010;

U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD 21010–5425;

U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701–5011;

U.S. Army Research Institute of Environmental Medicine, Natick, MA 01760–5007.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records of military members, civilian employees, and non-Department of Defense civilian volunteers participating in current and future research sponsored by the U.S. Army Medical Research and Development Command and the U.S. Army Chemical Research, Developments, and Engineering Center.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, and other information necessary to locate the individual. Individual consent agreements, test protocols, challenge materials, inspection/after-action reports, standard operating procedures, medical support plans, and summaries of pre-test and post-test physical examination parameters measured before and after testing.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 10 U.S.C. 1071–1090; 44 U.S.C. 3101; and Executive Order 9397.

PURPOSE(S):

To assure that the U.S. Army Medical Research and Development Command and the U.S. Army Chemical Research, Development, and Engineering Center can contact individuals who participated in research conducted/sponsored by the Command and Center in order to provide them with newly acquired information, which may have an impact on their health.

To answer inquiries concerning an individual's participation in research sponsored/conducted by USAMRDC and CRDEC.

To facilitate retrospective medical and/or scientific evaluations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Information may be disclosed to Headquarters, Department of the Army to contact volunteer human subjects later should it be in their best interests; to document and assist in determining the need for medical treatment at any future time for a condition proximately resulting from participation in a test; to adjudicate claims and determine benefits; to report medical conditions required by law to other federal, state, and local agencies; for retrospective medical/scientific evaluation; and for future scientific and legal significance.

Department of Veteran Affairs to assist in making determinations relative to claims for service-connected disabilities; and other such benefits.

The "Blanket Routine Uses" set forth at the beginning of the Army's compilation of record systems notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders; computer magnetic tapes, disks, and printouts.

RETRIEVABILITY:

By name and Social Security Number.

SAFEGUARDS:

U.S. Army Medical Research and Development Command: Computerized records are accessed by the custodian of the records system, and by persons responsible for servicing the records system in the performance of their duties. Computer equipment and files are located in separate and secured area.

U.S. Army Chemical Research, Developments, and Engineering Center: Paper records and data disks are kept in locked compartments with access limited to authorized personnel. Access to computerized data is by use of a valid site identification assigned to an individual terminal and by a valid user identification and password code assigned to an authorized user, changed periodically to avoid compromise. Data entry is on-line using a dial-up terminal. Computer files are controlled by keys known only to personnel assigned to work on the data base. Data base output is available only to designated computer operators. Computer facility has double barrier physical protection. The remote is in a room which is locked when vacated and the building is secured when unoccupied.

RETENTION AND DISPOSAL:

Records are destroyed after 65 years.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-HR, 5109 Leesburg Pike, Falls Church, VA 22041-3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-HR, 5109 Leesburg Pike, Falls Church, VA 22041-3258 or to Commander, U.S. Army Chemical Research, Development and Engineering Center, ATTN: SMCCR-HV, Aberdeen Proving Ground, MD 21010-5423.

For verification purposes; the individual should provide the full name, Social Security Number, military status or other information verifiable from the record itself.

For personal visits, the individual should be able to provide acceptable identification such as valid driver's license, employer, or other individually identifying number, and building pass.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-HR, 5109 Leesburg Pike. Falls Church, VA 22041-3258 or to Commander, U.S. Army Chemical Research, Development and Engineering Center, ATTN: SMCCR-HV, Aberdeen Proving Ground, MD 21010-5423.

For verification purposes, the individual should provide the full name, Social Security Number, current address, and telephone number of the requester.

For personal visits, the individual should be able to provide acceptable identification such as valid driver's license, employer, or other individually identifying number, and building pass.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340-21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, medical authorities, test director reports, documents prepared by staff supporting the test/research, and records/documents from records custodians.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0070-45DASG

System name:

Sandfly Fever Files (50 FR 22243, May 29, 1985)

Changes:

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Storage:

Delete entry and replace with "Random access disc files and backup on magnetic tape."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-DIA, 5109 Leesburg Pike, Falls Church, VA 22041-3258."

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commanders, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701-5011.

For verification purposes, the individual should provide details which will assist in locating the record."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commanders, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701-5011.

For verification purposes, the individual should provide details which will assist in locating the record."

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A0070-45DASG

SYSTEM NAMES:

Sandfly Fever Files

SYSTEM LOCATION:

U.S. Army Medical Research Institute of Infectious Diseases, Ft. Detrick, Frederick, MD 21701-5011.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All human volunteers who participated in the Sandfly fever studies at U.S. Army Medical Research Institute of Infectious Diseases.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records contain data on name, body temperature, pulse, blood pressure, respirations, urinalysis results, blood serology results.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301.

PURPOSE(S):

Information is being stored for possible future study. Data were collected and analyzed during a previous Sandfly fever study.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Random access disk files and backup on magnetic tape.

RETRIEVABILITY:

By individual's name, analyzed by parameter, pre- or post-infection day, and experimental versus controls.

SAFEGUARDS:

Files are maintained in a secured building locked during non-duty hours. Access is restricted to authorized personnel only.

RETENTION AND DISPOSAL:

Records will be maintained until they have no further research value.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGRD-DIA, 5109 Leesburg Pike, Falls Church, VA 22041-3268.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701-5011.

For verification purposes, the individual should provide details which will assist in locating the record.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army

Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD 21701–5011.

For verification purposes, the individual should provide details which will assist in locating the record.

RECORD SOURCE CATEGORIES:

From quantitative data obtained from investigative staff and clinical laboratory reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0351DASG

System name:

Army School Student Files: Physical Therapy Program (50 FR 22230, May 29, 1985).

Changes:

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System location:

Delete "The Pentagon, Washington, DC 20310" and replace with "5109 Leesburg Pike, Falls Church, VA 22041–3258."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258."

Notification procedure:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: DASG–DBP, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, maiden name if married, year of graduation, current address, institution and complete address to which transcript is to be mailed if other than that of individual concerned."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: DASG–DBP, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, maiden name if married, year of graduation, current address, institution and complete address to which transcript is to be mailed if other than that of individual concerned."

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A0351DASG

SYSTEM NAME:

Army School Student Files: Physical Therapy Program.

SYSTEM LOCATION:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Graduates of the U.S. Army Physical Therapy Program since 1928.

CATEGORIES OF RECORDS IN THE SYSTEM:

Academic grades only on graduates from 1973 to present. Academic grades and varying amounts and types of anecdotal information on performance: 1945–1972.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301.

PURPOSE(S):

To provide certification of graduation from an approved physical therapy program to the individual graduate.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders:

RETRIEVABILITY:

By last name of graduate.

SAFEGUARDS:

Records are in closed files, accessible only to designated officials having need therefor in the performance of their duties.

RETENTION AND DISPOSAL:

Records are permanent.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: DASG–DBP, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, maiden name if married, year of graduation, current address, institution and complete address to which transcript is to be mailed if other than that of individual concerned.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Office of the Surgeon General, Headquarters, Department of the Army, ATTN: DASG–DBP, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, maiden name if married, year of graduation, current address, institution and complete address to which transcript is to be mailed if other than that of individual concerned.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Staff and faculty of appropriate school and/or training hospital responsible for presentation of instruction.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0601–141DASG

System name:

Army Medical Procurement Applicant Files (50 FR 22172, May 29, 1985).

Changes:

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System location:

Delete "1900 Half Streets, SW, Washington, DC 20324" and replace with "5109 Leesburg Pike, Falls Church, VA 22041–3258."

* * * * *

Authority for maintenance of the system:

Add at the end "and Executive Order 9397."

* * * * *

Categories of records in the system:

Add at the end "Application for Appointment (DA Form 61), professional degrees, licenses certifications, quality assurance documents, prior service records, physical, and birth certificate."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258."

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, sufficient details to permit locating pertinent records, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, sufficient details to permit locating pertinent records, and signature."

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A0601–141DASG

SYSTEM NAME:

Army Medical Procurement Applicant Files.

SYSTEM LOCATION:

Primary system exists at the U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Segments are located at Army Medical Department Procurement Counselor field offices. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Potential applicants for the Army Medical Department procurement programs, to include applicants for appointment in the Regular Army and U.S. Army Reserve.

CATEGORIES OF RECORDS IN THE SYSTEM:

Interview sheets, counselor evaluations, resume, Curriculum Vitae, autobiography, letters of recommendation, selection/non-selection letters, Special Orders, correspondence to, from, and about applicant; Selection Board/Committee results, Statement of Interests, Objectives and Motivation, Letter of Appointment, service agreement, Application for Appointment (DA Form 61), professional degrees, license certifications, quality assurance documents, prior service records, physical, and birth certificate.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013 and 4301 and Executive Order 9397.

PURPOSE(S):

To evaluate an applicant's acceptability and potential for appointment in a component of the Army Medical Department; to evaluate qualifications for assignment to various career areas; to determine educational and experience background for award of constructive service credit; to determine dates of service and seniority; to document service agreement with the U.S. Army; to provide, statistical information for effective management of the Army Medical Department Personnel Procurement Program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The "Blanket Routine Uses" set forth at the beginning of the Army's compilation of record systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM: STORAGE:

Paper records in file folders.

RETRIEVABILITY:

By applicant's surname.

SAFEGUARDS:

Records are restricted to designated officials having need therefor in the performance of official duties.

RETENTION AND DISPOSAL:

Records of selected applicants are held for 10 years before being destroyed by shredding; those for applicants not selected are held 2 years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full names, Social Security Number, sufficient details to permit locating pertinent records, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

For verification purposes, the individual should provide the full name, Social Security Number, sufficient details to permit locating pertinent records, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual; academic transcripts; faculty evaluations; employer evaluations; military supervisor evaluations; American Testing Program; Educational Testing Service; selection board/committee records; prior military service records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt under 5 U.S.C. 552a(k) (5) as applicable.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b) (1), (2), and (3), (c) and (e) and published in 32 CFR part 505. For additional information contact the system manager.

A0608–1SDASG

System name:

Family Advocacy Case Management Files (50 FR 22223, May 29, 1985).

Changes:

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System location:

In the first paragraph, delete "HSHI, OPS(AFAP)" and replace with "HSHI-QPD"; and after "78234" add "-6070". In the second paragraph, delete "DASG-PSC-G, The Pentagon, Washington, DC 20310" to "SGPS-CP, 5109 Leesburg Pike, Falls Church, VA 22041-3258".

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Authority for maintenance of the system:

Add at the end "and Executive Order 9397."

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Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

In the fourth paragraph, ninth line, delete "joint Commission for the Accreditation of Hospitals" and replace with "Joint Commission on the Accreditation of Health Care Organizations".

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Retention and disposal:

Change "Records (DA Form 4461-R)" to "Statistical data from DD Form 2486".

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System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041-3258".

Notification procedure:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system, should address written inquiries to the commander of the medical center or hospital where treatment was received, or the Central Registry at the Patient Administration System and Biostatics Activity, Fort Sam Houston, TX 78234-6070. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number of the patient's sponsor, and current address, date and location of treatment, and any details that will assist in locating the record, and signature."

Record access procedures.

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the commander of the medical center or hospital where treatment was received, or the Central Registry at the Patient Administration System and Biostatics Activity, Fort Sam Houston, TX 78234-6070. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full names, Social Security Number of the patient's sponsor, and current address, date and location of treatment, and any details that will assist in locating the record, and signature."

* * * * *

A0608-18DASG

SYSTEM NAME:

Family Advocacy Case Management Files.

SYSTEM LOCATION:

Primary location is Commanders, U.S. Army Patient Administration Systems and Biostatistics Activity, ATTN: HSHI-QPD, Fort Sam Houston, TX 78234-6070.

Secondary location is Office of the Surgeon General, Headquarters, Department of the Army, ATTN: SGPS-CP, 5109 Leesburg Pike, Falls Church, VA 22041-3258; U.S. Army medical treatment facility and/or office on post, camp, or station where file was initiated or, in some cases, subsequently transferred upon reassignment of military member.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All family members entitled to care at Army medical and dental facilities whose abuse or neglect is brought to the attention of appropriate authorities and all persons suspected of abusing or neglecting such family members.

All family members of Department of the Army civilians who receive care in an Army operated or Army regulated activity.

All persons suspected of abusing or neglecting family members including contractors that work in Army operated or Army regulated activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical and Family Advocacy Case Management Team records of suspected or established cases of child abuse or neglect and cases of spouse abuse to include child abuse occurring in Army operated or regulated activities, extracts of law enforcement investigative reports, correspondence, family advocacy case management team reports, follow-up and evaluative reports, and other supportive data relevant to individual family advocacy case management files.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Child Abuse Prevention and Treatment and Child Abuse Prevention and Treatment and Adoption Program Reform Acts, 42 U.S.C. 5101, et seq; 5 U.S.C. 301, and 10 U.S.C. 3013 and Executive Order 9397.

PURPOSE(S):

To provide child abuse and neglect treatment services for abused and abusive spouses. Services include mental health, education, counseling, health care, protection, foster care, safe shelter, legal and referral for members and former members of the uniformed services, civilians, and dependents receiving care under Army auspices or in an Army regulated or operated facility.

To determine qualifications and suitability of Department of the Army civilians and contractors for duty assignments and fitness or continued military services.

To perform research studies and compile statistical data concerning uniformed services personnel, civilians, and dependents receiving medical care under Army auspices, or services through an Army operated or regulated activity.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information may be disclosed to departments and agencies of the Executive Branch of government in performance of their official duties relating to coordination of family advocacy programs, medical care and research concerning child abuse and neglect, and spouse abuse.

The Attorney General of the United States or his authorized representatives in connection with litigation or other matters under the direct jurisdiction of the Department of Justice or carried out as the legal representative of the Executive Branch agencies.

To federal, state, or local governmental agencies when it is deemed appropriate to use civilian resources in counseling and treating individuals or families involved in child abuse or neglect or spouse abuse; or when appropriate or necessary to refer a case to civilian authorities for civil or criminal law enforcement; or when a state, county, or municipal child protective service agency inquires about a prior record of substantiated abuse for the purpose of investigating a suspected case of abuse.

To the National Academy of Sciences, private organizations and individuals for health research in the interest of the Federal government and the public and authorized surveying bodies for professional certification and accreditation such as Joint Commission on the Accreditation of Health Care Organizations.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders, microfilm, magnetic tape or disc, punched cards, machine listings, and other computerized or machine readable media.

RETRIEVABILITY:

By name of the suspected abused child or the abused or abusive spouse, parent, or care taker and the name and/or Social Security Number, of the military member. (Information is never indexed by the name or Social Security Number of any other person not an Army employee or member.)

SAFEGUARDS:

Records are maintained in various kinds of filing equipment in specified monitored or controlled areas. Public access is not permitted. Records are accessible only to authorized personnel who are properly screened and trained, and have an official need to know. Computer terminals are located in supervised areas with access controlled by password or other user code system.

RETENTION AND DISPOSAL:

Records are retained in decentralized office files for 5 years after the end of the year in which the case is closed and are then destroyed. Statistical data from DD Form 2486 in the central registry at the primary location are retained until the child is age 23 after which information is erased/destroyed; information on adults is retained for 5 years after the end of the year in which the case was closed and is then erased.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the commander of the medical center or hospital where treatment was received, or the Central Registry at the U.S. Army Patient Administration Systems and Biostatistics Activity, ATTN: HSHI-QPD, Fort Sam Houston, TX 78234–6070. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number of the patient's sponsor, and current address, date and location of treatment, and any details that will assist in locating the record, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the commander of the medical center or hospital where treatment was received, or the Central Registry at the U.S. Army Patient Administration Systems and Biostatistics Activity, ATTN: HSHI-QPD, Fort Sam Houston, TX 78234–6070. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number of the patient's sponsor, and current address, date and location of treatment, and any details that will assist in locating the record, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial agency determinations by the concerned individual are published in the Department of the Army Regulation 340–21; 32 CFR Part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, educational institutions, medical institutions, police and investigating officers, state and local government agencies, witnesses, and records and reports prepared on behalf of the Army by boards, committees, panels, auditors, etc. Information may also derive from interviews, personal history statements, and observations of behavior by professional persons (i.e., social workers, physicians, including psychiatrists and pediatricians, psychologists, nurses, and lawyers).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt under 5 U.S.C. 552a(k) (2) and (5) as applicable.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b) (1), (2), and (3), (c), and (e) and published in 32 CFR Part 505. For additional information contact the system manager.

A0621–1DASG

System name:

Long-Term Civilian Training Student Contract Files (50 FR 22234, May 29, 1985).

Changes:

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System location:

Delete entry and replace with "U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22044–3258."

* * * * *

Authority for maintenance of the system:

Add at the end "and Executive Order 9397."

* * * * *

Storage:

Delete entry and replace with "Paper records and a database management system (DBMS)".

Retrievability:

Delete entry and replace with "By student's surname in the hard copy form and by a student code (stucode) in the DBMS. The stucode is comprised of first three letters of the student's surname plus the last four numbers of the Social Security Number".

Safeguards:

Delete "Building housing records require valid pass for entry." and replace with "Use of elevators to the floor housing records requires an electronic key for entry during on-duty hours. Microcomputer on which DBMS is maintained, requires a password for entry."

* * * * *

System manager(s) and address:

Delete entry and replace with "Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258."

Notification procedures:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Health Professional Support Agency, ATTN: SGPS–EDT, 5109 Leesburg Pike, Falls Church, VA 22044–3258.

For verification purposes, the individual should provide the full name,

Social Security Number, current address, (current unit of assignment if on active duty), sponsoring program and calendar years in training, and signature."

Record access procedures:

Delete entry and replace with "Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U. S. Army Health Professional Support Agency, ATTN: SGPS–EDT, 5109 Leesburg Pike, Falls Church, VA 22044–3258.

For verification purposes, the individual should provide the full name, Social Security Number, current address, current unit of assignment (if on active duty), sponsoring program and calendar years in training, and signature."

* * * * *

A0621–1DASG

SYSTEM NAME:

Long-Term Civilian Training Student Contract Files.

SYSTEM LOCATION:

U.S. Army Health Professional Support Agency, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Army Medical Department personnel currently participating in long-term civilian training on a fully funded basis.

CATEGORIES OF RECORDS IN THE SYSTEM:

Enrollment applications, notification of acceptance/rejection, contract between the Army and the civilian college or university, similar relevant documents and reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C., chapter 401, section 4301 and Executive Order 9397.

PURPOSE(S):

To negotiate contract between the Army and a civilian academic institution for the purpose of sending Army Medical Department officer and enlisted personnel for long-term civilian training under fully funded programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The "Blanket Routine Uses" set forth at the beginning of the Army's compilation of record systems notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and database management system (DBMS).

RETRIEVABILITY:

By student surname in the hard copy form and by a student code (stucode) in the DBMS. The stucode is comprised of the first three letters of the student's surname plus the last four numbers of the Social Security Number.

SAFEGUARDS:

All records are maintained in offices which are locked during non-duty hours, accessible only to designated officials having need therefor in the performance of official duties. Use of elevators to the floor housing records requires an electronic key for entry during non-duty hours. Microcomputer on which DBMS is maintained requires a password for entry.

RETENTION AND DISPOSAL:

Records destroyed 2 years after an individual has completed training or has been canceled or withdrawn from the program.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Army Health Professional Support Agency, ATTN: SGPS–EDT, 5109 Leesburg Pike, Falls Church, VA 22044–3258.

For verification purposes, the individual should provide the full names, Social Security Number, current address, current unit of assignment (if on active duty), sponsoring program and calendar years in training, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Health Professional Support Agency, ATTN: SGPS–EDT, 5109 Leesburg Pike, Falls Church, VA 22044–3258.

For verification purposes, the individual should provide the full names, Social Security Number, current address, current unit of assignment (if on active duty), sponsoring program and calendar years in training, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, or appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, Army records and reports, correspondence with the selecting academic institution.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 91–22826 Filed 9–23–91; 8:45 am]

BILLING CODE 3810–01–M

Department of the Navy

Intent to Prepare a Supplemental Draft Environmental Impact Statement For The Proposed Dredging of the Thames River, Naval Submarine Base New London, Groton, CT

Pursuant to the regulations implementing the procedural provisions of the National Environmental Policy Act, as implemented by the Council on Environmental Quality regulations, the requirements of Executive Order 12372, Intergovernmental Review of Federal Programs, the Department of the Navy announces its intention to prepare a Supplemental Draft Environmental Impact Statement (SDEIS) for the proposed dredging of the Thames River to allow safe passage of the SEAWOLF (SSN 21) submarine from the mouth of the river to the Naval Submarine Base (SUBASE) New London.

On May 10, 1991, the Navy filed a Draft Environmental Impact Statement (DEIS) with the U.S. Environmental Protection Agency for the proposed dredging of the river in support of the operational evaluation requirements of the SEAWOLF. The first Submarine of the Seawolf class is currently under construction at the Electric Boat Division of General Dynamics Cooperation, located in Groton, Connecticut. Following delivery to the Navy, this submarine (as well as those that follow) must undergo extensive operational and engineering evaluations. These evaluations are conducted by Submarine Development Squadron TWELVE located at SUBASE New London. The DEIS prepared for the proposed dredging of the Thames River was mailed to over 130 officials, agencies and interested citizens, and also placed in area libraries. A public

hearing to receive comments on this proposed action was conducted on May 28, 1991, at Mitchell College, New London, Connecticut.

Several comments received during the public comments period requested additional information on the impact of dredging and dredge disposal, particularly as it relates to impacts on the aquatic habitat of the Thames River and Long Island Sound, the location of the New London Disposal Site. In order to further qualify these impacts, the Navy will conduct additional sediment sampling and testing and will prepare an SDEIS to present the finding and results of this effort. Other concerns and issues raised during the DEIS public comment period will also be addressed in the SDEIS.

Agencies and the public are invited and encouraged to provide written comments regarding issues of concern. To be most helpful, these comments should clearly describe specific issues or topics which the commentator believes the SDEIS should address. Written statements and/or questions regarding the SDEIS should be mailed no later than 30 days from the date of this publication to the Commanding Officer, Northern Division, Naval Facilities Engineering Command, Building 77L, U.S. Naval Base, Philadelphia, PA 19112-5000 (attn: Code 2022). Additional information about this notice may be obtained by contacting Robert Ostermueller at (215) 897-6262.

Dated: September 13, 1991.

Wayne T. Baucino

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 91-22899; Filed 9-23-91; 8:45 am]

BILLING CODE 3810-AE-F

Patent License; Fiber Materials, Inc.

AGENCY: Department of the Navy

ACTION: Intent to Grant Exclusive Patent Licenses; Fiber Materials, Inc.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant exclusive license to practice the Government-owned invention described in U. S. Patent No. 4,012,089, "Electronic Equipment Enclosure" issued March 15, 1977.

Any one wishing to object to the grant of this license has 60 days from the date of this notice to file written objections along with supporting evidence, if any. Written objections are to be filed with the Office of the Chief of Naval Research (Code OOCCIP), 800 North Quincy Street, Arlington, Virginia 22217-5000.

FOR FURTHER INFORMATION CONTACT: Mr. R. J. Erickson, Staff Patent Attorney, Office of the Chief of Naval Research (Code OOCCIP), 800 N. Quincy Street, Arlington, Virginia 22217-5000, telephone (703) 696-4001.

Dated:September 13, 1991.

Wayne T. Baucino

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 91-22896 Filed 9-23-91; 8:45 am]

BILLING CODE 3810-AE-F

Patent License; Daniel R. Polly

AGENCY: Department of the Navy

ACTION: Intent to Grant Exclusive Patent Licenses;Daniel R. Polly

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Daniel R. Polly a revocable, nonassignable, exclusive license to practice the Government-owned invention described in the U. S. Patent No. 4,927,503, "Method of Assessment of Corrosion Activity in Reinforced Concrete" issued May 22, 1990.

Anyone wishing to object to the grant of this license has 60 days from the date of this notice to file written license objections along with supporting evidence, if any. Written objections are to be filed with the Office of the Chief of Naval Research (Code OOCCIP), 800 North Quincy Street, Arlington, Virginia 22217-5000.

DATES: September 24, 1991.

FOR FURTHER INFORMATION CONTACT: Mr. R. J. Erickson, Staff Patent Attorney, Office of the Chief of Naval Research (Code OOCCIP), N. Quincy Street, Arlington, Virginia 22217-5000, telephone (703) 696-4001.

Dated: September 13, 1991

Wayne T. Baucino

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 91-22897 Filed 9-23-91; 8:45 am]

BILLING CODE 3810-AE-F

DEPARTMENT OF ENERGY

Grant Agreement; California Public Health Foundation

AGENCY: Department of Energy.

ACTION: Intent to negotiate a grant with the California Public Health Foundation, Berkeley, California.

SUMMARY: Santa Susana Field Laboratory Health Assessment.

The U.S. Department of Energy (DOE), Field Office, San Francisco (SF), intends to negotiate, on a noncompetitive basis, a grant for approximately $342,000 with the California Public Health Foundation in Berkeley, California. This agreement will carry the action through September 14, 1992. This action is authorized by 42 U.S.C. 7101 *et seq* and is a direct result of the Secretary of Energy's Ten Point Plan designed to chart a new course for the DOE toward full accountability in the areas of environmental protection and public health and safety. The objective of the grant is to provide support for epidemiological investigations related to DOE activities at the Santa Susana Field Laboratory in Southern California. The project will provide funding for retrospective cohort morbidity studies of workers who had been or are employed at the site or otherwise employed on DOE projects. The authority and justification for determination of noncompetitive financial assistance is DOE Financial Assistance Rules 10 CFR part 600.7(b)(2)(i)(C). The applicant is a nonprofit organization and the activity to be supported is related to performance of a state governmental function within the subject jurisdiction, thereby precluding DOE provisions of support to another entity. Public response may be addressed to the Contracting Representative below:

CONTACT: U.S. Department of Energy, Field Office, San Francisco, 1333 Broadway, Oakland, CA 94612, Attn: Bobbie Vadnais, Contracting Officer, 415-273-4369.

Dated: September 16, 1991.

Sarah Eary,

Chief, M&O/DP/ER Branch.

[FR Doc. 91-22979 Filed 9-23-91; 8:45 am]

BILLING CODE 6450-01-M

Secretary of Energy Advisory Board, Task Force on Economic Modeling Related to Energy; Open Meeting:

Pursuant to the provisions of the Federal Advisory Commitee Act (Pub. L. 92-463, 86 Stat. 770, as amended), notice is hereby given of the following advisory committee task force meeting:

Name: Secretary of Energy Advisory Board Task Force on Economic Modeling Related to Energy.

Date and Time: Monday, October 7, 1991, 8:30 am—5 pm.

Place: Wattis Board of Trustees Room (room 111), Graduate School of Business—Littlefield Center, Stanford University, Stanford, CA 94305.

Contact: Susan D. Heard, Designated Federal Officer, 1000 Independence Avenue, SW., Washington, DC 20585, Telephone (202) 586-3770.

Purpose: The Task Force will advise the Department of Energy on how economic

models and tools of analysis can better be used to address issues of energy policy by developing recommendations to clarify analytical needs, facilitate communications between DOE analysts and policy makers, and create institutions within DOE that accumulate knowledge gained through the policy modeling process.

Tentative Agenda

Monday, October 7, 1991

8:30 a.m.—Call to Order and Welcome, Dr. Roger Noll, Co-Chair
9—Review of Events since last meeting, DOE Staff and David Bjornstad
10—Break
10:20—Discussion of Revised Terms of Reference and Action Items, Task Force
12—Lunch
1 p.m.—Discussion of Specific Activities, Task Force
3—Break
3:20—Discussion of Process for NEMS Review, Task Force
4:30—Scheduling of New Meeting, Dr. Roger Noll
4:45—Public Comment
5—Adjournment, Dr. Roger Noll

Public Participation: The meeting is open to the public. The Chairman of the Task Force is empowered to conduct the meeting in a fashion that will, in the Chairman's judgment, facilitate the orderly conduct of business.

Persons wishing to attend the public meeting who are interested in obtaining permission to use the limited parking facilities on the Stanford University campus should call (415) 725–1874, the Center for Economic Policy Research at Stanford University, by September 30, so that parking passes can be mailed. Requests will be filled on a first come, first served basis.

Any member of the public who wishes to make an oral statement pertaining to agenda items should contact the Designated Federal Officer at the address or telephone number listed above. Requests must be received before 3 p.m. (E.S.T.) Wednesday, October 2, 1991, and reasonable provision will be made to include the presentation during the public comment period. It is requested that oral presenters provide 15 copies of their statements at the time of their presentations.

Written testimony pertaining to agenda items may be submitted prior to the meeting. Written testimony must be received by the Designated Federal Officer at the address shown above before 5 p.m. (E.S.T.) Wednesday, October 2, 1991, to assure it is considered by Task Force members during the meeting.

Minutes: A transcript of the open, public meeting will be available for public review and copying approximately 30 days following the meeting at the Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, S.W., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday except Federal holidays.

Issued: Washington, DC, on: September 19, 1991.

Howard H. Raiken,

Advisory Committee Management Officer.

[FR Doc. 91–22980 Filed 9–23–91; 8:45 am]

BILLING CODE 6450–01–M

Office of Fossil Energy

[FE Docket No. 91–55–NG]

Hadson Gas Systems, Inc.; Application for Blanket Authorization To Import and Export Natural Gas From and to Mexico

AGENCY: Department of Energy, Office of Fossil Energy.

ACTION: Notice of application for blanket authorization to import and export natural gas from and to Mexico.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on July 26, 1991, of an application filed by Hadson Gas Systems, Inc. (Hadson), requesting blanket authorization to import up to 50 Bcf of natural gas from Mexico and to export up to 20 Bcf of gas to Mexico over a two-year period beginning on the date of the first import or export. Hadson states that it will utilize available capacity in existing pipelines and will submit quarterly reports detailing each transaction.

The application was filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204–111 and 0204–127. Protests, motions to intervene, notices of intervention and written comments are invited.

DATES: Protests, motions to intervene, or notices of intervention, as applicable, requests for additional procedures and written comments are to be filed in Washington, DC, at the address listed below no later than 4:30 p.m., Eastern time, October 24, 1991.

ADDRESSES: Office of Fuels, Programs, Fossil Energy, U.S. Department of Energy, room 3F–056, FE–50, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585

FOR FURTHER INFORMATION CONTACT:

Peter R. Lagiovane, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–094, FE–53, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9622.

Diane Stubbs, Office of Assistant General Counsel for Fossil Energy, U.S. Department of Energy, Forrestal Building, room 6E–042, GC–14, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–6667.

SUPPLEMENTARY INFORMATION: Hadson, an Oklahoma corporation with its principal place of business in Irving, Texas, is a wholly owned subsidiary of Hadson Corporation. Hadson gathers, aggregates and markets natural gas to commercial and industrial customers as well as local distribution companies, acting on its own behalf or as agent or broker for others. The applicant asserts that the terms of each short-term or spot sale under the proposed authorizations would be freely negotiated at arms length ensuring that such sales would be market responsive. Hadson notes some of the gas to be exported may be Mexican gas for which import authorization is being requested.

Hadson was granted blanket authority by DOE/FE Opinion and Order No. 498, 1 FE Para. 70,442, to import natural gas from Canada.

The decision on the import portion of this blanket application will be made consistent with DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984. In reviewing the export portion of this application, the domestic need for the natural gas to be exported is considered, and any other issue determined to be appropriate in a particular case, including whether the arrangement is consistent with DOE policy of promoting competition in the natural gas marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties, that may oppose this application, should comment on these matters as they relate to the requested import and export authority. The applicant asserts that the import and export authority requested would be in the public interest because it would facilitate short-term and spot market transactions and will ensure the efficient allocation of gas in the marketplace. Parties opposing this arrangement bear the burden of overcoming these assertions.

NEPA Compliance. The National Environmental Policy Act (NEPA), 42 U.S.C. 4321, *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed actions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures. In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from

persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the address listed above.

It is intended that a decisional record on the application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and response filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Hadson's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056 at the above address. The Docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC., on September 17, 1991.

Anthony J. Como,

Director, Office of Coal & Electricity, Office of Fuels Programs, Fossil Energy.

[FR Doc. 91–22982 Filed 9–23–91; 8:45 am]

BILLING CODE 6450–01–M

[FE Docket No. 91–65–NG]

Delhi Gas Pipeline Corp.; Application To Export Natural Gas to Mexico

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application for blanket authorization to export natural gas to Mexico.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on August 16, 1991, of an application filed by Delhi Gas Pipeline Corporation (Delhi) requesting blanket authorization to export from the United States to Mexico up to 73 Bcf of natural gas over a two-year period beginning with the date of first delivery. Delhi states that it will advise the DOE of the date of first delivery and submit quarterly reports detailing each transaction. Delhi would use existing pipeline facilities to implement the proposed exports.

The application was filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204–111 and 0204–127. Protests, motions to intervene, notices of intervention and written comments are invited.

DATES: Protests, motions to intervene, or notices of intervention, as applicable, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., eastern time, October 24, 1991.

ADDRESSES: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, room 3F–056, FE–50, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION:

Xavier Puslowski, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–056, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–4708.

Lot Cooke, Office of Assistant General Counsel for Fossil Energy, U.S. Department of Energy, Forrestal Building, room 6E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–0503.

SUPPLEMENTARY INFORMATION: Delhi is a Delaware corporation with its principal place of business in Dallas, Texas. Delhi requests authorization to export for its own account as well as for the accounts of others. The requested authority would be used primarily for spot market sales to Mexican purchasers on a short-term basis but could possibly be for terms of up to two years. The identity of actual purchasers is presently unknown but will be reported in Delhi's quarterly filing with the DOE. According to Delhi, the gas to be exported would be purchased from U.S. producers and would be surplus to domestic need. All sales would result from arms-length negotiations and prices would be determined by market conditions.

This export application will be reviewed under section 3 of the Natural Gas Act and the authority contained in DOE Delegation Order Nos. 0204–111 and 0204–127. In deciding whether the proposed export of natural gas is in the public interest, domestic need for the gas will be considered, and any other issue determined to be appropriate, including whether the arrangement is consistent with the DOE policy of promoting competition in the natural gas marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties, especially those that may oppose this application, should comment on these matters as they relate to the requested export authority. The applicant asserts that there is no current need for the domestic gas that would be exported under the proposed arrangements. Parties opposing this arrangement bear the burden of overcoming this assertion.

NEPA Compliance. The National Environmental Policy Act (NEPA) 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed action. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment procedures. In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the bases for any decision of the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the address listed above.

It is intended that a decisional record on the application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures by provided, such as additional written comments, an oral presentation, a conference, or trail-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why or oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclose of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and response filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Delhi's application is available for inspection and copying in the Office of Fuels Programs Docket Room 3F-056 at the above address. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC., on September 17, 1991.

Anthony J. Como,

Director Office of Coal & Electricity, Office of Fuels Programs, Fossil Energy.

[FR Doc. 91 22983 Filed 9-23-91; 8:45am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ER91-633-000, et al.]

Union Electric Co., et al; Electric Rate, Small Power Production, and Interlocking Directorate Filings

September 17, 1991.

Take notice that the following filings have been made with the Commission:

1. Union Electric Co.

[Docket No. ER91-633-000]

Take notice that on September 6, 1991, Union Electric Company (Union) tendered for filing a First Amendment dated July 19, 1991 to the Wholesale Electric Service Agreement dated September 1, 1989 between Sho-Me Power Corporation and Union. Said Amendment provides for a change in the delivery point between the two parties.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

2. Project Orange Associates, L.P.

[Docket No. QF88-296-002]

On September 11, 1991, Project Orange Associates, L.P., tendered for filing an amendment to its filing in this docket.

The amendment supplements certain aspects of facility's ownership structure.

Comment date: October 7, 1991 in accordance with Standard Paragraph E at the end of this notice.

3. Public Service Electric and Gas Co.

[Docket No. ER91-636-000]

Take notice that on September 11, 1991, the Public Service Electric and Gas Company (PSE&G) tendered for filing an initial Rate Schedule to provide interruptible transmission service to Continental Energy Associates for the delivery of a portion of the net electrical energy output of Continental Energy's qualifying facility located in Hazelton, Pennsylvania to the Consolidated Edison Company of New York, Inc.

PSE&G requests a waiver of § 35.3(a) of the Commission's Regulations so that the Rate Schedule can be made effective within sixty (60) days of the date of this filing.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

4. Orange and Rockland Utilities, Inc.

[Docket No. ER91-637-000]

Take notice that Orange and Rockland Utilities, Inc. (Orange and Rockland) on September 11, 1991 tendered for filing as a rate schedule an executed agreement dated June 1, 1991, between Orange and Rockland and Pennsylvania Power and Light Company (PP&L) for the sale of interruptible power and energy by Orange and Rockland to PP&L.

The rate schedule provides for an economy reservation charge not to exceed $15.00/MWH scheduled and an energy charge equal to the seller's marginal system cost.

Orange and Rockland requests waiver of the notice requirements of § 35.3 of the Commission's Regulations so that the proposed rate schedule can be made effective June 1, 1991 in accordance with the anticipated utilization by the parties.

Orange and Rockland states that a copy of its filing was served on Pennsylvania Power and Light Company.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

5. The United Illuminating Co.

[Docket No. ER91-638-000]

Take notice that on September 12, 1991, the United Illuminating Company ("UI") tendered for filing a rate schedule for short-term, coordination transactions involving the sale of capacity entitlements to Green Mountain Power Corporation (GMP). The rate schedule corresponds to four agreements. The commencement and termination dates for service under the agreements are listed below. UI proposes that the rate schedule commence and terminate on those dates and, by its filing, gives notice of termination.

Agreement	Commencement	Termination
GMP #1	Aug. 1, 1990	Aug. 31, 1990.
GMP #2	Sept. 1, 1990	Sept. 30, 1990.
GMP #3	Nov. 1, 1990	Mar. 31, 1991.
GMP #4	July 8, 1991	Aug. 31, 1991.

The service provided under the agreements is the provision of capacity entitlements and associated energy from various UI generating units and entitlements.

Copies of the filing were mailed to GMP. Copies of the filing have also been mailed to the Vermont Public Service Board.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

6. The United Illuminating Co.

[Docket No. ER91-639-000]

Take notice that on September 12, 1991, The United Illuminating Company (UI) tendered for filing rate schedules for short-term, coordination transactions involving the exchange of capacity with Chicopee Municipal Lighting Plant (Chicopee). The sales are pursuant to an agreement under which service commenced on January 1, 1988, and terminated on February 9, 1988. UI proposes that the rate schedules commence and terminate on those same dates and, by its September 12, 1991, filing, gives notice of termination.

The services under the agreement is the provision of capacity and associated energy and transmission from UI's

Bridgeport Harbor Station Unit 2 (an oil-fired generating unit) and Chicopee's Millstone Unit 3 (a nuclear generating unit). Copies of the filing were served upon Chicopee and on the Massachusetts Department of Public Utilities.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

7. Public Service Co.

[Docket No. ER91-643-000]

Take notice that on September 12, 1991, Public Service Company of New Hampshire (PSNH) tendered for filing a restated and amended Power and Transmission Contract between Public Service company of New Hampshire and Central Maine Power Company (Central Maine). The changes in this agreement (the PSNH/Central Maine agreement) made in this filing are necessary to take into account certain changes made by Yankee Atomic Electric Company (Yankee Atomic) in its agreement to sell power to PSNH (the Yankee Atomic/PSNH agreement).

PSNH and Central Maine are both stockholders in Yankee Atomic, but, since Central Maine is not located in a state adjacent to Massachusetts, it was not, under Massachusetts law, entitled to purchase power directly from Yankee Atomic. Instead, PSNH purchases 9.5% of Yankee Atomic's output and resells it to Central Maine under the PSNH/Central Maine agreement being amended by this filing. The arrangement is intended to flow through to Central Maine the same costs that PSNH pays Yankee Atomic. The payment provisions of the PSNH/Central Maine agreement are therefore the same as those of the Yankee Atomic/PSNH agreement.

The Yankee Atomic/PSNH agreement was amended in Docket No. ER90-47-000 where, by Letter Order dated May 1, 1990, the Commission accepted an offer of settlement filed by Yankee Atomic extending the agreement and reducing the rates, effective January 1, 1990. PSNH seeks to amend the PSNH/Central Maine agreement to take into account certain changes that were approved by the Commission in Docket No. ER90-47-000. PSNH requests waiver of the 60 day notice requirement so that the present filing may be made effective as of January 1, 1990 when the amendments to the Yankee Atomic/PSNH agreement filed in Docket No. ER90-47-000 became effective.

Copies of the filing have been mailed to Central Maine, the New Hampshire Public Utilities Commission and the Maine Public Utilities Commission.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

8. Pennsylvania Power & Light Co.

[Docket No. ER91-635-000]

Take notice that Pennsylvania Power & Light Company (PP&L) on September 11, 1991, tendered for filing an executed Transmission Service Agreement dated as of June 20, 1991 (Agreement), between PP&L and Continental Energy Associates (CEA). The Agreement sets forth the terms and conditions under which PP&L will transmit electric output from CEA's cogeneration facility in the Humboldt Industrial Park, Hazleton, Pennsylvania to Public Service Electric & Gas Company (PSE&G) for delivery and sale to Consolidated Edison Company (Con Ed).

The Agreement provides for a charge of $2.65 per Kw per month, PP&L's standard wheeling rate. These charges were developed utilizing Period II 1986 data from PP&L's wholesale rate filing at Pennsylvania Power & Light Co., Docket No. ER85-719-000. A Settlement Agreement filed October 2, 1985 in that docket was approved by the Commission by letter order dated October 29, 1985.

PP&L requests waiver of the notice requirements of section 205 of the Federal Power Act and § 35.3 of the Commission's Regulations so that the proposed rate schedule can be made effective upon commencement of CEA's energy sales to Con Ed.

PP&L states that a copy of its filing was served on PSE&E and the Pennsylvania Public Utility Commission.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

9. The United Illuminating Co.

[Docket No. ER91-632-000]

Take notice that on September 6, 1991, The United Illuminating Company (UI) tendered for filing rate schedules for short-term, coordination transactions involving the sale of capacity entitlements to UNITIL Power Corporation (UNITIL) and Fitchburg Gas and Electric Light Department (Fitchburg). The rate schedules correspond to three agreements, Fitchburg #1, Fitchburg #2, and UNITIL. The commencement and termination dates for service under the agreements are listed below. UI proposes that the rate schedules commence and terminate on those dates by its filing, gives notice of termination.

Agreement	Commencement	Termination
Fitchburg #1	Jan. 1, 1990	Jan. 28, 1991.
Fitchburg #2	Mar. 1, 1991	Mar. 31, 1991.
UNITIL	Jan. 1, 1991	Jan. 31, 1991.

The service provided under the agreements is the provision of capacity entitlements and associated energy from UI units.

Copies of the filing were mailed to Fitchburg and UNITIL. Copies of the filing have also been mailed to the Massachusetts Department of Public Utilities and the New Hampshire Public Utilities Commission.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

10. The Washington Water Power Co.

[Docket No. ER91-634-000]

Take notice that on September 9, 1991, The Washington Water Power Company (WWP), tendered for filing with the Federal Energy Regulatory Commission pursuant to 18 CFR 35.11 a rate revision for the Transmission Service Agreement (Agreement) between the Washington Water Power Company and Montana Power Company (MPC). WWP states that WWP provides MPC with 105 MW of firm transmission service from the WWP/MPC point of interconnection near the Burke 115 kV Switching Station to the WWP/Bonneville Power Administration 230 kV point of interconnection at the Noxon Switchyard. WWP requests that the Commission (a) accept the rate change for the 105 MW firm transmission service portion of the Agreement, effective as of October 1, 1991, and (b) grant a waiver of notice pursuant to 18 CFR 35.11, to allow the filing of the Agreement less than 60 days prior to the date on which service under the Agreement is to commence.

A copy of the filing was served upon Montana Power Company.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

11. The United Illuminating Co.

[Docket No. ER91-641-000]

Take notice that on September 12, 1991, The United Illuminating Company (UI) tendered for filing rate schedules for short-term, coordination transactions involving the sale of capacity entitlements to Central Vermont Public Service Corporation (CVPS). The rate schedule corresponds to an agreement, dated November 29, 1990, between UI and CVPS. The commencement date for service under

the agreement is November 1, 1990. UI proposes that the rate schedule commence on that date.

The service provided under the agreements is the provision of capacity entitlements and associated energy from UI.

Copies of the filing were mailed to CVPS. Copies of the filing have also been mailed to the Vermont Public Service Board.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

12. Pacific Gas and Electric Co.

[Docket No. ER91-489-000]

Take notice that on September 11, 1991, Pacific Gas and Electric Company tendered for filing an amended filing under FERC Docket No. ER91-489-000. This docket, initially filed on June 14, 1991, effected Rate Schedule FPC No. 29, with Pacific Power and Light Company (PP&L), and Rate Schedule FERC No. 119, with the Central California Power Agency (CCPA).

CCPA had questioned some of the terms and conditions discussed in the initial filing and on July 5, 1991, and on July 12, 1991, requested the Commission suspend its review of this docket for initially one week and then, in the second motion, for an additional 60 days. PG&E and CCPA have reached agreement upon the effective dates and on the use of an Automatic Adjustment Clause to revise Cost of Ownership charges in Rate Schedule FERC No. 119. PP&L was unaffected by these revisions. The amended filing seeks to establish the Automatic Adjustment Clause treatment, and a related Cost of Ownership charge change, effective upon the Commission's acceptance of the amended filing.

Copies of this filing have been served upon CCPA, PP&L and the CPUC.

Comment date: October 1, 1991, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's rules of practice and procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22909 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP91-3030-000, et al.]

Northern Natural Gas Co., et al., Natural Gas Certificate Filings

Take notice that the following filings have been made with the Commission:

1. Northern Natural Gas Co., et al.

[Docket Nos. CP91-3030-000, CP91-3031-000, CP91-3041-000, CP91-3033-000, and CP91-3034-000]

September 13, 1991.

Take notice that on September 10, 1991, Northern Natural Gas Company, 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188, and Texas Gas Transmission Corporation, 3800 Frederica Street, Owensboro, Kentucky 42301, (Applicants) filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under the blanket certificates issued in Docket No. CP86-435-000 and Docket No. CP88-686-000, respectively, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[1]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicants and is summarized in the attached appendix.

Comment date: October 18, 1991, in accordance with Standard Paragraph G at the end of this notice.

[1] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual MMBtu	Receipt points	Delivery points	Contract date, rate schedule service type	Related docket, start up date
CP91-3030-000 (9-10-91)	Production Gathering Company (marketer).	1,500 1,125 547,500	Various	Various	IT-1, Interruptible	ST91-1008-000 8-1-91.
CP91-3031-000 (9-10-91)	Continental Natural Gas, Inc. (end-user).	75,000 56,250 27,375,000	Various	Various	IT-1, Interruptible	ST91-10143-000 8-1-91.
CP91-3041-000 (9-10-91)	Terra International, Inc. (end-user).	27,000 20,250 8,855,000	Various	IA	FT-1, Firm	ST91-9927-000 8-1-91.
CP91-3033-000 (9-10-91)	Harbert Oil & Gas Corporation (customer).	50,000 50,000 18,250,000	Various	KY, IN	IT, Interruptible	ST91-10193-000 8-22-91.
CP91-3034-000 (9-10-91)	Harbert Oil & Gas Corporation (customer).	50,000 50,000 18,250,000	Various	KY, IN	IT, Interruptible	ST91-10192-000 8-22-91.

2. Manville Corp., et al.[2]

[Docket No. CI91-126-000]

September 13, 1991.

Take notice that on September 4, 1991, Manville Corporation, *et al.* (Manville) of 717 Seventeenth Street, Denver, Colorado 80202, filed an application pursuant to section 7 of the Natural Gas Act and the Federal Energy Regulatory Commission's (Commission) regulations thereunder for an unlimited-term blanket certificate with pregranted abandonment authorizing sales in interstate commerce for resale of (1) gas produced by Manville; (2) gas purchased from interstate natural gas pipelines pursuant to discount interruptible sales (ISS) programs; (3) gas purchased from producers, brokers or marketers of natural gas for Manville's end-use that is surplus to Manville's manufacturing needs; and (4) gas purchased from "non-first sellers' such as intrastate pipeline companies and local distribution companies, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Comment date: October 3, 1991, in accordance with Standard Paragraph J at the end of this notice.

[2] The *et al.* parties are Manville Sales Corporation, Riverwood Natural Resources Corporation, Riverwood International Corporation and Riverwood Energy Resources, Inc.

3. Texas Gas Transmission Corp., et al.

[Docket Nos. CP91-3035-000, CP91-3036-000 and CP91-3037-000]

September 13, 1991

Take notice that on September 10, 1991, Texas Gas Transmission Corporation, 3800 Frederica Street, Owensboro, Kentucky 42301, and Williams Natural Gas Company, P.O. Box 3288, Tulsa, Oklahoma 74101, (Applicants) filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under the blanket certificates issued in Docket No. CP88-686-000 and Docket No. CP86-631-000, respectively, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[3]

Information applicable to each transaction, including the identify of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicants and is summarized in the attached appendix.

Comment date: October 28, 1991, in accordance with Standard Paragraph G at the end of this notice.

[3] These prior notice requests are not consolidated.

Docket no. (date filed)	Shipper name (type)	Peak day, average day, annual MMBtu	Receipt points	Delivery points	Contract date, rate schedule, service type	Related docket start up date
CP91-3035-000 (9-10-91)	Harbert Oil & Gas Corporation.	50,000 50,000 18,250,000	Various	KY, OH, IN	2-13-91, IT, Interruptible.	ST91-10194-000 8-22-91.
CP91-3036-000 (9-10-91)	Harbert Oil & Gas Corporation.	50.000 50,000 18,250,000	Various	LA	2-13-91 IT, Interruptible.	ST91-10191-000 8-22-91.
CP91-3037-000 (9-10-91)	Mountain Iron & Supply Company (marketer).	3,300 3,300 [1] 1,204,500	CO, KS, MO, OK, TX, WY.	KA, MO	8-1-91, FTS, Firm	ST91-10230-000 8-1-91.

[1] WNG's quantities are in dekatherms.

4. Arkla Energy Resources, a division of Arkla, Inc.

[Docket No. CP91-3012-000]

September 16, 1991.

Take notice that on September 9, 1991, Arkla Energy Resources, Inc. (AER), 525 Milam Street, Shreveport, Louisiana 71151, filed in Docket No. CP91-3012-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to construct and operate 3 sales taps and related facilities for service to Arkansas Louisiana Gas Company (ALG), under AER's blanket certificate issued in Docket Nos. CP82-384-000 and CP82-384-001 pursuant to Section 7 of the NGA, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

AER states that it would install the taps for deliveries of natural gas to ALG, also a division of Arkla, Inc., for resale to domestic and commercial customers in Hot Springs County, Arkansas. It is asserted that AER would utilize the taps for the delivery of up to 25 Mcf of natural gas on a peak day and 5,700 Mcf on an annual basis. It is stated that the gas would be delivered from AER's system supply and that the gas supply is sufficient to provide the service. It is estimated that the construction cost would be $21,900, to be financed from internally generated capital.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

5. Tennessee Gas Pipeline Co.

[Docket No. CP91-3010-000]

September 16, 1991.

Take notice that on September 9, 1991, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP91-3010-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for

authorization to provide an interruptible transportation service for Peoples Natural Gas Company, a local distributor, under the blanket certificate issued in Docket No. CP87–115–000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Tennessee states that, pursuant to an agreement dated July 24, 1991, under its Rate Schedule IT, it proposes to transport up to 50,000 Dt per day equivalent of natural gas. Tennessee indicates that the gas would be transported from various receipt points on its system, and would be redelivered in other various delivery points to Peoples Natural Gas Company. Tennessee further indicates that it would transport 50,000 Dt on an average day and 18,250,000 Dt annually.

Tennessee advises that service under § 284.223(a) commenced August 8, 1991, as reported in Docket No. ST91–10288.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

6. Mid Louisiana Gas Co.

[Docket No. CP91–3025–000]

September 16, 1991.

Take notice that on September 9, 1991, Mid Louisiana Gas Company (Mid Louisiana), 5 Post Oak Park, suite 800, Houston, Texas 77027, filed in Docket No. CP91–3025–000 an application pursuant to section 7(b) of the Natural Gas Act requesting an order permitting and approving the partial abandonment and adjustment of peak day and annual entitlements for certain of its sales customers currently receiving service under its Rate Schedules G–1 and SG–1, all as more fully set forth in its application which is on file with the Commission and open to public inspection.

In its application Mid Louisiana requests authorization to reduce its peak day and annual obligations to Gulf States Utilities Company, the Town of Vidalia, and the City of Zachary and to reduce its peak day obligations but retain annual entitlements for Louisiana Gas Service Company.

Mid Louisiana also requests that the authorizations be made effective September 1, 1991, to reflect the intent of Mid Louisiana and each affected customer.

Comment date: October 7, 1991, in accordance with Standard Paragraph F at the end of the notice.

7. Panhandle Eastern Pipe Line Co.

[Docket Nos. CP91–3060–000, CP91–3061–000, and CP91–3062–000]

September 16, 1991.

Take notice that on September 11, 1991, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under its blanket certificate issued in Docket No. CP86–585–000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[4]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Panhandle and is summarized in the attached appendix.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

[4] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual Dth	Receipt points	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91–3060–000 (9–11–91)	Panhandle Trading Co (Marketer).	25,000 25,000 9,125,000	Various	MO	7–18–91,PT, Interruptible.	St91–10066–000, 8–1–91.
CP1–3061–000 (9–11–91)	Missouri Public Service (LDC).	6,861 6,861 2,504,265	KS	MO	8–1–91, PT, Firm	ST91–10069–000, 8–1–91.
CP91–3062–000 (9–11–91)	Access Energy Corporation (Marketer).	100,000 100,000 36,500,000	Various	IN	12–19–90, PT, Interruptible.	ST91–10072–000, 8–1–91.

8. Transcontinental Gas Pipe Line Corp.

[Docket No. CP91–3058–000]

September 16, 1991.

Take notice that on September 11, 1991, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77251, filed in Docket No. CP91–3058–000, a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to create an additional point of delivery for Public Service Electric & Gas Company (PSE&G) and to construct and operate certain appurtenant facilities, under the authorization issued in Docket No. CP82–426–000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

It is stated that PSE&G is currently a sales, transportation and storage customer of Transco under various rate schedules with a total firm mainline capacity entitlement of 430,549 Mcf of natural gas per day on Transco's system.

Transco states that it will install a hot tap and meter station at a new point of delivery for PSE&G located approximately at milepost 26.06 on Transco's existing Trenton Woodbury lateral in Burlington County, New jersey (hereinafter referred to as the Burlington Delivery Point). It is stated that the Burlington Delivery Point will be used by PSE&G to receive up to a maximum daily delivery point entitlement of 100,000 Mcf from Transco on a firm and interruptible basis in order to serve PSE&G's Burlington Generating Station.

Transco estimates that the facilities will cost approximately $966,000, and PSE&G will reimburse Transco for all costs associated with such facilities.

Transco states that the authorized total transportation and sales service entitlement for PSE&G will not be altered from the current level, and the addition of the Burlington Delivery Point will have no effect on Transco's peak day or annual deliveries to PSE&G. Furthermore, it is stated that Transco has sufficient system flexibility to accomplish deliveries at the Burlington Delivery Point without detriment or disadvantage to Transco's other gas transportation and sales customers. As such, Transco states that the addition of such point will have no effect on Transco's peak day or annual deliveries to such other customers. Also, it is stated that the addition of such delivery point is not prohibited by Transco's FERC Gas Tariff.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

9. East Tennessee Natural Gas Co.

[Docket No. CP91–3057–000]

September 16, 1991.

Take notice that on September 11, 1991, East Tennessee Natural Gas Company (East Tennessee), P.O. Box 10245, Knoxville, Tennessee 37939–0245, filed in Docket No. CP91–3057–000, a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to construct and operate a new delivery point for its existing customer the Knoxville Utilities Board (KUB), under the authorization issued in Docket No. CP82–412–000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

East Tennessee proposes to establish a new delivery point for KUB where East Tennessee's 16-inch pipeline crosses Tipton Station Road in Knox County, Tennessee. It is stated that the new delivery point will allow KUB to provide service to a presently unserved portion of Knox County which is growing rapidly and presently contains two schools, a new residential subdivision and expected commercial usage. East Tennessee submits that the installed cost of these facilities is estimated to be 110,000.

East Tennessee estimates that it would deliver 55 Mcf of natural gas in a maximum hour and 1,320 Mcf of natural gas on a peak day at this delivery point. It is submitted that the addition of this delivery point will not result in an increase in the total volumes currently authorized for delivery to KUB by East Tennessee.

It is stated that the proposal is not prohibited by its existing tariff and that it has sufficient capacity and/or transportation arrangements to accomplish the deliveries proposed without detriment or disadvantage to its other customers.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

10. ANR Pipeline Co. et al.

[Docket Nos. CP91–3047–000, CP91–3048–000, CP91–3063–000, and CP91–3064–000]

September 16, 1991.

Take notice that ANR Pipeline Company, 500 Renaissance Center, Detroit, Michigan 48243, and Northern Natural Gas Company, 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251–1188, (Applicants) filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under the blanket certificates issued in Docket No. CP88–532–000 and Docket No. CP86–435–000, respectively, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection. [5]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicants and is summarized in the attached appendix.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

[5] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day annual dt	Receipt [1] points	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-3047-000 (9-10-91)	Natgas U.S. Inc. (marketer).	100,000 100,000 36,500,000	Multiple	Multiple	6-12-90, ITS, Interruptible.	ST91-9877, 7-19-91.
CP91-3048-000 (9-10-91)	Allen-Bradley Company (Marketer).	3,000 3,000 1,095,000	Multiple	WI	1-16-90, ITS, Interruptible.	ST91-10005, 7-27-91.
CP91-3063-000 (9-11-91)	Texaco Gas Marketing (Marketer).	200,000 150,000 73,000,000	Multiple	Various	8-1-91, IT-1, Interruptible.	ST91-10141, 8-1-91
CP91-3064-000 (9-11-91)	Twister Transmission Company (Marketer).	20,000 15,000 7,300,000	Various	TX, OK	8-1-91, IT-1, Interruptible.	ST91-10089, 8-1-91.

[1] Offshore Louisiana and offshore Texas are shown as OLA and OTX.

11. Transwestern Pipeline Co. and ANR Pipeline Co.

[Docket Nos. CP91-3066-000 and CP91-3068-000]

September 16, 1991.

Take notice that Transwestern Pipeline Company, 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188, and ANR Pipeline Company, 500 Renaissance Center, Detroit, Michigan 48243, (Applicants) filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under the blanket certificates issued in Docket No. CP88-133-000 and Docket No. CP88-532-000, respectively, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[6]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicants and is summarized in the attached appendix.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

[6] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual	Receipt points	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-3066-000 (9-11-91)	Westar Transmission Co. (Intrastate).	40,000 30,000 14,600,000 (MMBtu)	AZ, NM, OK, TX	TX	7-10-91, ITS-1, Interruptible.	ST91-10290, 8-6-91.
CP91-3068-000 (9-11-91)	Jack D. Hodgden Operating Co. (Marketer).	67 67 24,455 (Dth)	OK	OK	4-16-91, ITS, Interruptible.	ST91-9998, 7-29-91.

12. Transcontinental Gas Pipe Line Corp.

[Docket No. CP91-3011-000]

September 16, 1991.

Take notice that on September 9, 1991, Transcontinental Gas Pipe Line Corporation (Transco), Post Office Box 1396, Houston, Texas 77251, pursuant to the prior notice procedure prescribed in § 157.212 of the Regulations under the Natural Gas Act (18 CFR 157.205, 157.212) and Transco's blanket certificate issued in Docket No. CP82-426-000, filed in Docket No. CP91-3011-000 a request for authorization to create additional capacity at an existing point of delivery for a certain existing transportation and storage customer and to construct and operate certain appurtenant facilities all as more fully set forth in the application that is on file with the Commission and open to public inspection.

It is stated that Piedmont Natural Gas Company (Piedmont) is currently a transportation and storage customer of Transco. Piedmont has a firm transportation service entitlement of 270,322 Mcf per day. Transco's existing tariff does not prohibit the expansion of the existing delivery point.

Transco states that it has agreed to expand facilities at an existing point of delivery for Piedmont located in Gaston County, North Carolina, hereinafter referred to as the Hickory Delivery Point, in order to provide increased firm transportation service at such point. The proposed expansion is designed to increase the physical capacity at the Hickory Delivery Point for 54,000 Mcf per day to 150,000 Mcf per day. The total firm service entitlement of Piedmont would not be altered from its current level of 270,322 Mcf per day. Further, the expansion of the Hickory Delivery Point will have no effect on Transco's peak day or annual volumetric deliveries to Piedmont, or any other existing customer. Transco states that upon completion of the proposed construction to increase service at the Hickory Delivery Point, Transco will file a revised DPE tariff sheet for Piedmont to reflect the proposed changes in transportation service.

It is stated that Transco would construct, install and operate at the Hickory Delivery Point a 12-inch tap valve, three 8-inch meter tubes and appurtenant facilities. The construction, installation and operation of such facilities will comply with the environmental requirements set forth in § 157.206 of the Regulations. Transco states that no non-jurisdictional facilities related to the instant application would be constructed.

Comment date: October 31, 1991, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, A hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is

required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to rule 214 of the Commission's procedural rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdraw within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Standard Paragraph

J. Any person desiring to be heard or make any protest with reference to said filings should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, .214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22910 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP91-3040-000, et al.]

Northwest Pipeline Corp., et al.; Natural Gas Certificate Filings

September 17, 1991

Take notice that the following filings have been made with the Commission:

1. Northwest Pipeline Corp.

[Docket No. CP91-3040-000]

Take notice that on September 10, 1991, Northwest Pipeline Corporation (Northwest), P.O. Box 58900, Salt Lake City, Utah 84158-0900, filed in Docket No. CP91-3040-000 a request pursuant to § 157.205, 157.211 and 157.212, and 157.216 of the Commission's Regulations under the Natural Gas Act for permission and approval to partially abandon facilities, and for authorization to construct and operate facilities, to add a new delivery point, to increase the minimum delivery pressure at various delivery points and to reallocate firm service under the authorization issued in Docket No. CP89-1740 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Northwest states that Intermountain Gas Company (Intermountain) has requested a reallocation of its maximum daily delivery obligations (MDDO) among most of its firm delivery points, along with delivery pressure changes, to better satisfy its current and projected firm service requirements in its distribution areas. Northwest proposes to implement these changes in part by partially abandoning and upgrading the existing metering facilities at the Meridian, Caldwell, Idaho State Penitentiary, Idaho Falls, Mountain Home, and Soda Springs meter stations. Northwest further proposes to construct a new delivery point in Ada County, Idaho which it states will enable Intermountain to meet increased load requirements.

Comment date: November 1, 1991, in accordance with Standard Paragraph G at the end of this notice.

2. Florida Gas Transmission Co.

[Docket No. CP91-3065-000 and CP91-3069-000]

Take notice that Florida Gas Transmission Company, 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188, (Applicant) filed in the above-referenced dockets prior notice requests pursuant to § 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under its blanket certificate issued in Docket No. CP89-555-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[1]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicant and is summarized in the attached appendix.

Comment date: November 1, 1991, in accordance with Standard Paragraph G at the end of this notice.

[1] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name	Peak day, average day, annual MMBtu	Receipt points	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-3065-000 ST91-9922 (9-11-91)	Peoples Gas System, Inc.	(1)	TX, LA	FL	11-1-89, FTS-1, Firm.	8-1-91.
CP91-3069-000 ST91-9922 (9-11-91)	People's Gas System, Inc.[3]	(2)	TX, LA	FL	11-1-89, FTS-1, Firm.	8-1-91.

	Phase I	Phase II
[1] Peak day	87,977	94,978
Average day	79,503	86,129
Annual	29,018,538	31,437,239

	Phase I	Phase II
[1] Peak day	8,031	8,569
Average day	6,877	7,068
Annual	2,510,001	2,579,770

Peoples Gas System, Inc. is successor-in-interest to Southern Gas Company, Division of Donovan Companies, Inc.

3. Columbia Gulf Transmission Co., et al.

[Docket Nos. CP91-3073-000, CP91-3074-000, CP91-3075-000, CP91-3076-000, CP91-3077-000, and CP91-3078-000]

Take notice that on September 13, 1991, Columbia Gulf Transmission Company, P.O. Box 683, Houston, Texas 77001, and Tennessee Gas Pipeline Company, P.O. Box 2511, Houston, Texas 77252, (Applicants) filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under the blanket certificates issued in Docket No. CP86-239-000 and Docket No. CP87-115-000, respectively, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[2]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicants and is summarized in the attached appendix.

Comment date: November 1, 1991, in accordance with Standard Paragraph G at the end of this notice.

[2] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual MMBtu	Receipt points	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-3073-000 (9-13-91)	Transco Energy Marketing Company (marketer).	200,000 160,000 58,400,000	On LA, Off LA	On LA, Off LA	7-1-87, ITS-2, Interruptible.	ST91-10102-000, 8-2-91.
CP91-3073-000 (9-13-91)	Phillips Petroleum Company (producer).	100,000 80,000 29,200,000	On LA, Off LA	TX	7-10-91, ITS-2, Interruptible.	ST91-10109-000, 8-1-91.
CP91-3075-000 (9-13-91)	Total Minatome Corporation (shipper).	100,000 80,000 29,200,000	Off LA, On LA	Various	10-25-88, ITS-2, ITS-1, Interruptible.	ST91-10107-000, 8-2-91.
CP91-3076-000 (9-13-91)	Neste Trading, Inc. (shipper).	300,000 240,000 87,600,000	On LA, Off LA	On LA, KY	9-1-90, ITS-2, ITS-1, Interruptible.	ST91-10108-000, 8-2-91.
CP91-3077-000 (9-13-91)	Phillips Petroleum Company (producer).	50,000 40,000 14,600,000	Off LA	On LA	6-13-89, ITS-2, Interruptible.	ST91-10110-000, 8-1-91.
CP91-3078-000 (9-13-91)	Texas-Ohio Gas, Inc. (shipper).	10,000 10,000 [1] 3,650,000	Various	Various	7-22-91, IT, Interruptible.	ST91-10153-000, 8-6-91.

[1] Tennessee's quantities are in dekatherms.

4. Florida Gas Transmission Co., et al.

[Docket Nos. CP91-3028-000, CP91-3029-000, CP91-3038-000, and CP91-3039-000]

Take notice that on September 10, 1991, Applicants filed prior notice requests with the Commission in the above-referenced dockets pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to transport natural gas on behalf of various shippers under the blanket certificates issued to Applicants pursuant to section 7 of the NGA, all as more fully set forth in the requests which are open to public inspection.[3]

The applicants have provided information applicable to each transaction, including the shipper's identity; the type of transportation service; the appropriate transportation rate schedule; the peak day, average day and annual volumes; the service initiation date; and related ST docket number of the 120-day transaction under § 284.223 of the Commission's Regulations, as summarized in appendix A. Applicant's addresses and transportation blanket certificates are shown in appendix B.

Comment date: November 1, 1991, in accordance with Standard Paragraph G at the end of this notice.

[3] These prior notice requests are not consolidated.

APPENDIX A

Docket No.	Shipper name (type)	Peak day, average day, annual MMBtu	Receipt points[1]	Delivery points	Contract date, rate schedule, service type	Related docket, start update
CP91-3028-000	Consolidated Metals, Inc. (shipper).	([2])	AL, FL, LA, OLA, MS, TX, OTX.	FL	7-1-91, PTS-1 Preferred Interruptible.	ST91-9945, 8-1-91
CP91-3029-000	Kissimmee Utility Authority (shipper).	([3])	LA, TX	FL	11-10-90, as amended, FTS-1, Firm.	ST91-9921, 8-1-91.
CP91-3038-000	Ford Motor Company (end-user).	([4]) 7,000 7,000 2,555,000	CO, KS, MO, OK, TX, WY.	KS, MO	8-1-91, FTS-2, Firm.	ST91-10,229. 8-1-91.
CP91-3039-000	Kansas Power and Light Company (local distributor).	25,000 25,000 9,125,000	CO, KS, MO, OK, TX, WY.	KS, MO, OK	8-1-91, FTS-1 & FTS-2, Firm.	ST91-10, 232. 8-1-91.

[1] Offshore Louisiana and offshore Texas are shown as OLA and OTX.

	Phase I	Phase II
[2]Peak day	1,431	1,380
Average day	1,073	1,035
Annual	522,393	503,764
[3]Peak day	1,827	2,106
Average day	1,177	1,511
Annual	429,458	551,424

[4] Dekatherms.

APPENDIX B

Applicant's address	Blanket docket
Florida Gas Transmission Company, 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188	CP89-555-000
Northern Natural Gas Company, Division of Enron Corp., 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188	CP86-435-000
Williams Natural Gas Company, P.O. Box 3288, Tulsa, Oklahoma 74101	CP86-631-000

5. Northwest Pipeline Corp.

[Docket No. CP91-3015-000]

Take notice that on September 9, 1991, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84108, filed in Docket No. CP91-3015-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to provide an interruptible transportation service for Chemstar Lime Company, an end-user, under the blanket certificate issued in Docket No. CP86-578-000, and for authorization to construct and operate a new meter to facilitate the transportation service, under Northwest's blanket certificate issued in Docket No. CP82-433-000, both pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Northwest states that, pursuant to an agreement dated June 3, 1991, under its Rate Schedule TI-1, it proposes to transport up to 2,500 MMBtu per day equivalent of natural gas. Northwest indicates that it would transport 2,400 MMBtu on an average day and 745,000 MMBtu annually. Northwest further indicates that the gas would be transported from various receipt points on its system and would be redelivered at various delivery points on its system, including the Chemstar Lime Plant, located in Caribou County, Idaho.

It is stated that Northwest will construct and operate a meter and related facilities for deliveries of natural gas to Intermountain Gas Company (IGC) for use by Chemstar in Chemstar's new lime processing plant. The construction cost is estimated at $207,010, to be paid for by Northwest pursuant to the facility reimbursement provisions in Volume No. 1-A of its Tariff.

Northwest advises that service under § 284.223(a) will commence on completion of the proposed construction and that an initial report will be filed at that time.

Comment date: November 1, 1991, in accordance with Standard Paragraph G at the end of this notice.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22907 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP90-22-014]

Algonquin Gas Transmission Co.; Proposed Changes in FERC Gas Tariff Additional Compliance Filing

September 17, 1991.

Take notice that Algonquin Gas Transmission Company ("Algonquin")

on September 13, 1991, tendered for filing proposed changes in its FERC Gas Tariff, Third Revised Volume No. 1, as set forth in the tariff sheets listed in appendix A:

Algonquin states that it is making the instant filing to incorporate the terms and conditions of the Stipulation and Agreement in Docket No. RP90–22–000 as filed on December 14, 1990 and approved, as modified, by the Commission's Order of April 19, 1991 into the tariff sheets listed in appendix A. Algonquin states that the instant filing is in addition to its compliance filing of August 1, 1991 in Docket No. RP90–22–013, which was accepted by Commission Order issued August 27, 1991.

Algonquin states the instant filing contains appropriate revised tariff sheets reflecting rates equivalent to the Settlement Base Rates under its rate schedules, adjusted as appropriate to reflect authorized changes as provided by Algonquin's FERC Gas Tariff.

Algonquin notes that copies of this filing were served upon each affected party and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before September 24, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91–22915 Filed 9–23–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM92–2–23–000]

Eastern Shore Natural Gas Co.; Proposed Changes in FERC Gas Tariff

September 17, 1991.

Take notice that Eastern Shore Natural Gas Company (ESNG) tendered for filing on September 13, 1991 certain revised tariff sheet included in appendix A attached to the filing. Such sheet is proposed to be effective as of October 1, 1991.

ESNG states that the purpose of the instant filing is to revise the billing amounts shown on Second Revised Sheet No. 6B to comply with the provisions of ordering Paragraph (B) of the Commission's August 26, 1988 order in ESNG's Docket No. RP88–226–000. The referenced order requires ESNG to file revised billing amounts to "track" any modifications to Transcontinental Gas Pipe Line Corporation's (Transco) take-or-pay charges ordered by the Commission. Transco filed on August 30, 1991 to eliminate the Fixed and Commodity Litigant Producer Settlement Payment (LPSP) charge which Transco was authorized to collect over a one-year amortization period October 1, 1990 through September 28, 1991 in their Docket No. RP90–179–000, et al. The impact on ESNG is a decrease of $3,593 per month (i.e. from $42,845 to $39,252) in the amount of fixed monthly take-or-pay charges, it will incur from Transco as of October 1, 1991.

ESNG states that copies of the filing have been served upon its jurisdictional customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion with the Federal Energy Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 and Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before September 24, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91–22913 Filed 9–23–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP90–70–005]

Equitrans, Inc.; Report of Refunds

September 17, 1991.

Take notice that on September 9, 1991, Equitrans, Inc. (Equitrans) in compliance with the Commission's ordering paragraph (D) of its Order issued July 25, 1991, tendered for filing a Report of Refunds Made on August 24, 1991.

Equitrans states the Report of Refunds Made encompasses all customers as required under the Settlement. Gross refunds distributed totaled $6,943,433.37, plus accrued interest thereon to the date of distribution of August 24, 1991 of $351,320.10 for a total of $7,294,753.47.

Equitrans states that a copy of its filing has been served upon its purchasers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before September 24, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91–22917 Filed 9–23–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM91–4–25–000]

Mississippi River Transmission Corp.; Rate Change Filing

September 17, 1991.

Take notice that on September 11, 1991, Mississippi River Transmission Corporation (MRT) tendered for filing the following tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1:

	Effective Date
Thirteenth Revised Sheet No. 4A.1.	October 12, 1991.
Tenth Revised Sheet No. 4A.4.	October 12, 1991.
Ninth Revised Sheet No. 4A.5.	October 12, 1991.
Fourth Revised Sheet No. 4A.6.	July 1, 1991.
Second Revised Sheet No. 4A.7.	December 1, 1990.

MRT states that the purpose of the instant filing is to reflect the flowthrough of take-or-pay refunds received by MRT on August 12, 1991 from Natural Gas Pipeline Company (Natural) in their Docket No. RP91–22–000 *et al.* MRT states that the refunds have been allocated to MRT's customers in accordance with MRT's June 26, 1991 Stipulation and Agreement on the Allocation and Recovery of Transition

Costs from Upstream Pipelines (Settlement) approved by Commission Order dated July 25, 1991. MRT states that Revised Sheet Nos. 4A.1, 4A.4 and 4A.5 also reflect a reconciliation of take-or-pay amounts paid to Natural by MRT compared to take-or-pay amounts collected by MRT from its jurisdictional customers.

MRT states that Sheet Nos. 4A.6 and 4A.7 are being reserved for future use. MRT states that Sheet No. 4A.6 previously related to United Gas Pipe Line Company's (United) take-or-pay activity which was transferred to Sheet No. 4A.1 in MRT's June 26, 1991 Settlement; thereby eliminating the need for Sheet No. 4A.6 and Sheet No. 4A.7 is being eliminated because the account was closed effective April 20, 1991.

MRT states that copies of the filing has been mailed to each of MRT jurisdictional customers and interested state commissions of Arkansas, Illinois and Missouri.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before September 24, 1991. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22914 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. IN86-6-009]

Ozark Gas Pipeline Corp.; Report of Refunds

September 17, 1991.

Take notice that on February 5, 1991, Ozark Gas Pipeline Corporation (Ozark) filed a report showing refunds of $329,872.00 to Columbia Gas Transmission Company (Columbia) and Tennessee Gas Pipeline Company (Tennessee) for the period January 1, 1990 through December 31, 1990.

Ozark states that the refunds were made in compliance with a Stipulation and Consent Agreement approved by Commission order issued August 3, 1987, which requires a $0.005 credit per volume of gas shipped to Columbia and Tennessee.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before September 24, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22911 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89-225-013]

South Georgia Natural Gas Co.; Refund Report

September 17, 1991.

Take notice that South Georgia Natural Gas Company (South Georgia) on September 11, 1991, pursuant to the Federal Energy regulatory Commission orders dated July 3, 1991 and October 29, 1990 tendered for filing a refund report in the above captioned proceeding.

South Georgia states that copies of the letter are being mailed to all of Southern's jurisdictional customers and interested state commissions.

Any persons desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before September 24, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22912 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER90-159-002]

South Carolina Electric & Gas Co.; Order on Remand and Announcing Policy With Respect To Pleadings Concerning Issues of Contract Interpretation

Issued September 17, 1991.

This case is on remand from the United States Court of Appeals for the District of Columbia Circuit.[1]

Background

By order issued on May 21, 1990, the Commission denied Central Electric Power Cooperative, Inc.'s (Central Electric) request for summary disposition or, in the alternative, suspension and hearing, and accepted without suspension or hearing South Carolina Electric & Gas Company's (South Carolina) proposed decrease in its wholesale energy charge.[2] The decrease in the wholesale energy charge was intended to track a decrease in South Carolina's retail energy charge pursuant to a 1984 settlement agreement.

Central Electric had argued that South Carolina violated the settlement agreement by using a different rate design for its wholesale rate than that used for its retail rate.[3] Specifically, Central Electric contended that South Carolina's proposal to implement the wholesale rate decrease by reducing only the energy charge would result in a "demand/energy ratio," after adjustment,[4] different than in the retail rate.

Central Electric argued that South Carolina's proposal would result in Central Electric paying approximately $20,000 more than it should pay under the settlement agreement and would violate the settlement agreement's requirement that South Carolina not maintain or place into effect a wholesale rate that has either its demand or energy component, as adjusted,greater than the retail rate. [5]

In the May 21 order, the Commission found that section 10, the pertinent provision of the settlement agreement, was "unclear and ambiguous concerning the appropriate methodology for

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[1] *Central Electric Power Cooperative, Inc.* v. *FERC*, No. 90-1425 (DC Cir. July 22, 1991).

[2] South Carolina Electric & Gas Company, 51 FERC ¶ 61,193, *reh'g denied*, 52 FERC ¶ 61,065 (1990).

[3] Central Electric did not protest the overall rate reduction. See 51 FERC at 61,529 n.6.

[4] Adjustments are to be made for differences in fuel cost recovery, which are not at issue in this case. See 52 FERC at 61,266 n.6.

[5] The City of Orangeburg, South Carolina filed a motion to intervene in support of South Carolina's filing, and South Carolina filed an answer in opposition to the motion for summary disposition.

ensuring that [South Carolina's] wholesale rate changes track its retail rate changes." [6] However, notwithstanding that section 10 was ambiguous, the Commission found that the settlement agreement as a whole was not ambiguous and that South Carolina's interpretation of the settlement agreement was more persuasive than Central Electric's. In so doing, the Commission read the pertinent provision of the settlement agreement in light of the other provisions of the settlement agreement. The Commission found no support for Central Electric's argument that the settlement agreement required a particular percentage relationship between demand and energy charges.[7]

On rehearing, Central Electric reasserted that it was entitled to summary disposition. Alternatively, Central Electric argued that if section 10 contained any ambiguity, the Commission should order a hearing at which the parties could offer extrinsic evidence of the intent of the parties in drafting the settlement agreement.

In denying rehearing, the Commission rejected Central Electric's claim that section 10 of the settlement agreement was unambiguous and could be read only in its favor. The Commission rejected Central Electric's argument that it should be permitted, in a hearing, to introduce extrinsic evidence of the parties' intent. The Commission determined that that principle of contract law did not apply because the settlement agreement as a whole was not ambiguous, *i.e.*, when the pertinent provision was read in the context of the entire settlement agreement there was no ambiguity.[8] The Commission therefore again concluded that South Carolina's interpretation of the settlement agreement was reasonable.

Central Electric subsequently appealed the Commission's orders to the United States Court of Appeals for the District of Columbia Circuit. While that appeal was pending, the Commission, citing the court's recent decision in *Cajun Electric Power Cooperative, Inc.* v. *FERC*,[9] which had been issued after the Commission had denied rehearing, filed a motion with the court to remand the instant case back to the Commission for further consideration. As noted, the court granted the Commission's motion.

[6] 51 FERC at 61,530.

[7] *Id.* at 61,530–31.

[8] 52 FERC at 61,266–67.

[9] *Cajun Electric Power Cooperative, Inc.* v. *FERC*, 924 F.2d 1132 (D.C. Cir. 1991).

Discussion

In *Cajun Electric Power Cooperative, Inc.* v. *Gulf States Utilities Company* (*Cajun*),[10] the Commission denied a complaint, which concerned an interpretation of a contract. The Commission found the contract unambiguous and found that it had no reason to consider the extrinsic evidence submitted by the complainant to determine the intent of the parties. On appeal, the court found that the pertinent language was ambiguous and remanded the case to the Commission for further proceedings, directing that the Commission order a hearing in which the complainant would have the opportunity to show whatever evidence it may adduce that is probative as to the intent of the parties.[11]

In view of the court's decision in the *Cajun* proceeding, which was issued after we had denied rehearing in this case, we have reexamined our earlier orders. Specifically, given that we cited extrinsic evidence in support of our determination,[12] we believe it appropriate to allow Central Electric an opportunity to proffer extrinsic evidence in support of its view of the parties' intent in negotiating the settlement agreement.

In short, in the unique circumstances of this case, where the court's decision in the *Cajun* proceeding followed our denial of rehearing but preceded final disposition of this case on appeal, we believe it appropriate to provide Central Electric one further opportunity to proffer evidentiary support, *i.e.*, affidavits, contemporaneous documentary evidence, written testimony, or the like, and to give the other parties an opportunity to respond.[13]

[10] 49 FERC ¶ 61,089 (1990), *reh'g denied*, 50 FERC ¶ 61,076 (1990).

[11] 924 F.2d at 1136–37. On remand, the Commission set the matter for hearing. *Cajun Electric Power Cooperative, Inc.* v. *Gulf States Utilities Company*, 55 FERC ¶ 61,060 (1991).

[12] The May 21 order noted that the Commission also reviewed the company's rate design reflected in the earlier original settlement rates and the periodic revisions that tracked retail rate changes. See 51 FERC at 61,530; 52 FERC at 61,266 n.15.

[13] In its Request for Rehearing, Central Electric asserted that the clear purpose and intent of Section 10 was to protect customers from a price squeeze resulting from an adverse rate design. However, it cited no evidence in support of that assertion. Request for Rehearing at 6. Citing case law and law review articles with respect to the introduction of extrinsic evidence and contract interpretation, Central Electric also argued that words can have different meanings. Again, however, it cited no evidence in support of its assertion as to the contract's meaning. Request for Rehearing at 11–12.

In its earlier intervention and protests, Central Electric likewise provided no evidence in support of its assertion as to the contract's meaning.

We will then, after examining such evidence, reevaluate whether an evidentiary hearing is warranted or whether summary disposition is appropriate and at that time we shall issue an order setting forth our determination. Absent the submission of sufficient evidentiary support by Central Electric, however, we would not be inclined to institute an evidentiary hearing.

We caution Central Electric that it will not automatically be entitled to an evidentiary hearing. Mere allegations of disputed facts are insufficient to mandate a hearing. Rather, the party seeking an evidentiary hearing must make an adequate proffer of evidence to support such allegations.[14] Thus, Central Electric's essentially bare allegations earlier in this proceeding were insufficient to mandate such a hearing. For Central Electric to be granted an evidentiary hearing, Central Electric must provide more than what it earlier provided.[15]

One additional comment of a general nature for the guidance of parties to future cases is in order. In the future, if parties believe that a contract or particular contractural language in dispute is unambiguous, we will expect them to clearly say so and to state why they believe it to be so. Likewise, if they instead believe that there is an ambiguity, we will expect them to clearly say so and to state why they believe it to be so. Moreover, we will expect parties to immediately proffer the extrinsic evidence they believe supports their view.[16]

The Commission orders:

(A) Within 30 days of the date of this order, Central Electric will be permitted to file a supplementary pleading in support of its request for summary

[14] See, *e.g.*, Woolen Mills Associates v. FERC, 917 F.2d 589, 592 (D.C. Cir. 1990); *accord, e.g.*, Pennsylvania Public Utility Commission v. FERC, 881 F.2d 1123, 1126 (D.C. Cir. 1989); Cerro Wire & Cable Co. v. FERC, 677 F. 2d 124, 128–29 (D.C. Cir. 1982); Pacificorp Electric Operations, 54 FERC ¶ 61,296 at 61,856 & n.71, *reh'g denied*, 55 FERC ¶ 61,461 (1991); Northeast Utilities Service Company, 52 FERC ¶ 61,336 at 61,318 & n. 44 (1990), *appeal filed sub nom.*, City of Holyoke Gas & Electric Department v. FERC, No. 91–1565 (D.C. Cir. filed Nov. 26, 1990) (citing, *inter alia*, General Motors Corporation v. FERC, 656 F. 2d 791, 798 n. 20 (D.C. Cir. 1981) and Rhode Island Consumers' Council v. FPC, 504 F. 2d 203, 212 (D.C. Cir. 1974)); Southern California Edison Co., 27 FERC ¶ 61,105 at 61,199 (1984); see also, *e.g.*, Century Power Corporation, 53 FERC ¶ 61,240 at 61,991 (1990), *order on reh'g*, 56 FERC ¶ 61,083 (1991); Pacific Gas and Electric Company, 52 FERC ¶ 61,032 at 61,167 & nn. 13–20 (1990).

[15] *See, e.g.*, Public Service Company of New Hampshire, 56 FERC ¶ 61,105 at 61,404 n. 27 (1991).

[16] This would be particularly so in cases in which parties seek an evidentiary hearing.

disposition or, alternatively, for a hearing, as discussed in the body of this order.

(B) Within 20 days of the date of Central Electric's supplementary submittal discussed in Ordering Paragraph (A), the other parties will be permitted to file responsive supplementary pleadings, as discussed in the body of this order.

(C) The Secretary shall promptly publish this order in the **Federal Register.**

By The Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22908 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ92-1-8-001]

South Georgia Natural Gas Co., Proposed Changes to FERC Gas Tariff

September 17, 1991.

Take notice that on September 12, 1991, South Georgia Natural Gas Company (South Georgia) tendered for filing the following tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1, with proposed effective dates as indicated:

Proposed sheets	Effective date
First Substitute Seventy-Sixth Revised Sheet No. 4.	Oct. 1, 1991.
Third Revised Sheet No. 32B	Mar. 1, 1991.
Fifth Revised Sheet No. 33	Mar. 1, 1991.
Seventh Revised Sheet No. 34A	Oct. 1, 1991.

South Georgia states that First Substitute Seventy-Sixth Revised Sheet No. 4 was submitted in order to correct an error in the computation of South Georgia's gas cost in Docket No. TQ92-1-8-000 which was submitted on August 30, 1991. South Georgia states further that the Current Adjustment will now reflect an increase in jurisdictional revenues of approximately $1.4 million and an increase in the demand component of $3.48 per Mcf from that contained in South Georgia's annual PGA filing in Docket No. TA91-1-8-000. The remaining tariff sheets are the same as those originally submitted in Docket No. TQ92-1-8-000.

South Georgia states that copies of the filing will be served upon all of South Georgia's purchasers, interested state commissions and interested parties as well as all parties of record in the subject proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before September 24, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22916 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-203-001]

Tennessee Gas Pipeline Co., Compliance Filing

September 17, 1991.

Take notice that on September 13, 1991, Tennessee Gas Pipeline Company (Tennessee) tendered for filing, Substitute Twenty-Fifth Revised Sheet No. 5 and Substitute Original Sheet No. 5A to Original Volume No. 2 of its FERC Gas Tariff. These revised tariff sheets are proposed to be effective February 1, 1992. Tennessee submits that the revised tariff sheets are filed in compliance with the Commission's August 30, 1991 order accepting for filing and suspending Tennessee's rate increase filing in this proceeding and reflect the Commission ordered revisions to the filed rate for Rate Schedule T-47. Tennessee also advises the Commission that no costs of facilities used to attach shipper-owned gas supplies are included in Tennessee's rate increase filing in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Procedure 18 CFR 385.211. All such protests should be filed on or before September 24, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-22918 Filed 9-23-91; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-59301A; FRL 3948-3]

Certain Chemical; Approval of a Test Marketing Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of an application for test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA) and 40 CFR 720.38. EPA has designated this application as TME-91-24. The test marketing conditions are described below.

EFFECTIVE DATE: September 16, 1991.

FOR FURTHER INFORMATION CONTACT: Vicki Anderson, New Chemicals Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M St., SW., Washington, DC 20460, (202) 260-4142.

SUPPLEMENTARY INFORMATION: Section 5(h)(1) of TSCA authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes if the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present an unreasonable risk of injury.

EPA hereby approves TME-91-24. EPA has determined that test marketing of the new chemical substance described below, under the conditions set out in the TME application, and for the time period and restrictions specified below, will not present an unreasonable risk of injury to health or the environment. Production volume, use, and the number of customers must not exceed that specified in the application. All other conditions and restrictions described in the application and in the notice must be met.

The following additional restrictions apply to TME-91-24. A bill of lading accompanying each shipment must state that the use of the substance is restricted to that approved in the TME. In addition, the applicant shall maintain

the following records until 5 years after the date they are created, and shall make them available for inspection or copying in accordance with section 11 of TSCA:

1. Records of the quantity of the TME substance produced and the date of manufacture.
2. Records of dates of the shipments to each customer and the quantities supplied in each shipment.
3. Copies of the bill of lading that accompanies each shipment of the TME substance.

TME-91-24

Date of Receipt: August 5, 1991.
Notice of Receipt: August 21, 1991 (56 FR 41560).
Applicant: Confidential.
Chemical: (G) Polyisobutylene amine (PIBA).
Use: (G) Gasoline additive.
Production Volume: Confidential.
Number of Customers: Confidential.
Test Marketing Period: Confidential.
Risk Assessment: EPA identified no significant health or environmental concerns for the test market substance. Therefore, the test market activities will not present any unreasonable risk of injury to health or the environment.

The Agency reserves the right to rescind approval or modify the conditions and restrictions of an exemption should any new information that comes to its attention cast significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to health or the enviornment.

Dated: September 16, 1991.

John W. Melone,

Director, Chemical Control Division, Office of Toxic Substances.

[FR Doc. 91-22964 Filed 9-23-91; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL MARITIME COMMISSION

Maryland Port Administration et al.; Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224-200566.
Title: Maryland Port Administration and Baltimore Forest Products Terminals Leasing Agreement.
Parties:
Maryland Port Administration ("MPA")
Baltimore Forest Products Terminals ("BALTERM")
Synopsis: The Agreement filed, September 11, 1991, provides for BALTERM to lease from MPA at the Dundalk Marine Terminal, 50,000 square feet in Shed 6; 100,000 square feet at Shed 4 and 5.39 acres of space located on the Northwest corner of North Service and Third Streets, which includes a storage shed consisting of 142,500 square feet at the Dundalk Marine Terminal.

Dated: September 18, 1991.

By Order of the Federal Maritime Commission.

Joseph C. Polking.

Secretary.

[FR Doc. 91-22921 Filed 9-23-91; 8:45 am]

BILLING CODE 6730-01-M

GENERAL SERVICES ADMINISTRATION

Office of Business, Industry and Governmental Affairs Business Advisory Board

Meeting Notice: Notice is hereby given that the General Services Administration (GSA) Business Advisory Board will meet October 17, 1991, from 10 a.m. to 3 p.m. at GSA's Central Office, 18th and F Streets NW., room 5141A, Washington, DC. Notice is required by the Federal Advisory Committee Act, 5 U.S.C. app. 2, and the implementing regulation, 41 CFR 101-6.

The purpose of the meeting is to provide a forum for discussion on key business and industry trends, emerging technologies and products, and other issues that may affect GSA's future policy and program formulation. The agenda for this meeting will include discussion on: commercial product acquisition reform; standards (national and international); customer satisfaction measurements; and internal and external communications.

The meeting will be open to the public.

For further information, contact Mary Ann Webster (202/501-4177) of the Office of Business, Industry and Governmental Affairs, GSA/AL, Washington, DC, 20405.

Dated September 16, 1991.

Donald C.J. Gray,

Associate Administrator for Business, Industry and Governmental Affairs, GSA.

[FR Doc. 91-22900 Filed 9-23-91; 8:45 am]

BILLING CODE 6820-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Members on Public Advisory Committees; OTC Drugs Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for six voting members and one nonvoting representative of industry interests to serve on the OTC Drugs Advisory Committee in FDA's Center for Drug Evaluation and Research. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule announcing the establishment of this committee.

DATES: Nominations should be received on or before October 24, 1991.

ADDRESSES: All nominations for membership, except for consumer-nominated members and the nonvoting representative of industry interests, should be sent to Jack Gertzog (address below). All nominations for the consumer-nominated members should be sent to Naomi Kulakow (address below). All nominations for the nonvoting representative of industry interests should be sent to William E. Gilbertson (address below).

FOR FURTHER INFORMATION CONTACT: *Regarding all nominations for membership, except for consumer-nominated members:* Jack Gertzog, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

Regarding all nominations for consumer-nominated members: Naomi Kulakow, Office of Consumer Affairs (HFE-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006.

Regarding all nominations for the nonvoting representative of industry interests: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug

Administration, 7520 Standish Place, Rockville, MD 20855–2737, 301–295–8000.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for six members on the OTC Drugs Advisory Committee. The function of the committee is to review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner of Food and Drugs either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications. The committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status of these various drug products and combinations thereof. The committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

Persons nominated for membership shall be knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, and related specialties. The committee may include one technically qualified member who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. A representative of industry interests will serve as a nonvoting liaison. The term of office is 4 years, except that initial appointments will be staggered to permit an orderly rotation of membership.

Interested persons may nominate one or more qualified persons for membership on the advisory committee. Nominations shall state that the nominee is willing to serve as a member of the advisory committee and appears to have no conflict of interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation or possible sources of conflict of interest.

Selection of a representative of consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for screening, interviewing, and recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Regarding nominations for a nonvoting member representing industry interests, a letter will be sent to each person who has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization indicating an interest in participating in the selection process to consult with the others in selecting a single member representing industry interests within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

FDA has special interest in assuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and therefore extends particular encouragement to nominations for appropriately qualified female, minority, or physically handicapped candidates.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. App. 2), section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394) as amended by the Food and Drug Administration Revitalization Act (Pub. L. 101–635), and 21 CFR part 14, relating to advisory committees.

Dated: September 16, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91–22984 Filed 9–23–91; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91F–0342]

Ciba Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2,2'-methylenebis(4-methyl-6-*tert*-butylphenol)monoacrylate as a stabilizer for adhesives intended for use in food-contact applications.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

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 petition (FAP 1B4284) has been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188.

The petition proposes to amend the food additive regulations to provide for the use of 2,2'-methylenebis(4-methyl-6-*tert*-butylphenol)monoacrylate as a stabilizer for adhesives complying with § 175.105 *Adhesives* (21 CFR 175.105) and § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) intended for use in food-contact applications.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: September 16, 1991.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91–22942 Filed 9–23–91; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91P–0335]

Canned Tuna Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Bumble Bee Seafoods, Inc., to market test products designated as "chunk light tuna with jalapeno in water" and "chunk light tuna with jalapeno in oil"

that deviate from the U.S. standard of identity for canned tuna (21 CFR 161.190). The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the products, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than December 23, 1991.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFF–414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0106.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identify promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Bumble Bee Seafood, Inc., 5775 Rosco Ct., San Diego, CA 92123.

The permit covers limited interstate marketing tests of canned tuna products formulated by adding chopped or diced jalapeno peppers that have been previously prepared and packed in brine. The food deviates from the U.S. standard of identity for canned tuna (21 CFR 161.190) in that the products contain diced or chopped green jalapeno peppers. The amount of Jalapeno peppers added will not exceed 10 percent of the water capacity of the can. Jalapeno peppers will replace part of the liquid (water or oil) and will not affect the tuna fish fill portion. The test products meet all requirements of the standards with the exception of this deviation. Because test preferences vary by area, along with social and environmental differences, the purpose of the permit is to test the product in various states in the southwestern United States.

For the purpose of this permit, the names of the products are "chunk light tuna with jalapeno in water" and "chunk light tuna with jalapeno in oil." The information panels of the labels will bear nutrition labeling in accordance with 21 CFR 101.9.

This permit provides for the temporary marketing of 300,000 cases containing 24 cans of tuna with jalapeno peppers in spring water, each can weighing 175 grams (g)(6⅛ ounces), and 300,000 cases containing 24 cans of tuna with jalapeno peppers in soybean oil, each can weighing 175 g (6⅛ ounces). The products will be manufactured at Bumble Bee Seafoods, Inc., Santa Fe Springs, CA 90067, and Bumble Bee International, Inc., Mayaguez, Puerto Rico 00708. The products will be distributed in Arizona, California, Colorado, Nevada, New Mexico, and Texas.

Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the foods are introduced or caused to be introduced into interstate commerce, but not later than December 23, 1991.

Dated: September 13, 1991.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91–22943 Filed 9–23–91; 8:45 am]

BILLING CODE 4160–01–M

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Meeting, National Advisory Board for Arthritis and Musculoskeletal and Skin Diseases

Pursuant to Public Law 92–463, notice is hereby given of this meeting of the National Advisory Board for Arthritis and Musculoskeletal and Skin Diseases on October 27, 1991. The meeting will be held at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814. The board will meet October 27, 7 p.m. to approximately 10 p.m.

The meetings, which will be open to the public, are being held to discuss the Board's activities and to continue evaluation of the National effort to combat arthritis and musculoskeletal and skin diseases. Attendance by the public will be limited to space available.

Ms. Geraldine B. Pollen, Executive Director, National Advisory Board for Arthritis and Musculoskeletal and Skin Diseases, 1801 Rockville Pike, suite 500, Rockville, Maryland 20852, (301) 496–6045, will provide on request an agenda and roster of the members. Summaries of the meeting may also be obtained by contacting her office.

Dated: September 17, 1991.

Samuel C. Rawling,

Acting NIH Committee Management Officer.

[FR Doc. 91–22924 Filed 9–23–91; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Extension of Public Comment Period on the Draft Revised Recovery Plan for the Southern Sea Otter

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Draft revised recovery plan; extension of public comment period.

SUMMARY: The U.S. Fish and Wildlife Service (Service), under the Endangered Species Act of 1973, as amended (Act), gives notice that the public comment period on the draft revised recovery plan for the southern sea otter (*Enhydra lutra nereis*) is extended for 30 days.

DATES: The comment period on the draft revised recovery plan for the southern sea otter is extended until November 1, 1991. Comments on the draft must be received on or before this date.

ADDRESSES: Persons wishing to review the draft revised recovery plan may obtain a copy by written request addressed to the Ventura Field Office, U.S. Fish and Wildlife Service, 2140 Eastman Avenue, suite 100, Ventura, California, 93003, or the Assistant Regional Director, Fish and Wildlife Enhancement, U.S. Fish and Wildlife Service, 911 NE. 11th Avenue, Portland, Oregon 97232–4181. Written comments and materials regarding the plan should be addressed to Mr. Carl Benz at the above Ventura, California address. Comments and materials received are available upon request for public inspection, by appointment, during normal business hours at the above Ventura, California address.

FOR FURTHER INFORMATION CONTACT: Mr. Carl Benz at the above Ventura, California address (telephone 805–644–1766 or FTS 983–6039).

SUPPLEMENTARY INFORMATION:

Background

Restoring endangered or threatened animals and plants to the point where they are again secure self-sustaining members of their ecosystems is a primary goal of the Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for the conservation of the species, establish criteria for the recovery levels for downlisting or delisting them, and estimate time and cost for implementing the recovery measures needed.

The Act requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4 (f) of the Act requires that public notice and an opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during the public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will also take these comments into account in the course of implementing approved recovery plans.

The southern (California) sea otter was listed as threatened in 1977 under the Federal Endangered Species Act. It is also recognized as a depleted population pursuant to the Marine Mammal Protection Act. Reduced range and population size, vulnerability to oil spills, and the oil spill risk from coastal tanker traffic were the primary reasons for the threatened status. The southern sea otter population contains about 2,000 individuals and ranges between Point Ano Nuevo south to Pismo Beach. About 14 otters are at San Nicolas Island as a result of translation efforts to establish an experimental population. After review of new biological information, the Service, with assistance of the Southern Sea Otter Recovery Team, has drafted for public review and comment a revised recovery plan.

The Service solicits written comments on the recovery plan described. All comments received by the date specified will be considered prior to approval of the plan.

Authority

The authority for this action in section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: September 3, 1991.

William E. Martin,

Acting Regional Director, U.S. Fish and Wildlife Service, Region 1.

[FR Doc. 91-22895 Filed 9-23-91; 8:45 am]

BILLING CODE 4310-55-M

Bureau of Land Management

[NV-010-91-4370-12]

Hearing on Use of Helicopters in Wild Horse Roundups on the Elko District in FY 1992

Notice is hereby given in accordance with section 9 of public law 92-165 that a hearing on the use of helicopters in gathering wild horses and burros, from areas on the Elko District, will be held on October 15, 1991. The hearing will start at 1 p.m. at the Elko District BLM office.

For further information contact: Rodney Harris, District Manager, P.O. Box 831, Elko, Nevada 89801 or phone (702) 753-0200.

Dated: September 13, 1991.

Nancy Phelps,

Acting District Manager.

[FR Doc. 91-22923 Filed 9-23-91; 8:45 am]

BILLING CODE 4310-HC-M

[ID-010-01-4320-02-ADVB]

Boise District Grazing Advisory Board; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting Idaho.

SUMMARY: The Boise District Grazing Advisory Board will meet November 6, 1991 to discuss the proposed expenditure of Range Improvement (8100) Funds for Fiscal Year 1992. Election of Grazing Advisory Board officers will be held. The meeting is open to the public and a comment period will be held at 2 p.m.

DATES: The meeting will begin at 9 a.m. on Wednesday, November 6, in the district office conference room.

ADDRESSES: The Boise District Office is located at 3948 Development Avenue, Boise, Idaho 83705.

FOR FURTHER INFORMATION CONTACT: Fred Schley, Boise District, BLM (208) 384-3457.

Dated: September 16, 1991.

Rodger E. Schmitt,

Associate District Manager.

[FR Doc. 91-22938 Filed 9-23-91; 8:45 am]

BILLING CODE 4310-66-M

[CA-060-01-4410-04-ADVB]

Meeting of the California Desert District Advisory Council

SUMMARY: Notice is hereby given, in accordance with Public Laws 92-463 and 94-579, that the California Desert District Advisory Council to the Bureau of Land Management, U.S. Department of the Interior, will meet in formal session Thursday, October 24, 1991, from 8:30 a.m. to 5 p.m., and Saturday, October 26, 1991, from 8 a.m. to 2:30 p.m., in the American Legion Hall in Lone Pine, California.

Agenda items for the meetings will include:

—An overview of the California Desert District's budget for Fiscal Year 1992.
—A status review of the 1989/1990 California Desert Conservation Area Plan amendments.
—Discussion of the 1991 California Desert Conservation Area Plan Recreation Element Amendment, with recommendations from the Council on the preferred amendment.
—An update on and discussion of the Draft South Coast Resource Management Plan.
—A report from the California Desert District's Futuring committee.
—A review and update on the current status of BLM's Wilderness package after the Congressional hearings.
—A briefing on the West Mojave Tortoise Management Plan.

All formal meetings are open to the public. Time is allocated for public comments, and time also may be made available by the Council Chairman during the presentation of various agenda items.

On Friday, October 25, from 7:30 a.m. to 5 p.m., Council members will participate in a field trip through Saline Valley to the Eureka Sand Dunes, with scheduled stops at Hunter Mountain, Hunter Canyon, and Waucoba Wash. The tour will focus on the management programs for each area.

The public is welcome to participate in the field tour, but should plan on providing their own transporation and drinks, as well as lunch on Friday. Anyone interested in participating should contact BLM at (714) 653-6950 for more information. The tour will assemble at the Dow Villa Motel at 7:15 a.m.

Written comments may be filed in advance of the meeting with the California Desert District Advisory Council Chairman, Mr. David Fisher, c/o Bureau of Land Management, Public Affairs Office, 6221 Box Springs Boulevard, Riverside, California 92507-0714. Written comments are also accepted at the time of the meeting and, if copies are provided to the recorder, will be incorporated into the minutes.

FOR FURTHER INFORMATION AND MEETING CONFIRMATION: Contact the Bureau of Land Management, California Desert District, Public Affairs Office, 6221 Box Springs Boulevard, Riverside, California 92507; (714) 653-6950.

Dated: September 19, 1991.

Gerald E. Hillier,

District Manager.

[FR Doc. 91-23110 Filed 9-23-91; 8:45am]

BILLING CODE 4310-40-M

[NV-930-91-4212-14; N-53988]

Non-Competitive Sale of Public Lands in Clark County, NV; Realty Action

The following described public land in Henderson, Clark County, Nevada has been determined to be suitable for sale utilizing non-competitive procedures, at not less than the fair market value. Authority for the sale is section 203 of Public Law 94-579, the Federal Land Policy and Management Act of 1976 (FLPMA). The lands will not be offered for sale until at least 60 days after the date of publication of this notice in the Federal Register.

Mount Diablo Meridian, Nevada

T. 21 S., R. 62 E.,
Sec. 35: NE¼SW¼
Aggregating 32.789 acres (gross).

This parcel of land, situated in Henderson is being offered as a direct sale to the city of Henderson.

This land is not required for any federal purposes. The sale is consistent with the Bureau's planning system. The sale of this parcel would be in the pubic interest.

In the event of a sale, conveyance of the available mineral interests will occur simultaneously with the sale of the land. The mineral interests being offered for conveyance have no know mineral value. Acceptance of a direct sale offer will constitute an application for conveyance of mineral interests. The applicant will be required to pay a $50.00 non-returnable filing fee for conveyance of the available mineral interests.

The patent, when issued, will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, Act of August 30, 1890, 26 Stat. 391, 43 U.S.C. 945.

2. Oil, gas, sodium potassium and saleable minerals.

and will be subject to:

1. An easement for streets, roads and public utilities in accordance with the transportation plan for Clark County.

2. Those rights for Airports marker purposes which have been granted to Federal Aviation Administration by Permit No. N-4245 under the Authority of 44 LD513.

3. Those rights for natural gas pipeline purposes which have been granted to Southwest Gas Corporation by Permit No. NEV-015814 under section 28 of the Mineral Leasing Act of 1920.

4. Those rights for water pipeline purposes which have been granted to Las Vegas Valley Water District by Permit No. NEV-043457 under the Act of October 21, 1976.

5. Those rights for access road purposes which have been granted to the City of Henderson by Permit No. N-31767 under the Act of October 21, 1976.

Upon publication of this notice in the **Federal Register**, the above described land will be segregated from all forms of appropriation under the public land laws, including the general mining laws. This segregation will terminate upon issuance of a patent or 270 days from the date of this publication, whichever occurs first.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Las Vegas District, P.O. Box 26569, Las Vegas, Nevada 89126. Any adverse comments will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, this realty action will become the final determination of the Department of the Interior. The Bureau of Land Management may accept or reject any of all offers, or withdraw any land or interest in the land from sale, if, in the opinion of the authorized officer, consummation of the sale would not be fully consistent with Public Law 94-579, or other applicable laws.

Dated: September 13, 1991.

William T. Combs,

Acting District Manager.

[FR Doc. 91-22939 Filed 9-23-91; 8:45am]

BILLING CODE 4310-HC-M

National Park Service

Baird Mountains, AK; Meeting

AGENCY: National Park Service, Interior.

ACTION: Public hearing regarding a proposed temporary closure of the federal subsistence sheep season in a portion of GMU 23.

SUMMARY: A public hearing is scheduled regarding a proposed temporary closure of the federal subsistence sheep season in a portion of GMU 23. Such a meeting is required for compliance with the temporary subsistence management regulations for public lands in Alaska (36 CFR 242.17 and 50 CFR 100.17. The purpose of the meeting will be to inform the public of the Federal Subsistence Board's intent to extend the closure and to hear public comment on the issue.

BACKGROUND: Three consecutive severe winters and a dramatic decline in sheep populations in 1991 require that federal subsistence seasons for sheep in the Baird Mountains unit of Game Management Unit 23 be closed for the 1991–92 regulatory year. The Federal Subsistence Board issued an emergency closure for the Baird Mountain Unit, effective August 10, 1991. The 60-day emergency closure expires on October 8, 1991, but may be extended if it is determined, after notice and hearing, that the closure should be extended. Based on biological data collected by the Alaska Department of Fish and Game and the National Park Service, the Board believes that the closure should be extended through the end of the 1991–92 regulatory year. The state Game Board has taken similar action by closing the state general sheep hunting season in the same area through the 1991–92 regulatory year.

DATES/LOCATION: The meeting will be held Tuesday, September 24, 1991, at 7:30 p.m. in the National Park Service Visitor Center, Kotzebue, Alaska.

FOR FURTHER INFORMATION CONTACT: Louis R. Waller, National Park Service, Alaska Regional Office, 2525 Gambell Street, room 107, Anchorage, Alaska 99503–2892, telephone: (907) 257–2646; or, Ralph Tingey, National Park Service, PO Box 1029, Anchorage, Alaska 99752, telephone: (907) 442–3890.

John M. Morehead,

Regional Director.

[FR Doc. 91–22654 Filed 9–23–91; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF JUSTICE

Lodging a Final Judgment by Consent Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

Notice is hereby given that on September 6, 1991 a proposed consent decree in *United States* v. *Beazer East, Inc., et al.* was lodged with the United States District Court for the Northern District of Ohio. The decree pertains to the Summit National Site in Deerfield Township, Portage County, Ohio.

The proposed consent decree requires Beazer East, Inc. to pay the United States $2,422,730.57, plus interest on the sum of $2,400,000 accruing from December 13, 1990 at the Superfund interest rate (7.99% per annum for the 1991 fiscal year), which equals 95% of the costs sought in the Civil Action.

The Department of Justice will receive comments relating to the proposed consent decree for a period of thirty days from the date of publication of this notice. Comments should be addressed to the Assistance Attorney General, Environment and Natural Resources Division, Department of Justice, Washington, DC, 20530, and should refer

to *United States* v. *Beazer East, Inc., et al.* (N.D. Ohio) and DOJ Ref. No. 90–11–2–318A. The proposed consent decree may be examined at the office of the United States Attorney, Northern District of Ohio, Akron Office, 2 South Main Street, Akron, Ohio, 44308, or at the office of the Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois, 60604. A copy of the proposed consent decree may also be examined at the Environmental Enforcement Section Document Center, 601 Pennsylvania, Avenue NW., Box 1097, Washington, DC 20004, (202) 347–7829. A copy of the proposed consent decree may be obtained in person or by mail from the Document Center. In requesting a copy please enclose a check in the amount of $3.00 (25 cents per page reproduction costs) payable to "Consent Decree Library".

Barry M. Hartman,

Acting Assistant Attorney General, Environment and Natural Resources Division.

[FR Doc. 91–22937 Filed 9–23–91; 8:45 am]

BILLING CODE 4410–01–M

Lodging of Consent Decree Under the Clean Air Act

In accordance with Department policy, 28 CFR 50.7, notice is hereby given that on the 10th day of September 1991, a proposed Consent Decree in *United States* v. *Nevada Power Company*, CV–S–87–861–RDF (D. Nev.), was lodged with the United States District Court for the District of Nevada. The Complaint sought civil penalties and injunctive relief against Nevada Power Company, pursuant to sections 111 and 114 of the Clean Air Act ("Act"), 42 U.S.C. 7411 and 42 U.S.C. 7414, respectively, and the new Source Performance Standards, at 40 CFR part 60, subparts A, D and Da.

The proposed Consent Decree requires Nevada Power Company to pay $400,000 in settlement of the United States' claims for civil penalties. The defendant is subject to a one year injunction against violation of the Act and/or the New Source Performance Standards. The decree requires payment of stipulated penalties in the event of violation of certain emission standards applicable to opacity and particulate matter.

For thirty (30) days from the date of publication of this notice, the Department of Justice will receive written comments relating to the Consent Decree from persons who are not parties to the action. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, Washington, DC 20530 and should refer to *United States* v. *Nevada Power Company*, D. J. Ref. No. 90–5–2–1–1148.

The proposed Consent Decree may be examined at the office to the United States Attorney, District of Nevada, 701 East Bridger Avenue, suite 800, Las Vegas, Nevada, 89101, and at the Region IX office of the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, California 94105.

A copy of the Consent Decree also may be examined at the Environmental Enforcement Section Document Center, 601 Pennsylvania Ave., NW., Box 1097, Washington, DC 20004, telephone number (202) 347–2072. A copy of the Consent Decree may be obtained in person or by mail from the Environmental Enforcement Section Document Center. In requesting a copy, please tender a check in the amount of $4.75 (25 cents per page reproduction charge) payable to "Consent Decree Library."

Barry M. Hartman,

Acting Assistant Attorney General, Environment and Natural Resources Division, United States Department of Justice.

[FR Doc. 91–22935 Filed 9–23–91; 8:45 am]

BILLING CODE 4410–01–M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the Office of Management and Budget Review of information collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paper Reduction Act (44 U.S.C. chapter 35).

1. *Type of submission, new, revision, or extension:* Revised.

2. *The title of the information collection:* Conforming Amendments to title 10 Code of Federal Regulations for Uranium Enrichment Regulation.

3. *The form number is applicable:* Not applicable.

4. *How often the collection is required:* Applications for licenses are submitted once.

5. *Who will be required or asked to report:* Applicants for a license for uranium enrichment.

6. *An estimate of the number of responses:* One response has currently been received. No other responses are anticipated from the commercial sector in the foreseeable future.

7. *An estimate of the total number of hours needed to complete the requirement or request:* Approximately 60,000 hours per licensee.

8. *An indication of whether section 3504(h), Public Law 96–511 applies:* Applicable.

9. *Abstract:* The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations concerning the licensing of uranium enrichment facilities to reflect changes made to the Atomic Energy Act of 1954, as amended (the Act) by the "Solar, Wind, Waste, and Geothermal Power Production Incentives Act of 1990," Public Law 101–575. The principal effect of these changes is that uranium enrichment facilities will be licensed subject to the provisions of the Act pertaining to source material and special nuclear material rather than the provisions pertaining to a production facility.

Copies of the submittal may be inspected or obtained for a fee from the NRC public Document Room, 2120 L Street, NW. (lower level), Washington, DC.

Comments and questions may be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs, (3150–0020, 3150–0011, 3150–0021, 3150–0009, 3150–0039), NEOB–3019, Washington, DC 20503.

Comments may also be communicated by telephone at (202) 395–3084.

The NRC Clearance Office is Brenda Jo. Shelton, (301) 492–8132.

Dated at Bethesa, Maryland, this 16th day of Sept., 1991.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 91–22958 Filed 9–23–91; 8:45 am]

BILLING CODE 7590–01–M

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection.

SUMMARY: The Nuclear Regulatory Commission has recently submitted to

OMB for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. *Type of submission, new, revision, or extension:* Revision.

2. *The title of the information collection:* 10 CFR parts 30, 40, 70, and 72; Decommissioning Recordkeeping and License Termination: Documentation Additions.

3. *The form number if applicable:* Not applicable.

4. *How often is the collection required:* Continuous update of the decommissioning listing until termination of license. One-time submittal of the list for those licensees requiring approval of a decommissioning plan. One-time submittal of a listing of all equipment to be left onsite at license termination

5. *Who will be required or asked to report:* 10 CFR parts 30, 40, 70 and 72 licensees.

6. *An estimate of the number of responses:* The majority of the approximately 9,000 NRC licensees will maintain the decommissioning listing documentation. An average of 8 licensees annually will submit the listing as part of their decommissioning plan. An average of 8 licensees annually will submit the equipment listings at license termination.

7. *An estimate of the number of hours annually needed to complete the requirement or request:* Two per licensee.

Note: Duration of license is for 5 years resulting in a 10 hour total response effort.

8. *An indication of whether section 3504(h), Public Law 96–511 applies:* Applicable.

9. *Abstract:* The proposed rule would require materials licensees to maintain a listing of all potential and known areas of radioactive contamination, including the location and content of onsite waste burial grounds. Also, additional information would be required prior to termination of license on the location and description of equipment involved in the licensed operation that is to remain onsite. For a very small number of licensees requiring decommissioning plans, this listing must accompany their decommissioning plan.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Comments and questions can be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs, (3150–0017, 3150–0020, 3150–0009, 3150–0132) NEOB–3109, Office of Management and Budget, Washington, DC. 20503

Comments may also be communicated by telephone at (202) 395–3084. The NRC Clearance Office is Brenda Jo. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 16th day of September 1991.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 91–22959 Filed 9–23–91; 8:45 am]

BILLING CODE 7590–01–M

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the Office of Management and Budget review of information collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. *Type of submission, (new, revision, or extension):* Revision.

2. *The title of the information collection:* NRC Form 171, " Paper to Paper Duplication Request", NRC Form 171A, "Microform Duplication Request", NRC Form 171B, "Microform to Paper Request".

3. *The form number if applicable:* NRC Forms 171, 171A and 171B.

4. *How often the collection is required:* On occasion.

5. *Who will be required or asked to report:* Individuals or companies requesting copies to be made by reproduction.

6. *An estimate of the number of responses:* 18,000 per year.

7. *An estimate of the total number of hours to complete the requirement or request:* 1,188 hours annually (18,000 forms × .066 hr/form) or about 4 minutes per individual.

8. *An indication of whether section 3504(h), Public Law 96–511 applies:* Not applicable.

9. *Abstract:* These forms are utilized by individual members of the public who request reproduction of publicly available documents in NRC's Headquarters Public Document Room (PDR). Copies are utilized by the reproduction contractor to accompany order and then discarded.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW., (Lower Level), Washington, DC.

Comments and questions can be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs 3150–0066, NEOB–3019, Officer of Management and Budget, Washington, DC 20503.

Comments can also be communicated by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 16th day of September 1991.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 91–22960 Filed 9–23–91; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–369]

Duke Power Co., McGuire Nuclear Station, Unit No. 1; Environmental Assessment and Finding of no Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from the provisions of 10 CFR 50.46, appendix K to 10 CFR part 50, and 10 CFR 50.44 to Duke Power Company (the licensee) for McGuire Nuclear Station, Unit No. 1, located in Mecklenburg County, North Carolina.

Environmental Assessment

Identification of Proposed Action: The proposed action would enable the licensee to use two demonstration fuel assemblies that contain some fuel rods whose zirconium based cladding composition is somewhat different from the zirconium based compound named Zircaloy. These demonstration assemblies would be loaded into McGuire Unit 1 during the upcoming September 1991 refueling outage and irradiated through fuel Cycles 8, 9, and 10.

The evaluation responds to the licensee's application dated April 18, 1991.

The Need for the Proposed Action: The proposed exemption to 10 CFR 50.46, appendix K to 10 CFR 50, and 10 CFR 50.44 is needed because these regulations specifically refer to light-water reactors containing fuel consisting of uranium oxide pellets enclosed in Zircaloy tubes. Zircaloy is a zirconium based alloy currently in use as cladding

for fuel pellets. A new zirconium based cladding has been developed which is not the same chemical composition as Zircaloy, and which the licensee wants to test in reactor operation. Since 10 CFR 50.46 and 10 CFR part 50 appendix K limit ECCS calculations to Zircaloy and 10 CFR 50.44 relates to the generation of hydrogen gas from a metal-water reaction with Zircaloy, exemption is required in order to place two demonstration assemblies in the core. The staff has reviewed the chemical composition of the new cladding and found no significant difference between the new composition and Zircaloy. Therefore, a special circumstance exists in which application of these regulations is not necessary to achieve the underlying purpose of the regulations and thus, an exemption is authorized by 10 CFR 50.12. The underlying purpose of 10 CFR 50.46 and 10 CFR part 50 appendix K is to establish requirements for calculations of emergency core cooling systems. The licensee addressed the safety impact of the demonstration assemblies on emergency core cooling system performance as part of the application for exemption and demonstrated that the new zirconium based cladding does not affect the ECCS calculations. The underlying purpose of 10 CFR 50.44 is to ensure that means are provided for the control of hydrogen gas that may be generated following a postulated loss-of-coolant accident. The licensee previously addressed hydrogen generation following a loss-of-coolant accident. The licensee's proposed action has no significant effect on the previous assessment of hydrogen gas production.

Environmental Impacts of the Proposed Action: With regard to potential radiological impacts to the general public, the proposed exemption involves features located entirely within the restricted area as defined in 10 CFR part 20. It does not affect the potential for radiological accidents and does not affect radiological plant effluents. The demonstration assemblies meet the same design bases as the fuel which is currently in the reactor. No safety limits have been changed or setpoints altered as a result of the use of these assemblies. the FSAR analyses are bounding for the demonstration assemblies as well as the remainder of the core. The advanced zirconium-based alloys have been shown through testing to perform satisfactorily under conditions representative of a reactor environment. In addition, the relatively small number of fuel rods involved does not represent a prohibitively large inventory of radioactive material which could be released into the reactor coolant in the event of cladding failure. The only credible consequence of this change would be a failure of the demonstration claddings. Even in the case of gross fuel failure, the number of rods involved (a maximum of 104 rods will use advanced clad compositions) is less than 1% of the core and thus, sufficiently small that environmental impact would be minimal, and is bounded by previous assessments. The small number of fuel rods involved in conjunction with the chemical similarity of the demonstration cladding to Zircaloy cladding ensures that hydrogen production would not be significantly different from previous assessments. As a result, the proposed exemption does not affect the consequences of radiological accidents. Consequently, the commission concludes that there are no significant radiological impacts associated with the proposed exemption.

With regard to the potential environmental impacts associated with the transportation of the demonstration assemblies, the advanced claddings have no impact on previous assessments determined in accordance with 10 CFR 51.52.

With regard to the potential nonradiological impacts, the proposed exemption does not affect nonradiological plant effluents and has no other environmental impact. Therefore, the commission concludes that there are no significant nonradiological environmental impacts associated with the proposed exemption.

Alternative to the Proposed Action: Because the commission's staff has concluded that there is no significant environmental impact associated with the proposed exemption, any alternative to this exemption will have either no significantly different environmental impact or greater environmental impact.

The principal alternative would be to deny the requested exemption. This would not reduce environmental impacts as a result of plant operations.

Alternative Use of Resources: This action does not involve the use of resources not previously considered in connection with the "Final Environmental Statement related to the operation of William B. McGuire Nuclear Station, Units 1 and 2," dated April 1976, and its addendum dated January 1981.

Agencies and Persons Consulted: The Commission's staff has reviewed the licensee's request that supports the proposed exemption. The staff did not consult other agencies or persons.

Finding of no Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed exemption.

Based upon the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the request for exemption dated April 18, 1991, which is available for public inspection at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC 20555 and at Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28223.

Dated at Rockville, Maryland this 16th day of September, 1991.

For the Nuclear Regulatory Commission.

David B. Matthews,

Director, Project Directorate II–3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 91–22961 Filed 9–23–91; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–366]

Georgia Power Co., et al. Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–5, issued to Georgia Power Company, et al. (the licensee), for operation of the Edwin I. Hatch Nuclear Plant, Unit 2 located in Appling County, Georgia.

The proposed amendment would involve a change to Hatch Unit 2 Technical Specification (TS) 3.3.6.6 for the Traversing Incore Probe (TIP) system. Specifically, the proposed change would require that three detectors be operable as opposed to the four required under TS 3.3.6.6. Also, Item c. of the applicability section is being deleted because the TIP system is no longer used to adjust the Average Power Range Monitor (APRM) setpoints.

The licensee stated that on September 8, 1991, during performance of rod maneuvers for the purpose of exchanging control rod sequences, it was discovered that the Hatch Unit 2 "C" TIP machine would not index properly due to a problem apparently associated with the indexing mechanism. Correcting the problem requires access to the primary

containment (drywell). However, with Unit 2 operating at 100% power, access is not possible at this time. The present TS requires four operable TIP machines for recalibration of the Local Power Range Monitor (LPRM) detectors every 31 Effective Full Power Days (EFPD). Performance of a core map within this period of time is necessary to maintain the validity and accuracy of the Periodic Core Performance Log (P1). P1 is the process computer program which calculates the Minimum Critical Power Ratio (MCPR), Linear Heat Generation Rate (LHGR) and Average Planar Linear Heat Generation Rate (APLHGR). Inability to determine compliance with these thermal limits per TSs 3.2.1, 3.2.3, and 3.2.4 would require reducing core thermal power to less than 25%.

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 woud 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. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The TIP system is not used to mitigate the consequences of or prevent any accident, nor are assumptions made in any accident analysis relative to the operation of the TIP system. Implementation of this proposed change will not change the function of any plant systems needed to prevent or mitigate the consequences of postulated accidents. Therefore, reducing the number of required Operable TIP machines from four to three and using substitute TIP traces for the calibration of LPRMs and the monitoring of thermal limits does not increase the probability of occurrence of a previously evaluated accident.

The change in power distribution determination in the process computer does not affect the consequences of anticipated operational occurrences (transients) described in the FSAR since the MCPR safety limit is not violated during the events. Provided the control rods are positioned in an "A" sequence and the total core TIP uncertainty for the cycle is less than or equal to 8.7%, neither the MCPR operating limit nor the safety limit need to be increased. The 8.7% uncertainty factor is the number used in the MCPR safety limit analysis (NEDE-24011-P-A-10, ["]General Electric Standard Application for Reactor Fuel," February, 1991). The current total core TIP uncertainty has been determined to be 8.1%, which does not exceed the 8.7% requirement.

Hatch Unit 2 has been operating in the octant symmetric "A" sequence since the beginning of the cycle. To provide an assessment of operating with the "C" TIP machine out of service, a simulation was performed to calculate the [e]ffect on thermal limits if a state point obtained before the inoperability of the "C" TIP was recalculated using the symmetric pairs in place of the "C" machine locations. The results of this simulation [shown elsewhere in the licensee's submittal dated September 13, 1991], indicate that the core is operating in a highly symmetric manner and that use of the substitute TIP readings will have a minimal affect on thermal limit calculatons. Hatch Unit 2 will continue to be operated in the "A" sequence for the duration of the "C" TIP outage. Plant procedures will be revised to reflect this.

Therefore, since the total core TIP uncertainty is acceptable and operation of Hatch Unit 2 will continue in the "A" sequence throughout the duration of the "C" TIP outage, reducing the number of required Operable TIP machines from four to three does not decrease the margin of safety to the MCPR operating and safety limits and the radiological dose consequences for previously analyzed accidents are not increased.

The proposed change which removes the reference to the ARPM setpoint is an administrative change. It reflects the fact that we [the licensee] no longer adjust the APRM trip or the APRM gain for high peaking factors. This change was made in 1984 and was done as part of the APRM/RBM [Rod Block Monitor] Technical Specification (ARTS) improvement program. Since neither plant operation nor equipment is being affected, this change does not increase the probabilty of occurrence of the consequences of a previously evaluated accident.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Using substitute TIP traces and changing the Hatch 2 Technical Specifications such that the TIP system is operable with three movable detectors does not change the basic operation of the plant. Nor does it change the operation of any safety related plant equipment.

Although the Process Computer will be operating differently in the calculation of core thermal limits, the difference only involves the assignment of incoming data to various arrays for the calculation of nodal powers, thermal limits, etc. Furthermore, the Process Computer is not required for the safe shutdown of the plant nor is is used for the mitigation of consequences of accidents. Therefore, changing this Technical Specification such that the TIP system is operable with three TIP machines does not increase the likelihood of an accident occurring different from any analyzed in the FSAR.

The proposed change removing the reference to APRM setpoint adjustment is administrative in nature, reflecting how the plant is actually operated. No changes to plant equipment or operation result from it, therefore, the probability of any accident occurring is not increased.

3. The proposed amendment does not result in a significant reduction in the margin of safety.

The margin of safety for some of the accidents analyzed in the FSAR is the Technical Specification fuel cladding integrity (MCPR) safety limit. This safety limit ensures that at least 99.9% of the fuel rods in the core will avoid transition boiling during an anticipated operational occurrence (transient). As documented in General Electric Generic Licensing Topical Report, GESTAR-II, the MCPR safety limit is based, in part, on a statistical combination of uncertainties in key parameters, including total core TIP uncertainty. As long as the total uncertainty is less than or equal to what was used to calculate the original MCPR safety limit (8.7%), the margin of safety is unchanged. Substitute TIP traces can be used to monitor thermal limits and calibrate LPRMs only if the core is loaded symmetrically and is operating with a symmetric, "A"sequence rod pattern.

The margin of safety is not reduced as a result of using this method because we [the licensee] have shown that the total core TIP uncertainty is less than 8.7% of the Hatch Unit 2 core is being operated in the "A" rod sequence. Unit 2 will continue to be operated in the "A" rod sequence at least until the return of the "C" TIP machine to service. Plant procedure will be revised to reflect this.

The proposed change to eliminate reference to the APRM setpoint adjustment is administrative in nature. No changes to plant equipment or plant operation results, thus the margin of safety is not reduced.

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 fifteen (15) days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written

comments may also be delivered to room P–223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By October 24, 1991, 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 20555 and at the local public document room located at Appling County Public Library, 301 City Hall Drive, Baxley, Georgia 31513.

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 a 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 interests. 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 fifteen (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 fifteen (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 contention 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 the amendment is issued before the expiration of 30 days, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, 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.

Normally, the Commission will not issue the amendment until the expiration of the 15-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 15-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. The Commission expects that the need to take this action will occur very infrequently.

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, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 325–6000 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to David B. Matthews: Petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Bruce W. Churchill, Esquire, Shaw, Pittman, and Trowbridge, 2300 N Street, NW., Washington, DC 20037 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 September 13, 1991, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room, located at Appling County Public Library, 301 City Hall Drive, Baxley, Georgia 31513.

Dated at Rockville, Maryland, this 17th day of September 1991.

For the Nuclear Regulatory Commission.

Kahtan N. Jabbour,

Project Manager, Project Directorate II–3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

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BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service; Consolidated Listing of Schedules A, B, and C Exceptions

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This gives a consolidated notice of all positions excepted under Schedules A, B, and C as of June 30, 1991, as required by Civil Service Rule VI, Exceptions from the Competitive Service.

SUPPLEMENTARY INFORMATION: Civil Service Rule VI (5 CFR 6.1) requires the Office of Personnel Management (OPM) to publish notice of all exceptions granted under Schedules A, B, and C. title 5, Code of Federal Regulations, § 213.103(c) further requires that a consolidated listing, current as of June 30 of each year, be published annually as a notice in the **Federal Register.** That notice follows. OPM maintains continuing information on the status of all Schedule A, B, and C excepted appointing authorities. Interested parties needing information about specific authorities during the year may obtain information by contacting the Staffing Operations Division, room 6A12, Office of Personnel Management, 1900 E Street, NW., Washington, DC 20415, or by calling (202) 606–0950.

The following exceptions were current on June 30, 1991.

Schedule A

Section 213.3102 Entire Executive Civil Service

(a) Positions of Chaplain and Chaplain's Assistant.

(b) (Reserved).

(c) Positions to which appointments are made by the President without confirmation by the Senate.

(d) Attorneys.

(e) Law clerk trainee positions. Appointments under this paragraph shall be confined to graduates of recognized law schools or persons having equivalent experience and shall be for periods not to exceed 14 months pending admission to the bar. No person shall be given more than one appointment under this paragraph. However, an appointment which was initially made for less than 14 months may be extended for not to exceed 14 months in total duration.

(f) Chinese, Japanese, and Hindu interpreters.

(g) Any nontemporary position the duties of which are part-time or intermittent in which the appointee will receive compensation during his or her service year that aggregates not more than 40 percent of the annual salary rate for the first step of grade GS–3. This limited compensation includes any premium pay such as for overtime, night, Sunday, or holiday work. It does not, however, include any mandatory within-grade salary increases to which the employee becomes entitled subsequent to appointment under this authority. Appointments under this authority may not be for temporary project employment.

(h) Positions in Federal mental institutions when filled by persons who have been patients of such institutions and have been discharged and are certified by an appropriate medical authority thereof as recovered sufficiently to be regularly employed but it is believed desirable and in the interest of the persons and the institution that they be employed at the institution.

(i) Subject to prior approval of OPM, positions requiring temporary, part-time, or intermittent employment in wage board type occupations (i.e., position excluded from Classification Act coverage by section 202(7) of the Act) on construction or repair work, where the activity is carried on in localities where examination coverage for the positions has not been provided and where because of employment conditions there is a shortage of available candidates for the positions. Appointments under this paragraph shall not extend beyond 1 year and the employment thereunder shall not exceed 180 working days a year. Seasonal employments of a recurring nature are not authorized under this paragraph.

(j) Positions filled by (1) appointment of persons previously employed as National Guard Technicians under 32 U.S.C. 709(a) in positions at the same or equivalent grade level, or below, who are applying for or receiving an annuity under the provisions of 5 U.S.C. 8337(h) or 5 U.S.C. 8457 by reason of a disability that disqualifies them from membership in the National Guard or from holding the military grade required as a condition of their National Guard employment; or (2) reassignment, promotion, or demotion within the same agency of former National Guard Technicians originally appointed under this authority.

(k) Positions without compensation provided appointments thereto meet the requirements of applicable laws relating to compensation.

(l) Positions requiring the temporary or intermittent employment of professional, scientific, or technical experts for consultation purposes.

(m) Nonsupervisory positions of custodial laborer (levels 1, 2, and 3) and general laborer (levels 2 and 3) in field establishments outside central office and regional office cities of OPM where examination coverage has not been provided for the positions, as follows:

(1) For temporary, intermittent, or seasonal employment (exclusive of positions covered by paragraph (1) of this section) not to exceed 180 working days a year in the Departments of Agriculture, Commerce, Interior, and Energy, in the Federal Aviation Agency, and in the International Boundary and Water Commission; or

(2) When it is specifically held by OPM that this authority is applicable for employment in localities that are isolated with respect to labor supply and where there is a shortage of available candidates for the positions.

(n) Any local physician, surgeon, or dentist employed under contract or on a part-time or fee basis.

(o) Positions of a scientific, professional, or analytical nature when filled by bona fide members of the faculty of an accredited college or university who have special qualifications for the positions to which appointed. Employment under this provision shall not exceed 130 working days a year.

(p) Positions of a scientific, professional, or analytical nature when filled by bona fide graduate students at accredited colleges or universities provided that the work performed for

the agency is to be used by the student as a basis for completing certain academic requirements toward a graduate degree. Appointments under this authority may not exceed 1 year, but may be extended for additional period(s) not to exceed 1 year as long as the conditions for appointment continue to be met. The appointment of any individual under this authority shall terminate upon the individual's completion of requirements for the graduate degree.

(q) Positions at grade GS–9, or equivalent, and below when appointees are to assist scientific, professional, or technical employees. Persons employed under this provision shall be (1) bona fide high school science or mathematics teachers; or (2) bona fide students at high schools or accredited colleges or universities who are pursuing courses related to the field in which employed. The appointment of any individual under this authority shall terminate upon the individual's ceasing to be enrolled in a qualifying educational program or to be employed as a teacher. No one shall be employed under this provision in routine clerical positions, routine trades and labor positions—unless such employment clearly relates to a scientific, professional, or technical curriculum—or in excess of 1,040 working hours a year. Appointments under this authority may be made only to positions for which qualification standards established under 5 CFR part 302 are consistent with the education and experience standards established for comparable positions in the competitive service. Appointments under this authority may not be used to extend the service limits contained in any other appointing authority.

(r)–(s) (Reserved).

(t) Positions when filled by mentally retarded persons in accordance with the guidance in Federal Personnel Manual chapter 306. Upon completion of 2 years of satisfactory service under this authority, the employee may qualify for conversion to competitive status under the provisions of Executive Order 12125 and implementing regulations issued by OPM.

(u) Positions when filled by severely physically handicapped persons who: (1) Under a temporary appointment have demonstrated their ability to perform the duties satisfactorily; or (2) have been certified by counselors of State vocational rehabilitation agencies or the Veterans' Administration as likely to succeed in the performance of the duties. Upon completion of 2 years of satisfactory service under this authority, the employee may qualify for conversion to competitive status under the provisions of Executive Order 12125 and implementing regulations issued by OPM.

(v) Between May 13 and September 30 only, temporary Summer Aid positions the duties of which involve work of a routine nature not regularly covered under the General Schedule requiring no specific knowledge or skills, when filled by youths, either (1) appointed under economic needs standards prescribed by OPM; or (2) who are mentally retarded or severely physically handicapped. Youths may not be appointed unless they have reached their 16th birthday. This paragraph shall apply only to positions for which pay is fixed at the highest Federal minimum wage rate established by the Fair Labor Standards Act of 1938, as amended.

(w) Part-time or intermittent positions, the duties of which involve routine work up to and including the GS–4 level of difficulty or equivalent under the Federal Wage System, when filled by bona fide students appointed under the Stay-in-School Program. Students may be appointed if they need the earnings from this employment to continue in school or if they are mentally retarded or severely physically handicapped, provided that the following conditions are met: (1) Appointees are enrolled in or accepted for enrollment as a resident student in a secondary school (or other appropriate school for mentally retarded students) or an institution of higher learning not above the baccalaureate level, accredited by a recognized accrediting body;

(2) Employment does not exceed 20 hours in any calendar week except that students may work full time during any period in which their school is officially closed and during any school vacation period.

(3) While employed, appointees continue to maintain an acceptable school standing, although they need not attend school during the summer;

(4) Appointees meet the economic criteria prescribed by the Office of Personnel Management, except that this requirement does not apply to mentally retarded or severely physically handicapped students appointed under the authority; and

(5) Salaries are fixed by the agency head at a level commensurate with the duties assigned and the expected level of performance.

Appointments under this authority may not extend beyond 1 year. However, such appointments may be made for additional periods of not to exceed 1 year, each, if the conditions for initial appointment are still met. Students may not be appointed under this authority unless they have reached their 16th birthday. No new appointments may be made between May 13 and August 31, inclusive.

(x) Positions for which a local recruiting shortage exists when filled by inmates of Federal, District of Columbia, and State (including the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands) penal and correctional institutions under workrelease programs authorized by the Prisoner Rehabilitation Act of 1965, the District of Columbia Work Release Act, or under work-release programs authorized by the States. Initial appointments under this authority may not exceed 1 year. An initial appointment may be extended for one or more periods not to exceed one additional year each upon a finding that the inmate is still in a work-release status and that a local recruiting shortage still exists. No person may serve under this authority longer than 1 year beyond the date of that person's release from custody.

(y) Positions at grade GS–2 and below for summer employment as defined in § 213.3101(d), of assistants to scientific, professional, and technical employees, when filled by finalists in national science contests.

(z) Not to exceed 30 positions of assistants to top-level Federal officials when filled by persons designated by the President as White House Fellows.

(aa) Scientific and professional research associate positions at GS–11 and above when filled on a temporary basis by persons having a doctoral degree in an appropriate field of study for research activities of mutual interest to appointees and their agencies. Appointments are limited to persons referred by the National Research Council under its postdoctoral research associate program, may not exceed 2 years, and are subject to satisfactory outcome of evaluation of the associate's research during the first year.

(bb) Positions when filled by aliens in the absence of qualified citizens. Appointments under this authority are subject to prior approval of OPM except when the authority is specifically included in a delegated examining agreement with OPM.

(cc) Positions at GS–15 and below when filled by persons identified as Interchange Executives by the President's Commission on Executive Exchange. Appointments made under this authority may not extend beyond 2 years.

(dd)–(ee) (Reserved).

(ff) Not to exceed 25 positions when filled in accordance with an agreement

between OPM and the Department of Justice by persons in programs administered by the Attorney General of the United States under Public Law 91–452 and related statutes. A person appointed under this authority may continue to be employed under it after he/she ceases to be in a qualifying program only as long as he/she remains in the same agency without a break in service.

(gg)–(hh) (Reserved).

(ii) Positions of Presidential Intern, GS–9 and 11, in the Presidential Management Intern Program. Initial appointments must be made at the GS–9 level. No one may serve under this authority for more than 2 years, unless extended with OPM approval for up to 1 additional year. Upon completion of 2 years of satisfactory service under this authority, the employee may qualify for conversion to competitive appointment under the provisions of Executive Order 12364, in accordance with requirements published in the Federal Personnel Manual.

(jj) Legal intern positions. Appointments under this paragraph shall be confined to bona fide students at recognized law schools who are candidates for J.D. or LL.B. degrees. Appointments under this authority may not exceed 1 year, but may be extended for additional period(s) not to exceed 1 year as long as the conditions for appointment continue to be met. The appointment of an individual under this authority shall terminate upon the individual's graduation from law school.

(kk) (Reserved).

(ll) Positions as needed of readers for blind employees, interpreters for deaf employees and personal assistants for handicapped employees, filled on a full-time, part-time, or intermittent basis.

Section 213.3103 Executive Office of the President

(a) *Office of Administration.* (1) Not to exceed 75 positions to provide administrative services and support to the White House office.

(b) *Office of Management and Budget.* (1) Not to exceed 10 positions at grades GS–9/15.

(c) *Council on Environmental Quality.* (1) Professional and technical positions in grades GS–9 through –15 on the staff of the Council.

(d)-(f) (Reserved).

(g) *National Security Council.* (1) All positions on the staff of the Council.

(h) *Office of Science and Technology Policy.* (1) Thirty positions of Senior Policy Analyst, GS–15; Policy Analyst, GS–11/14; and Policy Research Assistant, GS–9, for employment of anyone not to exceed 5 years on projects of a high priority nature.

(i) *Office of National Drug Control Policy.* (1) Not to exceed 35 positions, GS–15 and below, of senior policy analysts and other personnel with expertise in drug-related issues and/or technical knowledge to aid in anti-drug abuse efforts. Appointments under this authority may not exceed January 20, 1994.

Section 213.3104 Department of State

(a) *Office of the Secretary.* (1) All positions, GS–15 and below, on the staff of the Family Liaison Office, Office of the Under Secretary for Management.

(2)-(5) (Reserved).

(b) *American Embassy, Paris, France.* (1) Chief, Travel and Visitor Unit. No new appointments may be made under this authority after August 10, 1981.

(c) (Reserved).

(d) *International Boundary Commission, United States and Canada.* (1) Temporary 'and intermittent field employees such as instrumentmen, foremen, recorders, packers, cooks, and axemen, for not to exceed 180 working days within any one calendar year.

(e) *Bureau of Oceans and International Environmental and Scientific Affairs.* (1) Two Physical Science Administration Officer positions at GS–16.

(f) (Reserved).

(g) *Office of Refugee and Migration Affairs.* (1) Not to exceed 10 positions at grades GS–5 through 11 on the staff of the office.

(h) *Bureau of Administration.* (1) One Presidential Trip Specialist. No new appointments may be made under this authority after June 11, 1981.

Section 213.3105 Department of the Treasury

(a) *Office of the Secretary.* (1) Not to exceed 20 positions at the equivalent of GS–13 through GS–17 to supplement permanent staff in the study of complex problems relating to international financial, economic, trade, and energy policies and programs of the Government, when filled by individuals with special qualifications for the particular study being undertaken. Employment under this authority may not exceed 4 years.

(2) Not to exceed 20 positions, which will supplement permanent staff involved in the study and analysis of complex problems in the area of domestic economic and financial policy. Employment under this authority may not exceed 4 years.

(b) *U.S. Customs Service.* (1) Positions in foreign countries designated as "interpreter-translator" and "special employees," when filled by appointment of persons who are not citizens of the United States; and positions in foreign countries of messenger and janitor.

(2) (Reserved).

(3) Positions of part-time, intermittent, or temporary Customs Inspectors, and Port Directors in Alaska paid at a rate not above GS–9 and for not more than 130 working days in a service year.

(4) (Reserved).

(5) Positions at GS–9 and below of Customs Enforcement Officer, Customs Inspector, Customs Marine Clerk/Officer, Customs Aid (sampling), Customs Warehouse Officer, Port Director, Interpreter, and Laborer, with duties of a continuing nature that require the part-time or intermittent service of an employee for not more than 700 hours in his/her service year. An individual appointed under this exception may not be employed in the Bureau of Customs under a combination of this and any other exception for more than 700 hours in his/her service year.

(6) Twenty-five positions of Criminal Investigator for special assignments.

(7)-(8) (Reserved).

(9) Not to exceed 25 positions of Customs Patrol Officers in the Papago Indian Agency in the State of Arizona when filled by the appointment of persons of one-fourth or more Indian blood.

(c) *Office of the Comptroller of the Currency.* (1) Not to exceed six positions filled under the Professional Accounting Fellow Program. Appointments under this authority may not exceed 2 years.

(d) *Office of Thrift Supervision.* (1) All positions in the supervision policy and supervision operations functions of OTS. No new appointments may be made under this authority after October 8, 1992.

(e) *Internal Revenue Service.* (1) Twenty positions of investigator for special assignments.

(2) Two positions of Senior Visiting Pension Actuary, GS–1510–14/15. Appointments to these positions must be for periods not to exceed 24 months.

(f) (Reserved).

(g) *Bureau of Alcohol, Tobacco, and Firearms.* (1) One hundred positions of criminal investigator for special assignments.

(h) (Reserved).

(i) *Bureau of Government Financial Operations.* (1) Clerical positions at grades GS–5 and below established in Emergency Disbursing Offices to process emergency payments to victims of catastrophes or natural disasters requiring emergency disbursing services. Employment under this authority may not exceed 1 year.

Section 213.3106 Department of Defense

(a) *Office of the Secretary.* (1) Not to exceed 30 positions at grades GS–6/15 in the Office of Emergency Operations (OEO). No new appointments may be made under this authority after March 31, 1993.

(2)-(5) (Reserved).

(6) One Executive Secretary, US–USSR Standing Consultative Commission and Staff Analyst (SALT), Office of the Assistant Secretary of Defense (International Security Affairs).

(b) *Entire Department (including the Office of the Secretary of Defense and the Departments of the Army, Navy, and Air Force).* (1) Professional positions in Military Dependent School Systems overseas.

(2) Positions in attaché 1 systems overseas, including all professional and scientific positions in the Naval Research Branch Office in London.

(3) Positions of clerk-translator, translator, and interpreter overseas.

(4) Positions of Educational Specialist the incumbents of which will serve as Director of Religious Education on the Staffs of the Chaplains in the military services.

(5) Positions under the program for utilization of alien scientists approved under pertinent directives administered by the Director of Defense Research and Engineering of the Department of Defense when occupied by alien scientists initially employed under the program including those who have acquired United States citizenship during such employment.

(6) Positions in overseas installations of the Department of Defense when filled by dependents of military or civilian employees of the U.S. Government residing in the area. Employment under this authority may not extend longer than 2 months following the transfer from the area or the separation of a dependent's sponsor: *Provided,* that (i) a school employee may be permitted to complete the school year; and (ii) an employee other than a school employee may be permitted to serve up to one additional year when the military department concerned finds that the additional employment is in the interest of management.

(7) Fifteen secretarial and staff support positions at GS–12 or below on the White House Support Group.

(8) Positions in DOD research and development activities occupied by participants in the DOD Science and Engineering Apprenticeship Program for High School Students. Persons employed under this authority shall be bona fide high school students, at least 14 years old, pursuing courses related to the position occupied and limited to 1,040 working hours a year. Children of DOD employees may be appointed to these positions, notwithstanding the sons and daughters restriction, if the positions are in field activities at remote locations. Appointments under this authority may be made only to positions for which qualification standards established under 5 CFR part 302 are consistent with the education and experience standards established for comparable positions in the competitive service. Appointments under this authority may not be used to extend the service limits contained in any other appointing authority.

(c) *Defense Contract Audit Agency.* (1) Not to exceed two positions of Accounting Fellow, Auditor, GM–511–14, filled under the Accounting Fellowship Program. Appointments under this authority may not exceed 2 years.

(d) *General.* (1) Positions concerned with advising, administering, supervising or performing work in the collection, processing, analysis, production, evaluation, interpretation, dissemination, and estimation of intelligence information, including scientific and technical positions in the intelligence function; and positions involved in the planning, programming, and management of intelligence resources when, in the opinion of OPM, it is impracticable to examine. This authority does not apply to positions assigned to cryptologic and communications intelligence activities/functions.

(2) Positions involved in intelligence-related work of the cryptologic intelligence activities of the military departments. This includes all positions of intelligence research specialist, and similar positions in the intelligence classification series; all scientific and technical positions involving the applications of engineering, physical or technical sciences to intelligence work; and professional as well as intelligence technician positions in which a majority of the incumbent's time is spent in advising, administering, supervising, or performing work in the collection, processing, analysis, production, evaluation, interpretation, dissemination, or estimation of intelligence information or in the planning, programming, and management of intelligence resources.

(e) *Uniformed Services University of the Health Sciences.* (1) Positions of Dean, Associate Dean, Assistant Dean, faculty members, postdoctoral fellows, research associates, senior research associates, and visiting scientists.

(2) Positions established to perform work on projects funded from grants.

(f) *National Defense University.* (1) Not to exceed 16 positions of senior policy analyst, GS–15, at the Strategic Concepts Development Center. Initial appointments to these positions may not exceed 6 years, but may be extended thereafter in 1-, 2-, or 3-year increments, indefinitely.

(g) *Defense Communications Agency.* (1) Not to exceed 10 positions at grades GS–10/15 to staff and support the Crisis Management Center at the White House.

(h) *Defense Systems Management College, Fort Belvoir, Va.* (1) The Provost and professors in grades GS–13 through 15.

Section 213.3107 Department of the Army

(a) *General.* (1) Not to exceed 30 positions on the faculty and staff which are classified in the GS–1700 occupational group and the GS–1410 Librarian series, located at the U.S. Army Russian Institute, Garmisch, Germany, and the U. S. Army Foreign Language Training Center Europe, Munich, Germany.

(b) *Aviation Systems Command.* (1) One scientific and professional research position in the U.S. Army Research and Technology Laboratories, the duties of which require specific knowledge of aviation technology in non-allied nations.

(c) *Corps of Engineers.* (1) (Reserved).

(2) Nonsupervisory trades, crafts, and manual labor positions at grades WG–6 and below on survey, construction, short-term maintenance, or floating-plant operations, where because of turnover, lack of housing facilities, mobility of work site, or remoteness of personnel servicing facilities, an adequate labor force can be recruited only by immediate gate hiring on a local basis. This authority can be used only when OPM has determined that it is specifically applicable to a given situation; ordinarily, it will not be used for employment in OPM central office, regional, and branch office cities or in cities where there is a local OPM area office to service the employing establishment.

(d) *U.S. Military Academy, West Point, New York.* (1) Civilian professors, instructors, teachers (except teachers at the Children's School), Cadet Social Activities Coordinator, chapel organist and choir-master, Director of Intercollegiate Athletics, Associate Director of Intercollegiate Athletics, Facility Manager, Building Manager, three Physical Therapists (Athletic Trainers), Associate Director of Admissions for Plans and Programs, Deputy Director of Alumni Affairs; and

Librarian when filled by an officer of the Regular Army retired from active service, and the military secretary to the Superintendent when filled by a U. S. Military Academy graduate retired as a regular commissioned officer for disability.

(e) *U.S. Army School of the Americas, Fort Benning, Georgia:* (1) Positions of Translator (Typing), GS–1040–5/9, and Supervisory Translator, GS–1040–11. No new appointments may be made under this authority after December 31, 1985.

(f) *Central Identification Laboratory.* (1) One position of Scientific Director, GM–190–15, and four positions of Forensic Scientist, GM–190–14. Initial appointment to these positions is NTE 3–5 years, with provision for indefinite numbers of renewals in 1-, 2-, or 3-year increments.

(g) *Defense Language Institute.* (1) All positions on the faculty and staff which are classified in the GS–1700 occupational group, the GS–1040 Language Specialist series, and the GS–303 Bilingual Clerk series, that require either a proficiency in a foreign language or a knowledge of foreign language teaching methods.

(h) *Army War College, Carlisle Barracks, Pa.* (1) Five positions of Educational Specialist for employment of not to exceed 1 year: *Provided,* that such employment may, with the prior approval of OPM, be extended for not to exceed one additional year.

(2) Nine senior policy analyst positions, GS–14/15, at the Strategic Studies Institute, Army War College, with appointments to be made initially for up to 3 years and thereafter extended annually if needed.

(3) Five research oriented faculty positions, GS–14/15, with the U.S. Army War College, at Carlisle Barracks, Pennsylvania, with appointments to be made initially for up to 3 years and thereafter extended annually if needed.

(i) (Reserved).

(j) *U.S. Military Academy Preparatory School, Fort Monmouth, New Jersey.* (1) Positions of Academic Director, Department Head and Instructor.

Section 213.3108 Department of the Navy

(a) *General.* (1) (Reserved).

(2) Positions of Student Pharmacist for temporary, part-time, or intermittent employment in U.S. naval regional medical centers, hospitals, clinics and departments when filled by students who are enrolled in an approved pharmacy program in a participating nonfederal institution, and whose compensation is fixed under 5 U.S.C. 5351–54. Employment under this authority may not exceed 1 year.

(3) (Reserved).

(4) Not to exceed 50 positions of resident-in-training at U.S. naval regional medical centers, hospitals, and dispensaries which have residency training programs, when filled by residents affiliates for part of their training from nonfederal hospitals. Assignments shall be on a temporary (full-time or part-time) or intermittent basis, shall not amount to more than 6 months for any person, and shall be applied only to persons whose compensation is fixed under 5 U.S.C. 5351–54.

(5) (Reserved).

(6) Positions of Student Operating Room Technician for temporary, part-time or intermittent employment in U.S. naval regional medical centers and hospitals, when filled by students who are enrolled in an approved operating room technician program in a participating nonfederal institution, whose compensation is fixed under 5 U.S.C. 5351–54. Employment under this authority may not exceed 1 year.

(7) Positions of student social worker for temporary, part-time, or intermittent employment in U.S. naval regional medical centers, hospitals, and dispensaries, when filled by bona fide students enrolled in academic institutions: *Provided,* that the work performed in the agency is to be used by the student as a basis for completing certain academic requirements by such educational institution to qualify for a graduate degree in social work. This authority shall be applied only to students whose compensation is fixed under 5 U.S.C. 5351–54.

(8) Positions of student practical nurse for temporary, part-time, or intermittent employment in U.S. naval regional medical centers, hospitals, and dispensaries, when filled by trainees enrolled in a nonfederal institution in an approved program of educational and clinical training that meets the requirements for licensing as a practical nurse. This authority shall be applied only to trainees whose compensation is fixed under 5 U.S.C. 5351–54.

(9) (Reserved).

(10) Positions of medical technology intern in U.S. naval regional medical centers, hospitals, and dispensaries, when filled by students enrolled in approved programs of training in nonfederal institutions. Employment under this authority may be on a full-time, part-time, or intermittent basis but may not exceed 1 year. This authority shall be applied only to students whose compensation is fixed under 5 U.S.C. 5351–54.

(11) Positions of medical intern at U.S. naval regional medical centers, hospitals, and dispensaries, when filled by persons who are serving medical internships at participating nonfederal hospitals and whose compensation is fixed under 5 U.S.C. 5351–54. Employment under this authority may not exceed 1 year.

(12) Positions of student speech pathologist at U.S. naval regional medical centers, hospitals, and dispensaries, when filled by persons who are enrolled in participating nonfederal institutions and whose compensation is fixed under 5 U.S.C. 5351–54. Employment under this authority may not exceed 1 year.

(13) Positions of student dental assistant in U.S. naval dental centers, clinics, and departments, when filled by students who are enrolled in an approved dental assistant program in a participating nonfederal institution, and whose compensation is fixed under 5 U.S.C. 5351–54. Employment under this authority may not exceed 1 year.

(14) (Reserved).

(15) Marine positions assigned to a coastal or seagoing vessel operated by a naval activity for research or training purposes.

(16) All positions necessary for the administration and maintenance of the official residence of the Vice President.

(b) *Naval Academy, Naval Postgraduate School, and Naval War College.* (1) Professors, instructors, and teachers; the Director of Academic Planning, Naval Postgraduate School; and the librarian, organist-choirmaster, registrar, the dean of admissions, and social counselors at the Naval Academy.

(c) *Chief of Naval Operations.* (1) One position at grade GS–12 or above that will provide technical, managerial, or administrative support on highly classified functions to the Deputy Chief of Naval Operations (Plans, Policy, and Operations).

(d) *Military Sealift Command.* (1) All positions on vessels operated by the Military Sealift Command.

(e) *Pacific Missile Range Facility, Barking Sands, Hawaii.*

(1) All positions. This authority applies only to positions that must be filled pending final decision on contracting of Facility operations. No new appointments may be made under this authority after July 29, 1988.

(f) (Reserved).

(g) *Office of Naval Research.* (1) Not to exceed five positions of Liaison Scientists, GS–13/15, in the Naval Research Branch Office in Japan, when filled by research scientists who have specialized experience in scientific disciplines of current interest to the Department and who have a

demonstrated ability to deal with the Japanese scientific community in their disciplines. An appointment under this authority may be made initially for a period not to exceed 2 years. With the prior approval of OPM, total employment under this authority may be for as long as 3 years.

Section 213.3109 Department of the Air Force

(a) *Office of the Secretary.* (1) One Special Assistant in the Office of the Secretary of the Air Force. This position has advisory rather than operating duties except as operating or administrative responsibilities may be exercised in connection with the pilot studies.

(b) *General.* (1) Professional, technical, managerial and administrative positions supporting space activities, when approved by the Secretary of the Air Force.

(2) Sixty-five positions engaged in interdepartmental activities in support of national defense projects involving scientific and technical evaluations.

(c) Not to exceed 20 professional positions, GS–11 through GS–15, in Detachments 6 and 51, SM–ALC, Norton and McClellan Air Force Bases, California, which will provide logistic support management to specialized research and development projects.

(d) *U.S. Air Force Academy, Colorado.* (1) Positions of Cadet Hostesses, Instructors in Physical Education, Instructors in Music (choirmasters), one Training Instructor (Parachuting), one Training Instructor (Code of Conduct and Evasion), and two Physical Therapists (Athletic Trainers).

(e) Not to exceed five positions, GS–12 through GS–15, in the Specialized Management Office (WR–ALC/QL) at Robins Air Force Base, Georgia, which will provide logistic support management staff guidance for highly sensitive and high priority programs and projects. Employment under this authority is not to exceed May 30, 1988.

(f) *Air Force Office of Special Investigations.* (1) Not to exceed 250 positions of Criminal Investigators/ Intelligence Research Specialists, GS–5 through GS–15.

(g) Not to exceed eight positions, GS–12 through 15, in Headquarters Air Force Logistics Command, DCS Materiel Management, Office of Special Activities, Wright Patterson Air Force Base, Ohio, which will provide logistic support management staff guidance to classified research and development projects.

(h) *Air University, Maxwell Air Force Base, Alabama.* (1) Positions of professor, instructor, or lecturer associated with courses of instruction of at least 10 months duration, for employment not to exceed 3 years, which may be renewed in 1-, 2, or 3–year increments indefinitely thereafter.

(i) *Air Force Institute of Technology, Wright-Patterson Air Force Base, Ohio.* (1) Civilian deans and professors.

(j) *Air Force Logistics Command.* (1) One Supervisory Logistics Management Specialist, GM–346–14, in Detachment 2, 2762 Logistics Management Squadron (Special), Greenville, Texas.

(k) One position of Supervisory Logistics Management Specialist, GS–346–15, in the 2762nd Logistics Squadron (Special) at Wright-Patterson Air Force Base, Ohio.

Section 213.3110 Department of Justice

(a) *General.* (1) Deputy U.S. Marshals employed on an hourly basis for intermittent service.

(2) (Reserved).

(3) U.S. Marshal in the Virgin Islands.

(b) *Immigration and Naturalization Service.* (1) Not to exceed 350 positions at grades GS–15 and below engaged in planning for and implementing the processing of claims for resident status which may be submitted by aliens already in the United States as authorized by immigration control and reform legislation. New appointments under this authority may not be made after April 15, 1993.

(2) Not to exceed 25 positions, GS–15 and below, with proficiency in speaking, reading, and writing the Russian language and serving in the Soviet Refugee Processing Program with permanent duty location in Moscow, USSR. Employment under this authority may not exceed 4 years. No new appointments may be made under this authority after September 30, 1991.

(c) *Drug Enforcement Administration.* (1) (Reserved)

(2) One hundred and fifty positions of Intelligence Research Agent and/or Intelligence Operation Specialist in the GS–132 series, grades GS–9 through GS–15.

(3) Not to exceed 200 positions of Criminal Investigator (Special Agent). New appointments may be made under this authority only at grades GS–7/11.

Section 213.3112 Department of the Interior

(a) *General.* (1) Technical, maintenance, and clerical positions at or below grades GS–7, WG–10, or equivalent in the field service of the Department of the Interior, when filled by the appointment of persons who are certified as maintaining a permanent and exclusive residence within, or contiguous to, a field activity or district, and as being dependent for livelihood primarily upon employment available within the field activity of the Department.

(2) All positions on Government-owned ships or vessels operated by the Department of the Interior.

(3) Temporary or seasonal caretakers at temporarily closed camps or improved areas to maintain grounds, buildings, or other structures and prevent damages or theft of Government property. Such appointments shall not extend beyond 130 working days a year without the prior approval of OPM.

(4) Temporary, intermittent, or seasonal field assistants at GS–7, or its equivalent, and below in such areas as forestry, range management, soils, engineering, fishery and wildlife management, and with surveying parties. Employment under this authority may not exceed 180 working days a year.

(5) Temporary positions established in the field service of the Department for emergency forest and range fire prevention or suppression and blister rust control for not to exceed 180 working days a year: *Provided,* that an employee may work as many as 220 working days a year when employment beyond 180 days is required to cope with extended fire seasons or sudden emergencies such as fire, flood, storm, or other unforeseen situations involving potential loss of life or property.

(6) Persons employed in field positions, the work of which is financed jointly by the Department of the Interior and cooperating persons or organizations outside the Federal service.

(7) All positions in the Bureau of Indian Affairs and other positions in the Department of the Interior directly and primarily related to providing services to Indians when filled by the appointment of Indians. The Secretary of the Interior is responsible for defining the term "Indian."

(8) Temporary, intermittent, or seasonal positions at GS–7 or below in Alaska, as follows: Positions in nonprofessional mining activities, such as those of drillers, miners, caterpillar operators, and samplers. Employment under this authority shall not exceed 180 working days a year and shall be appropriate only when the activity is carried on in a remote or isolated area and there is a shortage of available candidates for the positions.

(9) Temporary, part-time, or intermittent employment of mechanics, skilled laborers, equipment operators and tradesmen on construction, repair, or maintenance work not to exceed 180

working days a year in Alaska, when the activity is carried on in a remote or isolated area and there is a shortage of available candidates for the positions.

(10) Seasonal airplane pilots and airplane mechanics in Alaska, not to exceed 180 working days a year.

(11) Temporary staff positions in the Youth Conservation Corps Centers operated by the Department of the Interior. Employment under this authority shall not exceed 11 weeks a year except with prior approval of OPM.

(12) Positions in the Youth Conservation Corps for which pay is fixed at the Federal minimum rate. Employment under this authority may not exceed 10 weeks.

(b) (Reserved).

(c) *Indian Arts and Crafts Board.* (1) The Executive Director.

(d) (Reserved).

(e) *Office of the Assistant Secretary, Territorial and International Affairs.* (1) (Reserved)

(2) Not to exceed four positions of Territorial Management Interns, grades GS–5, GS–7, or GS–9, when filled by territorial residents who are U.S. citizens from the Virgin Islands or Guam; U.S. nationals from American Samoa; or in the case of the Northern Marianas, will become U.S. citizens upon termination of the U.S. trusteeship. Employment under this authority may not exceed 6 months.

(3) (Reserved).

(4) Special Assistants to the Governor of American Samoa who perform specialized administrative, professional, technical, and scientific duties as members of his or her immediate staff.

(f) *National Park Service.* (1) Park Ranger positions (appropriate specializations) at salaries equivalent to GS–2 through GS–5 to perform practical and technical work supporting the management of Park Service areas and resources in the functional areas of interpretation, resources management, visitor protection, and visitor services; and positions at salaries equivalent to grades GS–6 and GS–7 in which the duties are supervisory or consist of highly specialized technical work in support of National Park Service operations in the functional areas delineated above. The total number of Park Ranger and Park Technician positions at salaries equivalent to GS–6 and GS–7 excepted under this paragraph shall not exceed 200. Employment under this paragraph is limited to persons who meet the qualification standards for each salary level which have been agreed upon by OPM and the Department. These standards include as a minimum the following number of previous seasons' experience at a salary equivalent to the next lower grade or equivalent experience in a Federal, State, or local park:

(i) For IGS–7: Two seasons at IGS–6 level in the National Park Service.

(ii) For IGS–6: Two seasons at IGS–5 level in the National Park Service.

(iii) For IGS–5: One season at IGS–4 level or its equivalent in experience.

(iv) For IGS–4: One season at IGS–3 level or its equivalent in experience.

(v) For IGS–3: One season at IGS–2 level or its equivalent in experience. Employment under this paragraph shall be only for duty that is temporary, intermittent, or seasonal, and no person shall be employed by the same appointing office in the National Park Service under this paragraph or a combination of this and any other excepting authorities in excess of 180 working days a year.

(2) (Reserved).

(3) Seven full-time permanent and 31 temporary, part-time, or intermittent positions in the Redwood National Park, California, which are needed for rehabilitation of the park, as provided by Public Law 95–250.

(4) One Special Representative of the Director.

(g) *Bureau of Reclamation.* (1) Appraisers and examiners employed on a temporary, intermittent, or part-time basis on special valuation or prospective-entrymen-review projects where knowledge of local values or conditions or other specialized qualifications not possessed by regular Bureau employees are required for successful results. Employment under this provision shall not exceed 130 working days a year in any individual case: *Provided,* that such employment may, with prior approval of OPM, be extended for not to exceed an additional 50 working days in any single year.

(h) *Office of the Deputy Assistant Secretary for Territorial Affairs.* (1) Positions of Territorial Management Interns, GS–5, when filled by persons selected by the Government of the Trust Territory of the Pacific Islands. No appointment may extend beyond 1 year.

Section 213.3113 Department of Agriculture.

(a) General. (1) Agents employed in field positions the work of which is financed jointly by the Department and cooperating persons, organizations, or governmental agencies outside the Federal service. Except for positions for which selection is jointly made by the Department and the cooperating organization, this authority is not applicable to positions in the Agricultural Research Service or the Statistical Reporting Service. This authority is not applicable to the following positions in the Agricultural Marketing Service: Agricultural Commodity grader (grain) and (meat), (poultry), and (dairy) agricultural commodity aid (grain), and tobacco inspection positions.

(2)–(4) (Reserved).

(5) Temporary, intermittent, or seasonal employment in the field service of the Department in positions at and below GS–7 and WG–10 in the following types of positions: Field assistants for subprofessional services; caretakers at temporarily closed camps or improved areas; forest workers engaged primarily for fire prevention or suppression activities and other forest workers employed at headquarters other than forest supervisor and regional offices; State performance assistants in the Agricultural Stabilization and Conservation Service; agricultural helpers, helper-leaders, and workers in the Agricultural Research Service and the Animal and Plant Health Inspection Service; and subject to prior OPM approval granted in the calendar year in which the appointment is to be made, other clerical, trades, crafts, and manual labor positions. Total employment under this subparagraph may not exceed 180 working days in a service year: *Provided,* that an employee may work as many as 220 working days in a service year when employment beyond 180 days is required to cope with extended fire seasons or sudden emergencies such as fire, flood, storm, or other unforeseen situations involving potential loss of life or property. This paragraph does not cover trades, crafts, and manual labor positions covered by paragraphs (i) and (m) of § 213.3102.

(6) (Reserved).

(7) Not to exceed 34 Program Assistants, whose experience acquired in positions excepted from the competitive civil service in the administration of agricultural programs at the State level is needed by the Department for the more efficient administration of its programs. No new appointment may be made under this authority after December 31, 1985.

(b) (Reserved).

(c) *Forest Service.* (1) (Reserved).

(2) Positions in Alaska of Laborers, Boat Operators, Mechanics, Equipment Operators, and Carpenters whose duties require the operation of boats in coastal waters and/or the establishment and maintenance of work camps in remote areas.

(d) *Agricultural Stabilization and Conservation Service.*

(1) Not to exceed 34 positions of Agricultural Program Specialist, GS–

1145–7/12, engaged in conversion of ASCS' directives and information system to a completely automated format. Appointments to these positions may be made initially at the GS–7/11 levels and may not exceed September 30, 1989.

(2) Members of State Committees: *Provided,* that employment under this authority shall be limited to temporary intermittent (WAE) positions whose principal duties involve administering farm programs within the State consistent with legislative and Departmental requirements and reviewing national procedures and policies for adaptation at State and local levels within established parameters. Individual appointments under this authority are for 1 year and may be extended only by the Secretary of Agriculture or his designee. Members of State Committees serve at the pleasure of the Secretary.

(e) *Farmers Home Administration.* (1) (Reserved).

(2) County committeemen to consider, recommend, and advise with respect to the Farmers Home Administration program.

(3) Temporary positions whose principal duties involve the making and servicing of natural disaster emergency loans pursuant to current statutes authorizing natural disaster emergency loans. Appointments under this provision shall not exceed 1 year unless extended for one additional period not to exceed 1 year, but may, with prior approval of OPM, be further extended for additional periods not to exceed 1 year each.

(4)–(5) (Reserved).

(6) Professional and clerical positions in the Trust Territory of the Pacific Islands when occupied by indigenous residents of the Territory to provide financial assistance pursuant to current authorizing statutes.

(f) *Agricultural Marketing Service.* (1) Positions of Agricultural Commodity Graders, Agricultural Commodity Technicians, and Agricultural Commodity Aids at grades GS–9 and below in the tobacco, dairy, and poultry commodities; Meat Acceptance Specialists, GS-11 and below; Clerks, Clerk-Typists, and Computer Clerks at grades GS–4 and below; and Laborers under the Wage System. Employment under this authority is limited to either 1,280 hours or 180 days in a service year.

(2) Positions of Agricultural Commodity Graders, Agricultural Commodity Technicians, and Agricultural Commodity Aids at grades GS–11 and below in the cotton, raisin, and processed fruit and vegetable commodities. Employment under this authority may not exceed 180 days in a service year. In unforeseen situations such as bad weather or crop conditions, unanticipated plant demands, or increased imports, employees may work up to 240 days in a service year. Cotton Agricultural Commodity Graders, GS–5, may be employed as trainees for the first appointment for an initial period of 6 months for training without regard to the service year limitation.

(3) Milk Market Administrators.

(4) All positions on the staffs of Milk Market Administrators.

(g)–(i) (Reserved).

(j) *Food and Nutrition Service.* (1) (Reserved).

(2) Three hundred fifty positions of Food Assistance Program Specialist, GS–5/7, under the Child Nutrition Summer Feeding Program, for temporary employment not to begin before March 1 and not to exceed September 30 of each year, on a full-time, part-time, or intermittent basis.

(k) (Reserved)

(l) *Food Safety and Inspection Service.* (1)–(2) (Reserved).

(3) Positions of meat and poultry inspectors (veterinarians at GS–11 and below and nonveterinarians at appropriate grades below GS–11) for employment on a temporary, intermittent, or seasonal basis, not to exceed 1,280 hours a year.

(m) *Federal Grain Inspection Service.* (1) One hundred and fifty positions of Agricultural Commodity Aid (Grain), GS–2/4; 100 positions of Agricultural Commodity Technician (Grain), GS–4/7; and 60 positions of Agricultural Commodity Grader (Grain), GS–5/9, for temporary employment on a part-time, intermittent, or seasonal basis not to exceed 1,280 hours in a service year.

Section 213.3114 Department of Commerce

(a) *General.* (1)–(2) (Reserved).

(3) Not to exceed 50 scientific and technical positions whose duties are performed primarily in the Antarctic. Incumbents of these positions may be stationed in the continental United States for periods of orientation, training, analysis of data, and report writing.

(b) *Office of the Secretary.* (1) One position of Administrative Assistant, GS–301–8, in the Office of Economic Affairs. New appointments may not be made after March 30, 1979.

(c) (Reserved).

(d) *Bureau of the Census.* (1) Managers, supervisors, technicians, clerks, interviewers, and enumerators in the field service, for (1) temporary, part-time or intermittent employment in connection with major economic and demographic censuses or with surveys of a nonrecurring or noncyclical nature; and (2) indefinite employment for the duration of each decennial census for key employees located at the Master District Offices (MDO) and Processing Offices (PO): *Provided,* that temporary, parttime employment of the nature described in (1) above will be for periods not to exceed 1 year; and that such appointments may be extended for additional periods of not to exceed 1 year each; but that prior Office approval is required for extension of total service beyond 2 years.

(2) Current Program Interviewers employed on an intermittent or part-time basis in the field service.

(3) Not to exceed 20 professional and scientific positions at grades GS–9 through GS–12 filled by participants in the ASA research trainee program. Employment of any individual under this authority may not exceed 2 years.

(e)–(h) (Reserved).

(i) *Office of the Under Secretary for International Trade.*

(1) Thirty positions at GS–12 and above in specialized fields relating to international trade or commerce in units under the jurisdiction of the Under Secretary for International Trade. Incumbents will be assigned to advisory rather than to operating duties, except as operating and administrative responsibility may be required for the conduct of pilot studies or special projects. Employment under this authority will not exceed 2 years for an individual appointee.

(2) Not to exceed 40 positions of Managers and Deputy Managers of International Trade Fairs and Exhibit Programs in foreign countries when the duties require a considerable portion of the employee's time to be spent in foreign countries.

(3) Not to exceed 30 positions in grades GS–12 through GS–15, to be filled by persons qualified as industrial or marketing specialists; who possess specialized knowledge and experience in industrial production, industrial operations and related problems, market structure and trends, retail and wholesale trade practices, distribution channels and costs, or business financing and credit practices applicable to one or more of the current segments of U.S. industry served by the Under Secretary for International Trade, and the subordinate components of his organization which are involved in Domestic Business matters. Appointments under this authority may be made for a period of not to exceed 2 years and may, with prior approval of

OPM, be extended for an additional period of 2 years.

(j) *National Oceanic and Atmospheric Administration.* (1) Subject to prior approval of OPM, which shall be contingent upon a showing of inadequate housing facilities, meteorological aid positions at the following stations in Alaska: Barrow, Bethal, Kotzebue, McGrath, Northway, and St. Paul Island.

(2) (Reserved).

(3) All civilian positions on vessels operated by the National Ocean Service.

(4) Temporary positions required in connection with the surveying operations of the field service of the National Ocean Service. Appointment to such positions shall not exceed 8 months in any one calendar year.

(5) Field positions, GS–9 and below, in the National Marine Fisheries Service conducting fish and processed fish products inspection, funded by the private sector. New appointments under this authority may not be made after July 1, 1991.

(k) (Reserved).

(l) National Telecommunication and Information Administration. (1) Seventeen professional positions in grades GS–13 through GS–15.

Section 213.3115 Department of Labor

(a) *Office of the Secretary.* (1) Chairman and five members, Employees' Compensation Appeals Board.

(2) Chairman and eight members, Benefits Review Board.

(b) *Bureau of Labor Statistics.* (1) Not to exceed 500 positions involving part-time and intermittent employment for field survey and enumeration work in the Bureau of Labor Statistics. This authority is applicable to positions where the salary is equivalent to GS–6 and below. Employment under this authority may not exceed 1,600 work hours in a service year. No new appointment may be made under this authority after December 31, 1984.

(c) (Reserved).

(d) *Employment and Training Administration.* (1) Not to exceed 10 positions of Supervisory Manpower Development Specialist and Manpower Development Specialist, GS–7/15, in the Division of Indian and Native American Programs, when filled by the appointment of persons of one-fourth or more Indian blood. These positions require direct contact with Indian tribes and communities for the development and administration of comprehensive employment and training programs.

Section 213.3116 Department of Health and Human Services.

(a) (Reserved).

(b) *Public Health Service.* (1) Not to exceed five positions a year of Medical Technologist Resident, GS–644–7, in the Blood Bank Department, Clinical Center, of the National Institutes of Health. Appointments under this authority will not exceed 1 year.

(2) Positions at Government sanatoria when filled by patients during treatment or convalescence.

(3) (Reserved).

(4) Positions concerned with problems in preventive medicine financed or participated in by the Department of Health and Human Services and a cooperating State, county, municipality, incorporated organization, or an individual in which at least one-half of the expense is contributed by the cooperating agency either in salaries, quarters, materials, equipment, or other necessary elements in the carrying on of the work.

(5) Medical and dental interns, externs, and residents; and student nurses.

(6) Positions of scientific, professional, or technical nature when filled by bona fide students enrolled in academic institutions: *Provided,* that the work performed in the agency is to be used by the student as a basis for completing certain academic requirements required by an educational institution to qualify for a scientific, professional, or technical field. This authority shall be applied only to positions with compensation fixed under 5 U.S.C. 5351–5356.

(7) Not to exceed 50 positions associated with health screening programs for refugees.

(8) All positions in the Public Health Service and other positions in the Department of Health and Human Services directly and primarily related to providing services to Indians when filled by the appointment of Indians. The Secretary of Health and Human Services is responsible for defining the term "Indian."

(9) Twelve positions of Therapeutic Radiologic Technician Trainee in the Radiation Oncology Branch, National Cancer Institute. Employment under this authority shall not exceed 1 year for any individual. This authority shall be applied only to positions with compensation fixed under 5 U.S.C. 5351–5356.

(10) Health care positions of the National Health Service Corps for employment of any one individual not to exceed 4 years of service in health manpower shortage areas.

(11) Pharmacy Resident positions at GS–7 in the National Institutes of Health's Clinical Center, Pharmacy Department. Employment in these positions is confined to graduates of approved schools of pharmacy and is limited to a period not to exceed 12 months pending licensure.

(12) Hospital Administration Resident positions at GS–9 in the National Institutes of Health's Clinical Center, Bethesda, Maryland. Employment in these positions is confined to graduates of approved hospital or health care administration programs and is limited to a period not to exceed 1 year.

(13) Not to exceed 30 positions of Cancer Control Science Associate in the Division of Cancer Prevention and Control, National Cancer Institute, National Institutes of Health, for assignments at a level of difficulty and responsibility at or equivalent to GS–11/13. No one may be employed under this authority for more than 3 years, and no more than 10 appointments will be made under the authority in any 1 year.

(14) Not to exceed 30 positions at grades GS-11/13 associated with the postdoctoral training program for interdisciplinary toxicologists in the National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, North Carolina.

(c) (Reserved).

(d) *Social Security Administration.* (1) Six positions of social insurance representative in the district offices of the Social Security Administration in the State of Arizona when filled by the appointment of persons of one-fourth or more Indian blood.

(2) Seven positions of social insurance representative in the district offices of the Social Security Administration in the State of New Mexico when filled by the appointment of persons of one-fourth or more Indian blood.

(3) Two positions of social insurance representative in the district offices of the Social Security Administration in the State of Alaska when filled by the appointment of persons of one-fourth or more Alaskan Native blood (Eskimos, Indians, or Aleuts).

(e) (Reserved).

(f) *The President's Council on Physical Fitness.* (1) Four staff assistants, The President's Council on Physical Fitness.

(g)–(i) (Reserved).

(j) *Health Care Financing Administration.* (1) (Reserved)

(2) Not to exceed 10 professional positions, GS–9 through GS–15, to be filled under the Health Care Financing Administration Professional Exchange

Program. Appointments under this authority will not exceed 1 year.

(k) *Office of the Secretary.* (1) (Reserved).

(2) Not to exceed 10 positions at grades GS–9/14 in the Office of the Assistant Secretary for Planning and Evaluation filled under the Policy Research Associate Program. New appointments to these positions may be made only at grades GS–9/12. Employment of any individual under this authority may not exceed 2 years.

Section 213.3117 Department of Education

(a) Positions concerned with problems in education financed and participated in by the Department of Education and a cooperating State educational agency, or university or college, in which there is joint responsibility for selection and supervision of employees, and at least one-half of the expense is contributed by the cooperating agency in salaries, quarters, materials, equipment, or other necessary elements in the carrying on of the work.

Section 213.3124 Board of Governors, Federal Reserve System

(a) All positions.

Section 213.3126 Defense Nuclear Facilities Safety Board

(a) All positions on the staff. No new appointments may be made under this authority after December 26, 1991.

Section 213.3127 Department of Veterans Affairs.

(a) *Construction Division.* (1) Temporary construction workers paid from "purchase and hire" funds and appointed for not to exceed the duration of a construction project.

(b) Not to exceed 400 positions of rehabilitation counselors, GS–3 through GS-11, in Alcoholism Treatment Units and Drug Dependence Treatment Centers, when filled by former patients.

(c) *Board of Veterans' Appeals.* (1) Positions, GS–15, when filled by a member of the Board. Except as provided by section 201(d) of Public Law 100–687, appointments under this authority shall be for a term of 9 years, and may be renewed.

(2) Positions, GS–15, when filled by a non-member of the Board who is awaiting Presidential approval for appointment as a Board member.

(d) Not to exceed 600 positions at grades GS–3 through GS-11, involved in the Department's Vietnam Era Veterans Readjustment Counseling Service.

Section 213.3128 U.S. Information Agency

(a) *Office of Congressional and Public Liaison.* (1) Two positions of Liaison Officer (Congressional), GS–14.

(b) Five positions of Supervisory International Exchange Officer (Reception Center Director), GS–13 and GS–14, located in USIA's field offices of New Orleans, New York, Miami, San Francisco and Honolulu. Initial appointments will not exceed December 31 of the calendar year in which appointment is made with extensions permitted up to a maximum period of 4 years.

Section 213.3129 Thrift Oversight Board

(a) All positions. No new appointments may be made under this authority after December 31, 1994.

Section 213.3130 Securities and Exchange Commission

(a)–(b) (Reserved).

(c) Positions of accountant and auditor, GS–13 through 15, when filled by persons selected under the SEC Accounting Fellow Program, as follows: (1) Seven positions, for employment of any one individual not to exceed 2 years; and

(2) Two additional identical positions, for employment of any one individual not to exceed 90 days, which may be used to provide a period of transition and orientation between Fellowship appointments. These additional identical positions must be filled by persons who either have completed a 2-year Fellowship or have been selected as replacement Fellows for a 2-year term. Appointments of outgoing Fellows under this authority must be made without a break in service of 1 workday following completion of their 2-year terms; incoming Fellows appointed under this provision must be appointed to 2-year Fellowships without a break in service of 1 workday following their 90-day appointments.

(d) Positions of Economist, GS–13 through 15, when filled by persons selected under the SEC Economic Fellow Program. No more than four positions may be filled under this authority at any one time. An employee may not serve under this authority longer than 2 years unless selected under provisions set forth in the Intergovernmental Personnel Act (IPA), 5 U.S.C. 3372(b) (2).

(e) Not to exceed 10 positions of accountant, GS–12/13, when filled by persons selected as SEC Accounting Fellows for the Full Disclosure Program. Employment under this authority may not exceed 2 years.

Section 213.3131 Department of Energy.

(a) (Reserved).

(b) *Bonneville Power Administration.* (1) Five Area Managers.

Section 213.3132 Small Business Administration

(a) When the President under 42 U.S.C. 1855–1855g, the Secretary of Agriculture under 7 U.S.C. 1961, or the Small Business Administration under 15 U.S.C. 636(b)(1) declares an area to be a disaster area, positions filled by temporary appointment of employees to make and administer disaster loans in the area under the Small Business Act, as amended. Service under this authority may not exceed 4 years, and no more than 2 years may be spent on a single disaster. Exception to this time limit may only be made with prior Office approval. Appointments under this authority may not be used to extend the 2-year service limit contained in paragraph (b) below. No one may be appointed under this authority to positions engaged in long-term maintenance of loan portfolios.

(b) When the President under 42 U.S.C. 1855–1855g, or the Secretary of Agriculture under 7 U.S.C. 1961 or the Small Business Administration under 15 U.S.C. 636(b)(1), declares an area to be a disaster area, positions filled by temporary appointment of employees to make and administer disaster loans in that area under the Small Business Act, as amended. No one may serve under this authority for more than an aggregate of 2 years without a break in service of at least 6 months. Persons who have had more than 2 years of service under paragraph (a) of this section must have a break in service of at least 8 months following such service before appointment under this authority. No one may be appointed under this authority to positions engaged in long-term maintenance of loan portfolios.

(c) Positions of Community Economic-Industrial Planner, GS–7 through 12, when filled by local residents who represent the interest of the groups to be served by the Minority Entrepreneurship Teams of which they are members. No new appointments may be made under this authority after May 1, 1977.

Section 213.3133 Federal Deposit Insurance Corporation

(a) All Liquidation Graded, temporary field positions concerned with the work of liquidating the assets of closed banks or savings and loan institutions, of

liquidating loans to banks or savings and loan institutions, or of paying the depositors of closed insured banks or savings and loan institutions. New appointments may be made under this authority only during the 5-year period following a bank or savings and loan institution closing and/or establishment of a consolidated liquidation site.

(b) Not to exceed 300 positions in field offices of the Resolution Trust Corporation. No new appointments may be made under this authority after September 30, 1992.

Section 213.3136 U.S. Soldiers' and Airmen's Home

(a) (Reserved).

(b) Positions when filled by member-residents of the Home.

Section 213.3137 General Services Administration

(a) (Reserved).

(b) Not to exceed 25 positions at grades GS-14/15, in order to bring into the agency current industry expertise in various program areas. Appointments under this authority may not exceed 2 years.

(c) All law clerk positions in the Board of Contract Appeals' Law Clerk Fellows Program. Appointments under this authority at GS–11 and GS–12 will be limited to 2 years, with provision for a 1-year extension at the GS–13 level only in cases of exceptional circumstances as determined by the Chief Judge and Chairman.

Section 213.3138 Federal Communications Commission

(a) Fifteen positions of Telecommunications Policy Analyst, GS/GM–301-13/14/15. Initial appointment to these positions will be for a period of not to exceed 2 years with provision for two 1-year extensions.

Section 213.3141 National Labor Relations Board

(a) Election Examiners for temporary, part-time or intermittent employment in connection with elections under the Labor-Management Relations Act.

Section 213.3142 Export-Import Bank of the United States.

(a) One Special Assistant to the Board of Directors, grade GS-14 and above.

Section 213.3146 Selective Service System

(a) State Directors.

(b)–(c) (Reserved).

(d) Executive Secretary, National Selective Service Appeal Board.

Section 213.3148 National Aeronautics and Space Administration

(a) One hundred and fifty alien scientists having special qualifications in the fields of aeronautical and space research where such employment is deemed by the Administrator of the National Aeronautics and Space Administration to be necessary in the public interest.

(b) Not to exceed 40 positions of fully qualified pilot and mission specialists astronauts.

(c)–(e) (Reserved).

(f) positions of Program Coordinator/Counselor at grades GS–7/9/11 for part-time and summer employment in connection with the High School Students Summer Research Apprenticeship Program.

Section 213.3152 U.S. Government Printing Office

(a) Not to exceed three positions of Research Associate at grades GS–15 and below, involved in the study and analysis of complex problems relating to the reduction of the Government's printing costs and to provision of more efficient service to customer agencies and the public. Appointments under this authority may not exceed 1 year, but may be extended for not to exceed one additional year.

(b) Positions in the printing trades when filled by students majoring in printing technology employed under a cooperative education agreement with the University of the District of Columbia.

Section 213.3156 Commission on Civil Rights

(a) Twenty-five positions at grade GS–11 and above of employees who collect, study, and appraise civil rights information to carry out the national clearinghouse responsibilities of the Commission under Public Law 88–352, as amended. No new appointments may be made under this authority after March 31, 1976.

Section 213.3174 Smithsonian Institution

(a) Not to exceed 25 positions at grades GS–11 and below which support planning and production of the Annual American Folklife Festival. Employment under this authority may not exceed 6 months in connection with any one Festival.

(b) All positions located in Panama which are part of or which support the Smithsonian Tropical Research Institute.

Section 213.3175 Woodrow Wilson International Center for Scholars

(a) One East Asian Studies Program Administrator, one International Security Studies Program Administrator, one Latin American Program Administrator, one Russian Studies Program Administrator, one West European Program Administrator, and one Social Science Program Administrator.

Section 213.3182 National Foundation on the Arts and the Humanities

(a) *National Endowment for the Arts.*

(1) Until September 30, 1990, one position of Assistant Director, Artists-in-Education Programs, Office for Partnership, GS–301–14.

(2) Until September 30, 1990, one position of Assistant Director for State Programs.

(3) Until September 30, 1990, one position of Director of Literature Programs.

(4) Until September 30, 1990, one position of Assistant Director of Theatre Programs.

(5) Until September 30, 1990, one position of Director of Folk Arts Programs.

(6) Until September 30, 1990, one position of Director, Opera/Musical Theatre Programs.

(7) Until September 30, 1990, one position of Assistant Director of Opera/Musical Theatre Programs.

(8) Until September 30, 1990, one position of Assistant Director of Literature Programs.

(9) Until September 30, 1990, one position of Director of Locals Test Programs, Office of the Deputy to the Chairman for Public Partnership.

(10) Until September 30, 1990, one position of Deputy Chairman for Public Partnership.

(11) Until September 30, 1990, four Project Evaluators.

(12) Until September 30, 1990, one position of Director of Museum Programs.

(13) Until September 30, 1990, one position of Assistant Director of Folk Arts, Office of the Deputy Chairman for Programs.

(14) Until September 30, 1990, one position of Assistant Director of Music Programs.

(15) Until September 30, 1990, one position of Director of Expansion Arts Programs.

(16) Until September 30, 1990, one position of Director of Media Arts Programs.

(17) Until September 30, 1990, one position of Director, Challenge and Advancement Grant Program.

(18) Until September 30, 1990, one position of Assistant Director, Challenge and Advancement Grant Programs.

(19) Until September 30, 1990, one position of Art Specialist, International Programs.

(20) Until September 30, 1990, one position of Director of Inter Arts Program.

(21) Until September 30, 1990, one position of Assistant Director of Expansion of Arts Programs.

(22) Until September 30, 1990, one position of Assistant Director of Media Arts Programs.

(23) Until September 30, 1990, one position of Assistant Director of Design Arts Program.

(24) Until September 30, 1990, one position of Assistant Director of Dance Programs.

(25) Until September 30, 1990, one position of Assistant Director of Visual Arts Programs.

(26) Until September 30, 1990, one position of Assistant Director of Museum Programs.

(27)–(29) (Reserved).

(30) Until September 30, 1990, one position of Director of Education Programs.

(31) Until September 30, 1990, one position of Director of Music Programs.

(32) Until September 30, 1990, one position of Director of Theater Programs.

(33) Until September 30, 1990, one position of Director of Dance Programs.

(34) Until September 30, 1990, one position of Director of Visual Arts Programs.

(35) Until September 30, 1990, one position of Director of Design Arts Program.

(36) (Reserved).

(37) Until September 30, 1990, one Director for State Programs.

(38) Until September 30, 1990, one Director for Artists-in-Education Programs.

(39) Until September 30, 1990, one position of Assistant Director of Inter-Arts Program.

(40) Until September 30, 1990, one position of Assistant Director of the International Program.

Section 213.3184 Department of Housing and Urban Development

(a) One position of Special Advisor to the Regional Administrator, GS–301–14, in San Francisco. Employment under this authority may not exceed 2 years.

Section 213.3187 Federal Housing Finance Board

(a) All positions. No new appointments may be made under this authority after December 31, 1992.

Section 213.3191 Office of Personnel Management

(a) Not to exceed 500 positions in Federal Job Information Centers, to be filled under the Community Outreach Information Network program. Appointments under this authority may not exceed 90 days, and no one may receive more than one appointment under the authority.

(b)–(c) (Reserved).

(d) Part-time and intermittent positions of test examiners at grades GS–8 and below.

Section 213.3194 Department of Transportation

(a) *U.S. Coast Guard.* (1) Not to exceed 25 positions of Marine Traffic Controller (Pilot), at grade GS–11 and below for temporary, intermittent or seasonal employment in the State of Louisiana. Temporary appointments may not exceed 1 year, and temporary appointees may be reappointed under this authority only after a break in service of at least 6 months. Intermittent or seasonal employment may not exceed 180 working days in a service year, except that this limitation for an individual employee may be extended to 220 days when necessitated by emergencies caused by unusual flooding conditions or high river stages.

(2) Lamplighters.

(3) Professors, Associate Professors, Assistant Professors, Instructors, one Principal Librarian, one Cadet Hostess, and one Psychologist (Counseling) at the Coast Guard Academy, New London, Conn.

(b) (Reserved).

(c) *Federal Highway Administration.* (1) Temporary, intermittent, or seasonal employment in the field service of the Federal Highway Administration at grades not higher than GS–5 for subprofessional engineering aide work on the highway surveys and construction projects, for not to exceed 180 working days a year, when in the opinion of OPM, appointment through competitive examination is impracticable.

(d) (Reserved).

(e) *Maritime Administration.* (1)–(2) (Reserved).

(3) All positions on Government-owned vessels or those bareboats chartered to the Government and operated by or for the Maritime Administration.

(4)–(5) (Reserved).

(6) U.S. Merchant Marine Academy, positions of: Professors, Instructors, and Teachers: Including heads of Departments of Physical Education and Athletics, Humanities, Mathematics and Science, Maritime Law and Economics, Nautical Science, and Engineering; Coordinator of Shipboard Training; the Commandant of Midshipmen, the Assistant Commandant of Midshipmen; Director of Music; three Battalion Officers; three Regimental Affairs Officers; and one Training Administrator.

(7) U.S. Merchant Marine Academy positions of: Associate Dean; Registrar; Director of Admissions; Assistant Director of Admissions; Director, Office of External Affairs; Placement Officer; Administrative Librarian; Shipboard Training Assistant; three Academy Training Representatives; and one Education Program Assistant.

Section 213.3195 Federal Emergency Management Agency

(a) Field positions at grades GS–15 and below, or equivalent, which are engaged in work directly related to unique response efforts to environmental emergencies not covered by the Disaster Relief Act of 1974, Public Law 93–288, as amended. Employment under this authority may not exceed 36 months on any single emergency. Persons may not be employed under this authority for long-term duties or for work not directly necessitated by the emergency response effort.

(b) Not to exceed 30 positions at grades GS–15 and below in the Offices of Executive Administration, General Counsel, Inspector General, Comptroller, Public Affairs, Personnel, Acquisition Management, and the State and Local Program and Support Directorate which are engaged in work directly related to unique response efforts to environmental emergencies not covered by the Disaster Relief Act of 1974, Public Law 93–288, as amended. Employment under this authority may not exceed 36 months on any single emergency, or for long-term duties or work not directly necessitated by the emergency response effort. No one may be reappointed under this authority for service in connection with a different emergency unless at least 6 months have elapsed since the individual's latest appointment under this authority.

(c) Not to exceed 350 professional and technical positions at grades GS–5 through GS–15, or equivalent, in Mobile Emergency Response Support Detachments (MERS).

Section 213.3199 Temporary organizations

(a) Positions at GS–15 and below on the staffs of temporary boards and commissions which are established by law or Executive order for specified periods not to exceed 4 years to perform specific projects. A temporary board or commission originally established for less than 4 years and subsequently extended may continue to fill its staff positions under this authority as long as its total life, including extension(s) does not exceed 4 years. No board or commission may use this authority for more than 4 years to make appointments and position changes unless prior approval of the Office is obtained.

(b) Positions at GS–15 and below on the staffs of temporary organizations established within continuing agencies when all of the following conditions are met: (1) The temporary organization is established by an authority outside the agency, usually by law or Executive order; (2) the temporary organization is established for an initial period of 4 years or less and, if subsequently extended, its total life including extension(s) will not exceed 4 years; (3) the work to be performed by the temporary organization is outside the agency's continuing responsibilities; and (4) the positions filled under this authority are those for which other staffing resources or authorities are not available within the agency. An agency may use this authority to fill positions in organizations which do not meet all of the above conditions or to make appointments and position changes in a single organization during a period longer than 4 years only with prior approval of the Office.

Schedule B

Section 213.3202 Entire executive civil service

The provisions established under paragraphs (a) through (i) are authorized under provisions of E.O. 12015 and support career-related work-study programs. OPM's requirements relating to appointment under paragraphs (a) through (i) will be published in the Federal Personnel Manual. Further, appointments under paragraphs (a) through (i) are subject to all the requirements and conditions governing career or career-conditional appointments, including investigation by OPM to establish an appointee's qualifications and suitability. Appointments of participants may be converted to career or career-conditional at any time within a 120-day period after satisfactory completion of a career-related work-study program.

(a) Student positions established in connection with a bachelor's degree cooperative education program which provide for a formally arranged schedule of attendance at an institution of higher learning combined with at least 26 weeks, or 1,040 hours, of study-related work in a Federal agency. The periods of work and study together must satisfy requirements for a bachelor's degree and must provide the experience necessary for a career or career-conditional appointment to administrative, professional or technical positions in the Federal career service upon the student's graduation.

(b) Student positions established in support of cooperative education programs for graduate students which provide for scheduled periods of attendance at a graduate school combined with at least 16 weeks or 640 hours of study-related work in a Federal agency. The periods of work and study must satisfy requirements for the graduate degree and provide experience necessary for career or career-conditional appointment in the Federal career service upon the student's graduation.

(c) Student positions established in connection with associate degree cooperative education programs which provide for formally arranged schedules of attendance at a recognized 2–year educational institution combined with at least 26 weeks or 1,040 hours of study-related work in a Federal agency. The periods of work and study together must satisfy the requirements for graduation and must provide the experience necessary for career or career-conditional appointment in selected occupations in the Federal career service upon the student's graduation.

(d) Student positions established in connection with the Harry S. Truman Foundation Scholarship Program under the provisions of Public Law 93–642 to permit scheduled periods of attendance at institutions of higher education combined with at least 26 weeks or 1,040 hours of study-related work in a Federal agency. The periods of work and study must satisfy requirements of programs established by agreement between the Harry S. Truman Scholarship Foundation and the employing agency and provide the experience necessary for career or career-conditional appointment in the Federal career service upon the student's graduation.

(e) Student positions established in support of the Cooperative Education (Vocational Education) Programs for high school students which provide for scheduled periods of classroom study combined with at least 16 weeks or 640 hours of study-related work in a Federal agency. The periods of study and work must satisfy requirements for a high school diploma and provide experience necessary for career or career-conditional appointment into office and administrative support, technician, assistant, helper, and preapprentice occupations in the Federal career service upon the student's graduation.

(f) Positions under the Federal Junior Fellowship Program, a career-related work-study program covered under the provisions of Executive Order 12015.

(g) Student positions established in support of the Cooperative Education Program in which the student is enrolled in an undergraduate certificate or diploma program in an accredited college, technical, trade, vocational, or business school which provides for scheduled periods of classroom study combined with at least 16 weeks or 640 hours of study-related work in a Federal agency. The periods of study and work must satisfy requirements for an undergraduate certificate or diploma and provide experience necessary for career or career-conditional appointment into office and administrative support, technician, assistant, helper, and preapprentice occupations in the Federal career service upon the student's graduation.

(h)–(i) (Reserved).

(j) Special executive development positions established in connection with Senior Executive Service candidate development programs which have been approved by OPM. A Federal agency may make new appointments under this authority for any period of employment not exceeding three years for one individual.

(k) Positions at grades GS–15 and below when filled by individuals who (1) are placed at a severe disadvantage in obtaining employment because of a psychiatric disability evidenced by hospitalization or outpatient treatment and have had a significant period of substantially disrupted employment because of the disability; and (2) are certified to a specific position by a State vocational rehabilitation counselor or a Veterans Administration counseling psychologist (or psychiatrist) who indicates that they meet the severe disadvantage criteria stated above, that they are capable of functioning in the positions to which they will be appointed, and that any residual disability is not job related. Employment of any individual under this authority may not exceed 2 years following each significant period of mental illness.

(l) (Reserved).

(m) Positions when filled under any of the following conditions:

(1) Appointment at grades GS–15 and above, or equivalent, in the same or a different agency without a break in service from a career appointment in the Senior Executive Service (SES) of an individual who:

(i) Has completed the SES probationary period;

(ii) Has been removed from the SES because of less than fully successful executive performance or a reduction in force; and

(iii) Is entitled to be placed in another civil service position under 5 U.S.C. 3594(b).

(2) Appointment in a different agency without a break in service of an individual originally appointed under paragraph (m)(1).

(3) Reassignment, promotion, or demotion within the same agency of an individual appointed under this authority.

Section 213.3203 Executive Office of the President

(a) (Reserved).

(b) *Office of the Special Representative for Trade Negotiations.* (1) Seventeen positions of economist at grades GS–12 through GS–15.

Section 213.3204 Department of State

(a)–(c) (Reserved).

(d) Fourteen positions on the household staff of the President's Guest House (Blair and Blair-Lee Houses).

(e) Four Physical Science Administration Officer positions at GS–11 and GS–12 under the Bureau of Oceans and International Environmental and Scientific Affairs' Science, Engineering and Diplomacy Fellowship Program. Employment under this authority is not to exceed 2½ years.

(f) Scientific, professional, and technical positions at grades GS–12 to GS–15 when filled by persons having special qualifications in foreign policy matters. Total employment under this authority may not exceed 4 years.

Section 213.3205 Department of the Treasury

(a) Positions of Deputy Comptroller of the Currency, Chief National Bank Examiner, Assistant Chief National Bank Examiner, Regional Administrator of National Banks, Deputy Regional Administrator of National Banks, Assistant to the Comptroller of the Currency, National Bank Examiner, Associate National Bank Examiner, and Assistant National Bank Examiner, whose salaries are paid from assessments against national banks and other financial institutions.

(b) Not to exceed 10 positions engaged in functions mandated by Public Law 99–190, the duties of which require expertise and knowledge gained as a present or former employee of the Synthetic Fuels Corporation, as an employee of an organization carrying out projects or contracts for the Corporation, or as an employee of a Government agency involved in the Synthetic Fuels Program. Appointments under this authority may not exceed 4 years.

(c) Not to exceed two positions of Accountant (Tax Specialist) at grades GS–13 and above to serve as specialists on the accounting analysis and treatment of corporation taxes. Employments under this paragraph shall not exceed a period of 18 months in any individual case.

(d) Positions concerned with the protection of the life and safety of the President and members of his immediate family, or other persons for whom similar protective services are prescribed by law, when filled in accordance with special appointment procedures approved by OPM. Service under this authority may not exceed (1) a total of 4 years; or (2) 120 days following completion of the service required for conversion under Executive Order 11203, whichever occurs first.

Section 213.3206 Department of Defense

(a) *Office of the Secretary.* (1) (Reserved).

(2) Professional positions at GS–11 through GS–15 involving systems, costs, and economic analysis functions in the Office of the Assistant Secretary (Program Analysis and Evaluation); and in the Office of the Deputy Assistant Secretary (Systems Policy and Information) in the Office of the Assistant Secretary (Comptroller).

(3)–(4) (Reserved).

(5) Four Net Assessment Analysts.

(b) *Interdepartmental activities.* (1) Five positions to provide general administration, general art and information, photography, and/or visual information support to the White House Photographic Service.

(c) *National Defense University.* (1) Sixty-one positions of professor, GS–13/15, for employment of any one individual on an initial appointment not to exceed 3 years, which may be renewed in any increment from 1 to 6 years indefinitely thereafter.

(d) *General.* (1) One position of Law Enforcement Liaison Officer (Drugs), GS–301–15, U.S. European Command.

(e) *Office of the Inspector General.* (1) Positions of Criminal Investigator, GS–1811–5/15.

(f) *Department of Defense Polygraph Institute, Fort McClellan, Alabama.* (1) One Director, GM–15.

Section 213.3207 Department of the Army

(a) *U.S. Army Command and General Staff College.* (1) Seven positions of professors, instructors, and education specialists. Total employment of any individual under this authority may not exceed 4 years.

(b) *Brooke Army Medical Center, Fort Sam Houston, Texas.* (1) Two Medical Officer (Surgery) positions, GS–12, in the Clinical Division, U.S. Army Institute of Surgical Research, whose incumbents are enrolled in medical school surgical residency programs. Employment under this authority shall not exceed 12 months.

Section 213.3208 Department of the Navy

(a) *Naval Underwater Systems Center, New London, Connecticut.* (1) One position of oceanographer, grade GS–14, to function as project director and manager for research in the weapons systems applications of ocean eddies.

(b) All civilian faculty positions of professors, instructors, and teachers on the staff of the Armed Forces Staff College, Norfolk, Virginia.

(c) One Director and four Research Psychologists at the professor or GS–15 level in the Defense Personnel Security Research and Education Center.

(d) All civilian professor positions at the Marine Corps Command and Staff College.

(e) One position of Staff Assistant, GS–301–12, whose incumbent will manage the Navy's Executive Dining facilities at the Pentagon.

Section 213.3209 Department of the Air Force

(a) Not to exceed eight interdisciplinary positions for the Air Research Institute at the Air University, Maxwell Air Force Base, Alabama, for employment to complete studies proposed by candidates and acceptable to the Air Force. Initial appointments are made not to exceed 3 years, with an option to renew or extend the appointments in increments of 1, 2, or 3 years indefinitely thereafter.

(b) (Reserved).

(c) One Director of Instruction and 14 civilian Instructors at the Defense Institute of Security Assistance Management, Wright-Patterson Air Force Base, Dayton, Ohio. Individual appointments under this authority will be for an initial 3-year period, which

may be followed by an appointment of indefinite duration.

(d) Six positions of professor, associate professor, or professional academic staff at the Air University, Maxwell Air Force Base, Alabama, associated with courses of instruction of less than 10 months duration, for employment not to exceed 3 years, which may be renewed in 1-, 2-, or 3-year increments indefinitely thereafter.

(e) One position of Director of Development and Alumni Programs, GS–301–13, with the U.S. Air Force Academy, Colorado.

Section 213.3210 Department of Justice

(a) Criminal Investigator (Special Agent) positions in the Drug Enforcement Administration. New appointments may be made under this authority only at grades GS–5 through 11. Service under the authority may not exceed 4 years. Appointments made under this authority may be converted to career or career-conditional appointments under the provisions of Executive Order 12230, subject to conditions agreed upon between the Department and OPM.

(b) Positions of Port Receptionist and Supervisory Port Receptionist, Immigration and Naturalization Service.

(c) Not to exceed 400 positions at grades GS–5 through 15 assigned to regional task forces established to conduct special investigations to combat drug trafficking and organized crime.

(d) (Reserved).

(e) Positions, other than secretarial, GS–6 through GS–15, requiring knowledge of the bankruptcy process, on the staff of the offices of United States Trustees or the Executive Office for U. S. Trustees.

Section 213.3213 Department of Agriculture

(a) *Office of International Cooperation and Development.* (1) Positions of a project nature involved in international technical assistance activities. Service under this authority may not exceed 2 years on a single project for any individual unless delayed completion of a project justifies an extension up to but not exceeding 2 years.

(b) *General.* (1) Temporary positions of professional Research Scientists, GS–15 or below, in the Agricultural Research Service and the Forest Service, when such positions are established to support the Research Associateship Program and are filled by persons having a doctoral degree in an appropriate field of study for research activities of mutual interest to appointees and the agency. Appointments are limited to proposals approved by the appropriate Administrator. Appointments may be made for initial periods not to exceed 2 years and may be extended for up to 2 additional years. Extensions beyond 4 years, up to a maximum of 2 additional years, may be granted, but only in very rare and unusual circumstances, as determined by the Department's Director of Personnel.

Section 213.3214 Department of Commerce

(a) *Bureau of the Census.* (1) (Reserved).

(2) Not to exceed 50 Community Services Specialist positions at the equivalent of GS–5 through GS–12.

(3) Not to exceed 300 Community Awareness Specialist positions at the equivalent of GS–7 through GS–12. Employment under this authority may not exceed December 31, 1992.

(b) (Reserved).

(c) *Minority Business Development Agency.* (1) One position of minority business opportunity specialist at grades GS–9 through GS–15. This authority may not be used for new appointments after December 31, 1977.

(d) *National Telecommunications and Information Administration.* (1) Not to exceed 10 positions of Telecommunications Policy Analysts, grades GS–11 through 15. Employment under this authority may not exceed 2 years.

Section 213.3215 Department of Labor

(a) Positions of Chairman and Member, Wage Appeals Board.

(b) *Office of the Inspector General.* (1) Not to exceed 110 positions of Criminal Investigator (Special Agent), GS–1811–5/15, in the Office of Labor Racketeering.

Section 213.3216 Department of Health and Human Services

(a) *Public Health Service.* (1) Not to exceed 68 positions at GS–11 and below on the Health and Nutrition Examination Survey teams of the National Center for Health Statistics.

(2) One Public Health Education Specialist, GS–1725–15, in the Centers for Disease Control, Atlanta, Georgia.

(b)–(c) (Reserved).

(d) *National Library of Medicine.* (1) Ten positions of Librarian, GS–7, the incumbents of which will be trainees in the Library Associate Training Program in Medical Librarianship and Biomedical Communications. Employment under this authority is not to exceed 1 year.

Section 213.3217 Department of Education

(a) Seventy-five positions, not in excess of GS–13, of a professional or analytical nature when filled by persons, other than college faculty members or candidates working toward college degrees, who are participating in midcareer development programs authorized by Federal statute or regulation, or sponsored by private nonprofit organizations, when a period of work experience is a requirement for completion of an organized study program. Employment under this authority shall not exceed 1 year.

(b) Fifty positions, GS–7 through GS–11, concerned with advising on education policies, practices, and procedures under unusual and abnormal conditions. Persons employed under this provision must be bona fide elementary school and high school teachers. Appointments under this authority may be made for a period of not to exceed 1 year, and may, with the prior approval of the Office of Personnel Management, be extended for an additional period of 1 year.

Section 213.3227 Department of Veterans Affairs

(a) Not to exceed 800 principal investigatory, scientific, professional and technical positions at grades GS–11 and above in the medical research program. Employment under this authority may not exceed 7 years for any individual.

Section 213.3228 U.S. Information Agency

(a) *Voice of America.* (1) Not to exceed 200 positions at grades GS–15 and below in the Office of Cuba Broadcasting. Appointments may not be made under this authority to administrative, clerical, and technical support positions.

(b) Positions of English Language Radio Broadcast Intern, GS–1001–5/7/9. Employment is not to exceed 2 years for any intern.

Section 213.3231 Department of Energy

(a) Twenty Exceptions and Appeals Analyst positions at grades GS–7 through 11, when filled by persons selected under DOE's fellowship program in its Office of Hearings and Appeals, Washington, DC. Appointments under this authority shall not exceed 3 years.

Section 213.3234 Federal Trade Commission

(a) Positions filled under the Economic Fellows Program. No more than five new

appointments may be made under this authority in any fiscal year. Service of an individual Fellow may not exceed 4 years.

Section 213.3236 U. S. Soldiers' and Airmen's Home

(a) Three GS–11 Medical Officer positions under a fellowship program on geriatrics.

(b) Director, Health Care Services; Director, Member Services; Director, Logistics; and Director, Plans and Programs.

Section 213.3237 General Services Administration

(a) One position of Deputy Director of Network Services.

Section 213.3242 Export-Import Bank of the U.S.

(a) One position of Food Service Worker WG–7804–3/4/5, in the Office of the President and Chairman.

Section 213.3248 National Aeronautics and Space Administration

(a) Not to exceed 40 positions of Command Pilot, Pilot and Mission Specialist candidates at grades GS–7 through 15 in the Space Shuttle Astronaut program. Employment under this authority may not exceed 3 years.

Section 213.3257 National Credit Union Administration

(a) *Central Liquidity Facility.* (1) All managerial and supervisory positions at pay levels greater than the equivalent of GS–13.

Section 213.3259 ACTION

(a) *Office of Domestic and Anti-Poverty Operations.* (1) Not to exceed 25 positions of Program Specialist at grades GS–9 through GS–15.

(b) *Office of Policy and Research.* (1) Three positions of Program Specialist at grades GS–7 through GS–15.

Section 213.3264 U.S. Arms Control and Disarmament Agency

(a) Twenty-five scientific, professional, and technical positions at grades GS–12 through GS–15 when filled by persons having special qualifications in the fields of foreign policy, foreign affairs, arms control, and related fields. Total employment under this authority may not exceed 4 years.

Section 213.3274 Smithsonian Institution

(a) *National Zoological Park.* (1) Four positions of Veterinary Intern, GS–8/9/11. Employment under this authority is not to exceed 36 months.

(b) *Freer Gallery of Art.* (1) Not to exceed four positions of Oriental Art Restoration Specialist at grades GS–9 through GS–15.

Section 213.3278 Armed Forces Retirement Home

(a) *Naval Home.* (1) One Resource Management Officer position and one Public Works Officer position, GS/GM–15 and below, with the Naval Home, Armed Forces Retirement Home, in Gulfport, Mississippi.

Section 213.3276 Appalachian Regional Commission

(a) Two Program Coordinators.

Section 213.3282 National Foundation on the Arts and the Humanities.

(a) (Reserved)

(b) *National Endowment for the Humanities.* (1) Until September 30, 1990, Humanities Administrator, Reference Materials Programs, Division of Research Programs.

(2) Until September 30, 1990, Humanities Administrator (Assistant Director), Humanities Projects in Higher Education Program, Division of Education Programs.

(3) Until September 30, 1990, Deputy Director, Division of Education Programs.

(4) Until September 30, 1990, Director, Division of Research Grants.

(5) Until September 30, 1990, one position of Director, GS–1701–15, one position of Deputy Director, GS–1701–14, and seven positions of Humanities Administrator, GS–1701–13, Division of State Programs.

(6) Until September 30, 1990, one Director and one Deputy Director, Division of Fellowships and Seminars.

(7) Until September 30, 1990, one Humanities Administrator, Fellowships for College Teachers, Division of Fellowships.

(8) Until September 30, 1990, seven positions of Humanities Administrator, Media Program, Division of General Programs.

(9) Until September 30, 1990, one position of Humanities Administrator, Humanities Projects in Higher Education Program, Division of Education Programs.

(10) Until September 30, 1990, one position of Assistant Director for the Elementary and Secondary Education Program, Division of Education Programs.

(11) Until September 30, 1990, one position of Assistant Director for the Museums and Historical Organizations Program, Division of General Programs.

(12) Until September 30, 1990, four positions of Humanities Administrator, Museums and Historical Organizations Program, Division of General Programs.

(13) Until September. 30, 1990, four positions of Humanities Administrator, Elementary and Secondary Education Program, Division of Education Programs.

(14) Until September 30, 1990, Director of General Programs.

(15) Until September 30, 1990, one Assistant to the Director, General Programs.

(16) Until September 30, 1990, one Humanities Administrator, Younger Scholars Programs, Division of Fellowships and Seminars.

(17) Until September 30, 1990, one Humanities Administrator, Public Humanities Projects, Division of General Programs.

(18) Until September 30, 1990, one position of Director, Division of Education Programs.

(19) Until September 30, 1990, one Humanities Administrator (Assistant Director), Texts Programs, Division of Research Programs.

(20) Until September 30, 1990, one Humanities Administrator, Centers for Advanced Study, Division of Research Programs.

(21) Until September 30, 1990, one Challenge Grants Officer.

(22) Until September 30, 1990, one Assistant Director, Media Program, Division of General Programs.

(23) Until September 30, 1990, one position of Humanities Administrator, Publications Program, Division of Research Grants.

(24) Until September 30, 1990, one Deputy Director, Division of Research Grants.

(25) Until September 30, 1990, one Humanities Administrator, Summer Seminars for College Teachers, Division of Fellowships and Seminars.

(26) Until September 30, 1990, two positions of Humanities Administrator, Humanities Libraries Projects, Division of General Programs.

(27) Until September 30, 1990, one position of Humanities Projects Assessment Officer and one position of Humanities Administrator, Office of the Assistant Chairman for Programs.

(28) Until September 30, 1990, one position of Humanities Administrator, Public Humanities Projects, Division of General Programs, GS–14.

(29) Until September 30, 1990, one position of Humanities Administrator, GS–1701–14, in the Interpretive Research Programs, Division of Research Programs.

(30) Until September 30, 1990, one Humanities Administrator, Office of Challenge Grants.

(31) (Reserved).

(32) Until September 30, 1990, one Assistant Director, Fellowships Program, Division of Fellowships and Seminars.

(33) (Reserved).

(34) Until September 30, 1990, one Humanities Administrator, GS–1701–12, Humanities Projects in Higher Education Program, Division of Education Programs.

(35) Until September 30, 1990, two Humanities Administrators, Humanities Projects in Higher Education Program, Division of Education Programs.

(36) Until September 30, 1990, three Humanities Administrators, Humanities Projects in Higher Education Program, Division of Education Programs.

(37) Until September 30, 1990, two Humanities Administrators, Summer Seminars for Secondary School Teachers, Division of Fellowships and Seminars.

(38) Until September 30, 1990, one Humanities Administrator, Summer Stipends, Division of Fellowships and Seminars.

(39) Until September 30, 1990, one Humanities Administrator, Travel to Collections, Division of Fellowships and Seminars.

(40) Until September 30, 1990, one Humanities Administrator, Translation Program, Reference Works Program, Division of Research Programs.

(41) Until September 30, 1990, one Humanities Administrator, Editions Program, Reference Works Program, Division of Research Programs.

(42) (Reserved).

(43) Until September 30, 1990, one Humanities Administrator, Foundations of American Society Program, Division of Fellowships and Seminars.

(44) Until September 30, 1990, one Humanities Administrator, Humanities Projects in Museums and Historical Organizations, Division of General Programs.

(45) Until September 30, 1990, four Humanities Administrators, Office of Preservation.

(46) Until September 30, 1990, one Director, Office of Preservation.

(47) Until September 30, 1990, one Humanities Administrator (Program Officer), Regrant Programs, Division of Research Programs.

(48) Until September 30, 1990, one Director, Office of Planning and Budget.

(49) Until September 30, 1990, one Humanities Administrator, Tools Program, Reference Materials Program, Division of Research Programs.

(50) Until September 30, 1990, one Humanities Administrator, Access Program, Reference Materials Program, Division of Research Programs.

(51) Until September 30, 1990, one Humanities Administrator, Project Research, Interpretive Research Program, Division of Research Programs.

(52) Until September 30, 1990, one Humanities Administrator, Humanities, Science, and Technology Program, Interpretive Research Program, Division of Research Programs.

(53) Until September 30, 1990, one Humanities Administrator, Office of the Assistant Chairman for Programs and Policy.

Section 213.3285 Pennsylvania Avenue Development Corporation

(a) One position of Civil Engineer (Construction Manager).

Section 213.3291 Office of Personnel Management

(a) Not to exceed eight positions of Associate Director at the Executive Seminar Centers at grades GS–13 and GS–14. Appointments may be made for any period up to 3 years and may be extended without prior approval for any individual. Not more than half of the authorized faculty positions at any one Executive Seminar Center may be filled under this authority.

(b) Twelve positions of faculty members at grades GS–13 through 15, at the Federal Executive Institute. Initial appointments under this authority may be made for any period up to 3 years and may be extended in 1-, 2-, or 3-year increments indefinitely thereafter.

Section 213.3294 Department of Transportation

(a) *Federal Railroad Administration.* (1) Regional Director of Railroad Safety, Fort Worth, Texas.

Schedule C

Section 213.3303 Executive Office of the President

Council of Economic Advisors

CEA 1 Secretary to the Chairman.
CEA 4 Secretary to the Chairman.
CEA 5 Secretary to the Council Member.
CEA 6 Secretary to the Council Member.

Council on Environmental Quality:

CEQ 2 Executive Assistant to the Chairman.
CEQ 3 Confidential Assistant to the Chairman.
CEQ 4 Confidential Assistant to the Chairman.

Office of Management and Budget:

OMB 10 Confidential Assistant to the Associate Director for Natural Resources, Energy, and Science.
OMB 21 Confidential Assistant to the Director.
OMB 30 Special Assistant to the Associate Director for Congressional Affairs.
OMB 46 Special Assistant to the Associate Director for Legislative Affairs.
OMB 50 Legislative Assistant to the Associate Director for Congressional Affairs.
OMB 59 Public Affairs Assistant to the Director of External Affairs.
OMB 62 Staff Assistant to the Director, reporting to the Executive Assistant to the Director.
OMB 65 Legislative Assistant to the Associate Director for Congressional Affairs.
OMB 66 Secretary to the Associate Director for Economic Policy.
OMB 72 Confidential Assistant to the Associate Director for Human Resources, Veterans and Labor.
OMB 75 Deputy Director of External Affairs.
OMB 76 Confidential Assistant to the Associate Director for Congressional Affairs.
OMB 78 Secretary to the Administrator, Office of Information and Regulatory Affairs.
OMB 79 Special Assistant to the Deputy Director.
OMB 80 Confidential Assistant to the Executive Assistant to the Director.
OMB 81 Confidential Assistant to the Executive Associate Director.
OMB 82 Confidential Assistant to the Executive Assistant to the Director.
OMB 83 Legislative Assistant to the Associate Director for Legislative Affairs.
OMB 84 Special Assistant to the Associate Director for Legislative Affairs.
OMB 85 Legislative Assistant to the Associate Director for Legislative Affairs.

Office of National Drug Control Policy:

ONDCP 1 Special Assistant to the Director and White House Liaison (Executive Secretariat).
ONDCP 2 Staff Assistant to the Deputy Director, Demand Reduction.
ONDCP 3 Confidential Assistant to the Deputy Director, Demand Reduction.
ONDCP 4 Legislative Assistant to the Director, Congressional Relations.
ONDCP 5 Legislative Assistant to the Director, Congressional Relations.
ONDCP 7 Confidential Assistant to the Special Assistant to the Director and White House Liaison.
ONDCP 12 Staff Assistant to the Chief of Staff.
ONDCP 15 Legislative Assistant to the Director, Congressional Relations.
ONDCP 20 Staff Assistant to the Special Assistant to the Director and White House Liaison.
ONDCP 21 Confidential Assistant to the Special Assistant to the Director.
ONDCP 23 Confidential Assistant to the Director.
ONDCP 25 Confidential Assistant to the General Counsel.
ONDCP 27 Confidential Assistant to the Director, Congressional Relations.
ONDCP 28 Special Assistant to the Associate Director, State and Local Affairs.
ONDCP 29 Special Assistant for Prevention to the Deputy Director, Demand Reduction.
ONDCP 30 Special Assistant for Treatment/Health for State and Local Affairs to the Associate Director, State and Local Affairs.

ONDCP 32 Staff Assistant to the Special Assistant to the Director.
ONDCP 33 Staff Assistant to the Deputy Director, Supply Reduction.
ONDCP 34 Confidential Assistant to the Associate Director, State and Local Affairs.
ONDCP 35 Staff Assistant to the Special Assistant to the Director.
ONDCP 36 Special Assistant to the Chairman, President's Drug Advisory Council.
ONDCP 37 Staff Assistant to the Chairman, President's Drug Advisory Council.
ONDCP 38 Staff Assistant for Scheduling to the Executive Assistant to the Director.
ONDCP 39 Staff Assistant to the Associate Director, State and Local Affairs.
ONDCP 40 Law Clerk to the General Counsel.
ONDCP 42 Public Affairs Specialist (Press Secretary) to the Deputy Chief of Staff.
ONDCP 43 Confidential Assistant to the Public Affairs Specialist (Press Secretary).
ONDCP 44 Staff Assistant to the Director of Congressional Relations.
ONDCP 46 Staff Assistant for Scheduling to the Executive Assistant to the Director.

Office of Science and Technology Policy:

OSTP 1 Public Information Assistant to the Director.
OSTP 8 Confidential Secretary to the Director.
OSTP 9 Administrative Assistant (Typing) to the Chief of Staff.

President's Commission on Executive Exchange:

PCEE 1 Confidential Assistant to the Executive Director.
PCEE 5 Public Affairs Specialist to the Executive Director.
PCEE 11 Associate Director for Education to the Executive Director.
PCEE 12 Public Affairs Specialist to the Executive Director.
PCEE 13 Assistant to the Associate Director for Education.

Office of the United States Trade Representative:

USTR 14 Confidential Secretary to the Ambassador/United States Trade Representative.
USTR 20 Deputy Assistant United States Trade Representative for Congressional Affairs.
USTR 28 Congressional Affairs Officer to the Assistant United States Trade Representative for Congressional Affairs.
USTR 30 Confidential Assistant to the Deputy United States Trade Representative—Geneva.
USTR 31 Confidential Secretary to the Ambassador/United States Trade Representative.
USTR 32 Associate Director, Office of Private Sector Liaison, to the Assistant United States Trade Representative for Public Affairs and Private Sector Liaison.
USTR 33 Confidential Secretary to the Chief Textile Negotiator.

Section 213.3304 Department of State

ST 38 Staff Assistant to the Assistant Secretary, Bureau of Public Affairs.
ST 43 Secretary (Steno) to the Assistant Secretary, Bureau of Intelligence and Research.
ST 51 Special Assistant to the Legal Adviser.
ST 59 Secretary (Steno) to the Under Secretary for Economic Affairs.
ST 67 Secretary (Steno) to the Assistant Secretary, Bureau of Politico-Military Affairs.
ST 68 Staff Assistant to the Special Assistant, Office of White House Liaison, Bureau of Public Affairs.
ST 105 Special Assistant to the Assistant Secretary, Bureau of International Organization Affairs.
ST 107 Secretary to the Assistant Secretary, Bureau of Economic and Business Affairs.
ST 112 Member, Policy Planning Staff, to the Director, Policy Planning Staff.
ST 113 Senior Policy Advisor to the Ambassador-at-Large for Refugee Affairs.
ST 116 Staff Assistant to the Counselor of the Department.
ST 117 Confidential Clerk to the Secretary.
ST 122 Staff Assistant to the Under Secretary for Management.
ST 124 Special Assistant to the Assistant Secretary, Bureau of Inter-American Affairs.
ST 127 Secretary (Steno) to the Assistant Secretary, Bureau of Human Rights and Humanitarian Affairs.
ST 128 Legislative Management Officer to the Assistant Secretary, Bureau of Legislative Affairs.
ST 129 Staff Assistant to the Secretary.
ST 132 Secretary (Typing) to the Assistant Secretary, Bureau of International Organization Affairs.
ST 134 Secretary (Steno) to the Deputy Secretary.
ST 139 Protocol Officer (Visits) to the Chief of Protocol.
ST 145 Member, Policy Planning Staff, to the Director, Policy Planning Staff.
ST 149 Special Assistant to the Assistant Secretary, Bureau of Inter-American Affairs.
ST 161 Secretary (Steno) to the Under Secretary for Management.
ST 167 Protocol Officer (Visits) to the Chief of Protocol.
ST 168 Staff Assistant to the Legal Adviser.
ST 170 Special Assistant to the Deputy Secretary.
ST 173 Special Assistant to the Under Secretary for Management.
ST 175 Legislative Management Officer to the Principal Deputy Assistant Secretary for Legislative Affairs.
ST 179 Congressional Relations Officer to the Principal Deputy Assistant Secretary for Legislative Affairs.
ST 180 Director of Programs to the Assistant Secretary, Bureau of Human Rights and Humanitarian Affairs.
ST 181 Director, Office of Public Liaison, to the Senior Deputy Assistant Secretary, Bureau of Public Affairs.
ST 183 Public Affairs Advisor to the Assistant Secretary, Bureau of Human Rights and Humanitarian Affairs.
ST 189 Staff Assistant to the Deputy Assistant Secretary for Legislative Affairs.
ST 205 Secretary (Steno) to the Assistant Secretary, Bureau of East Asian and Pacific Affairs.
ST 209 Protocol Officer (Visits) to the Chief of Protocol.
ST 214 Secretary (Typing) to the Assistant Secretary, Bureau of Economic and Business Affairs.
ST 219 Policy Advisor to the Ambassador-at-Large/Permanent Representative to the Organization of American States.
ST 224 Special Assistant to the Assistant Secretary, Bureau of East Asian and Pacific Affairs.
ST 225 Foreign Affairs Officer to the Assistant Secretary, Bureau of Human Rights and Humanitarian Affairs.
ST 242 Special Program Assistant to the Director of Human Rights Legislation and Public Diplomacy, Bureau of Human Rights and Humanitarian Affairs.
ST 243 Program Specialist to the Chief of Protocol.
ST 244 Legislative Management Officer to the Assistant Secretary, Bureau of Legislative Affairs.
ST 248 Special Assistant to the Deputy Assistant Secretary for International Social and Humanitarian Affairs, Bureau of International Organization Affairs.
ST 249 Staff Assistant to the Deputy Secretary.
ST 250 Public Information Officer to the Deputy Assistant Secretary for International Social and Humanitarian Affairs, Bureau of International Organization Affairs.
ST 252 Protocol Officer (Visits) to the Chief of Protocol.
ST 258 Secretary (Steno) to the Inspector General.
ST 259 Special Assistant to the Legal Adviser.
ST 262 Associate Director, Office of Equal Employment Opportunity and Civil Rights, to the Deputy Assistant Secretary for Equal Employment Opportunity and Civil Rights.
ST 263 Special Assistant to the Secretary.
ST 265 Staff Assistant to the Secretary.
ST 266 Special Assistant to the Secretary.
ST 267 Secretary to the Assistant Secretary, Bureau of Public Affairs.
ST 268 Staff Assistant to the Secretary.
ST 269 Supervisory Protocol Officer to the Chief of Protocol.
ST 271 Member, Policy Planning Staff, to the Director, Policy Planning Staff.
ST 272 Staff Assistant to the Deputy Secretary.
ST 276 Member, Policy Planning Staff, to the Director, Policy Planning Staff.
ST 277 Special Assistant to the Director, Policy Planning Staff.
ST 278 Secretary (Steno) to the Director, Policy Planning Staff.
ST 279 Staff Assistant to the Coordinator of Intergovernmental Affairs.
ST 280 Special Programs Assistant to the Director of Human Rights Legislation and Public Diplomacy, Bureau of Human Rights and Humanitarian Affairs.
ST 281 Foreign Affairs Officer (Visits) to the Chief of Protocol.
ST 282 Special Assistant to the Ambassador-at-Large for Refugee Affairs.

ST 284 Secretary (Steno) to the Coordinator for Counterterrorism.
ST 285 Staff Assistant to the Assistant Secretary for International Narcotics Matters.
ST 286 Secretary (Steno) to the United States' Permanent Representative to the Organization of American States.
ST 289 Secretary to the Permanent United States Representative to the United Nations.
ST 290 Secretary (Steno) to the Ambassador-at-Large for Burdensharing.
ST 291 Senior Policy Advisor to the Assistant Secretary for Legislative Affairs.
ST 293 Special Assistant to the U.S. Negotiator for Defense and Space.
ST 294 Secretary (Steno) to the Under Secretary for Security Assistance, Science and Technology.
ST 296 Secretary (Steno) to the Chief Financial Officer.
ST 297 Foreign Affairs Officer to the Chief of Protocol.
ST 299 Staff Assistant to the Secretary.
ST 301 Staff Assistant to the Deputy Assistant Secretary for Policy, Plans, and Program Evaluation, Bureau of International Narcotics Matters.
ST 302 Staff Assistant to the U.S. Negotiator for Defense and Space.
ST 303 Secretary (Typing) to the Coordinator, Bureau of International Communication and Information Policy.
ST 304 Special Assistant to the Assistant Secretary, Bureau of Consular Affairs.
ST 305 Director, Public Affairs Staff, to the Assistant Secretary, Bureau of Consular Affairs.
ST 307 Deputy Assistant Secretary for Planning and Development to the Assistant Secretary, Bureau of Diplomatic Security.
ST 308 Deputy Assistant Secretary for Emergency Plans and Counterterrorism to the Assistant Secretary, Bureau of Diplomatic Security.
ST 309 Special Assistant to the Under Secretary for Economic Affairs.
ST 310 Secretary (Typing) to the Assistant Secretary for Legislative Affairs.
ST 311 Staff Assistant to the Under Secretary for Political Affairs.
ST 313 Staff Assistant to the Under Secretary for Economic Affairs.
ST 315 Deputy Assistant Secretary to the Assistant Secretary, Bureau of Human Rights and Humanitarian Affairs.
ST 316 Special Assistant to the Assistant Secretary, Bureau of Near Eastern and South Asian Affairs.
ST 317 Program Analyst to the Deputy Assistant Secretary for Policy and Counterterrorism.
ST 318 Special Assistant to the Coordinator, Bureau of International Communications and Information Policy.
ST 319 Correspondence Officer to the Principal Deputy Assistant Secretary for Legislative Affairs.
ST 320 Program Assistant to the Assistant Secretary, Bureau of Diplomatic Security.
ST 322 Program Specialist to the Director, Office of Public Liaison, Bureau of Public Affairs.
ST 326 Deputy U. S. Negotiator to the U.S. Negotiator for Defense and Space.

Section 213.3305 Department of the Treasury

TREA 27 Executive Assistant to the Secretary.
TREA 39 Special Assistant to the Assistant Secretary for Legislative Affairs.
TREA 44 Legislative Manager to the Assistant Secretary for Legislative Affairs.
TREA 61 Special Assistant to the Assistant Secretary for Public Affairs and Public Liaison.
TREA 79 Legislative Analyst to the Assistant Secretary for Legislative Affairs.
TREA 92 Director, Consumer Affairs, to the Assistant Secretary for Business and Consumer Affairs.
TREA 128 Confidential Assistant to the Secretary.
TREA 139 Director of Scheduling to the Assistant Secretary for Policy Management.
TREA 143 Deputy Director of Scheduling to the Assistant Secretary of Policy Management.
TREA 145 Travel Assistant to the Deputy Assistant Secretary for Administration.
TREA 153 Legislative Specialist to the Assistant Secretary for Legislative Affairs.
TREA 170 Assistant Director for Travel and Special Event Services, to the Deputy Assistant Secretary for Administration.
TREA 185 Legislative Manager to the Assistant Secretary for Legislative Affairs.
TREA 186 Public Affairs Specialist to the Treasurer of the United States.
TREA 188 Special Assistant (Policy Analysis) to the Secretary.
TREA 189 Special Assistant (Personnel) to the Secretary.
TREA 191 Special Assistant to the Deputy Assistant Secretary for Departmental Finance and Management.
TREA 192 Confidential Assistant to the Secretary.
TREA 193 Director, Office of Intergovernmental Affairs, to the Deputy Assistant Secretary for Public Liaison.
TREA 196 Confidential Assistant to the Executive Secretary.
TREA 199 Executive Assistant to the Deputy Secretary.
TREA 200 Legislative Manager to the Assistant Secretary for Legislative Affairs.
TREA 202 Director, Office of Legislative Affairs, to the Assistant Secretary for Legislative Affairs.
TREA 203 Staff Assistant (Correspondence Review) to the Executive Secretary.
TREA 204 Staff Assistant to the Assistant Secretary for Policy Management.
TREA 207 Legislative Manager to the Assistant Secretary for Legislative Affairs.
TREA 209 Special Assistant to the Under Secretary for Finance.
TREA 210 Staff Assistant to the Director of the Mint.
TREA 213 Confidential Assistant to the Assistant Secretary for Legislative Affairs.
TREA 214 Special Assistant to the Deputy Assistant Secretary for Corporate Finance.
TREA 216 Special Assistant to the Assistant Secretary for Policy Management.
TREA 217 Special Assistant to the Assistant Secretary for International Affairs.
TREA 218 Special Assistant to the Deputy Assistant Secretary for Corporate Finance.
TREA 219 Special Assistant to the Assistant Secretary for Economic Policy.
TREA 220 Secretary to the Commissioner of Internal Revenue.
TREA 221 U.S. Executive Director, African Development Bank, to the Assistant Secretary for International Affairs.
TREA 222 Special Assistant to the Under Secretary for International Affairs.
TREA 226 Assistant to the Commissioner of Internal Revenue.
TREA 227 Special Assistant to the Assistant Secretary for Management.
TREA 230 Staff Assistant to the Director of Public Affairs.
TREA 234 Special Assistant to the Director of the Mint.
TREA 235 Special Assistant for Administrative Operations to the Deputy Assistant Secretary for Management.
TREA 236 Staff Assistant to the Deputy Assistant Secretary for Public Liaison.
TREA 237 Special Assistant to the Director, Office of Thrift Supervision.
TREA 238 Confidential Assistant to the Assistant Secretary for International Affairs.
TREA 239 Special Assistant to the Director, Office of Thrift Supervision.
TREA 240 Staff Assistant to the Assistant Secretary for Policy Management.
TREA 242 Executive Secretary to the Assistant Secretary for Policy Management.
TREA 243 Special Assistant to the Assistant Secretary for International Affairs.
TREA 244 Administrative Assistant to the Director, Office of Thrift Supervision.
TREA 245 Confidential Assistant to the Deputy Assistant Secretary for Departmental Finance and Management.
TREA 246 Ombudsman to the Commissioner of Customs.
TREA 247 Special Assistant to the Assistant Secretary for Policy Management.
TREA 248 Associate Director for the Resolution Trust Corporation to the Director, Office of Thrift Supervision.
TREA 249 Staff Assistant to the Director, Office of Thrift Supervision.
TREA 250 Director, Office of Public Affairs, to the Deputy Assistant Secretary for Public Affairs.
TREA 251 Confidential Assistant to the Under Secretary for International Affairs.
TREA 252 Counselor to the Chief Counsel.
TREA 253 Confidential Assistant to the Treasurer of the United States.
TREA 254 Review Officer to the Executive Secretary.
TREA 255 Director, Office of Congressional Relations, to the Director, Office of Thrift Supervision.
TREA 256 Public Affairs Specialist to the Deputy Assistant Secretary for Public Liaison.
TREA 257 Marketing Specialist to the Executive Director, U.S. Savings Bonds Division.
TREA 258 Legislative Assistant to the Deputy Assistant Secretary for Legislative Affairs.
TREA 259 Deputy Director (Operations) to the Director, U.S. Savings Bonds Division.
TREA 260 Special Assistant to the Director, U.S. Savings Bonds Division.

TREA 261 Travel Assistant to the Deputy Assistant Secretary for Administration.
TREA 262 Confidential Assistant to the Executive Director, U.S. Savings Bonds Division.
TREA 263 Special Assistant to the Deputy Director (Operations), U.S. Savings Bonds Division.
TREA 264 Special Assistant to the Deputy Assistant Secretary for Corporate Finance.
TREA 265 Special Assistant to the General Counsel.
TREA 266 Associate Director for Public Affairs to the Director, Office of Thrift Supervision.
TREA 268 Senior Legislative Manager to the Deputy Assistant Secretary for Legislative Affairs.
TREA 269 Review Assistant to the Executive Secretary.
TREA 270 Confidential Assistant to the Deputy Treasurer of the United States
TREA 271 Speechwriter to the Associate Director for Public Affairs, Office of Thrift Supervision.
TREA 272 Public Affairs Specialist to the Commissioner of Customs.
TREA 273 Special Assistant (Banking Policy) to the Secretary.
TREA 274 Special Assistant (Banking Legislation) to the Secretary.

Section 213.3306 Department of Defense

DOD 5 Private Secretary to the Deputy Secretary.
DOD 19 Personal and Confidential Assistant to the Assistant Secretary for Program Analysis and Evaluation.
DOD 22 Private Secretary to the Assistant Secretary (Atomic Energy).
DOD 23 Confidential Assistant to the Military Assistant to the Secretary.
DOD 24 Chauffeur to the Secretary.
DOD 30 Secretary (Steno) to the Defense Advisor to U.S. NATO.
DOD 33 Personal Secretary to the Deputy Secretary.
DOD 34 Private Secretary to the Principal Deputy Assistant Secretary for International Security Affairs.
DOD 35 Confidential Assistant to the Special Assistant to the Secretary and Deputy Secretary.
DOD 54 Private Secretary to the Judge, U. S. Court of Military Appeals.
DOD 56 Private Secretary to the Judge, U. S. Court of Military Appeals.
DOD 62 Management Officer to the Chairman, President's Intelligence Oversight Board.
DOD 66 Private Secretary to the Physician to the President.
DOD 75 Chauffeur to the Deputy Secretary.
DOD 84 Private Secretary to the Principal Deputy Assistant Secretary for Force Management and Personnel.
DOD 89 Secretary (Typing) to the Principal Deputy Assistant Secretary for Public Affairs.
DOD 101 Private Secretary to the Director of Net Assessment.
DOD 119 Private Secretary to the Principal Deputy Assistant Secretary for Program Analysis and Evaluation.
DOD 133 Public Affairs Specialist to the Assistant Secretary for Public Affairs.
DOD 174 Private Secretary to the Under Secretary for Policy.
DOD 175 Personal and Confidential Assistant to the Judge, U. S. Court of Military Appeals.
DOD 194 Private Secretary to the Assistant Secretary for International Security Policy.
DOD 205 Personal and Confidential Assistant to the Judge, U. S. Court of Military Appeals.
DOD 212 Private Secretary to the Deputy Under Secretary for International Programs.
DOD 214 Assistant to the Secretary.
DOD 216 Private Secretary to the Principal Deputy Assistant Secretary for International Security Policy.
DOD 217 Personal and Confidential Assistant to the Assistant Secretary for Command, Control, Communications and Information.
DOD 236 Director for Programs to the Assistant Secretary for Public Affairs.
DOD 241 Personal and Confidential Assistant to the Assistant Secretary for International Security Policy.
DOD 250 Director for Editorial Services to the Assistant Secretary for Public Affairs.
DOD 254 Special Assistant for Emergency Planning to the Assistant Secretary (Production and Logistics).
DOD 255 Personal and Confidential Assistant to the Deputy Secretary.
DOD 256 Staff Assistant to the Assistant Secretary for Force Management and Personnel.
DOD 261 Special Assistant for European Security and Political Affairs to the Deputy Assistant Secretary for European and NATO Policy.
DOD 270 Private Secretary to the Director, Strategic Defense Initiative Organization.
DOD 271 Private Secretary to the Principal Deputy Assistant Secretary for Reserve Affairs.
DOD 275 Assistant for European Security Negotiations to the Deputy Assistant Secretary (Negotiations Policy).
DOD 283 Special Assistant to the Assistant Secretary for Public Affairs.
DOD 287 Special Assistant for Strategic Defense and Space Arms Control Policy to the Deputy Assistant Secretary (Nuclear Forces and Arms Control Policy).
DOD 295 Special Assistant to the Assistant Secretary for Force Management and Personnel.
DOD 299 Family Policy Specialist to the Deputy Assistant Secretary for Family Support, Education, and Safety.
DOD 301 Personal and Confidential Assistant to the Assistant Secretary for Production and Logistics.
DOD 311 Staff Assistant to the Assistant to the Chairman, Joint Chiefs of Staff.
DOD 314 Personal and Confidential Assistant to the Under Secretary for Acquisition.
DOD 316 Law Clerk to the Judge, U. S. Court of Military Appeals.
DOD 317 Personal and Confidential Assistant to the Director, Defense Research and Engineering.
DOD 320 Executive Assistant to the Secretary.
DOD 321 Staff Assistant to the Assistant to the Vice President for National Security Affairs.
DOD 322 Personal and Confidential Assistant to the U. S. Ambassador to NATO.
DOD 324 Confidential Assistant to the Comptroller.
DOD 325 Special Assistant for Foreign Affairs to the Assistant Secretary for Legislative Affairs.
DOD 326 Special Assistant for International Security Affairs to the Assistant Secretary for Legislative Affairs.
DOD 327 Special Assistant for Special Operations and Drug Policy to the Assistant Secretary for Legislative Affairs.
DOD 328 Personal and Confidential Assistant to the Assistant to the Secretary.
DOD 329 Special Assistant to the Under Secretary for Policy.
DOD 332 Personal and Confidential Assistant to the Assistant Secretary for International Security Affairs.
DOD 333 South American Country Director to the Assistant Secretary for International Security Affairs.
DOD 334 Public Affairs Specialist to the Assistant Secretary for Public Affairs.
DOD 335 Public Affairs Specialist to the Assistant Secretary for Public Affairs.
DOD 336 Public Affairs Specialist to the Assistant Secretary for Public Affairs.
DOD 337 Special Assistant (Operations) to the Assistant Secretary for Public Affairs.
DOD 339 Speechwriter to the Assistant Secretary for Public Affairs.
DOD 344 Program Analyst to the Deputy Under Secretary for Industrial and International Programs.
DOD 345 Program Analyst to the Deputy Under Secretary for Industrial and International Programs.
DOD 346 Program Analyst to the Deputy Under Secretary for International Programs.
DOD 348 Special Assistant for Technology Transfer to the Deputy Under Secretary for Trade Security Policy.
DOD 349 Special Assistant to the Assistant Secretary for International Security Affairs.
DOD 351 Special Assistant to the Assistant Secretary for International Security Affairs.
DOD 352 Confidential Assistant to the General Counsel.
DOD 355 Special Assistant for Strategic Modernization to the Assistant Secretary for Legislative Affairs.
DOD 356 Director, Humanitarian Assistance, to the Deputy Assistant Secretary for Global Affairs.
DOD 358 Assistant for Multi-Lateral Negotiations to the Assistant Secretary for International Security Affairs.
DOD 359 Private Secretary to the Principal Deputy Assistant Secretary for Special Operations/Low Intensity Conflict.
DOD 361 Special Assistant for Production and Logistics and Energy to the Assistant Secretary for Legislative Affairs.
DOD 362 Education Programs Officer to the Deputy Assistant Secretary for Drug Enforcement Policy.

DOD 363 Research Analyst to the Deputy Assistant Secretary for Drug Enforcement Policy.
DOD 365 Staff Assistant to the Deputy Director, Office of Presidential Personnel.
DOD 366 Private Secretary to the Associate Director, Office of Presidential Personnel.
DOD 367 Special Assistant to the Principal Deputy Under Secretary for Strategy and Resources.
DOD 368 Personal and Confidential Secretary to the Assistant Secretary for Legislative Affairs.
DOD 369 Representative of the Secretary to the Conference on Disarmament, reporting to the Assistant Secretary for International Security Policy.
DOD 370 Personal and Confidential Assistant to the Principal Deputy Under Secretary for Acquisition.
DOD 372 Special Assistant to the Assistant Secretary for Production and Logistics.
DOD 374 Attorney-Advisor (General) to the Assistant General Counsel/Legal Counsel.
DOD 375 Special Assistant for Research to the Assistant Secretary for Legislative Affairs.
DOD 376 Special Assistant to the Deputy Assistant to the Vice President.
DOD 377 Law Clerk to the Judge, U.S. Court of Military Appeals.
DOD 378 Government Affairs Officer to the Deputy Assistant Secretary for Drug Enforcement Policy.
DOD 379 Principal Director for Drug Enforcement Policy to the Deputy Assistant Secretary for Drug Enforcement Policy.
DOD 380 Director of Protocol to the Secretary.
DOD 381 Special Assistant for International Counternarcotics Matters to the Deputy Assistant Secretary for Inter-American Affairs.
DOD 382 Executive Assistant to the Deputy Assistant Secretary for Environment.
DOD 383 Special Assistant for International Security Programs to the Deputy Under Secretary for Security Policy.
DOD 384 Director of Competitive Strategies to the Principal Deputy Under Secretary for Policy.
DOD 386 Personal and Confidential Assistant to the Assistant Secretary for Reserve Affairs.
DOD 387 Assistant for Political-Military Analysis and Strategic Assessment to the Deputy Assistant Secretary for Policy and Requirements.
DOD 388 Speechwriter to the Director, Strategic Defense Initiative Organization.
DOD 389 Drug Testing, Health and Rehabilitation Programs Officer to the Deputy Assistant Secretary for Drug Enforcement Policy.
DOD 390 Special Assistant to the Assistant Secretary for Legislative Affairs.

Section 213.3307 Department of the Army

ARMY 3 Secretary (Steno) to the Assistant Secretary (Manpower and Reserve Affairs).
ARMY 5 Secretary (Steno) to the Assistant Secretary (Installations, Logistics and Environment).
ARMY 6 Secretary (Typing) to the Assistant Secretary (Research, Development and Acquisition).
ARMY 21 Secretary (Steno) to the General Counsel.
ARMY 55 Secretary (Typing) to the Assistant Secretary (Financial Management).
ARMY 57 Staff Assistant to the Assistant Secretary (Manpower and Reserve Affairs).
ARMY 58 Staff Assistant to the Secretary.
ARMY 59 Staff Assistant to the Secretary.
ARMY 61 Staff Assistant to the Assistant Secretary (Manpower and Reserve Affairs).
ARMY 64 Plans Coordinator to the Chief of Public Affairs.

Section 213.3308 Department of the Navy

NAV 2 Staff Assistant to the Secretary.
NAV 5 Private Secretary to the Assistant Secretary for Financial Management.
NAV 23 Special Assistant to the Military Assistant to the President.
NAV 24 Private Secretary to the Assistant Secretary for Manpower and Reserve Affairs.
NAV 30 Staff Assistant to the Deputy Under Secretary for Policy.
NAV 31 Staff Assistant to the Under Secretary.
NAV 41 Staff Assistant to the Under Secretary.
NAV 43 Staff Assistant to the Under Secretary.
NAV 46 Private Secretary to the Assistant Secretary for Research, Development and Acquisition.

Section 213.3309 Department of the Air Force

AF 1 Secretary (Steno) to the Secretary.
AF 2 Secretary (Steno) to the Under Secretary.
AF 5 Secretary (Steno) to the Assistant for Research, Development and Logistics.
AF 6 Secretary (Steno) to the Assistant Secretary for Manpower and Reserve Affairs, Installations and Environment.
AF 8 Secretary (Steno) to the General Counsel.
AF 22 Secretary (Typing) to the Assistant to the Vice President for National Security Affairs.
AF 28 Special Counsel to the General Counsel.
AF 29 Confidential Assistant to the Secretary.
AF 31 Staff Assistant to the Assistant to the Vice President for National Security Affairs.
AF 34 Secretary (Steno) to the Assistant Secretary for Space.
AF 35 Special and Confidential Assistant to the Secretary.
AF 36 Special Assistant to the Assistant to the Vice President for National Security Affairs.
AF 37 Confidential Assistant to the Under Secretary.
AF 38 Special and Confidential Assistant to the Assistant to the Vice President for Legislative Affairs.
AF 39 Secretary (Steno) to the Assistant Secretary for Financial Management and Comptroller.

Section 213.3110 Department of Justice

JUS 21 Confidential Assistant to the Assistant Attorney General, Antitrust Division.
JUS 25 Confidential Assistant (Private Secretary) to the Assistant Attorney General, Criminal Division.
JUS 27 Confidential Assistant to the Assistant Attorney General, Environment and Natural Resources Division.
JUS 83 Confidential Assistant to the Attorney General.
JUS 100 Confidential Assistant to the Director of Congressional and Public Affairs, Immigration and Naturalization Service.
JUS 132 Special Assistant for Policy Development to the Commissioner, Immigration and Naturalization Service.
JUS 137 Special Projects Director to the Deputy Commissioner, Immigration and Naturalization Service.
JUS 141 Attorney-Advisor to the Assistant Attorney General, Office of Legislative Affairs.
JUS 149 Counsel to the Assistant Attorney General, Environment and Natural Resources Division.
JUS 176 Public Affairs Specialist to the Director, Office of Public Affairs.
JUS 227 Staff Assistant to the Director, Community Relations Service.
JUS 240 Special Assistant to the Deputy Assistant Attorney General for Legislation and Litigation, Civil Rights Division.
JUS 257 Attorney-Advisor to the Assistant Attorney General, Civil Division.
JUS 271 Confidential Assistant to the Director, Office of Policy Development.
JUS 281 Congressional and Public Liaison Officer to the Assistant Attorney General, Office of Justice Programs.
JUS 297 Special Assistant to the Assistant Attorney General, Civil Division.
JUS 305 Deputy Director to the Director of Congressional Affairs, Immigration and Naturalization Service.
JUS 315 Confidential Assistant to the Director, National Obscenity Enforcement Unit, Criminal Division.
JUS 320 Special Assistant to the Assistant Attorney General, Antitrust Division.
JUS 323 Confidential Assistant to the Assistant Attorney General, Office of Justice Programs.
JUS 331 Special Assistant to the Director, National Institute of Justice.
JUS 340 Chief of Staff to the Director, Community Relations Service.
JUS 342 Confidential Assistant to the Commissioner, Immigration and Naturalization Service.
JUS 344 Confidential Assistant to the Attorney General.
JUS 345 Special Assistant to the Director, Community Relations Service.
JUS 348 Staff Assistant to the Attorney General.
JUS 350 Deputy Assistant to the Attorney General, reporting to the Assistant to the Attorney General.
JUS 351 Staff Assistant to the Attorney General.
JUS 353 Confidential Assistant to the Solicitor General.
JUS 354 Attorney-Advisor to the General Counsel.
JUS 355 Special Assistant to the Chairman, Foreign Claims Settlement Commission.

JUS 356 Staff Assistant to the Attorney General.
JUS 357 Confidential Assistant to the Deputy Attorney General.
JUS 359 General Attorney to the Assistant Attorney General, Office of Justice Programs.
JUS 360 Assistant Director, Asylum Policy and Review Unit, Office of Policy Development.
JUS 362 Special Assistant to the Director, Office of Policy Development.
JUS 364 Special Assistant to the Deputy Assistant Attorney General, Office of Justice Programs.
JUS 366 Counsel to the Director, United States Marshals Service.
JUS 368 Attorney-Advisor (Special Counsel) to the Assistant Attorney General, Civil Division.
JUS 369 Deputy Director to the Director, Office of Policy Development.
JUS 370 Special Counsel to the Director, Office of Liaison Services.
JUS 371 Senior Liaison Officer to the Director, Office of Liaison Services.
JUS 372 Public Affairs Specialist to the Director, Office of Liaison Services.
JUS 373 Deputy Director to the Director, Office of Liaison Services.
JUS 374 Staff Assistant to the Director, Office of Liaison Services.
JUS 375 Staff Assistant to the Attorney General.
JUS 376 Confidential Assistant to the Director, Office of Liaison Services.
JUS 377 Secretary (Typing) to the Deputy Director, Office of Public Affairs.
JUS 379 Staff Assistant to the Director, Office of Public Affairs.
JUS 381 Confidential Assistant to the Deputy Director, Office of Policy Development.
JUS 382 Secretary (Typing) to the Director, Office of Public Affairs.
JUS 383 Staff Assistant to the Attorney General.
JUS 384 Staff Assistant to the Attorney General.
JUS 385 Staff Assistant to the Attorney General.
JUS 386 Senior Liaison Officer to the Director, Office of Liaison Services.
JUS 387 Public Affairs Specialist to the Chief Spokesman, Office of Public Affairs.
JUS 389 Research Assistant to the Assistant Attorney General, Office of Legal Counsel.
JUS 390 Staff Assistant to the Attorney General.

Section 213.3312 Department of the Interior

INT 21 Confidential Assistant to the Assistant Secretary for Fish and Wildlife and Parks.
INT 112 Special Assistant to the Assistant to the Secretary and Director, External Affairs.
INT 162 Special Assistant to the Assistant Secretary for Territorial and International Affairs.
INT 191 Special Assistant to the Director, Bureau of Land Management.
INT 192 Staff Assistant to the Assistant to the Secretary and Director, External Affairs.
INT 198 Special Assistant to the Secretary and Executive Director of Correspondence, reporting to the Special Assistant for Policy and Programs (Chief of Staff).
INT 203 Special Assistant to the Assistant Director for Refuges and Wildlife, Fish and Wildlife Service.
INT 242 Special Assistant to the Assistant Director for Legislative and Congressional Affairs, National Park Service.
INT 252 Legislative Assistant to the Associate Director for Offshore Minerals Management, Minerals Management Service.
INT 268 Special Assistant to the Director, Office of Surface Mining Reclamation and Enforcement.
INT 287 Assistant to the Director and Deputy Director, Office of External Affairs, Bureau of Land Management.
INT 288 Staff Assistant to the Director, Bureau of Land Management.
INT 300 Special Assistant to the Solicitor.
INT 311 Special Assistant to the Assistant Secretary for Policy, Budget, and Administration.
INT 317 Special Assistant to the Assistant Director of External Affairs, Fish and Wildlife Service.
INT 324 Special Assistant to the Assistant to the Secretary and Director, External Affairs.
INT 327 Special Assistant to the Director, National Park Service.
INT 337 Special Assistant to the Solicitor.
INT 340 Special Assistant to the Director, Bureau of Land Management.
INT 342 Assistant Director, Legislative and Congressional Affairs, to the Director, National Park Service.
INT 343 Special Assistant to the Director, External Affairs Office, Bureau of Reclamation.
INT 345 Special Assistant to the Director, Fish and Wildlife Service.
INT 348 Special Assistant to the Director, Office of Surface Mining Reclamation and Enforcement.
INT 354 Special Assistant to the Director, National Park Service.
INT 355 Special Assistant to the Assistant Secretary for Territorial and International Affairs.
INT 356 Special Assistant to the Director, Bureau of Mines.
INT 358 Special Assistant to the Director, National Park Service.
INT 360 Special Assistant to the Director, Bureau of Mines.
INT 363 Special Assistant to the Director, National Park Service.
INT 365 Special Assistant to the Director, National Park Service.
INT 366 Deputy Assistant Secretary for Territorial and International Affairs.
INT 369 Staff Assistant to the Director, Office of Surface Mining Reclamation and Enforcement.
INT 371 Special Assistant to the Director, Bureau of Mines.
INT 377 Special Assistant to the Assistant Secretary for Land and Minerals Management.
INT 378 Special Assistant to the Director, Office of Surface Mining Reclamation and Enforcement.
INT 384 Confidential Assistant to the Director, Office of Surface Mining Reclamation and Enforcement.
INT 385 Special Assistant to the Assistant Secretary for Policy, Budget and Administration.
INT 386 Chief, Division of Public Affairs, to the Deputy Director, External Affairs, Bureau of Land Management.
INT 389 Special Assistant to the Deputy Commissioner, Bureau of Reclamation.
INT 391 Special Assistant to the Assistant Secretary for Policy, Budget and Administration.
INT 392 External Affairs Officer (Intergovernmental Affairs) to the Director, Minerals Management Service.
INT 393 Special Assistant to the Assistant Director for External Affairs, Minerals Management Service.
INT 394 Special Assistant to the Assistant Director for Fish and Wildlife Enhancement, Fish and Wildlife Service.
INT 396 Special Assistant to the Assistant to the Under Secretary (Take Pride in America Staff).
INT 397 Special Assistant to the Assistant to the Under Secretary (Take Pride in America Staff).
INT 398 Special Assistant to the Director, Office of Program Analysis, Office of Policy, Management and Budget.
INT 399 Special Assistant to the Assistant Secretary for Policy, Management and Budget.
INT 401 Special Assistant to the Executive Assistant to the Director, Fish and Wildlife Service.
INT 403 Special Assistant (Chief of Staff) to the Solicitor.
INT 404 Special Assistant to the Associate Director for Information and Analysis, Bureau of Mines.
INT 406 Staff Assistant to the Director, Bureau of Land Management.
INT 408 Executive Assistant to the Director, Minerals Management Service.
INT 409 Special Assistant to the Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.
INT 410 Staff Assistant to the Director, External Affairs Division, Bureau of Reclamation.

Section 213.3313 Department of Agriculture

AGR 5 Special Assistant to the Chief of Staff.
AGR 12 Private Secretary to the Under Secretary for International Affairs and Commodity Programs.
AGR 13 Private Secretary to the Assistant Secretary for Food and Consumer Services.
AGR 24 Confidential Assistant to the Administrator, Farmers Home Administration.
AGR 26 Confidential Assistant to the Administrator, Farmers Home Administration.
AGR 27 Private Secretary to the Administrator, Farmers Home Administration.
AGR 30 Private Secretary to the Manager, Federal Crop Insurance Corporation.
AGR 31 Staff Assistant to the Administrator, Agricultural Stabilization and Conservation Service.

AGR 32 Special Assistant to the Administrator, Agricultural Stabilization and Conservation Service.
AGR 33 Confidential Assistant to the Administrator, Agricultural Stabilization and Conservation Service.
AGR 44 Private Secretary to the Assistant Secretary for Economics.
AGR 47 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 48 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 56 Private Secretary to the Assistant Secretary for Congressional Relations.
AGR 76 Confidential Assistant to the Assistant Secretary for Marketing and Inspection Services.
AGR 77 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 79 Confidential Assistant to the Administrator, Farmers Home Administration.
AGR 81 Confidential Assistant to the Administrator, Farmers Home Administration.
AGR 96 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 100 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 103 Confidential Assistant to the Administrator, Foreign Agricultural Service.
AGR 106 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 110 Confidential Assistant to the General Counsel.
AGR 114 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 116 Confidential Assistant to the Director, Office of Public Affairs.
AGR 118 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 128 Staff Assistant to the Administrator, Federal Grain Inspection Service.
AGR 131 Private Secretary to the Deputy Assistant Secretary for Natural Resources and Environment.
AGR 139 Staff Assistant to the Secretary.
AGR 141 Confidential Assistant to the Administrator, Food Safety and Inspection Service.
AGR 143 Confidential Assistant to the Administrator, Agricultural Marketing Service.
AGR 151 Executive Assistant to the Administrator, Agricultural Marketing Service.
AGR 154 Staff Assistant to the Administrator, Food and Nutrition Service.
AGR 158 Private Secretary to the Assistant Secretary for Science and Education.
AGR 161 Confidential Assistant to the Director, Office of Public Affairs.
AGR 162 Confidential Assistant to the Administrator, Federal Grain Inspection Service.
AGR 164 Confidential Assistant to the Assistant Secretary for Science and Education.
AGR 167 Administrator, Human Nutrition Information Services, to the Assistant Secretary for Food and Consumer Services.
AGR 169 Private Secretary to the Deputy Assistant Secretary for Economics.
AGR 177 Confidential Assistant to the Administrator, Office of Transportation.
AGR 182 Staff Assistant to the Administrator, Rural Electrification Administration.
AGR 183 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 184 Staff Assistant to the Secretary.
AGR 188 Northeast Area Director to the Deputy Administrator, Office of State and County Operations.
AGR 190 Midwest Area Director to the Deputy Administrator, Office of State and County Operations.
AGR 191 Northwest Area Director to the Deputy Administrator, Office of State and County Operations.
AGR 192 Southwest Area Director to the Deputy Administrator, Office of State and County Operations.
AGR 194 Private Secretary to the Under Secretary for Small Community and Rural Development.
AGR 200 Confidential Assistant to the Assistant Secretary for Administration.
AGR 201 Confidential Assistant to the Executive Assistant to the Secretary.
AGR 203 Confidential Assistant to the Executive Assistant to the Secretary.
AGR 206 Director, Office of the Consumer Advisor to the Assistant Secretary for Food and Consumer Services.
AGR 207 Member, Board of Directors, to the Secretary, Federal Crop Insurance Corporation.
AGR 208 Member, Board of Directors, to the Secretary, Federal Crop Insurance Corporation.
AGR 213 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 218 Staff Assistant to the Assistant Secretary for Administration.
AGR 222 Confidential Assistant to the Manager, Federal Crop Insurance Corporation.
AGR 224 Director, Congressional and Public Affairs Division, to the Manager, Federal Crop Insurance Corporation.
AGR 225 Confidential Assistant to the Manager, Federal Crop Insurance Corporation.
AGR 226 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 231 Deputy Director, Intergovernmental Affairs, Office of Public Affairs.
AGR 232 Confidential Assistant (Director, Legislative Affairs and Public Information Staff) to the Administrator, Farmers Home Administration.
AGR 234 Confidential Assistant to the Administrator, Office of International Cooperation and Development.
AGR 236 Confidential Assistant to the Administrator, Animal and Plant Health Inspection Service.
AGR 237 Private Secretary to the Administrator, Agricultural Marketing Service.
AGR 242 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 243 Confidential Assistant to the Director, Office of Intergovernmental Affairs.
AGR 244 Confidential Assistant to the Chief, Soil Conservation Service.
AGR 247 Private Secretary to the Inspector General.
AGR 257 Executive Assistant to the Assistant Secretary for Food and Consumer Services.
AGR 261 Special Assistant to the Director, Office of Public Affairs.
AGR 263 Confidential Assistant to the Assistant Secretary for Natural Resources and Environment.
AGR 266 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 267 Staff Assistant to the Director, Office of Public Affairs.
AGR 268 Director of Legislative and Public Affairs to the Deputy Administrator for Management and Policy Support, Rural Electrification Administration.
AGR 274 Confidential Assistant to the Chief, Soil Conservation Service.
AGR 276 Confidential Assistant to the Administrator, Agricultural Research Service.
AGR 277 Confidential Assistant to the Chief, Soil Conservation Service.
AGR 281 Confidential Assistant to the Administrator, Agricultural Stabilization and Conservation Service.
AGR 282 Confidential Assistant to the Administrator, Foreign Agricultural Service.
AGR 284 Confidential Assistant to the Administrator, Food Safety and Inspection Service.
AGR 287 Confidential Assistant to the Administrator, Foreign Agricultural Service.
AGR 290 Confidential Assistant to the Administrator, Animal and Plant Health Inspection Service.
AGR 291 Special Assistant to the General Counsel.
AGR 293 Confidential Assistant to the Administrator, Foreign Agricultural Service.
AGR 295 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 296 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 298 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 299 Confidential Assistant to the Administrator, Farmers Home Administration.
AGR 300 Confidential Assistant to the Manager, Federal Crop Insurance Corporation.
AGR 301 Confidential Assistant to the Administrator, Food and Nutrition Service.
AGR 302 Staff Assistant to the Administrator, Agricultural Stabilization and Conservation Service.
AGR 303 Staff Assistant to the Chief, Soil Conservation Service.

AGR 304 Staff Assistant to the Administrator, Food and Nutrition Service.
AGR 305 Associate Director, Special Emphasis Outreach Programs, to the Director, Office of Advocacy and Enterprise.
AGR 306 Confidential Assistant to the Press Secretary.
AGR 307 Staff Assistant to the Director, Office of Press and Media Relations, Office of Public Affairs.
AGR 308 Confidential Assistant to the Administrator, Agricultural Stabilization and Conservation Service.
AGR 309 Confidential Assistant to the Chief, Soil Conservation Service.
AGR 311 Confidential Assistant to the Administrator, Agricultural Research Service.
AGR 312 Confidential Assistant to the Administrator, Farmers Home Administration.
AGR 313 Confidential Assistant to the Administrator, Farmers Home Administration.
AGR 314 Confidential Assistant to the Director, Office of Public Affairs.
AGR 315 Director, Public Liaison, Office of Public Affairs.
AGR 316 Confidential Assistant to the Chief, Soil Conservation Service.
AGR 317 Executive Assistant to the Administrator, Farmers Home Administration.
AGR 318 Staff Assistant to the Administrator, Foreign Agricultural Service.
AGR 322 Director, "Ag in the Classroom" Program, to the Administrator, Cooperative State Research Service.
AGR 323 Confidential Assistant to the Assistant Secretary for Congressional Relations.
AGR 324 Private Secretary to the Deputy Under Secretary for Small Community and Rural Development.
AGR 325 Secial Assistant to the Director, Office of Public Affairs.
AGR 326 Private Secretary to the Director, Office of Public Affairs.
AGR 327 Staff Assistant to the Director, Programs and Planning, Office of Public Affairs.
AGR 329 Confidential Assistant to the Director, Office of Public Affairs.
AGR 330 Confidential Assistant to the Director, Intergovernmental Affairs, Office of Public Affairs.
AGR 331 Director, Press and Media Relations, to the Director, Office of Public Affairs.
AGR 332 Confidential Assistant to the Director, Legislative Affairs and Public Information Staff, Farmers Home Administration.
AGR 333 Confidential Assistant to the Manager, Federal Crop Insurance Corporation.
AGR 334 Staff Assistant to the Manager, Federal Crop Insurance Corporation.
AGR 337 Special Assistant to the Deputy Administrator for Program Operations, Farmers Home Administration.

Section 213.3314 Department of Commerce

COM 2 Confidential Assistant to the Secretary.
COM 4 Confidential Assistant to the Counsellor to the Secretary.
COM 5 Special Assistant to the Director, Office of White House Liaison.
COM 10 Confidential Assistant to the Special Assistant to the Deputy Secretary.
COM 12 Special Assistant to the Deputy Secretary.
COM 19 Chauffeur to the Secretary.
COM 48 Confidential Assistant to the Under Secretary for Travel and Tourism.
COM 136 Special Assistant to the Deputy Assistant Secretary for Export Enforcement.
COM 151 Confidential Assistant to the Chief of Staff.
COM 158 Director of Public Affairs to the Under Secretary for Travel and Tourism.
COM 161 Confidential Assistant to the Deputy Under Secretary for International Trade.
COM 182 Private Secretary to the Assistant Secretary for Communications and Information.
COM 183 Confidential Assistant to the Assistant Secretary for Communications and Information.
COM 190 Director, Office of Congressional Affairs, to the Assistant Secretary for Communications and Information.
COM 193 Confidential Assistant to the Deputy Assistant Secretary for Trade Development.
COM 194 Special Assistant to the Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration.
COM 207 Chief, Congressional Affairs Division, to the Director, Office of Legislative Affairs, National Oceanic and Atmospheric Administration.
COM 217 Special Assistant to the Director, Office of Public Affairs.
COM 225 Director, Congressional Affairs Staff, to the Under Secretary for Export Administration.
COM 232 Special Assistant to the Assistant Secretary for Economic Development.
COM 248 Special Assistant to the Deputy Secretary.
COM 252 Confidential Assistant to the Secretary.
COM 257 Confidential Assistant to the Deputy Assistant Secretary for Africa, Near East, and South Asia, International Trade Administration.
COM 259 Director of Congressional Affairs to the Under Secretary for International Trade.
COM 260 Confidential Assistant to the Deputy Assistant Secretary for Legislative Affairs.
COM 261 Confidential Assistant to the Assistant Secretary for Trade Development.
COM 265 Special Assistant to the Deputy Assistant Secretary for Export Administration.
COM 267 Confidential Assistant to the Assistant Secretary for Export Administration.
COM 268 Confidential Assistant to the Chief of Staff.
COM 275 Confidential Assistant to the Director, Office of Business Liaison.
COM 280 Congressional Liaison Assistant to the Assistant Secretary for Legislative and Intergovernmental Affairs.
COM 282 Special Assistant to the Deputy Director, Office of Congressional Affairs.
COM 287 Congressional Liaison Assistant to the Deputy Assistant Secretary for Congressional Affairs.
COM 288 Confidential Assistant to the Director, Office of Business Liaison.
COM 289 Confidential Assistant to the Deputy Assistant Secretary for Intergovernmental Affairs.
COM 293 Confidential Assistant to the Deputy Assistant Secretary for Intergovernmental Affairs.
COM 295 Confidential Assistant to the Director, Office of White House Liaison.
COM 296 Confidential Assistant to the Special Assistant to the Staff Director.
COM 297 Confidential Assistant to the Chief Financial Officer.
COM 298 Special Assistant to the Assistant Secretary for Communications and Information.
COM 300 Confidential Assistant to the Deputy Under Secretary for International Trade.
COM 302 Special Assistant to the Director, Office of Public Affairs, National Oceanic and Atmospheric Administration.
COM 303 Confidential Assistant to the Assistant Secretary for Administration.
COM 304 Special Assistant to the Under Secretary for Travel and Tourism.
COM 306 Confidential Assistant to the Assistant Secretary for Legislative and Intergovernmental Affairs.
COM 307 Confidential Assistant to the Assistant Secretary for Import Administration.
COM 310 Confidential Assistant to the Deputy Under Secretary for Travel and Tourism.
COM 311 Confidential Assistant to the Director, Office of White House Liaison.
COM 312 Confidential Assistant to the Director General, U.S. and Foreign Commercial Service.
COM 314 Special Assistant to the Director, Office of White House Liaison.
COM 316 Confidential Assistant to the Deputy Assistant Secretary for Trade Information and Analysis, International Trade Administration.
COM 317 Confidential Assistant to the Assistant Secretary for Trade Development.
COM 319 Confidential Assistant to the Deputy Assistant Secretary for Compliance, International Trade Administration.
COM 321 Director, Office of Public Affairs, to the Under Secretary for International Trade.
COM 325 Confidential Assistant to the Deputy Assistant Secretary for International Economic Policy, International Trade Administration.
COM 328 Confidential Assistant to the Deputy Assistant Secretary for Automotive and Consumer Goods, International Trade Administration.
COM 329 Congressional Liaison Assistant to the Director of Congressional Affairs, International Trade Administration.
COM 332 Confidential Assistant to the Deputy Assistant Secretary for Capital

Goods and International Construction, International Trade Administration.
COM 334 Confidential Assistant to the Assistant Secretary for Import Administration.
COM 336 Special Assistant to the Assistant Secretary for Export Enforcement.
COM 337 Congressional Liaison Assistant to the Deputy Assistant Secretary for Legislative Affairs.
COM 338 Press Secretary to the Director, Office of Public Affairs.
COM 340 Special Assistant to the Under Secretary for Oceans and Atmosphere.
COM 345 Confidential Assistant to the Under Secretary for International Trade.
COM 346 Confidential Assistant to the Director, Office of White House Liaison.
COM 347 Confidential Assistant to the Director, Office of Public Affairs.
COM 348 Special Assistant to the Director, Office of Public Affairs.
COM 350 Deputy Director to the Director, Office of Business Liaison.
COM 352 Special Assistant to the Chief of Staff.
COM 357 Deputy Director to the Director, Office of Export Trading Company Affairs, International Trade Administration.
COM 360 Director of Congressional Affairs to the Under Secretary for Economic Affairs.
COM 363 Congressional Affairs Specialist to the Director, Office of Legislative Affairs, National Oceanic and Atmospheric Administration.
COM 376 Confidential Assistant to the Director, Office of White House Liaison.
COM 380 Confidential Assistant to the Deputy Assistant Secretary for Import Administration.
COM 386 Confidential Assistant to the Deputy Under Secretary for Travel and Tourism.
COM 389 Confidential Assistant to the Under Secretary for International Trade.
COM 390 Confidential Assistant to the Under Secretary for Economic Affairs.
COM 391 Confidential Assistant to the Chief Economist.
COM 392 Special Assistant to the Deputy Assistant Secretary for Basic Industries, International Trade Administration.
COM 395 Confidential Assistant to the Deputy Assistant Secretary for U. S. and Foreign Commercial Service.
COM 397 Congressional Affairs Officer to the Director, Bureau of the Census.
COM 399 Special Assistant to the Deputy Assistant Secretary for Grant Programs, Economic Development Administration.
COM 403 Confidential Assistant to the Assistant Secretary for Oceans and Atmosphere.
COM 405 Confidential Assistant to the Deputy Assistant Secretary for Science and Electronics, International Trade Administration.
COM 408 Confidential Assistant to the General Counsel.
COM 409 Confidential Assistant to the Chief of Staff.
COM 410 Confidential Assistant to the Director, Office of Public Affairs, International Trade Administration.
COM 412 Confidential Assistant to the Deputy Assistant Secretary for Trade Information and Analysis, International Trade Administration.
COM 414 Congressional Affairs Specialist to the Director, Office of Legislative Affairs, National Oceanic and Atmospheric Administration.
COM 415 Congressional Affairs Specialist to the Director, Office of Legislative Affairs, National Oceanic and Atmospheric Administration.
COM 420 Special Assistant to the Assistant Secretary and Director General, U.S. and Foreign Commercial Service.
COM 423 Director of Congressional Affairs to the Assistant Secretary and Commissioner of Patents and Trademarks.
COM 425 Director, Office of Public Affairs, to the Under Secretary for Export Administration.
COM 430 Special Assistant to the Assistant Secretary for Export Administration.
COM 433 Senior Advisor to the Assistant Administrator for Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.
COM 435 Confidential Assistant to the Counselor to the Deputy Secretary.
COM 436 Director, Office of Private Sector Initiatives, to the Director, Office of Business Liaison.
COM 438 Confidential Assistant to the Director, Office of Business Liaison.
COM 439 Special Counsel to the General Counsel.
COM 440 Confidential Assistant to the Director, Office of Executive Programs.
COM 441 Special Assistant to the Deputy Under Secretary for Economic Affairs.
COM 442 Director of Public Affairs to the Assistant Secretary for Communications and Information.
COM 445 Director, Office of Public Affairs, to the Assistant Secretary for Economic Development.
COM 448 Confidential Assistant to the Assistant Secretary for International Economic Policy, International Trade Administration.
COM 449 Director, Office of General Industrial Machinery, to the Deputy Assistant Secretary for Capital Goods and International Construction, International Trade Administration.
COM 450 Special Assistant to the Director, Bureau of the Census.
COM 453 Congressional Liaison Assistant to the Deputy Assistant Secretary for Legislative Affairs.
COM 454 Special Assistant to the Assistant Secretary for Technology Policy.
COM 457 Special Assistant to the Director, Ocean and Coastal Resource Management, National Oceanic and Atmospheric Administration.
COM 458 Special Assistant to the Deputy Assistant Secretary for Services, International Trade Administration.
COM 460 Director, Office of Intergovernmental Affairs, to the Assistant Secretary for Legislative and Intergovernmental Affairs.
COM 461 Confidential Assistant to the Director, Office of External Affairs.
COM 462 Deputy Director of Congressional Affairs to the Assistant Secretary and Commissioner of Patents and Trademarks.
COM 464 Confidential Assistant to the Deputy Assistant Secretary for Loan Programs, Economic Development Administration.
COM 465 Confidential Assistant to the Director, Office of White House Liaison.
COM 466 Director of Public Affairs to the Deputy Under Secretary for Technology.
COM 467 Confidential Assistant to the Director, Office of External Affairs.
COM 468 Confidential Assistant to the Director, Congressional Affairs Staff.
COM 469 Confidential Assistant to the Deputy to the Chief of Staff and Executive Secretary.
COM 472 Confidential Assistant to the Deputy Assistant Secretary for Technology Policy.
COM 473 Confidential Assistant to the Chief Counsel for Technology.
COM 474 Confidential Assistant to the Deputy Under Secretary for International Trade.
COM 475 Special Assistant to the Senior Advisor to the Secretary.
COM 477 Director of Legislative and Intergovernmental Affairs to the Under Secretary for Travel and Tourism.
COM 479 Director, Office of International Technology Policy and Programs, to the Assistant Secretary for Technology Policy.
COM 480 Director of Congressional Affairs to the Under Secretary for Technology.
COM 481 Confidential Assistant to the Under Secretary for Technology.
COM 482 Director, Executive Secretariat, to the Chief of Staff.
COM 483 Confidential Assistant to the Managing Director, U. S. and Foreign Commercial Service.
COM 484 Special Assistant to the Under Secretary for Technology.
COM 485 Special Assistant to the Assistant Secretary and Counsellor to the Secretary.
COM 487 Special Assistant to the Director, Office of White House Liaison.
COM 488 Confidential Assistant to the Press Secretary to the Secretary.
COM 489 Special Assistant to the Assistant Secretary for Legislative and Intergovernmental Affairs.
COM 490 Director of Scheduling to the Assistant Secretary and Counsellor to the Secretary.
COM 491 Special Assistant to the Deputy Under Secretary for Technology.
COM 493 Congressional Liaison Officer to the Under Secretary for Economics and Statistics.
COM 494 Deputy Press Secretary to the Press Secretary.
COM 495 Special Assistant and Director of Operations to the Secretary.
COM 496 Chief Intergovernmental Affairs Division, to the Director, Legislative Affairs, National Oceanic and Atmospheric Administration.
COM 497 Intergovernmental Affairs Specialist to the Chief Intergovernmental Affairs Division, National Oceanic and Atmospheric Administration.
COM 498 Congressional Liaison Specialist to the Director, Congressional Affairs, International Trade Administration.

COM 499 Director for Strategic Resource Management to the Deputy Assistant Secretary for Program Support, Economic Development Administration.
COM 500 Special Assistant to the Under Secretary for Travel and Tourism.
COM 502 Deputy Counsellor to the Secretary.
COM 503 Public Affairs Specialist to the Director, Office of Public Affairs, Bureau of Export Administration.
COM 504 Congressional Affairs Specialist to the Congressional Affairs Officer, Bureau of the Census.
COM 505 Special Assistant to the Deputy Assistant Secretary for Economic Development.
COM 506 Congressional Liaison Specialist to the Director of Congressional Affairs, International Trade Administration.
COM 507 Confidential Assistant to the Deputy Under Secretary for International Trade.
COM 508 Special Assistant to the Director, Office of Space Commerce.
COM 509 Director, Office of Space Commerce, to the Deputy Secretary.

Section 213.3315 Department of Labor

LAB 3 Special Assistant to the Secretary.
LAB 17 Special Assistant to the Assistant Secretary for Congressional Affairs.
LAB 25 Senior Legislative Officer to the Assistant Secretary for Congressional Affairs.
LAB 41 Staff Assistant to the Chief of Staff, Office of Congressional and Intergovernmental Affairs.
LAB 43 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 44 Senior Liaison Officer to the Assistant Secretary for Congressional Affairs.
LAB 49 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 62 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 64 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 66 Special Assistant to the Director, Office of Federal Contract Compliance Programs, Employment Standards Administration.
LAB 76 Special Assistant to the Director, Women's Bureau.
LAB 83 Staff Assistant to the Assistant Secretary for Pension and Welfare Benefits.
LAB 86 Staff Assistant to the Assistant Secretary for Employment Standards.
LAB 91 Confidential Staff Assistant to the Deputy Under Secretary for Congressional Affairs.
LAB 92 Special Assistant to the Chief of Staff.
LAB 93 Special Assistant to the Chief of Staff.
LAB 100 Special Assistant to the Deputy Under Secretary for International Labor Affairs.
LAB 103 Secretary's Representative.
LAB 104 Secretary's Representative.
LAB 105 Secretary's Representative.
LAB 106 Secretary's Representative.
LAB 108 Secretary's Representative.
LAB 109 Secretary's Representative.
LAB 110 Secretary's Representative.
LAB 111 Secretary's Representative.
LAB 112 Secretary's Representative.
LAB 115 Secretary (Typing) to the Secretary's Representative.
LAB 116 Secretary (Typing) to the Secretary's Representative.
LAB 122 Assistant to the Secretary's Representative.
LAB 125 Special Assistant to the Assistant Secretary for Employment Standards.
LAB 127 Staff Assistant to the Director, Office of Workers' Compensation Programs, Employment Standards Administration.
LAB 129 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 130 Special Assistant to the Secretary.
LAB 131 Special Assistant to the Assistant Secretary for Employment and Training.
LAB 132 Senior Legislative Officer to the Assistant Secretary for Congressional Affairs.
LAB 133 Special Assistant to the Director, Women's Bureau.
LAB 137 Staff Assistant to the Deputy Assistant Secretary for Public Affairs/ Director, Office of Information and Public Affairs.
LAB 139 Executive Assistant to the Administrator, Wage and Hour Division, Employment Standards Administration.
LAB 153 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 154 Special Assistant to the Assistant Secretary for Congressional and Intergovernmental Affairs.
LAB 161 Staff Assistant to the Secretary.
LAB 163 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 169 Special Assistant to the Deputy Assistant Secretary for Program Economics and Research and Technical Support.
LAB 171 Director of Advance to the Chief of Staff.
LAB 172 Confidential Assistant to the Deputy Secretary.
LAB 177 Confidential Assistant to the Secretary.
LAB 180 Senior Legislative Officer to the Assistant Secretary for Congressional Affairs.
LAB 181 Staff Assistant to the Deputy Under Secretary for International Labor Affairs.
LAB 183 Staff Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 186 Special Assistant to the Director, Women's Bureau.
LAB 189 Special Assistant to the Assistant Secretary for Occupational Safety and Health.
LAB 190 Special Assistant to the Assistant Secretary for Policy.
LAB 195 Special Assistant to the Assistant Secretary for Employment and Training.
LAB 196 Executive Assistant to the Assistant Secretary for Veterans' Employment and Training.
LAB 199 Deputy Legislative Officer to the Associate Assistant Secretary for Congressional Affairs.
LAB 200 Special Assistant (Speech Writer) to the Assistant Secretary for Employment and Training.
LAB 202 Confidential Staff Assistant to the Assistant Secretary for Employment and Training.
LAB 204 Special Assistant to the Assistant Secretary for Veterans' Employment and Training.
LAB 205 Special Assistant to the Assistant Secretary for Congressional and Intergovernmental Affairs.
LAB 208 Deputy Legislative Officer to the Assistant Secretary for Congressional Affairs.
LAB 209 Confidential Assistant to the Assistant Secretary for Veterans' Employment and Training.
LAB 212 Staff Assistant to the Secretary.
LAB 213 Special Assistant to the Assistant Secretary for Employment and Training.
LAB 217 Special Assistant to the Assistant Secretary for Public and Intergovernmental Affairs.
LAB 219 Special Assistant to the Director, Office of Intergovernmental Affairs.
LAB 220 Special Assistant to the Assistant Secretary for Public and Intergovernmental Affairs.
LAB 221 Special Assistant to the Assistant Secretary for Public Affairs.
LAB 226 Confidential Assistant to the Assistant Secretary for Pension and Welfare Benefits.
LAB 227 Special Assistant to the Deputy Assistant Secretary for Mine Safety and Health.
LAB 230 Special Assistant to the Chief of Staff, Office of Public Affairs.
LAB 231 Staff Assistant to the Assistant Secretary for Public and Intergovernmental Affairs.
LAB 232 Special Assistant to the Director, Office of Federal Contract Compliance Programs, Employment Standards Administration.
LAB 233 Staff Assistant to the Director, Office of Federal Contract Compliance Programs, Employment Standards Administration.
LAB 234 Senior Liaison Officer to the Deputy Under Secretary for Congressional Affairs.
LAB 240 Assistant to the Secretary's Representative.
LAB 241 Special Assistant to the Director, Office of Information and Public Affairs.
LAB 243 Staff Assistant to the Assistant Secretary for Congressional and Intergovernmental Affairs.
LAB 246 Assistant to the Secretary's Representative.
LAB 248 Special Assistant to the Assistant Secretary for Public and Intergovernmental Affairs.
LAB 249 Assistant to the Secretary's Representative.
LAB 251 Staff Assistant to the Assistant Secretary for Mine Safety and Health.
LAB 252 Special Assistant to the Assistant Secretary for Public and Intergovernmental Affairs.

LAB 255 Staff Assistant to the Assistant Secretary for Public Affairs.
LAB 256 Staff Assistant to the Assistant Secretary for Labor Management Standards.
LAB 257 Special Assistant to the Assistant Secretary for Labor Management Standards.
LAB 258 Deputy Secretary's Representative.
LAB 261 Staff Assistant to the Deputy Assistant Secretary for Mine Safety and Health.
LAB 262 Staff Assistant to the Assistant Secretary for Employment Standards.
LAB 265 Special Assistant for Public Affairs to the Director, Office of Federal Contract Compliance Programs, Employment Standards Administration.
LAB 266 Staff Assistant to the Deputy Under Secretary for International Labor Affairs.
LAB 267 Special Assistant to the Associate Assistant Secretary for Intergovernmental Affairs
LAB 268 Staff Assistant to the Deputy Assistant Secretary for Occupational Safety and Health.
LAB 269 Deputy Legislative Officer to the Assistant Secretary for Congressional and Intergovernmental Affairs.

Section 213.3316 Department of Health and Human Services

HHS 5 Writer to the Secretary.
HHS 14 Special Assistant to the Executive Secretary.
HHS 17 Director, Scheduling, Security and Protection, to the Secretary.
HHS 26 Special Assistant to the Executive Secretary.
HHS 53 Special Assistant to the Assistant Secretary for Legislation.
HHS 119 Confidential Secretary to the General Counsel.
HHS 167 Executive Director, Federal Council on Aging, to the Assistant Secretary for Human Development Services.
HHS 213 Steward to the Secretary.
HHS 226 Confidential Assistant to the Director, Office of Civil Rights.
HHS 233 Confidential Assistant to the Director, Office of Consumer Affairs.
HHS 267 Special Initiatives Coordinator to the Secretary.
HHS 273 Special Assistant to the Deputy Assistant Secretary for Legislation (Human Services).
HHS 305 Special Assistant to the Deputy Under Secretary for Intergovernmental Affairs, Boards and Commissions.
HHS 306 Special Assistant to the Director, Office of Policy, Planning and Legislation, Office of Human Development Services.
HHS 331 Special Assistant to the Administrator, Health Care Financing Administration.
HHS 332 Executive Assistant to the Assistant Secretary for Human Development Services.
HHS 344 Congressional Liaison Specialist to the Deputy Assistant Secretary for Legislation (Congressional Liaison).
HHS 353 Confidential Assistant to the Deputy Under Secretary for Intergovernmental Affairs, Boards and Commissions.
HHS 358 Congressional Liaison Specialist to the Deputy Assistant Secretary for Legislation (Congressional Liaison).
HHS 363 Special Assistant to the Director, Office of Public Affairs, Office of Human Development Services.
HHS 371 Confidential Assistant to the Executive Assistant to the Secretary.
HHS 372 Special Assistant to the Director, Office of Policy, Planning and Legislation, Office of Human Development Services.
HHS 374 Confidential Assistant to the Executive Secretary.
HHS 394 Confidential Assistant to the Executive Secretary.
HHS 406 Special Assistant to the Assistant Secretary for Health.
HHS 415 Confidential Assistant to the Secretary.
HHS 424 Staff Assistant (Scheduling) to the Director of Scheduling, Security and Protection.
HHS 436 Associate Commissioner for Family and Youth Services to the Commissioner, Administration for Children, Youth and Families.
HHS 439 Director, Office of Family Planning, to the Deputy Assistant Secretary for Population Affairs.
HHS 442 Director, Office of Adolescent Pregnancy Programs, to the Deputy Assistant Secretary for Population Affairs.
HHS 457 Special Assistant to the Under Secretary.
HHS 462 Special Assistant for Liaison Activities to the Administrator, Alcohol, Drug Abuse and Mental Health Administration, Public Health Service.
HHS 468 Deputy Director, Office of Community Services, Family Support Administration.
HHS 495 Confidential Staff Assistant to the Associate Administrator, Office of Communications, Family Support Administration.
HHS 497 Special Assistant to the Director, Office of Community Services, Family Support Administration.
HHS 506 Congressional Relations Specialist to the Deputy Commissioner for Policy and External Affairs, Social Security Administration.
HHS 510 Deputy Director, Office of Public Liaison, Health Care Financing Administration.
HHS 511 Special Assistant to the Associate Commissioner, Head Start Bureau, Administration for Children, Youth and Families.
HHS 513 Confidential Assistant to the Administrator, Health Care Financing Administration.
HHS 518 Special Assistant to the Director, Office of Family Assistance, Family Support Administration.
HHS 522 Special Assistant to the Associate Administrator, Office of Communications, Family Support Administration.
HHS 523 Special Assistant to the Assistant Secretary for Health.
HHS 524 Private Sector Initiatives Coordinator to the Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion).
HHS 526 Confidential Staff Assistant to the Administrator, Health Care Financing Administration.
HHS 528 Special Assistant to the Deputy Assistant Secretary for Human Development Services.
HHS 531 Special Assistant to the Assistant Secretary for Management and Budget.
HHS 532 Special Assistant to the Commissioner, Social Security Administration.
HHS 533 Special Assistant to the Commissioner, Social Security Administration.
HHS 534 Confidential Assistant to the Executive Secretary.
HHS 535 Special Assistant to the Assistant Secretary for Health.
HHS 536 Confidential Staff Assistant to the Assistant Secretary for Health.
HHS 537 Special Assistant to the Associate Commissioner, Office of Public Affairs, Social Security Administration.
HHS 538 Special Assistant to the Deputy Commissioner for Programs, Social Security Administration.
HHS 539 Special Assistant to the General Counsel.
HHS 540 Special Assistant to the Director, Office of Legislation and Policy, Health Care Financing Administration.
HHS 541 Director, Office of State and Project Assistance, to the Director, Office of Community Services, Family Support Administration.
HHS 542 Special Assistant to the Commissioner, Administration for Children, Youth and Families.
HHS 543 Special Assistant to the Commissioner, Food and Drug Administration.
HHS 544 Special Assistant to the Deputy Assistant Secretary for Population Affairs.
HHS 545 Special Assistant to the Associate Commissioner for Public Affairs, Food and Drug Administration.
HHS 546 Special Assistant to the Associate Commissioner, Office of Public Affairs, Social Security Administration.
HHS 547 Confidential Assistant to the Associate Commissioner, Office of Public Affairs, Social Security Administration.
HHS 548 Confidential Assistant to the Director, Office of State and Project Assistance, Family Support Administration.
HHS 550 Speechwriter to the Secretary.
HHS 551 Special Assistant for Legislative Affairs to the Associate Commissioner for Legislative Affairs, Food and Drug Administration.
HHS 552 Director, Office of External Affairs, to the Associate Commissioner, Office of Public Affairs, Social Security Administration.
HHS 554 Speechwriter to the Assistant Secretary for Human Development Services.
HHS 555 Legislative Liaison to the Associate Commissioner, Office of Legislation and Congressional Affairs, Social Security Administration.
HHS 556 Director of Speechwriting to the Deputy Assistant Secretary for Public Affairs (Media).
HHS 561 Special Assistant to the Director, Office of Refugee Resettlement.

HHS 563 Confidential Staff Assistant to the Commissioner, Social Security Administration.
HHS 564 Confidential Assistant to the Director, Office of Prepaid Health Care, Health Care Financing Administration.
HHS 565 Special Assistant to the Associate Commissioner for Public Affairs, Social Security Administration.
HHS 568 Special Assistant to the Assistant Secretary for Family Support.
HHS 570 Confidential Assistant (Advance) to the Secretary.
HHS 571 Special Assistant to the Commissioner, Administration on Developmental Disabilities.
HHS 572 Deputy Director to the Director of Communications.
HHS 573 Special Assistant to the Associate Commissioner, Office of Disability, Social Security Administration.
HHS 575 Special Assistant to the Deputy Assistant Secretary for Public Affairs (Media).
HHS 576 Speechwriter to the Surgeon General.
HHS 577 Special Assistant to the Administrator, Alcohol, Drug Abuse and Mental Health Administration, Public Health Service.
HHS 581 Special Assistant to the Deputy Commissioner for Programs, Social Security Administration.
HHS 582 Director of Advance to the Executive Secretary.

Section 213.3317 Department of Education

EDU 8 Confidential Assistant to the Assistant Secretary for Civil Rights.
EDU 9 Special Assistant to the Assistant Secretary for Elementary and Secondary Education.
EDU 10 Confidential Assistant to the Assistant Secretary for Postsecondary Education.
EDU 15 Special Assistant to the Deputy Under Secretary for Management.
EDU 33 Special Assistant to the Assistant Secretary for Elementary and Secondary Education.
EDU 38 Special Assistant to the Assistant Secretary for Postsecondary Education.
EDU 43 Confidential Assistant to the Assistant Secretary for Legislation.
EDU 46 Special Assistant to the Assistant Secretary for Vocational and Adult Education.
EDU 51 Special Assistant to the Director, Intergovernmental Affairs Staff, Office of Intergovernmental and Interagency Affairs.
EDU 53 Special Assistant to the Director, Intergovernmental Affairs Staff, Office of Intergovernmental and Interagency Affairs.
EDU 54 Confidential Assistant to the Chief of Staff.
EDU 55 Special Assistant to the Director, Intergovernmental Affairs Staff, Office of Intergovernmental and Interagency Affairs.
EDU 61 Special Assistant to the Deputy Under Secretary for Intergovernmental and Interagency Affairs.
EDU 65 Confidential Assistant to the Executive Assistant to the Under Secretary.
EDU 67 Special Assistant to the Chief of Staff/Counselor to the Secretary.
EDU 72 Confidential Assistant to the Assistant Secretary for Legislation.
EDU 74 Executive Assistant to the Assistant Secretary for Legislation.
EDU 77 Executive Assistant to the Assistant Secretary for Civil Rights.
EDU 89 Special Assistant to the Assistant Secretary for Elementary and Secondary Education.
EDU 90 Special Assistant to the Assistant Secretary for Vocational and Adult Education.
EDU 94 Confidential Assistant to the Assistant Secretary for Postsecondary Education.
EDU 105 Secretary's Regional Representative.
EDU 106 Secretary's Regional Representative.
EDU 107 Secretary's Regional Representative.
EDU 108 Secretary's Regional Representative.
EDU 109 Secretary's Regional Representative.
EDU 111 Secretary's Regional Representative.
EDU 117 Director, Historically Black Colleges and Universities, to the Assistant Secretary for Postsecondary Education.
EDU 121 Special Assistant to the Assistant Secretary for Special Education and Rehabilitative Services.
EDU 124 Secretary's Regional Representative.
EDU 129 Director, Center for International Education, to the Deputy Assistant Secretary for Higher Education Programs.
EDU 133 Special Assistant to the Deputy Under Secretary for Planning, Budget and Evaluation.
EDU 135 Special Assistant to the Assistant Secretary for Educational Research and Improvement.
EDU 137 Special Assistant to the Comptroller.
EDU 138 Special Assistant to the Deputy Under Secretary for Management.
EDU 140 Special Assistant to the Deputy Assistant Secretary for Operations, Office of Civil Rights.
EDU 147 Secretary's Regional Representative.
EDU 148 Executive Assistant to the Deputy Under Secretary for Management.
EDU 150 Special Assistant to the Deputy Assistant Secretary for Special Education and Rehabilitative Services.
EDU 154 Executive Director, Intergovernmental Advisory Council on Education, to the Deputy Under Secretary for Intergovernmental and Interagency Affairs.
EDU 159 Confidential Assistant to the Assistant Secretary for Postsecondary Education.
EDU 161 Special Assistant to the Deputy Assistant Secretary for Higher Education Programs, Office of Postsecondary Education.
EDU 162 Special Assistant to the Assistant Secretary for Elementary and Secondary Education.
EDU 171 Director, Legislative Liaison, to the Deputy Assistant Secretary for Legislation.
EDU 173 Confidential Assistant to the Assistant Secretary for Civil Rights.
EDU 186 Staff Assistant to the Secretary's Regional Representative.
EDU 191 Special Assistant to the Secretary.
EDU 192 Deputy Director to the Director, Office of Bilingual Education and Minority Languages Affairs.
EDU 196 Special Assistant to the Commissioner, Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services.
EDU 198 Confidential Assistant to the Director, Issues Analysis Staff.
EDU 199 Special Assistant to the Assistant Secretary for Special Education and Rehabilitative Services.
EDU 200 Director, Intergovernmental Affairs, to the Deputy Under Secretary for Intergovernmental and Interagency Affairs.
EDU 202 Confidential Assistant to the Director, Intergovernmental Affairs.
EDU 207 Director, Regional Liaison Staff, to the Deputy Under Secretary for Intergovernmental and Interagency Affairs.
EDU 209 Special Assistant to the Assistant Secretary for Educational Research and Improvement.
EDU 220 Confidential Assistant to the Director, Recognition Division, Office of Educational Research and Improvement.
EDU 223 Confidential Assistant to the Chief of Staff/Counselor to the Secretary.
EDU 226 Confidential Assistant to the Director, Public Affairs Service, Office of Planning, Budget and Evaluation.
EDU 238 Confidential Assistant to the Deputy Under Secretary for Intergovernmental and Interagency Affairs.
EDU 240 Confidential Assistant to the Assistant Secretary for Civil Rights.
EDU 241 Director, Division of Adult Education and Literacy, to the Assistant Secretary for Vocational and Adult Education.
EDU 243 Special Assistant to the Administrator for Management Services.
EDU 251 Special Assistant to the Director, Intergovernmental Affairs/Outreach Staff, Office of Intergovernmental and Interagency Affairs.
EDU 256 Congressional Liaison Specialist to the Director, Legislation and Congressional Affairs.
EDU 258 Special Assistant to the Director of Executive Programs.
EDU 262 Director, Interagency Operations Staff, to the Deputy Under Secretary for Intergovernmental and Interagency Affairs.
EDU 263 Confidential Assistant to the Chief of Staff/Counsellor to the Secretary.
EDU 264 Confidential Assistant to the Director, Office of Bilingual Education and Minority Languages Affairs.
EDU 266 Special Assistant to the Assistant Secretary for Postsecondary Education.
EDU 275 Confidential Assistant to the Assistant Secretary for Vocational and Adult Education.
EDU 280 Executive Assistant to the Assistant Secretary for Elementary and Secondary Education.
EDU 293 Special Assistant to the General Counsel.
EDU 296 Confidential Assistant to the Director, Scheduling and Briefing.

EDU 297 Confidential Assistant to the Director, Scheduling and Briefing.
EDU 304 Confidential Assistant to the Executive Assistant, Private Education Staff.
EDU 307 Confidential Assistant to the Director, Corporate and Community Liaison Staff, Office of the Secretary.
EDU 308 Confidential Assistant to the Director, Corporate and Community Liaison Staff, Office of the Secretary.
EDU 310 Special Assistant to the Deputy Under Secretary for Intergovernmental and Interagency Affairs.
EDU 313 Special Assistant to the Deputy Under Secretary for Management.
EDU 314 Confidential Assistant to the Deputy Assistant Secretary for Legislation.
EDU 315 Congressional Liaison Specialist to the Director, Legislation and Congressional Affairs.
EDU 316 Director, Recognition Division, to the Assistant Secretary for Educational Research and Improvement.
EDU 317 Confidential Assistant to the Deputy Under Secretary for Management.
EDU 318 Special Assistant to the Director, Interagency Operations Staff, Office of Intergovernmental and Interagency Affairs.
EDU 323 Confidential Assistant to the Assistant Secretary for Educational Research and Improvement.
EDU 324 Special Assistant to the Deputy Under Secretary for Planning, Budget and Evaluation.
EDU 325 Director, Scheduling and Briefing Staff, to the Chief of Staff/Counselor to the Secretary.
EDU 326 Special Assistant to the Deputy Assistant Secretary for Higher Education Programs, Office of Postsecondary Education.
EDU 330 Special Assistant to the Secretary's Regional Representative.
EDU 334 Special Assistant to the Director, Fund for the Improvement and Reform of Schools and Teaching, Office of Educational Research and Improvement.
EDU 336 Staff Assistant to the Director, Regional Liaison Staff.
EDU 338 Confidential Assistant to the Assistant Secretary for Vocational and Adult Education.
EDU 339 Special Assistant to the Director, Fund for the Improvement and Reform of Schools and Teaching, Office of Educational Research and Improvement.
EDU 340 Deputy Secretary's Regional Representative.
EDU 343 Confidential Assistant to the Secretary's Regional Representative.
EDU 344 Special Assistant to the Deputy Under Secretary for Management.
EDU 345 Confidential Assistant to the Assistant Secretary for Civil Rights.
EDU 346 Deputy Secretary's Regional Representative.
EDU 347 Deputy Secretary's Regional Representative.
EDU 349 Special Assistant to the Director, Public Affairs Service, Office of Planning, Budget and Evaluation.
EDU 350 Deputy Secretary's Regional Representative.
EDU 351 Confidential Assistant to the Assistant Secretary for Elementary and Secondary Education.
EDU 352 Confidential Assistant to the Assistant Secretary for Vocational and Adult Education.
EDU 355 Congressional Liaison Specialist to the Director, Legislation and Congressional Affairs.
EDU 356 Deputy Director to the Director, Office of Public Affairs.
EDU 358 Deputy Director to the Director, Corporate and Community Liaison Staff.
EDU 359 Confidential Assistant to the Director, Center for International Education, Office of Postsecondary Education.
EDU 361 Confidential Assistant to the Special Advisor to the Secretary on Teacher Education.
EDU 362 Confidential Assistant to the Director, Office of Bilingual Education and Minority Languages Affairs.
EDU 363 Confidential Assistant to the Assistant Secretary for Vocational and Adult Education.
EDU 364 Special Assistant to the Director, Intergovernmental Affairs Staff, Office of Intergovernmental and Interagency Affairs.

Section 213.3318 Environmental Protection Agency

EPA 5 Confidential Assistant to the Deputy Administrator.
EPA 10 Special Assistant to the Administrator.
EPA 18 Special Assistant to the Deputy Administrator.
EPA 19 Associate Assistant Administrator to the Assistant Administrator for Water.
EPA 33 Director, Division of State/Local Relations, to the Associate Administrator for Regional Operations and State/Local Relations.
EPA 41 Staff Assistant to the Associate Administrator for Communications and Public Affairs.
EPA 44 Staff Assistant to the Director, Office of Congressional Liaison.
EPA 53 Special Assistant to the Deputy Administrator.
EPA 54 Congressional Liaison Specialist to the Director, Office of Congressional Liaison.
EPA 55 Special Assistant to the Administrator.
EPA 61 Special Assistant to the Assistant Administrator for Administration and Resources Management.
EPA 62 Congressional Liaison Specialist to the Director, Office of Congressional Liaison.
EPA 73 Congressional Relations Officer to the Director, Office of Congressional Liaison.
EPA 89 Special Assistant to the Assistant Administrator for Water.
EPA 94 Special Assistant to the Regional Administrator.
EPA 97 Special Assistant to the Deputy Associate Administrator for Communications and Public Affairs.
EPA 99 Special Assistant to the Associate Assistant Administrator for Administration and Resources Management.
EPA 100 Staff Assistant to the Director, Regional Operations Division.
EPA 102 Staff Assistant to the Special Assistant to the Administrator.
EPA 103 Staff Assistant to the Director, External Relations and Education Division.
EPA 116 Program Advisor to the Associate Assistant Administator for Administration and Resources Management.
EPA 117 Staff Assistant to the Director, Office of Communications and Intergovernmental Relations.
EPA 118 Staff Assistant to the Assistant Administrator for Enforcement and Compliance Monitoring.
EPA 122 Congressional Liaison Specialist to the Director, Office of Congressional Liaison.
EPA 126 Deputy Associate Administrator to the Associate Administrator for Communications and Public Affairs.
EPA 127 Special Assistant to the Assistant Administrator for Administration and Resources Management.
EPA 128 Staff Assistant to the Assistant Administrator for Administration and Resources Management.
EPA 129 Program Advisor to the Assistant Administrator for International Activities.
EPA 130 Staff Assistant to the Assistant Administrator for Pesticides and Toxic Substances.
EPA 131 Special Assistant to the Assistant Administrator for Water.
EPA 135 Chief Scheduler to the Chief of Staff.

Section 213.3319 Administrative Conference of the United States

ACUS 2 Confidential Assistant to the Chairman.
ACUS 4 Confidential Assistant to the Chairman.

Section 213.3322 Interstate Commerce Commission

ICC 2 Confidential Assistant to a Commissioner.
ICC 6 Confidential Assistant to a Commissioner.
ICC 27 Staff Advisor (Economics) to a Commissioner.
ICC 29 Staff Advisor (Management) to a Commissioner.
ICC 43 Attorney-Advisor (Transportation) to a Commissioner.
ICC 49 Associate Director for Intergovernmental Affairs to the Director, Office of External Affairs.
ICC 51 Special Assistant to the Director, Office of Congressional and Legislative Affairs.
ICC 53 Attorney-Advisor (Transportation) to a Commissioner.
ICC 54 Confidential Assistant to a Commissioner.
ICC 55 Special Assistant to the Chairman.

Section 213.3325 Tax Court of the United States

TCOUS 40 Secretary and Confidential Assistant to the Judge.
TCOUS 41 Secretary and Confidential Assistant to the Judge.
TCOUS 42 Secretary and Confidential Assistant to the Judge.
TCOUS 43 Secretary and Confidential Assistant to the Judge.
TCOUS 44 Secretary and Confidential Assistant to the Judge.

TCOUS 46 Secretary and Confidential Assistant to the Judge.
TCOUS 47 Secretary and Confidential Assistant to the Judge.
TCOUS 48 Secretary and Confidential Assistant to the Judge.
TCOUS 49 Secretary and Confidential Assistant to the Judge.
TCOUS 50 Secretary and Confidential Assistant to the Judge.
TCOUS 51 Secretary and Confidential Assistant to the Judge.
TCOUS 52 Secretary and Confidential Assistant to the Judge.
TCOUS 53 Secretary and Confidential Assistant to the Judge.
TCOUS 54 Secretary and Confidential Assistant to the Judge.
TCOUS 55 Secretary and Confidential Assistant to the Judge.
TCOUS 56 Secretary and Confidential Assistant to the Judge.
TCOUS 57 Secretary and Confidential Assistant to the Judge.
TCOUS 58 Secretary and Confidential Assistant to the Judge.
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TCOUS 60 Secretary and Confidential Assistant to the Judge.
TCOUS 61 Secretary and Confidential Assistant to the Judge.
TCOUS 62 Secretary and Confidential Assistant to the Judge.
TCOUS 63 Secretary and Confidential Assistant to the Judge.
TCOUS 64 Secretary and Confidential Assistant to the Judge.
TCOUS 65 Secretary and Confidential Assistant to the Judge.
TCOUS 66 Trial Clerk to the Judge.
TCOUS 67 Trial Clerk to the Judge.
TCOUS 68 Trial Clerk to the Judge.
TCOUS 70 Trial Clerk to the Judge.
TCOUS 71 Trial Clerk to the Judge.
TCOUS 72 Trial Clerk to the Judge.
TCOUS 73 Trial Clerk to the Judge.
TCOUS 74 Trial Clerk to the Judge.
TCOUS 75 Trial Clerk to the Judge.
TCOUS 77 Trial Clerk to the Judge.
TCOUS 78 Trial Clerk to the Judge.
TCOUS 79 Trial Clerk to the Judge.
TCOUS 80 Secretary and Confidential Assistant to the Judge.

Section 213.3327 Department of Veterans Affairs

VA 2 Special Assistant to the Secretary.
VA 5 Special Assistant to the Principal Deputy Assistant Secretary for Acquisition and Facilities.
VA 11 Special Assistant to the Assistant Secretary for Information Resources.
VA 14 Special Assistant to the Director, National Cemetery System.
VA 16 Special Assistant to the Assistant Secretary for Human Resources and Information.
VA 50 Special Assistant to the Secretary.
VA 51 Director, Intergovernmental Affairs, to the Deputy Assistant Secretary for Veterans Liaison.
VA 52 Special Assistant to the Assistant Secretary for Finance and Planning.
VA 54 Special Assistant to the Assistant Secretary for Veterans Liaison and Program Coordination.
VA 55 Special Assistant to the Deputy Assistant Secretary for Congressional Affairs.
VA 56 Special Assistant to the Assistant Secretary for Congressional and Public Affairs.
VA 57 Special Assistant to the Assistant Secretary for Acquisition and Facilities.
VA 58 Special Assistant to the Assistant Secretary for Acquisition and Facilities.
VA 59 Special Assistant to the Assistant Secretary for Acquisition and Facilities.

Section 213.3328 United States Information Agency

USIA 12 Special Assistant to the Director, Office of Congressional Liaison.
USIA 14 Special Assistant to the Associate Director for Programs.
USIA 22 Director, New York Foreign Press Center, to the Associate Director for Programs.
USIA 26 Staff Assistant to the Associate Director for Programs.
USIA 31 Special Assistant to the Senior Advisor to the Director.
USIA 37 Staff Specialist to the Director, Office of Citizen Exchanges, Bureau of Educational and Cultural Affairs.
USIA 45 Special Assistant to the Associate Director for Programs.
USIA 57 Special Assistant to the Director, Office of International Visitors, Bureau of Educational and Cultural Affairs.
USIA 67 Chief, Voluntary Visitor Division, to the Associate Director for Educational and Cultural Affairs.
USIA 73 Executive Assistant (Cultural Property) to the Director, Creative Arts Division, Bureau of Educational and Cultural Affairs.
USIA 77 White House Liaison Officer to the Director.
USIA 80 Special Assistant (Writer-Editor) to the Director, Office of Public Liaison.
USIA 83 Special Assistant to the Director, Office of Research.
USIA 91 Program Officer to the Coordinator, U. S.-Soviet Exchange Initiative.
USIA 93 Program Assistant to the Deputy Director.
USIA 97 Corporate Liaison Officer to the Associate Director for Programs.
USIA 101 Program Officer to the Director, New York Foreign Press Center.
USIA 103 Equal Employment Manager to the Associate Director for Management.
USIA 104 Special Assistant to the Director, Private Sector Committees.
USIA 107 Public Affairs Assistant to the Director, Voice of America.
USIA 109 Confidential Assistant to the Director, Voice of America.
USIA 111 Special Assistant to the Associate Director for Programs.
USIA 112 Special Assistant to the Director, Office of Program Coordination and Development.
USIA 113 Special Assistant to the Associate Director, Bureau of Educational and Cultural Affairs.
USIA 114 Special Assistant to the Commissioner General, Seville Expo.
USIA 115 Special Assistant to the Commissioner General, Seville Expo.
USIA 116 Special Assistant to the Associate Director for Programs.

Section 213.3330 Securities and Exchange Commission

SEC 2 Executive Aide (Typing) to the Executive Assistant to the Chairman.
SEC 3 Confidential Assistant to a Commissioner.
SEC 4 Confidential Assistant to a Commissioner.
SEC 5 Confidential Assistant to a Commissioner.
SEC 6 Confidential Assistant to a Commissioner.
SEC 8 Secretary (Steno) to the Chief Accountant.
SEC 9 Secretary (Typing) to the General Counsel.
SEC 11 Confidential Assistant to the Chairman.
SEC 12 Supervisory Public Affairs Specialist to the Chairman.
SEC 15 Secretary (Steno) to the Director, Division of Market Regulation.
SEC 16 Secretary (Steno) to the Director, Division of Enforcement.
SEC 18 Secretary (Steno) to the Director, Division of Investment Management.
SEC 19 Secretary (Typing) to the Director, Division of Corporation Finance.
SEC 24 Secretary (Typing) to the Chief Economist.
SEC 25 Research Specialist to the Chairman.

Section 213.3331 Department of Energy

DOE 40 Legal Advisor to a Member, Federal Energy Regulatory Commission.
DOE 60 Confidential Assistant to a Member, Federal Energy Regulatory Commission.
DOE 68 Confidential Assistant to a Member, Federal Energy Regulatory Commission.
DOE 105 Confidential Assistant to a Member, Federal Energy Regulatory Commission.
DOE 106 Confidential Assistant to a Member, Federal Energy Regulatory Commission.
DOE 108 Confidential Assistant to the Chief of Staff and Counsellor to the Chairman.
DOE 174 Special Assistant to the Assistant Secretary for Fossil Energy.
DOE 175 Staff Assistant to the Assistant Secretary for Conservation and Renewable Energy.
DOE 186 Special Assistant to the Director, Public Affairs Division, Federal Energy Regulatory Commission.
DOE 197 Director, Congressional Affairs and State Liaison Division, to the Director, Office of External Affairs, Federal Energy Regulatory Commission.
DOE 200 Special Assistant to the Deputy Secretary.
DOE 212 Staff Assistant to the Assistant Secretary for Nuclear Energy.
DOE 249 Special Assistant to the Administrator, Economic Regulatory Administration.
DOE 250 Director, Public and Intergovernmental Affairs Division, to the Director, Office of External Affairs, Federal Energy Regulatory Commission.

DOE 251 Special Assistant to the Director, Congressional Affairs Division, Federal Energy Regulatory Commission.
DOE 258 Staff Assistant to the Deputy Under Secretary for Policy, Planning and Analysis.
DOE 285 Executive Assistant to the Secretary.
DOE 292 Chauffeur to the Secretary.
DOE 323 Special Assistant to the Assistant Secretary for Fossil Energy.
DOE 331 Staff Assistant to the Assistant Secretary for Management and Administration.
DOE 363 Staff Assistant to the Deputy General Counsel for Environment, Conservation and Legislation.
DOE 264 Staff Assistant to the General Counsel.
DOE 373 Staff Assistant to the Assistant Secretary for Fossil Energy.
DOE 374 Staff Assistant to the Assistant Secretary for Fossil Energy.
DOE 376 Staff Assistant to the Assistant Secretary for International Affairs and Energy Emergencies.
DOE 377 Staff Assistant to the Principal Deputy Assistant Secretary for Conservation and Renewable Energy.
DOE 381 Staff Assistant to the Assistant Secretary for International Affairs and Energy Emergencies.
DOE 382 Staff Assistant to the Principal Deputy Assistant Secretary for International Affairs and Energy Emergencies.
DOE 383 Staff Assistant to the Assistant Secretary for International Affairs and Energy Emergencies.
DOE 384 Staff Assistant to the Deputy Under Secretary for Policy, Planning and Analysis.
DOE 387 Staff Assistant to the Principal Deputy Assistant Secretary for International Affairs and Energy Emergencies.
DOE 397 Staff Assistant to the Principal Deputy Assistant Secretary for International Affairs and Energy Emergencies.
DOE 401 Special Assistant to the Deputy Under Secretary for Policy, Planning and Analysis.
DOE 405 Deputy Director to the Director, Congressional Affairs and State Liaison Division, Federal Energy Regulatory Commission.
DOE 406 Director, Office of Consumer and Public Liaison, to the Deputy Assistant Secretary for Intergovernmental and Public Liaison.
DOE 409 Public Affairs Specialist to the Director, Office of Public Affairs.
DOE 413 Legislative Affairs Specialist to the Deputy Assistant Secretary for House Liaison.
DOE 416 Staff Assistant to the Assistant Secretary for Fossil Energy.
DOE 422 Intergovernmental Affairs Specialist to the Deputy Assistant Secretary for Intergovernmental and Public Liaison.
DOE 423 Staff Assistant to the Assistant Secretary for Environment, Safety and Health.
DOE 424 Staff Assistant to the Principal Deputy Assistant Secretary for Fossil Energy.
DOE 426 Staff Assistant to the Director, Office of Minority Economic Impact.
DOE 430 Senior Policy Specialist to the Director, Office of New Production Reactors.
DOE 442 Staff Assistant to the Secretary.
DOE 447 Special Assistant to the Assistant Secretary for Defense Programs.
DOE 452 Staff Assistant to the Assistant Secretary for Conservation and Renewable Energy.
DOE 454 Staff Assistant to the Assistant Secretary for Fossil Energy.
DOE 456 Intergovernmental Affairs Specialist to the Deputy Assistant Secretary for Intergovernmental Affairs.
DOE 457 Staff Assistant to the Deputy Under Secretary for Policy, Planning and Analysis.
DOE 459 Legislative Affairs Specialist to the Deputy Assistant Secretary for Senate Liaison.
DOE 460 Staff Assistant to the General Counsel.
DOE 461 Confidential Assistant (Secretary) to the Principal Deputy Assistant Secretary for Congressional and Intergovernmental Affairs.
DOE 462 Public Affairs Specialist to the Press Secretary.
DOE 463 Principal Deputy to the Press Secretary.
DOE 464 Deputy Press Secretary for Issues Management to the Press Secretary.
DOE 465 Special Assistant to the Director, Office of Public Affairs.
DOE 466 Staff Assistant to the Deputy Assistant Secretary for International Affairs.
DOE 467 Staff Assistant to the Assistant Secretary for Fossil Energy.
DOE 468 Deputy Press Secretary for Field Operations to the Press Secretary.
DOE 469 Staff Assistant to the Assistant Secretary for Nuclear Energy.
DOE 471 Staff Assistant to the Assistant Secretary for Fossil Energy.
DOE 472 Special Assistant to the Chief of Staff.
DOE 473 Special Assistant to the Deputy Secretary.
DOE 474 Director of the Executive Secretariat to the Director of Administration and Human Resource Management.
DOE 475 Staff Assistant to the Director, Office of New Production Reactors.
DOE 476 Staff Assistant to the Chief of Staff.
DOE 477 Policy Specialist to the Director, Office of New Production Reactors.
DOE 478 Staff Assistant to the Deputy Assistant Secretary for International Affairs.
DOE 479 Associate Deputy Assistant Secretary for Legislative Strategies to the Assistant Secretary for Congressional and Intergovernmental Affairs.
DOE 480 Special Assistant to the Associate Director for Human Resource Management.
DOE 481 Staff Assistant to the Chief of Staff.
DOE 483 Senior Policy Advisor to the Director, Office of Environmental Restoration and Waste Management.
DOE 484 Staff Assistant to the Director, Office of Nuclear Safety.
DOE 485 Staff Assistant to the Assistant Secretary for International Affairs and Energy Emergencies.
DOE 486 Deputy Director to the Director, Office of Scheduling and Logistics.
DOE 487 Staff Assistant to the Director, Office of Civilian Radioactive Waste Management.
DOE 488 Special Assistant to the Assistant Secretary for Defense Programs.
DOE 490 Director of Scheduling and Logistics to the Secretary.
DOE 491 Public Affairs Specialist to the Director, Office of Public Affairs.
DOE 492 Public Affairs Specialist to the Director, Office of Public Affairs.
DOE 494 Staff Assistant to the Senior Policy Specialist, Office of New Production Reactors.
DOE 495 Director of Policy Coordination to the Deputy Under Secretary for Policy, Planning and Analysis.
DOE 497 Staff Assistant to the Director, Office of Civilian Radioactive Waste Management.
DOE 498 Staff Assistant to the Superconducting Super Collider Project Manager, Office of Engineering Research.
DOE 499 Special Assistant to the Secretary.
DOE 501 Staff Assistant to the Assistant Secretary for Environment, Safety and Health.
DOE 502 Staff Assistant (Attorney) to the Associate General Counsel for Legal Policy and Analysis.
DOE 504 Staff Assistant to the Director, Office of Nuclear Safety.
DOE 505 Staff Assistant to the Director, Office of Management and Resources.
DOE 506 Staff Assistant to the General Counsel.
DOE 507 Staff Assistant to the Director, Office of Special Projects.
DOE 508 Deputy Director for Education Initiatives to the Director, Office of Special Projects.
DOE 509 Staff Assistant to the Director of Administration and Human Resource Management.
DOE 510 Staff Assistant to the Director of Administration and Human Resource Management.
DOE 511 Staff Assistant to the Director of Administration and Human Resource Management.
DOE 512 Confidential Assistant to the Director, Secretary of Energy Advisory Board.
DOE 513 Staff Assistant to the Director, Office of Scheduling and Logistics.
DOE 514 Staff Assistant to the Director, Office of Special Projects.
DOE 515 Advance Coordinator to the Director, Office of Scheduling and Logistics.
DOE 516 Special Assistant to the Director, Office of Scheduling and Logistics.
DOE 517 Deputy Director to the Director, Office of Minority Economic Impact.

DOE 519 Staff Assistant to the Special Assistant to the Secretary.
DOE 520 Staff Assistant to the Special Assistant and Director, Office of Community Services, Office of Administration and Human Resource Management.
DOE 521 Legislative Affairs Specialist to the Deputy Assistant Secretary for Senate Liaison.
DOE 522 Small Business Specialist to the Director, Office of Small and Disadvantaged Business Utilization.

Section 213.3332 Small Business Administration

SBA 12 Special Assistant to the Administrator.
SBA 19 Executive Assistant to the Deputy Administrator.
SBA 37 Special Assistant to the Administrator.
SBA 39 Assistant Administrator for Public Communications.
SBA 41 Special Assistant to the Associate Deputy Administrator for Financial Assistance.
SBA 51 Special Assistant to the Chief of Staff.
SBA 59 Deputy Assistant Administrator for Public Communications.
SBA 64 Special Assistant to the Regional Administrator.
SBA 65 Special Assistant to the Regional Administrator.
SBA 66 Special Assistant to the Regional Administrator.
SBA 68 Special Assistant to the Regional Administrator.
SBA 69 Special Assistant to the Regional Administrator.
SBA 71 Special Assistant to the Regional Administrator.
SBA 72 Special Assistant to the Regional Administrator.
SBA 73 Special Assistant to the Regional Administrator.
SBA 90 Confidential Assistant to the Administrator.
SBA 96 Special Assistant to the Associate Administrator for Business Development.
SBA 134 Special Assistant to the Associate Administrator for Business Development.
SBA 139 Special Assistant to the Associate Administrator for Business Development.
SBA 141 Special Assistant to the Associate Deputy Administrator for Special Programs.
SBA 142 Special Assistant to the Administrator.
SBA 144 Special Assistant to the Associate Deputy Administrator for Finance, Investment and Procurement.
SBA 145 Director, Office of International Trade, to the Associate Deputy Administrator for Special Programs.
SBA 147 Deputy Associate Administrator for Business Development.
SBA 150 Special Assistant to the Administrator.
SBA 152 Director of Intergovernmental Affairs to the Chief of Staff.
SBA 153 Special Assistant to the Associate Deputy Administrator for Special Programs.

Section 213.3333 Federal Deposit Insurance Corporation

FDIC 2 Secretary to a Member.
FDIC 6 Special Assistant to the Director, Congressional Liaison Staff.
FDIC 9 Legislative Advisor to the Director, Office of Legislative Affairs.
FDIC 10 Legislative Advisor to the Director, Office of Legislative Affairs.

Section 213.3334 Federal Trade Commission

FTC 2 Director, Office of Public Affairs, to the Chairman.
FTC 6 Director, Office of Congressional Relations to the Chairman.
FTC 12 Special Assistant to the Chairman.
FTC 14 Congressional Liaison Specialist to the Chairman.
FTC 18 Executive Secretary to the Chairman.

Section 213.3337 General Services Administration

GSA 11 Executive Assistant to the Administrator.
GSA 51 Confidential Assistant to the Deputy Administrator.
GSA 58 Special Assistant to the Deputy Administrator.
GSA 64 Confidential Assistant to the Associate Administrator for Operations and Industry Relations.
GSA 70 Special Assistant to the Associate Administrator for Public Affairs.
GSA 74 Confidential Assistant to the Associate Administrator for Congressional Affairs.
GSA 78 Confidential Assistant to the Regional Administrator.
GSA 79 Confidential Assistant to the Regional Administrator.
GSA 81 Staff Assistant to the Associate Administrator for Operations and Industry Relations.
GSA 82 Confidential Assistant to the Regional Administrator.
GSA 85 Confidential Assistant to the Regional Administrator.
GSA 90 Congressional Relations Officer to the Associate Administrator for Congressional Affairs.
GSA 93 Executive Assistant to the Associate Administrator for Operations.
GSA 94 Staff Assistant to the Associate Administrator for Congressional Affairs.
GSA 97 Special Assistant to the Commissioner, Federal Property Resources Service.
GSA 100 Director, Office of the Executive Secretariat, to the Administrator.
GSA 101 Staff Assistant for Special Projects to the Administrator.
GSA 102 Confidential Assistant to the Regional Administrator.
GSA 103 Staff Assistant to the Director of Child Care and Development Programs.
GSA 106 Confidential Assistant to the Associate Administrator for Public Affairs.
GSA 109 Confidential Assistant to the Regional Administrator.
GSA 114 Confidential Assistant to the Regional Administrator.
GSA 116 Assistant General Counsel for Policy to the General Counsel.
GSA 117 Director of Regional Operations to the Associate Administrator for Operations and Industry Relations.
GSA 119 Confidential Assistant to the Regional Administrator.
GSA 121 Intergovernmental Relations Officer to the Associate Administrator for Congressional Affairs.
GSA 122 Director of Client Relations to the Associate Administrator for Operations and Industry Relations.
GSA 123 Confidential Assistant to the Regional Administrator.

Section 213.3338 Federal Communications Commission

FCC 11 Special Assistant to the Chief, Office of Public Affairs.
FCC 13 Congressional Liaison Specialist to the Director, Office of Legislative Affairs.
FCC 19 Confidential Staff Assistant to the General Counsel.
FCC 20 Special Assistant to the Chief, Office of Public Affairs.
FCC 21 Special Assistant to the Chief, Common Carrier Bureau.

Section 213.3339 U. S. International Trade Commission

ITC 1 Confidential Assistant to a Commissioner.
ITC 3 Staff Assistant (Economics) to a Commissioner.
ITC 6 Staff Assistant (Legal) to a Commissioner.
ITC 7 Staff Assistant (Economics) to a Commissioner.
ITC 9 Confidential Assistant to a Commissioner.
ITC 12 Staff Assistant (Economics) to a Commissioner.
ITC 17 Staff Assistant (Legal) to a Commissioner.
ITC 18 Confidential Assistant to a Commissioner.
ITC 19 Staff Assistant (Economics) to a Commissioner.
ITC 20 Staff Assistant (Economics) to a Commissioner.
ITC 22 Staff Assistant (Legal) to a Commissioner.
ITC 25 Staff Assistant (Legal) to a Commissioner.
ITC 29 Senior Staff Assistant (Legal) to a Commissioner.
ITC 30 Confidential Assistant to a Commissioner.

Section 213.3340 National Archives and Records Administration

NARA 3 Presidential Diarist to the Archivist of the United States.
NARA 4 Assistant to the Presidential Diarist.

Section 213.3341 National Labor Relations Board

NLRB 3 Confidential Assistant to a Board Member.
NLRB 6 Confidential Assistant to a Board Member.

Section 213.3342 Export-Import Bank of the United States

EXIM 1 Executive Assistant to the President and Chairman.
EXIM 2 Personal and Confidential Assistant to the First Vice President and Vice Chairman.

EXIM 3 Administrative Assistant to a Director.
EXIM 5 Administrative Assistant to a Director.
EXIM 15 Secretary (Typing) to the President and Chairman.
EXIM 16 Administrative Assistant to the General Counsel.
EXIM 24 Secretary (Steno) to the Executive Vice President.
EXIM 30 Administrative Assistant to a Director.
EXIM 32 Special Assistant to the First Vice President and Vice Chairman.
EXIM 33 Secretary (Typing) to the Vice President for Congressional and External Affairs.

Section 213.3343 Farm Credit Administration

FCA 1 Special Assistant to the Chairman.
FCA 3 Executive Assistant to the Chairman.
FCA 8 Secretary to the Board.
FCA 10 Public Affairs Specialist to the Director, Office of Congressional and Public Affairs.
FCA 11 Special Assistant to a Member.

Section 213.3344 Occupational Safety and Health Review Commission

OSHRC 2 Special Assistant to the Chairman.
OSHRC 6 Confidential Assistant to a Commissioner.
OSHRC 8 Counsel to a Commissioner.

Section 213.3346 Selective Service System

SSS 9 Assistant Director of Congressional and Intergovernmental Affairs.

Section 213.3348 National Aeronautics and Space Administration

NASA 1 Secretary (Steno) to the Administrator.
NASA 2 Secretary (Steno) to the Deputy Administrator.
NASA 13 Special Assistant to the Associate Administrator for External Relations.
NASA 14 Public Affairs Specialist to the Deputy Associate Administrator for Communications.

Section 213.3351 Federal Mine Safety and Health Review Commission

FM 1 Secretary (Steno) to a Commissioner.
FM 5 Confidential Assistant to the Chairman.
FM 7 Attorney-Advisor (General) to a Commissioner.
FM 8 Attorney-Advisor (General) to a Commissioner.

Section 213.3352 Government Printing Office

GPO 3 Director, Congressional, Legislative and Public Affairs, to the Public Printer.
GPO 18 Chief of Staff to the Public Printer.
GPO 19 Special Assistant to the Chief of Staff.
GPO 20 Special Assistant to the Public Printer.

Section 213.3356 Commission on Civil Rights

CCR 9 Executive Assistant to the Staff Director.
CCR 12 Special Assistant to a Commissioner.
CCR 13 Special Assistant to a Commissioner.
CCR 15 Special Assistant to a Commissioner.
CCR 23 Special Assistant to a Commissioner.
CCR 28 Special Assistant to a Commissioner.
CCR 29 Special Assistant to a Commissioner.
CCR 30 Special Assistant to a Commissioner.

Section 213.3357 National Credit Union Administration

NCUA 9 Staff Assistant to the Chairman.
NCUA 18 Special Assistant to the Chairman.
NCUA 20 Executive Assistant to a Board Member.
NCUA 21 Secretary (Typing) to a Board Member.

Section 213.3359 ACTION

ACT 29 Special Assistant to the Director.
ACT 45 Director of Public Affairs to the Director.
ACT 72 Assistant Director for Older Americans Volunteer Programs to the Associate Director for Domestic and Anti-Poverty Operations.
ACT 79 Assistant Director for VISTA/Student Community Service Programs to the Associate Director for Domestic and Anti-Poverty Operations.

Section 213.3360 Consumer Product Safety Commission

CPSC 7 Special Assistant (Legal) to a Commissioner.
CPSC 16 Director, Office of Congressional Relations, to the Chairman.
CPSC 20 Special Assistant to a Commissioner.
CPSC 23 Special Assistant to a Commissioner.
CPSC 25 Staff Assistant to a Commissioner.
CPSC 38 Staff Assistant to the Chairman.

Section 213.3364 U. S. Arms Control and Disarmament Agency

ACDA 2 Secretary (Steno) to the Deputy Director.
ACDA 4 Secretary (Steno) to the Assistant Director for Verification and Intelligence.
ACDA 5 Secretary (Steno) to the Assistant Director for Nuclear and Weapons Control.
ACDA 10 Deputy Director, Office of Congressional Affairs.
ACDA 11 Congressional Affairs Specialist to the Director, Office of Congressional Affairs.
ACDA 15 Secretary (Typing) to the Chairman, General Advisory Committee.
ACDA 20 Special Assistant to the Director of Public Affairs.
ACDA 22 Secretary (Typing) to the Assistant Director for Multilateral Affairs.
ACDA 23 Staff Assistant to the Assistant Director for Multilateral Affairs.
ACDA 27 Special Assistant to the Director.
ACDA 29 Congressional Affairs Specialist to the Director of Congressional Affairs.
ACDA 32 Secretary (Steno) to the Assistant Director for Strategic Programs.

Section 213.3367 Federal Maritime Commission

FMC 2 Counsel to a Commissioner.
FMC 3 Counsel to a Commissioner.
FMC 4 Counsel to a Commissioner.
FMC 5 Confidential Assistant to the Counsel to a Commissioner.
FMC 7 Secretary (Typing) to a Commissioner.
FMC 8 Special Assistant to a Commissioner.
FMC 10 Special Assistant to a Commissioner.
FMC 22 Special Assistant to the Chairman.
FMC 26 Executive Assistant to the Chairman.
FMC 27 Assistant to the Chairman for International Affairs and Policy.

Section 213.3368 Agency for International Development

AID 4 Executive Assistant to the Administrator.
AID 20 Special Assistant to the Deputy Assistant Administrator, Bureau for Asia, the Near East and Europe.
AID 48 Special Assistant to the Director, Office of Policy Development and Program Review.
AID 68 Special Assistant to the Assistant Administrator for Private Enterprise.
AID 76 Public Affairs Specialist to the Director, Office of Public Liaison.
AID 82 Chief, Congressional Liaison Division, to the Deputy Assistant Administrator, Bureau of Legislative Affairs.
AID 85 Director, Office of Private Sector Development, to the Assistant Administrator, Bureau for Asia, the Near East and Europe.
AID 86 Special Assistant to the Assistant Administrator, Bureau for Asia, the Near East and Europe.
AID 88 Special Assistant to the Director, Office of Foreign Disaster Assistance.
AID 89 Special Assistant to the Assistant Administrator, Bureau for Private Enterprise.
AID 91 Special Assistant to the Assistant Administrator, Bureau for Food for Peace and Voluntary Assistance.
AID 92 Deputy Director (Program Manager), Office of Private and Voluntary Cooperation, to the Deputy Assistant Administrator, Bureau for Food for Peace and Voluntary Assistance.
AID 93 Special Assistant to the Administrator.
AID 94 Public Affairs Specialist (Deputy Director, Office of Public Liaison) to the Deputy Assistant Administrator, Bureau for External Affairs.
AID 95 Administrative Assistant to the Assistant Administrator, Bureau for Legislative Affairs.
AID 96 Special Assistant to the Assistant Administrator, Bureau for External Affairs.
AID 97 Special Assistant to the Assistant Administrator, Bureau for Latin America and the Caribbean.
AID 98 Supervisory Public Affairs Specialist to the Deputy Assistant Administrator, Bureau for External Affairs.

AID 99 Public Affairs Specialist to the Director, Office of Public Liaison.
AID 100 Public Affairs Specialist to the Special Assistant to the Assistant Administrator, Bureau for External Affairs.
AID 101 Confidential Assistant (Receptionist) to the Executive Assistant to the Director.
AID 102 Congressional Liaison Officer to the Chief, Congressional Liaison Division, Bureau for Legislative Affairs.
AID 103 Writer-Editor to the Senior Writer-Editor, Office of Publications.

Section 213.3371 Office of Government Ethics

OGE 1 Attorney-Advisor (General) to the Director.

Section 213.3376 Appalachian Regional Commission

ARC 8 Legislative and Policy Advisor to the Federal Co-Chairman.

Section 213.3377 Equal Employment Opportunity Commission

EEOC 2 Special Assistant to the Chairman.
EEOC 5 Confidential Assistant to a Member.
EEOC 17 Special Assistant to a Member.
EEOC 23 Special Assistant to a Member.
EEOC 25 Media Contact Specialist (Bilingual) to the Director, Communications Staff, Office of Communications and Legislative Affairs.
EEOC 33 Media Contact Specialist to the Director, Office of Communications and Legislative Affairs.
EEOC 40 Legislative Affairs Specialist to the Director, Office of Communications and Legislative Affairs.

Section 213.3379 Commodity Futures Trading Commission

CFTC 1 Administrative Assistant to the Chairman.
CFTC 3 Administrative Assistant to a Commissioner.
CFTC 6 Administrative Assistant to a Commissioner.
CFTC 7 Supervisory Public Affairs Specialist to the Chairman.
CFTC 12 Special Assistant to a Commissioner.
CFTC 21 Government Affairs Officer to the Chairman.

Section 213.3382 National Foundation on the Arts and the Humanities National Endowment for the Arts

NEA 9 Congressional Liaison Officer to the Chairman.
NEA 49 Associate Deputy Chairman for Programs.
NEA 50 Special Projects Coordinator (Development) to the Chairman.
NEA 62 Director of Public Affairs to the Senior Deputy Chairman.
NEA 63 Staff Assistant to the Senior Deputy Chairman. National Endowment for the Humanities
NEH 46 Special Assistant to the Deputy Chairman.
NEH 56 Special Assistant to the Deputy Chairman.
NEH 63 . Special Assistant to the Chairman, reporting to the Deputy Chairman.

Section 213.3384 Department of Housing and Urban Development

HUD 33 Legislative Officer to the Deputy Assistant Secretary for Legislation.
HUD 35 Legislative Officer to the Deputy Assistant Secretary for Legislation.
HUD 36 Assistant for Congressional Relations to the Deputy Assistant Secretary for Congressional Relations.
HUD 37 Assistant for Congressional Relations to the Deputy Assistant Secretary for Congressional Relations.
HUD 39 Assistant for Congressional Relations to the Deputy Assistant Secretary for Congressional Relations.
HUD 42 Assistant for Congressional Relations to the Deputy Assistant Secretary for Congressional Relations.
HUD 45 Assistant for Congressional Relations to the Deputy Assistant Secretary for Congressional Relations.
HUD 60 Director of Executive Scheduling to the Deputy Assistant Secretary for Executive Services.
HUD 65 Staff Assistant to the Assistant Secretary for Community Planning and Development.
HUD 120 Special Assistant (Speech Writer) to the Deputy Assistant Secretary for Public Affairs.
HUD 137 Special Assistant to the Assistant Secretary for Fair Housing and Equal Opportunity.
HUD 163 Special Assistant to the Deputy Assistant Secretary for Multifamily Housing Programs.
HUD 170 Staff Assistant to the Assistant Secretary for Policy Development and Research.
HUD 172 Special Assistant to the Assistant Secretary for Public and Indian Housing.
HUD 174 Assistant for Congressional Relations to the Deputy Assistant Secretary for Congressional Relations.
HUD 175 Assistant for Congressional Relations to the Assistant Secretary for Legislation and Congressional Relations.
HUD 187 Special Assistant to the Deputy Assistant Secretary for Single Family Housing Programs.
HUD 190 Specal Assistant to the Assistant Secretary for Housing.
HUD 191 Special Assistant to the Deputy Assistant Secretary for Policy Development.
HUD 199 Staff Assistant to the Assistant Secretary for Public and Indian Housing.
HUD 202 Executive Assistant to the Assistant Secretary for Legislation and Congressional Relations.
HUD 203 Legislative Officer to the Deputy Assistant Secretary for Legislation.
HUD 208 Intergovernmental Relations Officer to the Deputy Under Secretary for Intergovernmental Relations.
HUD 209 Intergovernmental Relations Officer to the Deputy Under Secretary for Intergovernmental Relations.
HUD 212 Staff Assistant to the Deputy Assistant Secretary for Research.
HUD 213 Staff Assistant to the Assistant Secretary for Program Development and Research.
HUD 215 Special Assistant to the Deputy Assistant Secretary for Multifamily Housing Programs.
HUD 217 Special Assistant to the Deputy Assistant Secretary for Policy Development.
HUD 218 Executive Assistant to the Regional Administrator.
HUD 222 Staff Assistant to the Regional Administrator.
HUD 224 Special Assistant to the Regional Administrator.
HUD 228 Executive Assistant to the Regional Administrator.
HUD 238 Special Assistant to the Secretary.
HUD 240 Executive Assistant to the Assistant Secretary for Public Affairs.
HUD 247 Executive Assistant to the Assistant Secretary for Housing.
HUD 249 Intergovernmental Relations Specialist to the Deputy Under Secretary for Intergovernmental Relations.
HUD 255 Executive Assistant to the Assistant Secretary for Policy Development and Research.
HUD 259 Special Assistant to the Secretary.
HUD 260 Executive Assistant to the Assistant Secretary for Public and Indian Housing.
HUD 268 Special Assistant to the General Deputy Assistant Secretary for Housing.
HUD 274 Special Assistant to the Secretary.
HUD 275 Special Assistant to the Deputy Secretary.
HUD 281 Special Assistant to the Regional Administrator.
HUD 286 Staff Assistant to the Assistant Secretary for Administration.
HUD 292 Special Assistant to the Deputy Assistant Secretary for Economic Development.
HUD 293 Special Assistant to the President, Government National Mortgage Association.
HUD 319 Executive Assistant to the Regional Administrator.
HUD 320 Special Assistant to the Assistant Secretary for Administration.
HUD 323 Executive Assistant to the Assistant Secretary for Housing.
HUD 324 Special Assistant to the Regional Administrator.
HUD 336 Special Assistant (Scheduling) to the Assistant Secretary for Public Affairs.
HUD 338 Special Assistant to the Deputy Assistant Secretary for Single Family Housing Programs.
HUD 339 Special Assistant to the Regional Administrator.
HUD 350 Special Assistant to the Regional Administrator.
HUD 351 Special Assistant to the Regional Administrator.
HUD 354 Special Assistant to the General Deputy Assistant Secretary for Public and Indian Housing.
HUD 363 Special Assistant to the Assistant Secretary for Policy Development and Research.
HUD 366 Special Assistant to the Deputy Assistant Secretary for Operations, Office of Housing.
HUD 368 Special Assistant to the Regional Administrator.
HUD 369 Special Assistant to the Assistant Secretary for Housing.
HUD 370 Special Assistant to the Assistant Secretary for Public and Indian Housing.

HUD 373 Special Assistant (Speech Issues) to the Assistant Secretary for Public Affairs.
HUD 379 Assistant Director, Office of Executive Secretariat, to the Special Assistant to the Secretary/Director, Executive Secretariat.
HUD 381 Special Assistant to the Secretary.
HUD 384 Special Assistant to the Assistant Secretary for Public and Indian Housing.
HUD 385 Special Assistant to the Assistant Secretary for Public Affairs.
HUD 386 Executive Assistant to the Deputy Secretary.
HUD 392 Special Assistant to the Regional Administrator.
HUD 394 Staff Assistant to the Assistant Secretary for Community Planning and Development.
HUD 398 Special Assistant to the Secretary for Field Coordination, reporting to the Deputy Under Secretary for Field Coordination.
HUD 399 Senior Special Assistant for Contract Management to the President, Government National Mortgage Association.
HUD 401 Special Assistant to the Assistant Secretary for Housing.
HUD 402 Special Assistant to the Assistant Secretary for Housing.
HUD 404 Special Assistant to the Regional Administrator.
HUD 406 Staff Assistant (Typing) to the Chief of Staff.
HUD 407 Executive Assistant to the Regional Administrator.
HUD 408 Special Projects Coordinator to the Deputy Assistant Secretary for Policy, Financial Management and Administration.
HUD 409 Special Assistant to the Deputy Assistant Secretary for Policy, Financial Management and Administration.
HUD 417 Special Assistant to the Assistant Secretary for Administration.
HUD 418 Special Assistant to the Deputy Assistant Secretary for Public and Indian Housing.
HUD 421 Assistant Director for Records Management to the Director, Executive Secretariat.
HUD 422 Staff Assistant to the Director, Executive Secretariat.
HUD 423 Assistant Director to the Director, Executive Secretariat.
HUD 424 Special Assistant-Multifamily Housing for Resident Initiatives to the Deputy Assistant Secretary for Multifamily Housing Programs.
HUD 425 Deputy Assistant Secretary for Resident Initiatives to the Assistant Secretary for Public and Indian Housing.
HUD 426 Special Assistant to the Assistant Secretary for Housing.
HUD 427 Special Assistant to the Deputy Assistant Secretary for Executive Services.
HUD 428 Special Assistant to the Deputy Assistant Secretary for Resident Initiatives, Office of Public and Indian Housing.

Section 213.3388 President's Commission on White House Fellows

PCWHF 2 Associate Director.
PCWHF 3 Assistant Director for Educational Programs to the Director.
PCWHF 4 Confidential Assistant to the Director.

Section 213.3389 National Mediation Board

NMB 52 Confidential Assistant to a Board Member.
NMB 53 Confidential Assistant to a Board Member.
NMB 54 Confidential Assistant to the Chairman.

Section 213.3391 Office of Personnel Management

OPM 7 Deputy Director for Congressional Relations to the Director, Office of Congressional Relations.
OPM 19 Special Assistant to the Associate Director for Administration.
OPM 21 Special Assistant to the Director for Communications.
OPM 25 Special Assistant to the Director, Office of Congressional Relations.
OPM 30 Special Assistant to the Director, Office of Communications.
OPM 33 Confidential Assistant to the Director, Office of Congressional Relations.
OPM 36 Staff Assistant to the Director, Office of Executive Administration.
OPM 38 Confidential Assistant to the General Counsel.
OPM 41 Special Assistant to the Director, Office of Communications.
OPM 43 Executive Assistant to the Director.
OPM 44 Director of Intergovernmental Affairs to the Director.
OPM 47 Special Assistant to the Deputy Director.
OPM 48 Staff Assistant to the Director, Office of Executive Administration.
OPM 49 Confidential Assistant to the Director.
OPM 50 Policy Analyst to the Director of Policy.
OPM 51 Director of Volunteer Activities to the Director.
OPM 52 Special Assistant to the Chief of Staff.

Section 213.3392 Federal Labor Relations Authority

FLRA 7 Congressional Affairs and Public Information Officer to the Chairman.

Section 213.3393 Pension Benefit Guaranty Corporation

PBGC 6 Confidential Assistant to the Executive Director.
PBGC 7 Special Assistant to the Executive Director.
PBGC 8 Staff Assistant to the Deputy Executive Director.

Section 213.3394 Department of Transportation

DOT 1 Staff Assistant to the Secretary.
DOT 20 Congressional Liaison Officer to the Director, Office of Congressional Affairs.
DOT 38 Special Assistant to the Administrator, National Highway Traffic Safety Administration.
DOT 54 Congressional Liaison Officer to the Director, Office of Congressional Affairs.
DOT 55 Congressional Liaison Officer to the Director, Office of Congressional Affairs.
DOT 69 Public Affairs Officer to the Administrator, Federal Railroad Administration.
DOT 70 Staff Assistant to the Assistant Secretary for Governmental Affairs.
DOT 77 Staff Assistant to the Director, Office of Small and Disadvantaged Business Utilization.
DOT 78 Staff Assistant to the Assistant Secretary for Governmental Affairs.
DOT 94 Staff Assistant to the Administrator, Federal Aviation Administration.
DOT 100 Chief, Consumer Affairs Division, to the Director, Office of Public and Consumer Affairs, National Highway Traffic Safety Administration.
DOT 121 Deputy Director to the Director, Office of Congressional Affairs.
DOT 127 Special Assistant to the Assistant Secretary for Budget and Programs.
DOT 128 Special Assistant to the Administrator, Federal Highway Administration.
DOT 147 Special Assistant to the Assistant Secretary for Public Affairs.
DOT 148 Director, Office of Media Relations and Special Projects, to the Assistant Secretary for Public Affairs.
DOT 156 Staff Assistant to the Assistant Secretary for Policy and International Affairs.
DOT 172 Staff Assistant to the Chief of Staff.
DOT 185 Special Assistant to the Deputy Assistant Secretary for Policy and International Affairs.
DOT 186 Director, Office of Public Affairs, to the Administrator, Urban Mass Transportation Administration.
DOT 191 Staff Assistant to the Assistant Administrator for Public Affairs, Federal Aviation Administration.
DOT 192 Staff Assistant to the Director, Office of Small and Disadvantaged Business Utilization.
DOT 197 Staff Assistant to the Secretary.
DOT 198 Special Assistant to the Administrator, Federal Highway Administration.
DOT 216 Staff Assistant to the Administrator, Federal Aviation Administration.
DOT 217 Special Assistant to the Administrator, Research and Special Programs Administration.
DOT 233 Staff Assistant to the General Counsel.
DOT 235 Special Assistant for Scheduling to the Secretary.
DOT 240 Special Assistant to the Assistant Administrator for Public Affairs, Federal Aviation Administration.
DOT 249 Deputy Executive Secretary for Policy to the Director, Executive Secretariat.
DOT 257 Staff Assistant to the Assistant Secretary for Public Affairs.
DOT 265 Special Assistant to the Director, Office of Public Affairs, Federal Highway Administration.
DOT 274 Special Assistant to the Assistant Secretary for Public Affairs.
DOT 277 Staff Assistant to the Deputy Administrator, Urban Mass Transportation Administration.
DOT 278 Staff Assistant to the Deputy Secretary.

DOT 279 Director, Office of Speech Writing and Research, to the Assistant Secretary for Public Affairs.
DOT 285 Special Assistant to the Administrator, National Highway Traffic Safety Administration.
DOT 288 Deputy Director of Industry Affairs to the Director, Office of Intergovernmental and Industry Affairs.
DOT 307 Director, Office of Intergovernmental and Industry Affairs, to the Assistant Secretary for Governmental Affairs.
DOT 309 Special Assistant to the Administrator, Federal Aviation Administration.
DOT 311 Staff Assistant to the Chief of Staff.
DOT 312 Special Assistant to the Administrator, Saint Lawrence Seaway Development Corporation.
DOT 313 Director, Office of Public and Consumer Affairs, to the Administrator, National Highway Traffic Safety Administration.
DOT 314 Staff Assistant to the Associate Administrator for Policy, Planning and International Aviation, Federal Aviation Administration.
DOT 315 Director of Intergovernmental Affairs to the Administrator, National Highway Traffic Safety Administration.
DOT 316 Special Assistant to the Deputy Assistant Secretary for Policy and International Affairs.
DOT 317 Deputy Assistant Administrator to the Assistant Administrator for Government and Industry Affairs, Federal Aviation Administration.
DOT 318 Staff Assistant to the Secretary.
DOT 319 Congressional Liaison Officer to the Assistant Administrator for Government and Industry Affairs, Federal Aviation Administration.
DOT 321 Staff Assistant to the Administrator, Federal Highway Administration.
DOT 322 Special Assistant to the Special Assistant and Director for Drug Enforcement and Program Compliance.
DOT 323 Staff Assistant to the Director, Office of Small and Disadvantaged Business Utilization.
DOT 325 Staff Assistant to the Chief of Staff.
DOT 326 Staff Assistant to the Administrator, Federal Railroad Administration.
DOT 329 Staff Assistant to the Secretary.
DOT 330 Staff Assistant to the Deputy Administrator, Federal Highway Administration.
DOT 331 Staff Assistant to the Assistant Administrator for Public Affairs, Federal Aviation Administration.
DOT 332 Staff Assistant to the Administrator, Maritime Administration.
DOT 333 Staff Assistant to the Secretary.
DOT 334 Staff Assistant to the Secretary.
DOT 335 Staff Assistant to the Director, Office of the Executive Secretariat.
DOT 336 Staff Assistant to the Secretary.
DOT 339 Director of Program and Policy Support to the Deputy Administrator, Research and Special Programs Administration.

Section 213.3395 Federal Emergency Management Agency

FEMA 3 Director of Congressional Affairs to the Director of External Affairs.
FEMA 28 Special Assistant to the Director.
FEMA 34 Executive Assistant to the Deputy Director.

Section 213.3396 National Transportation Safety Board

NTSB 1 Special Assistant to a Board Member.
NTSB 2 Secretary (Typing) to the Chairman.
NTSB 30 Confidential Assistant to the Chairman.
NTSB 31 Confidential Assistant to a Board Member.
NTSB 32 Confidential Assistant to a Board Member.
NTSB 33 Confidential Assistant to a Board Member.
NTSB 34 Confidential Assistant to a Board Member.
NTSB 92 Director, Office of Congressional and Intergovernmental Relations, to the Chairman.
NTSB 98 Special Assistant to the Vice Chairman.
NTSB 102 Special Assistant to a Board Member.
NTSB 106 Director of Public Affairs to the Chairman.

Authority: 5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218.

Office of Personnel Management.

Constance Berry Newman,

Director.

[FR Doc. 91–22837 Filed 9–23–91; 8:45 am]

BILLING CODE 6325–01–M

Pay-for-Performance Labor-Management Committee; Change in Meeting Schedule

The Office of Personnel Management announces a change of the date for the following meeting:

Name: Pay-for-Performance Labor-Management Committee.

Date and Time: The meeting scheduled for September 27, 1991, 9 a.m. to 5 p.m. has been changed to October 10, 1991, 9 a.m. to 5 p.m. due to the unavailability of committee members on the previously scheduled date.

Place: Office of Personnel Management, 1900 E Street NW., Washington, DC 20415–0001. The meeting will be held in room 1350.

Type of Meeting: Open.

Point of Contact: Ms. Doris Hausser, Chief of the Performance Management Division, room 7454, Office of Personnel Management, 1900 E Street NW., Washington, DC 20415–0001.

Purpose of Meeting: To consider ways to strengthen the linkage between the performance of General Schedule employees and their pay.

Agenda: Committee goals and objectives; scope of inquiry; research and resources regarding performance-based pay; basic issues and challenges facing the committee; committee administration; comments and observations; public input; closing.

SUPPLEMENTARY INFORMATION: The committee welcomes written data, views, or comments concerning pay-for-performance for General Schedule employees. All such submissions received by close of business (COB) on October 3, 1991 will be provided to the committee members and included in the record of the October 10, 1991 meeting.

If time permits, the committee will consider oral presentations relating to agenda items. Persons wishing to address the committee orally at a meeting should submit a written request to be heard by the deadline listed above. The request must include the name and address of the person wishing to appear, the capacity in which the appearance will be made, a short summary of the intended presentation, and an estimate of the amount of time needed.

All communications regarding this committee should be addressed to the Point of Contact named above.

U.S. Office of Personnel Management.

Constance Berry Newman,

Director.

[FR Doc. 91–22955 Filed 9–23–91; 8:45 am]

BILLING CODE 6325–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–29703; File No. SR–Amex–91–21]

Self-Regulatory Organizations; Filing of Proposed Rule Change by the American Stock Exchange, Inc., Relating To Increasing AUTO-EX Eligibility for Major Market Index Options

September 18, 1991.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on August 26, 1991, the American Stock Exchange, Inc. ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to increase, from

20 to 50 contracts, the size of the orders for Major Market Index ("XMI") options that are eligible for execution through the Exchange's automated execution system ("AUTO-EX").

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 self-regulatory organization 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 self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

AUTO-EX is the Exchange's automated execution system which enables member firms to route public customer market and marketable limit orders in options for automatic execution at the best bid or offer at the time the order is entered. If the best bid or offer is on the specialist's book, the income order is routed to the specialist's post where it is executed against the book order, thus assuring that public customer's orders on the book retain priority over orders in the crow. If the best bid or offer is not on the specialist's book, the contra side of the AUTO-EX trade is assigned on a rotation basis to either one of the Amex registered option traders who have signed on the system or to the specialist. AUTO-EX then reports such executions back to the entering member firms as well as to the last sale tape, thus, effectively resulting in "locked in" trades (since the Exchange submits both sides to comparison) and thereby eliminating operational burdens for such users.

When the Exchange began using the AUTO-EX system in December 1985, order eligibility (market and marketable limit orders) for AUTO-EX was 10 contracts and in September 1987 the Exchange received Commission approval to expand the eligible number to 20 contracts.[1] The Exchange now proposes to increase AUTO-EX order eligibility for the XMI from 20 to 50 contracts.

The XMI has been the Exchange's most active option since its inception in 1983. As such, customer order activity can be extremely high at times. Member firms who utilize the AUTO-EX system have expressed a great deal of satisfaction with the system's capabilities to avoid operational burdens by providing for the quick and timely execution of orders and the transmission of executed trade data for comparison. An increase in XMI AUTO-EX order eligibility will further enhance execution efficiencies and liquidity for public customers and should have great appeal to both retail and institutional users.

To continue to ensure that AUTO-EX participants (floor trades and the specialist) in XMI have adequate capitalization to cover their trades, each participant will continue to be assigned a maximum of 10 contracts per transaction. For example an AUTO-EX eligible order to buy 50 contracts will be split into five 10 contract pieces and assigned to five different participants. The entering firm will receive a single report with five contra sides.

The Exchange intends to implement this proposal in conjunction with the impending split of the XMI to one-half its present value.[2] The Exchange expects that the proposed split of the XMI index value, coupled with the increase in AUTO-EX eligibility to 50 contracts, will significantly help attract additional investor interest in XMI options.

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the Exchange since it will enhance the Exchange's services and provide better liquidity for public customers engaged in executing transactions in XMI options. Therefore, the Exchange believes that the proposed rule change is consistent with section 6(b)(5) of the Act which provides that the rules of the Exchange be designed to promote just and equitable principles of trade and to protect the investing public.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose a burden on competition.

(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

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by October 15, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[3]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-22976 Filed 9-23-91; 8:45 am]

BILLING CODE 8010-01-M

[1] See Securities Exchange Act Release No. 24899 (September 10, 1987) 52 FR 35012 (September 16, 1987) (order approving SR-Amex-87-21).

[2] *See* Securities Exchange Release No. 29534 (August 8, 1991) 56 FR 40649 (August 15, 1991) (notice of filing of SR-Amex-91-18).

[3] 17 CFR 200.30-3(a)(12) (1990).

[Release No. 34-29701; File No. SR-NASD-91-45]

Self-Regulatory Organizations; Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to Amendments to Schedule C to the NASD's By-Laws

September 18, 1991.

Pursuant to section 9(b)(1) of the Securities Exchange Act of 1934 (Act), 15 U.S.C. 78s(b)(1), notice is hereby given that on August 23, 1991, the National Association of Securities Dealers, Inc. (NASD or Association) 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 NASD.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD is proposing to amend Schedule C to the NASD's By-Laws to adopt deadlines for the consideration of applications for membership and to extend the effectiveness of membership restrictions to successors to the ownership or control of the applicant. Proposed new language is in italics, proposed deletions are in brackets.

Text of Proposed Amendment to Schedule C of the By-Laws

I

Applications for Membership

(1) Prememberships Interviews

(a) An applicant for membership in the Corporation shall furnish to the District Office for the District in which it has or intends to have its principal place of business:

(1) A copy of its current submission to the Securities and Exchange Commission pursuant to rule 15b1-2(c) under the Securities Exchange Act of 1934;

(2) Its most recent trial balance, balance sheet, supporting schedules and computation of net capital;

(3) A copy of its written supervisory procedures;

(4) A list of all officers, directors, general partners, employees and other persons who will be associated with it at the time of admission to membership;

(5) A description of business activities in which it intends to engage; and

(6) Such other relevant information and documents as may be requested by the District Office.

Unless otherwise determined by the District committee, an applicant's failure to respond or a materially inadequate response to a request for information by the District Office within sixty (60) days of the request shall result in the termination of that application.

(b) Before an applicant shall be admitted to membership in the Corporation, and within a reasonable time after receipt of the foregoing information, the District Office shall schedule a premembership interview at which the responsible personnel of the applicant, as determined by the District Office, shall personally appear at the District Office. At such interview, the applicant shall demonstrate, in accordance with the criteria listed in section 1(c) hereof, the appropriateness of its admission to membership in the Corporation to conduct the type of business intended in the manner specified in its submission. Unless otherwise determined by the District committee, an applicant shall have twelve (12) months, from the date of application made in accordance with section 1(a) above, to complete the premembership review process. Failure to complete requirements for review by the District committee by that date shall result in the termination of that application.

(c) The premembership interview shall address the applicant's business plans to determine their adequacy and consistency with the federal securities laws and the rules of the Corporation; good business practices in the investment banking or securities business; a member's fiduciary obligation to its customers; and the public interest and the protection of investors. The premembership interview shall review, among other things[,]:

(1) The nature, adequacy, source and permanence of applicant's capital and its arrangements for additional capital should a business need arise;

(2) The applicant's proposed recordkeeping system;

(3) the applicant's proposed internal procedures, including compliance procedures;

(4) The applicant's familiarity with applicable NASD rules and federal securities laws;

(5) The applicant's capability to properly conduct the type of business intended in view of the[:]:

A. Number, experience and qualifications of the persons to be associated with it at the time of its admission to membership[;],

B. Its planned facilities[;],

C. Arrangements, if any, with banks, clearing corporations and others, to assist in the conduct of its securities business[;],

D. Supervisory personnel, methods and procedures; and

(6) Other factors relevant to the scope and operation of its business.

(d) Within thirty (30) days after the conclusion of such premembership interview, or if further information and/or documents are requested, within thirty (30) days of the receipt of such information or documents, the District Office shall notify the applicant in writing whether its application had been granted, denied, or granted subject to restrictions on its business activities, and provide the rationale for such determination.

(e) In all cases where restrictions are placed on its business activities, the applicant shall, prior to approval of membership, execute a written agreement with the Corporation agreeing to abide by the restrictions specified in the determination and agreeing not to modify its business activities in any way inconsistent with such agreement without first notifying the Corporation and receiving its written approval. These restrictions shall remain in effect and are binding on the applicant and all successors to the ownership or control of the applicant until modified pursuant to paragraph (3) below.

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 NASD 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 NASD has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The NASD is proposing to amend part I, section 1 of schedule C to the NASD By-Laws, which sets forth the application review process for new member applications ("the premembership interview process" or "PMI process"), to adopt deadlines for the consideration of applications and to extend the effectiveness of membership

[1] The NASD filed three amendments to this proposed rule change that are technical in nature and available for inspection and copying in the public reference room.

restrictions to successors to the ownership or control of the applicant.

As part of the PMI process an application is subjected to scrutiny by the District staff prior to the actual interview. If the application is inadequate in any respect, or if the District staff requires more information in order to evaluate the applicant's qualifications for membership, requests for clarification or additional information may be made of the applicant. Section 1(a), as proposed, would allow the NASD to reject an application after sixty (60) days where the applicant has failed to respond to a request from the NASD for information, or where the applicant has failed to amend a materially inadequate response pursuant to a request from the NASD.

In the event an application is materially inadequate the applicant will be notified in writing of the inadequacies and of the information which is required to remedy the inadequacy. Once an applicant has been notified of the inadequacy, or of the additional information required, the NASD believes that it is the applicant's obligation to provide the information in a timely fashion. The NASD also believes it is important that the processing of an application not be unduly delayed and that information needed to properly evaluate an application should be promptly supplied. Indeed, section 1(b) requires the NASD to schedule a PMI "within a reasonable time" after the NASD receives the necessary information. The proposed amendment will impose similar promptness obligations on applicants, will allow the NASD to reject dormant or persistently inadequate applications and will expedite the PMI process for all applicants.

Similarly, certain applications contain deficiencies which cannot be corrected sufficiently to gain approval within twelve (12) months of the application date. Under section 1(d), within thirty (30) days of the conclusion of the applicant's PMI, or the receipt of further information or documents, the NASD is required to notify an applicant and inform the applicant that its application has been granted, denied, or granted with restrictions. Section 1(D), therefore, imposes substantial obligations on the NASD to act quickly on completed applications.

The NASD believes that applicants should be under a similar obligation to actively pursue the completion of the application process. Consequently, the NASD is proposing that section 1(b) be amended to allow the NASD to reject an application if the applicant does not complete the review process within twelve (12) months of the filing of the application. The proposed amendment will allow the NASD to reject any application which is not approved within twelve (12) months of the application's date, thereby cutting off further consideration of the application when the applicant fails to take the actions required to complete the application. Rejection will not occur if the delay in approval of the application is caused by the NASD.

Both of the proposed amendments to sections 1(a) and 1(b) are designed to streamline the application review process, not to prevent the full and fair review of applications. The normal communication between the NASD and the applicant during the PMI process will include notice of the deadlines imposed by the proposed amendments and the consequences of the failure to meet the deadlines. If an application is terminated pursuant to the proposed amendment to sections 1(a) and 1(b) the applicant will be free to reapply for membership by submitting a new application along with the appropriate application fee. Thus, the fundamental fairness of the PMI process will be preserved.

Finally, the NASD's approval of an application may include restrictions on the member's business activities designed to limit the member to the types or quantity of securities business activity which is consistent with the member's financial strength, internal procedures and the experience of its management. Such restricted approval is called a "restrictive agreement" and, pursuant to section 1(e), the applicant's membership in the NASD is contingent on its agreeing to abide by the restrictions.

If the ownership or control of the member changes, the NASD is concerned that the new owners or controlling persons understand that the restrictive agreement continues to limit the member's business. The member's business cannot be modified beyond the scope of the restrictive agreement until the member has made application to the Association and the modifications have been approved.

The NASD is proposing to amend section 1(e) to state that all restrictions placed on an applicant's business will remain in effect until modified pursuant to section 3 of part I, and will bind all successors to the applicant. This amendment codifies the NASD's view that a restrictive agreement is binding on the member firm, not just the principals, and the changes in ownership or control of the member do not operate to remove or reduce the limitations in the restrictive agreement. The proposed amendment will emphasize the NASD's requirement that restrictive agreements can be amended only after the approval of a written application submitted to the District in which the member has its principal place of business.

The NASD has requested that the rule change be effective on a date specified in a Notice to Members announcing the SEC's approval of the rule filing—with such date to be not later than thirty (30) days following the purblication of the Notice to Members. The NASD further intends that the proposed rule change shall be applicable to all new applications and applications in process on the effective date.

The NASD believes the proposed changes to Schedule C of the By-Laws are consistent with the provisions of section 15A(g)(3)(A) of the Act, which allow the NASD to deny or condition membership in the NASD on the member's ability to demonstrate financial reponsibility and operational capability pursuant to standards established by the NASD.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

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 reason for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change would be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions

should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the principal office of NASD. All submissions should refer to File No. SR-NASD-91-45 and should be submitted by October 15, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-22904 Filed 9-23-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29702; File No. SR-PHLX-91-13]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to the Exercise of Discretion by a Floor Broker Over a Registered Options Trader's Order

September 18, 1991.

On April 25, 1991, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") submitted to the Securities and Exchange Commission ("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 prohibit a floor broker from exercising any discretion over a Registered Options Trader's ("ROT") order. Currently, floor brokers are prohibited from exercising any discretion as to the class, quantity, or nature (*i.e.*, buy or sell) of an ROT's order.

The proposed rule change was published for comment in Securities Exchange Act Release No. 29179 (May 8, 1991), 56 FR 22502 (May 15, 1991). No comments were received on the proposed rule change.

Currently, PHLX Rule 1065 provides that it is a violation of Exchange rules for a floor broker to exercise discretion with respect to any options order's class, quantity or nature (*i.e.*, whether the order is to buy or sell). The current proposal will extend this prohibition to include the exercise of price discretion by a floor broker over an ROT order. Specifically, the proposal adds new Commentary .02 to rule 1065 which will expressly limit the ability of a broker to exercise any discretion with respect to any aspect of an ROT's order. The proposed rule change does not affect floor broker discretion as to the price of customer orders, which is still permitted.

The proposal makes conforming amendments to the Exchange's Option Floor Procedures Advice ("OFPA") C-3 (Handling Registered Option's Traders' Orders) to provide for specific fines to be imposed on floor brokers when they exercise any discretion over an ROT's order.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6.[3] Specifically, the Commission finds that the proposal to prohibit a floor broker from exercising any price discretion over an ROT's order is consistent with section 6(b)(5) in that it promotes just and equitable principals of trade by providing consistency in the application of exchange rules to ROTs and floor brokers.

Although Exchange rules currently prohibit an ROT from granting a floor broker discretionary authority over his orders, they only prohibit a floor broker from exercising discretion over the class, quantity, or nature (*i.e.*, buy or sell) of an ROT's order.[4] Exchange rules presently do not specifically prohibit a floor broker from exercising price discretion over an ROT's order. Therefore, under current Exchange rules, the exercise of price discretion by a floor broker over an ROT's order results in a rule violation for the ROT, but not for the floor broker exercising the discretion. The Phlx proposal will close this regulatory loop-hole and will result in the consistent application of Exchange rules regarding the exercise of discretionary authority by floor brokers over ROT orders.

It Is Therefore Ordered, Pursuant to section 19(b)(2) of the Act,[5] that the proposed rule change (SR-PHLX-91-13) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-22977 Filed 9-23-91; 8:45 am]

BILLING CODE 8010-01-M

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[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b-4 (1990).

[3] 15 U.S.C. 78f (1988).

[4] See PHLX Rule 1065 and OFPA B-4.

[5] 15 U.S.C. 78s(b)(2) (1988).

[6] 17 CFR 200.30-3(a)(12) (1990).

[Rel. No. IC-18324; 812-7228]

American Capital Comstock Fund, Inc., et al.; Application

September 18, 1991.

AGENCY: Securities and Exchange Commission (the "SEC" or "Commission").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 ("Act").

APPLICANTS: American Capital Asset Management, Inc. (the "Adviser"), American Capital Marketing, Inc. (the "Distributor"), American Capital Comstock Fund, Inc., American Capital Corporate Bond Fund, Inc., American Capital Emerging Growth Fund, Inc., American Capital Enterprise Fund, Inc., American Capital Equity Income Fund, Inc., American Capital Federal Mortgage Trust, American Capital Government Securities, Inc., American Capital Growth and Income Fund, Inc., American Capital Harbor Fund, Inc., American Capital High Yield Investments, Inc., American Capital Municipal Bond Fund, Inc., American Capital Pace Fund, Inc., American Capital Tax-Exempt Trust, and any other open-end management investment company for which the Adviser or the Distributor, or any successor thereof, serve as principal underwriter or investment adviser (such investment companies are collectively referred to as the "Funds").

RELEVANT ACT SECTIONS: Order requested under section 6(c) for an exemption from sections 2(a)(32), 2(a)(35), 18(f), 18(g), 18(i), 22(c) and 22(d) of the Act and rule 22c-1 thereunder.

SUMMARY OF APPLICATION: Applicants seek an order that would permit the Funds (a) to issue two classes of shares representing interests in the same portfolio of securities, one of which would convert to the other class after a specified period to permit investors to benefit from lower rule 12b-1 distribution fees, and (b) to assess a contingent deferred sales load ("CDSL") on certain redemption of shares of one

of the classes, and to waive the CDSL in certain cases.

FILING DATE: The application was filed on January 26, 1989 and amendments were filed on May 8, 1991, August 5, 1991, and September 4, 1991.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Any interested person may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on October 16, 1991, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, 2800 Post Oak Blvd., Houston, Texas 77056.

FOR FURTHER INFORMATION CONTACT: Felice R. Foundos, Staff Attorney, at (202) 272–2190 or Barry D. Miller, Branch Chief, at (202) 272–3030 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

A. The Dual Distribution System

1. Each of the Funds is an open-end management investment company registered under the Act. The Adviser serves as the Funds' investment adviser and manager and the Distributor acts as principal underwriter of the Funds' shares. Shares of the Funds are currently offered to the public at their net asset value plus a front-end sales load. Each of the Funds, except American Capital Comstock Fund, Inc. ("Comstock Fund"), makes rule 12b–1 payments to the Distributor at an annual rate of up to .25% of such Fund's average daily net assets.

2. Applicants propose to establish a dual distribution system (the "Dual Distribution System") to enable each of the Funds to offer investors the option of purchasing shares either subject to a conventional front-end sales load and a rule 12b–1 distribution fee (the "Front-End Option") or subject to a CDSL and a higher rule 12b–1 distribution fee (the "Deferred Option"). Applicants seek an exemption from sections 18(f)(1), 18(g), and 18(i) to the extent the Dual Distribution System may result in a senior security, as defined by section 18(g), the issuance and sale of which would be prohibited by section 18(f)(1), and to the extent the allocation of voting rights under the Dual Distribution System may violate the provisions of section 18(i).

3. If the requested relief is granted, each Fund will create a new class of shares designated Class B. Class B will be offered pursuant to the Deferred Option. The currently authorized shares will be designated Class A and will continue to be offered subject to the Front-End Option. The two classes will each represent interests in the same portfolio of securities of such Fund. The two classes will be identical except that (i) the Class B shares will be subject to a higher rule 12b–1 distribution fee; (ii) Class B shares will be subject to higher transfer agency costs and any other incremental expenses resulting from the deferred sales arrangement subsequently identified which shall be approved by the SEC pursuant to an amended order; (iii) the two classes will have different exchange privileges; (iv) only Class B shares will have a conversion feature; and (v) each class will vote separately as a class with respect to the Fund's rule 12b–1 distribution plan (except only Class B shareholders will vote for Comstock Fund's rule 12b–1 distribution plan).[1]

4. Under the Front-End Option, an investor will purchase Class A shares at net asset value plus a front-end sales load. The sales load will be subject to reductions for larger purchases, under a combined purchase privilege, under a right of accumulation or under a letter of intent. The sales load also will be subject to certain other reductions permitted by section 22(d) of the Act and set forth in the registration statement of the Fund. Each Fund except Comstock Fund will pay to the Distributor a distribution fee pursuant to each Fund's rule 12b–1 plan at an annual rate of up to .25 of 1% of the average daily net asset value of the Class A shares.

5. Investors choosing the Deferred Option will purchase Class B shares at net asset value without the imposition of a sales load at the time of purchase. Each Fund will pay to the Distributor a distribution fee pursuant to each Fund's rule 12b–1 plan at an annual rate of up to 1% of the average daily net asset value of the Class B shares. In addition, an investor's proceeds from a redemption of Class B shares made within a specified period of years of their purchase (which will be at least three years but will not exceed six years) generally will be subject to a CDSL, as described below. The Deferred Option is designed to permit the investor to purchase Class B shares without the assessment of a front-end sales load and at the same time permit the Distributor to pay financial intermediaries a commission on the sale of the Class B shares.

6. Under a Fund's distribution plan, the Distributor will not be entitled to any specific percentage of the net asset value of each class of shares of the Fund or any other specific amount. Each Fund's distribution plan will provide that payments will be made only to reimburse the Distributor for expenses incurred in providing distribution-related services (including in the case of Class B shares, commission expenses). Each Fund will accrue and pay a distribution fee at a rate fixed by the Fund's board of directors (but not in excess of the applicable maximum percentage rate). Such rate is intended to provide for accrual of expenses at a rate that will not exceed the unreimbursed amounts actually expended for distribution by the Distributor on behalf of the Fund. In no event will the amount paid by the Fund to the Distributor exceed the unreimbursed expenses previously incurred by the Distributor in providing distribution-related services.

7. Proceeds from the distribution fee and, in the case of Class B shares, the CDSL, will be used to compensate financial intermediaries with a service fee in an amount of up to .25%, annualized, of the average daily net asset value of the Class A shares or Class B shares maintained in each Fund by their customers and to defray the expenses of the Distributor with respect to providing distribution related services, including commissions paid on the sale of Class B shares.

8. The Distributor will furnish the directors of the Fund with quarterly and annual statements of distribution revenues and expenditures ("Statements"), in accordance with the requirements of paragraph (b)(3)(ii) of rule 12b–1, to enable the directors to make the findings required by paragraphs (d) and (e) of rule 12b–1. In the Statements, only distribution expenditures properly attributable to the

[1] Comstock Fund currently offers its shares subject to a front-end sales load but without any rule 12b–1 fee. Comstock Fund will have to enter into a rule 12b–1 distribution plan with the Distributor to provide for a distribution fee on Class B shares.

sale of a particular class will be used to justify the distribution fee charged to that class. Distribution expenses attributable to the sale of both classes of shares will be allocated annually to each class based upon the ratio in which the sales of each class bears to the sales of all the shares of the Fund.

9. The decision as to whether a particular distribution expenditure or category of distribution expenditures is properly attributable to the sale of a particular class or to the sale of both classes of shares (and thus allocated to each class of shares in accordance with the method described above) will be subject to the review and approval of the directors. Currently, it is anticipated that all distribution expenditures will be determined to be attributable to the sale of both classes of shares except (i) commission expenses related to the sale of the Class B shares and (ii) service fee payments (which will be separately calculated with respect to each class). In the future, however, the directors may determine that particular distribution expenditures, in addition to the two categories listed in the immediately preceding sentence, are attributable to the sale of a particular class. The Statements will disclose whether the distribution expenditures listed are attributable to the sale of a particular class or to the sale of both classes of shares.

10. All Class B shares of each Fund, other than those purchased through the reinvestment or dividends and distributions, will automatically convert to Class A shares after a certain number of years after the end of the calendar month in which the shareholder's order to purchase was accepted, in the circumstances and subject to the qualifications described below. Such number of years, which will be the same with respect to all Class B shares of each Fund, may be between four and eight. The purpose of the conversion feature is to relieve the holders of Class B shares that have been outstanding for a period of time sufficient for the Distributor to have been compensated for distribution expenses related to the Class B shares from most of the burden of additional distribution expenses. Thus, Class A shares will consist of shares purchased by investors prior to the implementation of the Dual Distribution System, shares purchased pursuant to the Front-End Option, Class B shares (including Class B shares purchased through the reinvestment of dividends and other distributions in respect of Class B shares) that have converted to Class A status, and shares purchased by holders of outstanding Class A shares through the reinvestment of dividends and distributions paid in respect of those outstanding Class A shares.

11. Shares purchased through the reinvestment of dividends and other distributions paid in respect of Class B shares will be treated as Class B shares except that, for purposes of conversion to Class A, all such shares that have not already converted into Class A shares will be considered held in a separate sub-account. Each time any Class B shares in the shareholder's account (other than those in the sub-account referred to in the preceding sentence) convert to Class A, an equal pro rata portion of the Class B shares in the sub-account also will convert to Class A.

12. The Funds will obtain an opinion of counsel that the assessment of the additional distribution fee and transfer agency costs and any other special allocations described above with respect to Class B shares does not result in any dividends or distributions constituting "preferential dividends" under the Internal Revenue Code of 1986, as amended ("IRC"), and that the conversion of Class B shares to Class A shares does not constitute a taxable event under current federal income tax law. The conversion of Class B shares to Class A shares may be suspended if such an opinion is no longer available at the time such conversion is to occur. In that event, no further conversions of Class B shares would occur, and shares might continue to be subject to the additional distribution fee for an indefinite period which may extend beyond the time at which the conversion of the shares would otherwise have occurred.

13. Class B shares of the Fund will be exchangeable only for Class B shares of any other fund in the Adviser's complex. Class A shares of a Fund may be exchanged for Class A shares of the other Funds upon payment of the excess, if any, of the sales charge rate applicable to such funds over the sales charge rate previously paid, upon payment of any applicable exchange fee, and subject to any applicable holding period for such fund.[2]

14. Except for the differences described above, the Class a shares of each Fund will have identical voting, dividend, liquidation and other rights, preferences, powers, restrictions, limitations, qualifications, designations and terms and conditions as the Class B shares of the Fund. All expenses incurred by the Funds not attributable to a specific class will be allocated to each class on the basis of the relative net asset value of the respective classes except for the expenses of the distribution plan and incremental transfer agency costs, which will be borne by Class B. Because of the additional expenses that will be borne solely by Class B, the net income attributable to and the dividends payable on Class B shares will be lower than the net income attributable to and the dividends payable on Class A shares. Initially, it is expected that the net asset value of the Class A shares will be higher than the net asset value of the Class B shares and the net asset value per share of the two classes will continue to diverge over time.

15. Each Fund will disclose in its prospectus the respective expenses, performance data, distribution arrangements, services, fees, sales loads, deferred sales loads, and exchange privileges applicable to each class of shares offered through the prospectus. Class A and Class B shares will be offered and sold through a single prospectus. The shareholder reports of each Fund will disclose the respective expenses and performance data applicable to each class of shares. The shareholder reports will contain, in the statement of assets and liabilities and statement of operations, information related to the Fund a whole generally and not on a per class basis. Each Fund's per share data, however, will be prepared on a per class basis with respect to all classes of shares of such Fund. To the extent any advertisement or sales literature describes the expenses or performance data applicable to Class A or B shares, it will disclose the expenses and/or performance data applicable to both classes. The information provided by Applicants for publication in any newspaper or similar listing of the Fund's net asset values and public offering prices will separately present Class A and Class B shares.

B. The CDSL

1. Applicants also seek an exemption from sections 2(a)(32), 2(a)(35), 22(c), and 22(d) of the Act, and rule 22c-1 thereunder to permit the Funds to assess a CDSL on certain redemptions of Class B shares, and to permit the Funds to assess a CDSL on certain redemptions of Class B shares, and to permit the Funds to waive the CDSL with respec to certain types of redemptions. The CDSL is expected to range from 3% to 5% (but may be higher or lower) on shares redeemed during the first year after purchase and will be reduced at a

[2] Various Funds presently require a 30 day holding period prior to an exchange and impose an exchange fee of $5 per exchange transaction.

rate of 1% (but may be higher or lower) per year over the applicable CDSL period. Redemptions of shares held after such period will not be subject to the CDSL. The CDSL schedule of the Funds must comply with the NASD sales load limitations and the provisions of proposed rule 6c–10.

2. The CDSL will not be imposed on redemptions of (a) shares which were purchased more than a specified period of up to six years (the "CDSL Period") prior to their redemption or (b) Class B shares derived from reinvestment of distributions. Furthermore, no CDSL will be imposed on an amount which represents an increase in the value of the shareholder's account resulting from capital appreciation above the amount paid for shares purchased during the CDSL Period. In determining whether a CDSL is applicable, it will be assumed that a redemption is made first of any Class A shares in a shareholder's Fund account, second of shares derived from reinvestment of distributions, third of shares held for a period longer than the CDSL Period, and fourth of shares held for a period not longer than the CDSL Period.

3. In addition, the Funds seek the ability to waive the CDSL on redemptions (a) following the death or disability, as defined in section 72(m)(7) of the IRC, of a shareholder, (b) in connection with certain distributions from an Individual Retirement Account, a custodial account maintained pursuant to IRC section 403(b)(7) or a qualified pension or profit-sharing plan and (c) in connection with the exercise of certain exchange privileges among the Class B shares of the Funds. If the Funds waive or reduce the CDSL, such waiver or reduction will be uniformly applied to all offerees in the class specified. Also, in waiving or reducing a CDSL, the Funds will comply with the requirements of rule 22d–1 under the Act as if such CDSL were a sales load.

4. If the directors of the Funds determine to discontinue the waiver of the CDSL, the disclosure in each Fund's prospectus will be appropriately revised. Also, any Class B shares purchased prior to the termination of such waiver would be able to have the CDSL waived as provided in such Fund's prospectus at the time of the purchase of such shares.

Applicants' Legal Conclusions

A. Dual Distribution System

1. Applicants believe that the Dual Distribution System will facilitate the distribution of shares by the Fund and provide investors with a broader choice of methods for financing the purchase of shares. Moreover, owners of both classes may be relieved of a portion of the fixed costs normally associated with open-end management investment companies since such costs would, potentially, be spread over a greater number of shares than would otherwise be the case. Finally, the conversion feature will benefit long-term Class B shareholders by relieving them of most of the burden of distribution expenses after a period of time sufficient for the Distributor to be compensated for the expenses incurred in connection with the distribution of such shares.

2. The proposed Dual Distribution System does not create the potential for the abuses that section 18 was designed to correct. The proposed arrangement will not increase the speculative character of the shares of the Funds since all such shares will participate pro rata in all of a Fund's income and expenses (with the exception of the differing rule 12b–1 distribution fees and transfer agency costs).

3. Both classes of shares will be redeemable at all times and no class of shares will have any preference or priority over any other class in the Funds in the usual sense (that is, no class will have distribution or liquidation preferences with respect to particular assets, no class will have any right to require that lapsed dividends be paid before dividends are declared on the other class, and no class will be protected by any reserve or other account). In addition, investors will not be given misleading impressions as to the safety or risk of the Class A and Class B shares since the similarities (and, with respect to the rule 12b–1 distribution plans and associated voting rights, the Class B conversion feature, the transfer agency costs, and the exchange privileges, dissimilarities) of the Class A and Class B shares will be fully disclosed in each Fund's prospectus and statement of additional information.

4. The interests of the two classes of shares as to the advisory fees of each Fund are the same and not in conflict. These fees are used solely to compensate the Adviser for providing management and advisory services that are common to all investors, regardless of the class of shares held. Further, the directors must analyze the reasonableness of the advisory fee and the distribution fee under the standards defined by section 36(b) of the Act.

5. The proposed allocation of expenses and voting rights relating to the rule 12b–1 distribution plan is equitable and will not discriminate against either group of shareholders. Investors purchasing Class A shares will bear a proportionately lower share of a Fund's distribution expenses and transfer agency costs than holders of the Class B shares. However, each class of shares will vote separately as a class with respect to each Fund's rule 12b–1 distribution plan.

B. The CDSL

1. Applicants believe its request for exemptive relief is consistent with the standards of section 6(c). The imposition of the CDSL on the Class B shares of the Funds is fair and in the best interests of its shareholders. The proposed Dual Distribution System permits Class B shareholders to have the advantage of greater investment dollars working for them from the time of their purchase of Class B shares of a Fund than if a sales load were imposed at the time of purchase, as is the case with the Class A shares. Furthermore, the CDSL is fair to Class B shareholders because it applies only to amounts representing purchase payments and does not apply to amounts representing increases in the value of an investor's account through capital appreciation, or to amounts representing reinvestment of distributions.

2. Applicants also believe that the imposition of the CDSL is appropriate in light of the relationship between the CDSL and the Fund's rule 12b–1 plan. When amounts attributable to Class B shares are redeemed prior to the expiration of the CDSL period, these amounts no longer contribute to the annual distribution fee. Therefore, it is fair to impose on the withdrawing Class B shareholder a lump sum payment reflecting expenses that have not been recovered through payments by the Fund. As noted above, the proceeds from the CDSL will reduce the amount of distribution expenses which must be borne by the remaining shares.

3. Applicants further believe that an order permitting the waivers of the CDSL described above would be consistent with the standards of section 6(c). Waiver of the CDSL in the extraordinary circumstances of death or total disability of the investor or in the case of certain distributions in connection with retirement plans is justified on the basis of considerations of fairness. Similarly, the waiver of the CDSL in the case of the exercise of any exchange privilege of the Class B shares of the Funds is justified by the fact that the investors will remain invested in a mutual fund advised by the Adviser and will be paying a rule 12b–1 distribution fee on Class B shares, and will have to pay any applicable CDSL upon redemption out of the fund complex.

Applicants' Conditions

Applicants agree that the order of the Commission granting the requested relief shall be subject to the following conditions:

A. Conditions Relating to the Dual Distribution System

1. The Class A and Class B shares will represent interests in the same portfolio of investments of the Funds, and be identical in all respects, except as set forth below. The only differences between Class A and Class B shares of the Funds will relate solely to: (a) The impact of the disproportionate rule 12b–1 distribution plan payments allocated to each of the Class A shareholders and Class B shareholders of a Fund, the incremental transfer agency costs attributable of the Class B shares of the Funds resulting from the Deferred Option arrangement, and any other incremental expenses subsequently identified that should be properly allocated to one class which shall be approved by the Commission pursuant to an amendment order, (b) the fact that each class will vote separately as a class with respect to a Fund's rule 12b–1 distribution plan, (c) the different exchange privileges of the Class A and Class B shares, (d) only Class B shares will have a conversion feature, and (e) the designation of each class of shares of the Funds.

2. The directors of the Funds, including a majority of the independent directors, shall have approved the Dual Distribution System prior to the implementation of the Dual Distribution System. The minutes of the meetings of the directors of the Funds regarding the deliberations of the directors with respect to the approvals necessary to implement the Dual Distribution System will reflect in detail the reasons for the directors' determination that the proposed Dual Distribution System is in the best interests of both the Funds and their respective shareholders.

3. On an ongoing basis, the directors of the Funds, pursuant to their fiduciary responsibilities under the Act and otherwise, will monitor the Funds for existence of any material conflicts between the interests of the two classes of shares. The directors, including a majority of the independent directors, shall take such action as is reasonably necessary to eliminate any such conflicts that may develop. The Adviser and the Distributor will be responsible for reporting any potential or existing conflicts to the directors. If a conflict arises, the Adviser and the Distributor at their own cost will remedy such conflict up to and including establishing a new registered management investment company.

4. Any rule 12b–1 plan adopted or amended to permit the assessment of a rule 12b–1 fee on any class of shares which has not had its rule 12b–1 plan approved by the public shareholders of that class will be submitted to the public shareholders of such class for approval at the next meeting of shareholders after the initial issuance of the class of shares. Such meeting is to be held within 16 months of the date that the registration statement relating to such class first becomes effective or, if applicable, the date that the amendment to the registration statement necessary to offer such class of shares first becomes effective.

5. The directors of the Funds will receive quarterly and annual Statements complying with the paragraph (b)(3)(ii) of rule 12b–1, as it may be amended from time to time. In the Statements, only distribution expenditures properly attributable to the sale of either the Class A or Class B shares will be used to support the rule 12b–1 fee charged to shareholders of such class of shares. Expenditures not related to the sale of a particular class of shares will not be presented to the directors to support the rule 12b–1 fee charged to shareholders of such class of shares. The Statements, including the allocations upon which they are based, will be subject to the review and approval of the independent directors in the exercise of their fiduciary duties.

6. Dividends paid by a Fund with respect to its Class A shares and Class B shares, to the extent any dividends are paid, will be calculated in the same manner, at the same time, on the same day, and will be in the same amount, except that distribution fee payments relating to each respective class of shares will be borne exclusively by that class and any incremental transfer agency costs relating to Class B shares will be borne exclusively by that class.

7. The methodology and procedures for calculating the net asset value and dividends and distributions of the two classes and the proper allocation of expenses between the two classes has been reviewed by an expert (the "Expert") who has rendered a report to the Applicants, which has been provided to the staff of the Commission, that such methodology and procedures are adequate to ensure that such calculations and allocations will be made in an appropriate manner. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made and, based upon such review, will render at least annually a report to the Funds that the calculations and allocations are being made properly. The reports of the Expert shall be filed as part of the periodic reports filed with the Commission pursuant to sections 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following the request by a Fund (which the Fund agrees to provide), will be available for inspection by the Commission staff upon the written request to the fund for such work papers by a senior member of the Division of Investment Management or of a Regional Office of the Commission, limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, and an Assistant Director and any Regional Administrators or Associate and Assistant Administrators. The initial report of the Expert is a "Special Purpose" report on the "Design of a System" and the ongoing reports will be "Special Purpose" reports on the "Design of a System and Certain Compliance Tests" as defined and described in SAS No. 44 of the AICPA, as it may be amended from time to time, or in similar auditing standards as may be adopted by the AICPA from time to time.

8. The Applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the net asset value and dividends and distributions of the two classes of shares and the proper allocation of expenses between the two clases of shares and this representation will be concurred with by the Expert in the initial report referred to in condition (7) above and will be concurred with by the Expert, or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in condition (7) above. Applicants will take immediate corrective measures if this representation is not concurred in by the Expert or appropriate substitute Expert.

9. The prospectus of each Fund will contain a statement to the effect that a salesperson and any other person entitled to receive compensation for selling Fund shares may receive different compensation for selling one particular class of shares over another in the Fund.

10. The Distributor will adopt compliance standards as to when Class A and Class B shares may appropriately be sold to particular investors. Applicants will require all persons selling shares of the Fund to agree to conform to such standards.

11. The conditions pursuant to which the exemptive order is granted and the duties and responsibilities of the directors of the Funds will respect to the Dual Distribution System will be set forth in guidelines which will be furnished to the directors.

12. Each Fund will disclose in its prospectus the respective expenses, performance data, distribution arrangements, services, fees, sales loads, deferred sales loads, and exchange privileges applicable to each class of shares offered through the prospectus. Class A and Class B shares will be offered and sold through a single prospectus. The shareholder reports of each Fund will disclose the respective expenses and performance data applicable to each class of shares.

The shareholder reports will contain, in the statement of assets and liabilities and statement of operations, information related to the Fund as a whole generally and not on a per class basis. Each Fund's per share data, however, will be prepared on a per class basis with respect to all classes of shares of such Fund. To the extent any advertisement or sales literature describes the expenses or performance data applicable to Class A or B shares, it will disclose the expenses and/or performance data applicable to both classes. The information provided by Applicants for publication in any newspaper or similar listing of the Funds' net asset values and public offering prices will separately present Class A and Class B shares.

13. The Applicants acknowledge that the grant of the exemptive order requested by this Application will not imply Commission approval, authorization or acquiescence in any particular level of payments that the Funds may make pursuant to its rule 12b-1 distribution plan in reliance on the exemptive order.

14. Class B shares will convert into Class A shares on the basis of the relative net asset values of the two classes, without the imposition of any sales load, fee or other charge.

B. Condition Relating to the CDSL

1. Applicants will comply with the provisions of proposed rule 6c-10 under the Act (see Investment Company Release No. 16619 (November 2, 1988)), as such rule is currently proposed and as it may be reproposed, adopted or amended.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-22974 Filed 9-23-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-18323; International Series Release No. 316; 812-7753]

The Emerging Germany Fund Inc. et al.; Application

September 18, 1991.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for exemption under the Investment Company act of 1940 ("1940 Act").

APPLICANTS: The Emerging Germany Fund Inc. (the "Fund"), Asset Management Advisors of Dresdner Bank—Gesellschaft fuer Vermoegensanlageberatung mbH ("AMA"), and ABD Securities Corporation ("ABD Securities").

RELEVANT 1940 ACT SECTIONS: Order requested under section 6(c) of the 1940 Act for exemption from the provisions of Section 15(a) of the 1940 Act.

SUMMARY OF APPLICATION: Applicants seek an order under section 6(c) of the 1940 Act exempting AMA and ABD Securities from the provisions of section 15(a) of the 1940 Act to the extent necessary to permit AMA and ABD Securities to continue to provide investment advisory services to the Fund until the earlier to occur of January 31, 1992 or the date on which the Fund's stockholders approve the Fund's investment advisory contracts.

FILING DATES: The application was initially filed on July 11, 1991 and was amended on September 17, 1991.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on October 15, 1991, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC'S Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. The Fund and ABD Securities, One Battery Park Plaza, New York, New York 10004. Attention: Martin J. Bentsen, Esq. AMA, Mainzer Landstrasse 11-13, D-6000, Frankfurt/Main 1, Germany. Attention: Klaus-Juergen Stroeter.

FOR FURTHER INFORMATION CONTACT: H.R. Hallock Jr., Special Counsel (202) 272-3030 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. The Fund is a non-diversified, closed-and management investment company organized under the laws of the State of Maryland and registered under the 1940 Act. The Fund's investment objective is to obtain long-term capital appreciation by investing primarily in equity and equity-linked securities of medium and smaller sized German companies. The Fund's registration statement under the Securities Act of 1933, as amended, became effective on March 29, 1990 and the Fund commenced investment operations on April 5, 1990.

2. The Fund's investment adviser is AMA, a corporation organized under the laws of the Federal Republic of Germany, and the Fund's manager and administrator is ABD Securities, a corporation organized under the laws of the State of Delaware. Pursuant to its Investment Advisory Agreement with the Fund, AMA recommends the purchase and sale of protfolio securities in accordance with the Fund's investment objective, policies and restrictions. Pursuant to its Management Agreement with the Fund, ABD Securities acts as the Fund's manager and administrator and determines whether AMA's securities recommendations would be suitable for investment by the Fund. ABD Securities has ultimate responsibility for decisions to buy or sell securities for the Fund's protfolio.

3. The Investment Advisory and Management Agreements (the "Agreements") were each initially approved by the Fund's board of directors, including a majority of the directors who are not parties to the Agreements or interested persons of such parties ("disinterested directors"), and its initial stockholder on March 15, 1990. In accordance with the Fund's

undertakings to the SEC contained in its registration statement, and as required by provisions in each Agreement stating that continuance of that Agreement required approval by the Stockholders at the first annual meeting of the Fund's stockholders, the Fund submitted the Agreements for approval at its first annual meeting, which initially convened on April 30, 1991.

4. As of March 11, 1991, the record date for the annual meeting of stockholders, the Fund has 592 holders of record and an estimated 8,000 beneficial owners of its common stock. The Fund estimnates that the beneficial owners of at least eight million of its approximately 14 million outstanding shares of common stock were foreign persons. Significant percentages of its shares were held by German and other West European, Japanese and Canadian investors as of March 11, 1991.

5. Of the 14,008,334 shares eligible to be represented and entitled to vote at the meeting on April 30, 1991, 58.7% of the shares (8,224,032 shares) were represented in person or by proxy. More than six million shares were voted by the Fund's nominee stockholders for election of the Fund's directors and ratification of selection of the Fund's independent accountant without instructions from the beneficial owners of such shares. Sufficient votes were received to elect the Fund's directors and to ratify selection of the Fund's independent accountants on April 30, 1991.

6. The Agreements did not receive approval of the majority of the outstanding voting securities of the Fund at the annual meeting as required by the Agreements. Member organizations of the New York Stock Exchange serving as nominee stockholders of the Fund's common stock indicated to the Fund that under applicable NYSE policies they were not authorized to vote on approval of the Agreements without instructions from the beneficial owners of such common stock. Other institutional nominee stockholders that are not NYSE members advised the Fund that they were subject to similar restrictions under applicable regulations and policies. At the stockholder meeting on April 30, 1991, only 14% of the Fund's outstanding shares (1,958,262 shares) were voted on the proposals to approve the Agreements.

7. In accordance with applicable Maryland law, which permits adjournment of stockholders' meetings for up to 120 days after the record date, the Fund adjourned the annual meeting until June 7, 1991 to permit further solicitation of proxies on the proposals to approve the Agreements. While more than 68% of the Fund's outstanding shares (9,586,632 shares) were represented in person or by proxy at the adjourned meeting, votes with respect to less than 30% of the Fund's outstanding shares were cast with respect to approval of the Agreements. Accordingly, the Fund further adjourned the annual meeting to July 8 and then to July 9, 1991, the latest date permitted by Maryland law, to permit further solicitation of proxies. About 70% of the Fund's outstanding shares (9,799,791 shares) were represented at the July 9 adjourned meeting, but votes with respect to only 32.5% of such shares were cast on the proposals to approve the Agreements. Of the shares voted, well over 90% were voted for approval of the Agreements. Apart from the particular reasons causing individual shareholders to vote against the proposals (which are unknown to the Fund), the Fund is unaware of any opposition to its current advisory arrangements.

8. The Fund believes that its inability to obtain stockholder approval of the Agreements resulted principally from the failure of its foreign stockholders to vote their shares on the proposals, despite the solicitation efforts by personnel of ABD Securities and two proxy solicitation firms.

9. At a meeting of the Fund's board of directors held on July 9, 1991, the directors, including a majority of the disinterested directors, approved identical amendments to the Agreements. The effect of the amendments is to provide for continuance of the Agreements notwithstanding the failure of each such Agreement to be approved by the Fund's stockholders at the annual meeting. The amendments did not modify any of the provisions of the Agreements other than the termination provisions.

10. The Fund has called a special meeting of stockholders scheduled to convene on October 23, 1991 (the "Special Meeting") for the purpose of voting on approval of the amended Agreements.

Applicants' Legal Analysis

1. Section 15(a) of the 1940 Act makes it unlawful for any person to serve or act as an investment adviser of a registered investment company except pursuant to a written contract which has been approved by the vote of a majority of the outstanding voting securities of such investment company. On the basis of the following analysis, the Applicants believe that limited and conditional relief from section 15(a) would be consistent with the exemptive standards prescribed by section 6(c) of the 1940 Act.

2. Rule 15a–4 under the 1940 Act provides that a person may act as an investment adviser for a registered investment company pursuant to a written contract which has not been approved by a stockholder vote as required by section 15(a) during the 120-day period after the termination of such investment advisory contract as a result of, among other events, the failure to renew such contract. Rule 15a–4 requires (a) that any such contract be approved by the investment company's board of directors, including a majority of the directors who are not interested persons thereof, and (b) that the compensation to be received under such contract does not exceed the compensation that would have been received under the most recent advisory contract that was approved by shareholders in accordance with the requirements of section 15(a).

3. The Applicants state that the two conditions to the application of Rule 15a–4 are satisfied in this case and, consequently, that the temporary exemption from section 15(a) afforded by Rule 15a–4 applies to the investment advisory services rendered to the Fund by AMA and ABD Securities under the amended Agreements from July 9, 1991 through November 6, 1991, the end of the 120-day period specified in Rule 15a–4. The Applicants acknowledge that neither the Commission nor the staff of the Commission has given any assurance to the Applicants as to the availability of Rule 15a–4 under the facts presented in the application.

4. The Applicants represent that, because of the significant foreign ownership of Fund shares, it is unlikely that the Fund will be able to obtain approval of the amended Agreements by November 6, 1991. The Applicants expect that one or more resolicitations of proxies, using a number of special measures, will be necessary to achieve the necessary quorum. Among other things, the Fund has retained a new proxy solicitation firm with additional expertise in conducting proxy solicitations of foreign stockholders of United States issuers; a special cover letter directed principally to its foreign stockholders and highlighting the circumstances requiring the resubmission of the Fund's Agreements to a stockholder vote will be included in the Fund's proxy materials; and the special cover letter and the form of proxy card will be translated into German and French and included in the proxy materials distributed to all stockholders of the Fund. The proxy

statement itself will be translated into German and made available to stockholders. It is believed that issuance of the order requested by the application would give the Fund the time needed to implement such special measures and thereby maximize its chances of obtaining shareholder approval of the Agreements.

5. The Applicants represent that issuance of an order granting the requested exemptive relief would enable the Fund to pursue a realistic timetable for obtaining approval of the amended Agreements at the Special Meeting; would not result in any harm to investors; and would be consistent with the expectations of the Fund's stockholders by permitting continuance of investment advisory arrangements disclosed in the Fund's registration statement and in its quarterly reports to stockholders, until the stockholders can vote on approval of the amended Agreements at the Special Meeting.

6. The Fund's board of directors, including all of the disinterested directors, has been advised that the Fund's advisory contracts with AMA and ADB Securities each will terminate without shareholder approval by January 31, 1992. In such event, the Board will make such arrangements as it believes appropriate, consistent with its fiduciary duty. AMA and ABD Securities acknowledge that, if the advisory contracts are not approved before January 31, 1991, their fiduciary responsibilities to the Fund would require them to continue to provide advisory services to the Fund until the implementation of alternative arrangements.

Applicant's Conditions

The Applicants agree that the following conditions may be imposed in any order of the SEC granting the requested exemptive relief:

1. The requirements set forth in paragraphs (a) and (b) of Rule 15a–4 shall be met from July 9, 1991 through the last day of the period covered by the Commission's order.

2. The Commission's order exempting AMA and ABD Securities from section 15(a) of the 1940 Act to allow AMA and ABD Securities to continue to provide investment advisory services to the Fund under the current investment advisory contracts (as amended on July 9, 1991) shall terminate automatically on the earlier to occur of January 31, 1991, or the date on which the stockholders of the Fund approve such investment advisory contracts.

3. Fees earned by AMA and ABD Securities under the Investment Advisory Agreement and the Management Agreement, respectively, during the period commencing on November 7, 1991 and ending on the earlier to occur of January 31, 1992 or the date on which the stockholders of the Fund approve such investment advisory contracts shall be deposited into an interest-bearing escrow account. Amounts in the account shall be paid to AMA and ABD Securities only upon approval of the foregoing investment advisory contracts by the stockholders of the Fund, and, in the absence of such approval, such amounts shall be paid to the Fund.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91–22975 Filed 9–23–91; 8:45 am]

BILLING CODE 8010–01–M

Sunshine Act Meetings

Federal Register
Vol. 56, No. 185
Tuesday, September 24, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

U.S. CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10:00 a.m., Thursday, September 26, 1991.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Closed to the Public.

MATTERS TO BE CONSIDERED:
Compliance Status Report.

The staff will brief the Commission on various compliance matters.

For a recorded message containing the latest agenda information, call (301) 492–5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207 (301) 492–6800.

Dated: September 19, 1991.

Sheldon D. Butts,

Deputy Secretary.

[FR Doc. 91–23114 Filed 9–20–91; 1:35 p.m.]

BILLING CODE 6355–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Friday, September 27, 1991.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: September 19, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91–23018 Filed 9–20–91; 10:38 am]

BILLING CODE 6210–01–M

NATIONAL TRANSPORTATION SAFETY BOARD

TIME AND DATE: 9:30 a.m., Tuesday, October 1, 1991.

PLACE: Board Room, Eighth Floor, 800 Independence Avenue, S.W., Washington, D.C. 20594.

STATUS: Open.

MATTERS TO BE CONSIDERED:

5576—Airport Fuel Storage Fire: Fuel Farm Fire at Stapleton International Airport, Denver, Colorado, November 25, 1990.

NEWS MEDIA CONTACT: Telephone (202) 382–0660.

FOR MORE INFORMATION CONTACT: Bea Hardesty, (202) 382-6525.

Dated: September 20, 1991.

Bea Hardesty,

Federal Register Liaison Officer.

[FR Doc. 91–23137 Filed 9–20–91; 2:04 pm]

BILLING CODE 7533–01–M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of September 23, 30, and October 7, and 14, 1991.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of September 23

Wednesday, September 25

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting)
a. Final Rule Entitled "Material Control and Accounting Requirements for Uranium Enrichment Facilities Producing Special Nuclear Material of Low Strategic Significance" and Conforming Amendments to 10 CFR Parts 2, 40, 70, and 74 (Tentative)

Week of September 30—Tentative

Tuesday, October 1

1:30 p.m.
General Discussion of High Level Waste Program (Public Meeting)
3:00 p.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 and 6)

Wednesday, October 2

3:30 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of October 7—Tentative

Monday, October 7

10:30 a.m.
Briefing on Use of Advanced Computers in AEOD and Status of Upgrading NRC Operations Center's Emergency Telecommunications Systems (Public Meeting)
3:00 p.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2)
4:00 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of October 14—Tentative

Thursday, October 17

9:00 a.m.
Collegial Discussion of Recent International Safety Issues (Public Meeting)
10:00 a.m.
Briefing on Staff Recommended Course of Action for Standardization of Advanced Reactor Designs (Public Meeting)
11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)
2:00 p.m.
Briefing on Commercial Grade Procurement and Dedication Programs (Public Meeting)

Friday, October 18

10:00 a.m.
Briefing on GE-Wilmington Incident (Public Meeting)

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To verify the status of meetings call (recording)—(301) 492–0292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 492–1661.

Dated: September 19, 1991.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 91–23149 Filed 9–20–91; 3:00 pm]

BILLING CODE 7590–01–M

RESOLUTION TRUST CORPORATION

Notice of Changes in Subject Matter of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the following changes have been made to the open agenda of the Resolution Trust Corporation Board of Directors meeting Tuesday, September 24, 1991 in the Board Room on the sixth floor of the FDIC Building located at 550–17th Street, N.W., Washington, D.C.:

The following subjects have been withdrawn from the agenda:

Memorandum re: Proposed regulations restricting the purchase of assets from RTC.

Memorandum re: Delegation of Authority to Execute Contracts.

Requests for further information concerning the meeting may be directed to Mr. John M. Buckley, Jr., Executive Secretary of the Corporation, at 202–416–7282.

Dated: September 19, 1991.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Executive Secretary.

[FR Doc. 91–23017 Filed 9–19–91; 4:32 pm]

BILLING CODE 6714–01–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of September 23, 1991.

A closed meeting will be held on Friday, September 27, 1991, at 10:00 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i), and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Schapiro, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Friday, September 27, 1991, at 10:00 a.m., will be:

Settlement of injunctive actions.

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings of an enforcement nature.

Institution of injunctive actions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Walter Stahr at (202) 272–2000.

Dated: September 19, 1991.

Jonathan G. Katz,

Secretary.

[FR Doc. 91–23048 Filed 9–20–91; 11:31 am]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 56, No. 185

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

Animal and Plant Health Inspection Service

7 CFR Part 354

9 CFR Part 130

[Docket No. 91-021]

RIN 0579-AA43

User Fees--Agricultural Quarantine and Inspection Services, Phytosanitary Certificates, Animal Quarantine Services, Veterinary Diagnostics, Export Health Certificates

Correction

In proposed rule document 91-18614 beginning on page 37481 in the issue of Wednesday, August 7, 1991, make the following corrections:

1. On page 37488, in the first column, in the last paragraph, in the second line "Impact" should read "Import".

§ 130.12 [Corrected]

2. On page 37498, in the third column, in § 130.12, in the table, the entry Bovine Respiratory Syncytial Virus: Antiserum the Fee/unit (dollars) now reading "3.50" should read "83.50".

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP91-187-000]

Florida Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

Correction

In notice document 91-16477 beginning on page 31634 in the issue of Thursday, July 11, 1991, make the following correction:

On page 31635, in the first column, in the file line at the end of the document, "FR Doc: 91-16476" should read "FR Doc. 91-16477".

BILLING CODE 1505-01-D

FEDERAL TRADE COMMISSION

16 CFR Part 435

Mail Order Merchandise Trade Regulation Rule

Correction

In proposed rule document 91-21641 beginning on page 41633, in the issue of Tuesday, September 10, 1991, make the following correction:

On page 41634, in the 1st column, in **SUPPLEMENTARY INFORMATION**, in the 17th line, "not" should read "now".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N-0216]

Bolar Pharmaceutical Co., Inc., and Sanofi Animal Health, Inc.; Withdrawal of Approval of NADA's

Correction

In notice document 91-18760 beginning on page 37556 in the issue of Wednesday, August 7, 1991, make the following correction:

On page 37556, in the third column, under **SUPPLEMENTARY INFORMATION**, in the fifth line, "beig" should read "being".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT-020-01-4351-08]

Notice of Intent To Amend the Randolph Management Framework Plan

Correction

In notice document 91-16835 appearing on page 32443 in the issue of Tuesday, July 16, 1991, in the second column, in the file line at the end of the document, "FR Doc. 91-16836" should read "FR Doc. 91-16835".

BILLING CODE 1505-01-D

federal register

Tuesday
September 24, 1991

Part II

Environmental Protection Agency

40 CFR Part 86

Air Pollution Control; New Motor Vehicles and Engines: On-Board Diagnostic Systems on 1994 and Later Model Year Light-Duty Vehicles and Light-Duty Trucks; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[AMS-FRL-3994-7]

RIN 2060-AC65

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Regulations Requiring On-Board Diagnostic Systems on 1994 and Later Model Year Light-Duty Vehicles and Light-Duty Trucks

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: Today's action proposes a rule requiring on-board diagnostic (OBD) systems for light-duty vehicles and light-duty trucks commencing in the 1994 model year. Section 207(a) of the Clean Air Act Amendments of 1990 (CAAA) requires EPA to promulgate final OBD rules by May 15, 1992; this action is an initial step in that process. Today's proposal requires manufacturers to install systems which monitor the functioning of emission control components and alert the vehicle operator to the need for repair. In addition, when a malfunction occurs, diagnostic information must be stored in the vehicle's computer to assist the mechanic in diagnosis and repair. Also proposed are requirements which would make available to the service and repair industry information necessary to perform repair and maintenance service on on-board diagnostic systems and other emission-related vehicle components.

DATES: Written comments on this notice will be accepted until December 9, 1991.

EPA will conduct a public hearing on this Notice of Proposed Rulemaking on November 6, 1991. The hearing will convene at 10 a.m. and will adjourn at such time as necessary to complete the testimony. Further information on the public hearing can be found in **"SUPPLEMENTARY INFORMATION"**, section IX, Public Participation.

ADDRESSES: Written comments should be submitted (in duplicate if possible) to: The Air Docket, room M-1500 (LE-131), Waterside Mall, Attention: Docket No. A-90-35, 401 M Street SW., Washington, DC 20460.

The public hearing will be held at Domino's Farms Activities, 44 Frank Lloyd Wright Drive, Ann Arbor, Michigan 48106.

Materials relevant to this proposed rulemaking are contained in Docket No. A-90-35. The docket is located on the first floor of the above address and may be inspected from 8:30 a.m. until noon and from 1:30 p.m. until 3:30 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying docket material.

FOR FURTHER INFORMATION CONTACT: Robert Larson, Certification Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, Michigan 48105, telephone (313) 668-4277.

SUPPLEMENTARY INFORMATION:

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II. Summary of Proposal

For 1994 and later model years, all light-duty vehicles (LDVs) and light-duty trucks (LDTs), for which emission standards are currently in place or subsequently adopted, will be required under today's proposal to contain an OBD system which will monitor emission-related components for malfunctions or deterioration.[1] The OBD system shall be capable of detecting malfunctions or deterioration of emission-related components or elements of design before such malfunctions or deterioration individually cause emission increases during Federal Test Procedure (FTP) testing greater than certain thresholds set by EPA. When such a malfunction or deterioration is detected, a malfunction indicator light (MIL) will illuminate and codes identifying the malfunction will be stored in the computer for access by a repair technician.

The proposed rule requires that the OBD system monitor the performance of the catalyst and oxygen sensor and detect engine misfire. It is proposed a trouble code be stored identifying the likely problem and the MIL be illuminated upon detection of any of the following problems:

(1) Catalyst deterioration before it results in an exhaust emission increase of greater than 0.4 g/mi HC, 3.4 g/mi CO, or 1.0 g/mi NOx as measured on the standardized Federal Test Procedure (FTP).

(2) Engine misfire before it results in an exhaust emission increase of greater than 0.4 g/mi HC, 3.4 g/mi CO, or 1.0 g/mi NOx as measured on the FTP. In addition to detecting misfire, the system must store a code indicating which cylinder is misfiring or that multiple cylinders are misfiring.

(3) Oxygen sensor deterioration before it results in an exhaust emission increase of greater than 0.2 g/mi HC, 1.7 g/mi CO, or 0.5 g/mi NOx as measured on the FTP. In addition to detecting oxygen sensor deterioration causing increased exhaust emissions, the system must detect any malfunction or deterioration of the sensor that renders it incapable of satisfactorily performing its functions as part of the OBD system.

Rather than specifying what other components must be monitored, the proposed rule provides the manufacturer with the flexibility to determine the need to monitor. Manufacturers would be required to monitor malfunction or deterioration of any other system or component that results in an FTP exhaust emission increase of 0.2 g/mi HC, 1.7 g/mi CO, or 0.5 g/mi NOx, or results in leakage or other malfunction of the vapor recovery or purge systems that results in an evaporative emissions increase of 2.0 g/test. Manufacturers are required to detect additional malfunctions only if they occur in actual use.

The proposed rule also requires the OBD system to monitor for electrical disconnect of any emission-related component which, either directly or indirectly, sends information to or receives information from the vehicle's on-board computer. If electrical disconnect occurs which prevents or limits the operation of the component, the MIL must be illuminated and a trouble code stored.

The computer must be protected from tampering and the stored codes must be as accessible to independent repair facilities and other interested persons as to new vehicle dealer-owned facilities. In addition, manufacturers must make available, in a timely fashion and at a

[1] In addition to the standards already in place, EPA is developing standards which would be applicable to vehicles when operating on compressed natural gas (CNG).

reasonable cost, all emission-related diagnostic and repair information necessary to properly use the OBD system and make emission-related repairs.

In accordance with the requirements of the CAAA, EPA proposes to implement all requirements, except perhaps that for evaporative emissions, beginning with the 1994 model year. Manufacturers can request waivers for OBD requirements for up to two years which EPA will consider on a case-by-case basis. EPA proposes to implement the evaporative emissions OBD requirements coincident with the effective model year of EPA's revised evaporative emissions test procedures if comments support the need and appropriateness of such an action for the industry as a whole; in no case would the applicability of evaporative emissions OBD requirements be in place later than the 1996 model year. This may result in delaying implementation of the evaporative emissions OBD requirements until the 1995 or 1996 model year.

Today's proposal makes an allowance for manufacturers to satisfy the Federal OBD requirements during the initial years of implementation by installing systems which satisfy California OBD II requirements pertaining to those model years. This proposed allowance means that manufacturers could concentrate on designing one system to meet the OBD II requirements and installing that system nationwide during allowable model years. In response to concerns expressed by industry representatives (see section IV B.8. for discussion) the Agency will give consideration to allowing California OBD II systems to fulfill the requirements of proposed § 86.094–17 for some period beginning with the 1994 model year, but in no case beyond the 2002 model year. The specific duration for acceptance of OBD II as an alternative standard will be based on the merits of information and data provided in response to this proposed rule. Further, any extended use of the California OBD II system will only apply to vehicles covered by the California OBD regulations. All other LDVs (e.g., diesel vehicles without feedback fuel control) will be required to comply with the Federal OBD system effective with the 1994 model year.

Should EPA decide to accept OBD systems that meet the OBD II standards, as an interim alternative to the OBD standards proposed today, all Federal requirements with the exception of § 86.094–17 would continue to apply to these covered vehicles. These requirements would include, for example, certification, selective enforcement audit, warranty, and recall. Compliance in-use would be determined against the OBD II emission thresholds and other requirements, however the federal in-use warranty and recall provisions would apply. In addition, the requirements of § 86.094–38 for service information would apply to all vehicles starting with the 1994 model year without regard to the status of waivers from OBD requirements or to what OBD standards the vehicle is certified.

Today's proposed rule is expected to result in lifetime average reductions per LDV of 35.0 pounds HC, 216.4 pounds CO, and 15.4 pounds NOx, and lifetime average reductions per LDT of 74.9 pounds HC, 396.8 pounds CO, and 26.2 pounds NOx, all at a 10% discount rate. This results in emission reductions within non-attainment areas of 0.48 million tons/year HC, 4.01 million tons/year CO, and 0.28 million tons/year NOx, or 47%, 45%, and 25% reductions in annual emissions for HC, CO, and NOx, respectively, by the year 2015 compared to baseline projections of emission levels without the benefits of OBD.

As discussed in more detail in section VII of this preamble, the total costs associated with these reductions, including increased vehicle costs and repair costs, and consumer savings associated with improved fuel economy and improved repair effectiveness, is estimated to range between $485 million and $1.2 billion annually assuming annual non-California sales of 13.1 million vehicles and a 70%/30% LDV/LDT sales split.

III. Background and Development

On November 15, 1990, the CAAA were signed into law. These amendments include the addition of paragraph (m) to section 202, which directs the EPA to promulgate regulations requiring manufacturers to install on all new LDVs and LDTs diagnostic systems capable of:

(1) Accurately identifying for the vehicle's useful life emission-related system deterioration or malfunction, including, at a minimum, the catalytic converter and oxygen (O_2) sensor, which could cause or result in failure of the vehicles to comply with emission standards;

(2) Alerting the vehicle's owner or operator to the likely need for emission-related components or systems maintenance or repair;

(3) Storing and retrieving fault codes specified by the Administrator; and

(4) Providing access to stored information in a manner specified by the Administrator.

In addition, this section of the amended Clean Air Act (hereafter, the Act) requires manufacturers to make available to interested persons all necessary emission-related maintenance and repair information, including information needed to make use of the OBD system. Such information is to be provided according to regulations to be adopted by EPA.

As of August 1990, 96 urban areas were in violation of the National Ambient Air Quality Standard (NAAQS) for ozone and 41 areas could not attain the carbon monoxide (CO) standard. Non-attainment of the NAAQSs for ozone and CO is partly due to emissions from vehicles with malfunctioning emission control systems. As the emission standards for properly functioning vehicles have been reduced, emissions from malfunctioning vehicles have accounted for an increasing share of the total emissions from motor vehicles. EPA estimates that currently 60% of the total tailpipe HC emissions from LDVs are caused by the 20% of vehicles with serious emission control system malfunctions or degradation. The more stringent standards mandated by the Act are likely to increase further the proportion of emissions from malfunctinning vehicles. Since many of these malfunctions do not noticeably affect vehicle performance, the owners of malfunctioning vehicles are usually unaware that any problem exists.

EPA supports several programs to address the problem of excessive emissions from in-use vehicles, most notably the in-use compliance and inspection/maintenance (I/M) programs. As part of the in-use compliance program, emission tests are performed on properly maintained in-use vehicles. A manufacturer is required to recall and fix a class of vehicles if a substantial number of those vehicles are found to violate the requirements of section 202 of the Act. The current in-use compliance program does not typically address random failures of emission control systems which occur infrequently or failures due to poor maintenance. In addition, the individual malfunctioning vehicles are not identified at the time malfunction occurs.

EPA also offers support to state I/M programs. I/M programs are the only enforcement related programs currently in place designed to identify individual malfunctioning vehicles regardless of whether they have been properly maintained or not. Intermittent failure problems or problems which occur in driving modes not included in the I/M test cannot be detected in I/M programs.

Since the OBD system will monitor emission-related components during all actual driving conditions, additional failure modes should be detected. Hence, in the future, I/M programs will be able to check the OBD system for failure codes in the computer, thus increasing the effectiveness of getting problem vehicles repaired.

Manufacturers have for some time been aware of the potential of on-board monitoring and computer systems to detect malfunctions; for several years many vehicles have come equipped with dashboard "Check Engine" lights. These lights illuminate when the vehicle's monitoring system detects an engine malfunction. At the same time the light illuminates, trouble codes indicating the source of the problem are stored in the vehicle's computer, where they may be accessed by repair personnel, sometimes using a plug-in tool to aid in diagnosis. Some vehicles store trouble codes but are not equipped with a dashboard MIL.

Current OBD systems usually target malfunctions that cause driveability problems. However, many malfunctions that increase emissions do not cause driveability problems and, thus, are not detected by current systems. These malfunctions are among the more difficult to detect and repair without OBD assistance.

The major benefit of existing OBD systems has been to assist dealership mechanics. The codes and means of accessing the system vary from manufacturer to manufacturer, making it difficult for non-dealership mechanics to use them. Presently, the availability of OBD service information by manufacturers to service facilities other than dealerships is neither adequate nor uniform. Depending on the policy of a manufacturer, repair information to independent facilities may be available on a regular basis, at the end of a model year, or not at all. Even where information is available, it may not be cost effective for the independent mechanic to purchase the large number of shop manuals or other publications needed to cover the wide variety of systems encountered. The receipt of appropriate information by independent facilities is particularly important in light of the increasing complexity of electronic emission control systems and the fact that 80% of repairs are done by nondealer mechanics.

Both the California Air Resources Board (CARB), which regulates vehicles sold in California, and EPA have studied ways to use OBD systems to detect emission problems. In 1985, CARB promulgated their OBD I regulations which required the vehicle's on-board computer to monitor some critical emission-related components for proper operation and to provide a warning to the vehicle operator when vehicle malfunctions occurred. OBD I took effect beginning with the 1988 model year.

OBD I did not require monitoring of several critical emission-related components and was insufficiently sensitive to malfunctions that were monitored. Since the issuance of OBD I, CARB has been working with EPA, vehicle manufacturers, component suppliers, and other technical experts to refine and expand the scope of OBD I. EPA has also been involved in discussions with CARB regarding the technical feasibility of monitoring additional components. As a result, CARB has recently adopted OBD II which provides more stringent requirements and other improvements to the OBD system. OBD II is scheduled to be phased-in beginning with the 1994 model year, with full compliance by the 1996 model year.

EPA believes that manufacturers will not voluntarily choose to install such systems on vehicles sold in the remaining states because of the hardware costs associated with monitoring some components, the potential for increased warranty expense, and the possibility of customer dissatisfaction should the MIL illuminate too frequently. Therefore, the adoption of similar Federal regulations and controls are necessary to ensure that the air quality benefits of OBD are achieved nationwide, and to facilitate the use of standardized OBD systems which assist mechanics in making repairs and offer the potential for OBD incorporation into I/M programs. Adoption of these regulations will also satisfy the mandates of the CAAA.

Today's proposed action resembles the OBD II rule. OBD II specifies the technical monitoring requirements in greater detail than the rule being proposed today. The requirements being proposed today are expressed as emission performance standards. Setting emission performance standards provides the manufacturer with flexibility in determining which components or systems the OBD system should monitor. Manufacturers will also be allowed to determine alternative means of monitoring without seeking Agency regulatory approval. However, manufacturers have the additional burden of selecting OBD system calibrations to assure compliance with emission performance standards for each unique design they produce.

It is EPA's expectation that these proposed Federal OBD rules will be sufficiently consistent with the existing California OBD II rules such that manufacturers need not develop substantially different monitoring hardware nor implement a basically different OBD strategy to satisfy Federal rules. However, the Agency recognizes that the different form of its requirements may require some degree of additional work on the part of manufacturers as they assure themselves each design complies. The Agency expects manufacturers will be able to develop identical systems to comply with both Federal and California regulations in most cases, but additional testing and calibrations development may be necessary for the manufacturers to assure proper optimization of their systems. In some circumstances, unique Federal calibrations might be necessary. EPA has estimated these incremental costs and has included them under the category of "application costs" in the Regulatory Impact Analysis (RIA).

As stated previously, manufacturers have expressed concern about the need to make these additional expenditures simultaneously with the development of California OBD systems. Hence, EPA is considering accepting compliance with the California OBD II standards as an alternative means of meeting certain portions of the Federal requirements during the initial years of implementation. As noted later in this preamble, comments are requested on EPA's estimated vehicle application costs and on the advantages and disadvantages of accepting compliance with OBD II requirements for some interim period of time.

IV. Proposed Regulations

A. Summary

Today's proposed regulation would require all 1994 and subsequent model year LDVs and LDTs to incorporate on-board diagnostic systems. The OBD system would monitor emission-related components for malfunctions or excessive deterioration that would cause the vehicle's emissions to exceed a specified emission threshold during its useful life. (The proposed emission thresholds are described previously in the Summary of Proposal). When the system detects a malfunction, it would illuminate a malfunction indicator light on the dashboard and store codes identifying the malfunction in the on-board computer.

In addition to OBD hardware requirements, manufacturers would also be required to supply to any person, in a timely manner, repair information sufficient to facilitate accurate repair of emission-related components. Certain

other proposed requirements are discussed below.

B. Discussion

1. General System Requirements

The purpose of an OBD system is, first, to detect malfunction or deteriorated performance of a vehicle's emission-related components which result in an excessive increase in emissions. Second, the OBD system should aid in the proper diagnosis and repair of those emission-related problems.

The Act requires EPA to promulgate regulations requiring OBD systems that are able to accurately identify any emission-related deterioration or malfunction that could cause or result in exceedance of an emission standard. EPA acknowledges that a properly designed and operating vehicle could have emission levels approaching or even equaling the emission standards. In such cases, a very slight malfunction or minor deterioration could result in failure to meet an emission standard. As discussed in the Technical Feasibility section following, it is currently not feasible to detect the deterioration or malfunction of many components which would have a slight impact on emissions.

In other situations, a vehicle might not experience much emission performance deterioration even though an individual component's performance has reached a detectable level of malfunction or deterioration. Replacement of the component at this stage would provide little emission benefit, especially considering the cost of the repair, and could, in fact, be inappropriate if the component was incorrectly identified as having reached a detectable level of malfunction or deterioration.

The threshold approach being proposed today allows EPA to recognize both the technical feasibility of malfunction detection and the costs and emission benefits of repair. EPA has focused on these issues and has required the OBD system to detect only those problems which can reliably be detected and whose repair would result in a significant improvement in emission performance. Thus, the thresholds being proposed today represent the minimum levels of significant emission impact which are technically feasible to detect. As other information becomes available to EPA demonstrating the technical ability and appropriateness of setting lower threshold levels, EPA would plan to propose revisions to these thresholds.

The proposed rule places a minimum of specific monitoring requirements on the manufacturer. As required by the Act, the OBD system must monitor catalyst and oxygen sensor performance. In addition, EPA believes that sufficient probability and emissions impact of engine misfire exists to warrant mandatory monitoring. Further, the risk of catalyst damage from misfire warrants its monitoring. Therefore, the proposed rule requires each vehicle's OBD system to detect significant engine misfire.

In addition, for vehicles equipped with sequential fuel injection, EPA proposes that fuel to the misfiring cylinder be shut off during the period misfiring occurs. Shutting off fuel would provide protection from catalyst overheating. No additional hardware would be required. EPA requests comment on this fuel shutoff proposal, particularly the safety concerns associated with such a requirement and whether or not fuel shutoff should be required only when catalyst damage is imminent. The Agency also requests comment on the extent to which manufacturers would incorporate fuel shutoff (e.g., to reduce potential warranty expenses for catalyst replacement, particularly considering the new 80,000 mile warranty covering catalysts) absent such a requirement.

In addition, the proposed rule would require the OBD system to monitor for electrical disconnect any emission-related component or system which directly or indirectly sends information to or receives information from the vehicle's computer. This requirement recognizes the importance of insuring all such emission-related components are properly connected electrically and is consistent with CARB's OBD II regulations.

EPA requests comment concerning the need to further define "emission-related" components. At a meeting on April 19, 1991, to discuss the draft NPRM, manufacturers suggested that "emission-related" be tied to the emission warranty parts list to avoid the need to identify the potential case of high emissions caused by malfunctions in systems or components not normally considered emission-related (e.g. low tire pressure). However, the Agency is concerned about the potentially constraining situation of trying to define what an emission-related component is or listing all the potential components, which may require updates as new technologies are developed. The Agency is also concerned that such a definition may run counter to the performance standards approach adopted for today's proposal. The Agency requests comment on how "emission-related" could be defined with consideration to these concerns.

EPA believes that the advent of cold temperature CO standards will result in the development of emission control strategies at cold ambient temperatures that are more consistent with emission control strategies currently designed for 75 degree F standards. As a result of this enhanced control, it is anticipated that any significant emission increase occurring at cold temperatures as a result of component failure will be detectable by a vehicle's OBD system at 75 degrees F. Thus, evaluation of a vehicle's OBD system at 75 degrees F will be adequate for ensuring proper system operation at cold ambient temperature as well.

Evaluation of in-use vehicles indicates that many other problems may occur. However, manufacturers have the ability to incorporate design or construction improvements which could eliminate specific problems. For example, manufacturers could utilize hose material less susceptible to cracking or connectors less likely to become detached. Consequently, this proposed rule does not mandate the monitoring of all other systems or components over their full range of possible states of malfunction or deterioration which could conceivably result in an emission problem. Rather, the manufacturer has discretion to either monitor components and their failure modes likely to result in in-use emission problems, or incorporate design improvements to minimize or eliminate the likelihood that such emission-related problems will occur. The ability to reduce the complexity and cost of the OBD system provides the manufacturer with an additional incentive to improve emission-related designs. As discussed in the later section on enforcement, EPA would monitor in-use emission performance to assure adequate OBD designs.

By encouraging the manufacturer to focus on in-use emission performance of the total vehicle, EPA is also deferring to some extent to manufacturers to appropriately specify those unique components or systems which must be monitored by OBD. This reduces the possibility of EPA requiring costly but unnecessary monitoring hardware or of overlooking problems which might prove significant in use. Static detailed regulatory requirements could also result in unnecessary OBD hardware or overlooked problems as engine and emission control system designs change over time.

Under section 202(m)(1) of the Act, EPA is to promulgate regulations requiring installation of on-board emission diagnostic systems that are

capable of "accurately identifying * * * emission-related systems deterioration or malfunction * * * which could cause or result in failure of the vehicles to comply with emission standards * * *." Today's proposal requires an OBD system with a MIL that illuminates if component deterioration or malfunction causes emissions to increase above specified threshold levels. In setting these thresholds, EPA has considered such factors as technological feasibility, costs, and air quality benefits. EPA believes it is authorized under section 202(m) to establish such threshold levels, and to consider such factors.

Section 202(m) does not set an objective, numerical standard. Instead Congress specified that EPA promulgate the OBD regulations under the general authority of section 202(a), with no indication that EPA was precluded from considering factors such as technological feasibility, cost, and air quality benefits, all factors typically relevant in rulemaking under section 202(a).

The legislative history of section 202(m) also supports the approach taken by EPA. Although different in certain respects, both the Senate and House versions of the CAAA contained OBD requirements.[2] The OBD version adopted by Congress followed the Senate version, with the Senate Report showing keen Congressional awareness of California's OBD regulations, including OBD II, and a desire to extend the benefits of such an OBD system nationwide.[3] EPA's use of emission thresholds based on consideration of the above factors is consistent with these goals. For example, California's OBD II regulations also establish, in many cases, emissions thresholds for MIL illumination, up to 1.5 times applicable emission standards. EPA believes that today's proposed OBD requirements are equally or more stringent than the OBD II regulations.

The Senate was also clearly concerned about the accuracy of the OBD system. In discussing manufacturer recall liabilities, the Senate Report states" * * *. [T]he Administrator may order a recall and repair of the [OBD] system in cases where there is a systematic misdiagnosis, even if the vehicle is passing emission standards, either by not alerting the operator to the need for necessary repairs or by flagging a repair which is not necessary." [4]

[2] Section 205, S. 1630 (Senate bill); section 208, S. 1630 (House bill).

[3] S. Rep. No. 101–228, 101st Cong., 1st Sess. 96–98, 828 (1989).

[4] S. Rep. No. 101–228, 101st Cong., 1st Sess. 98 1989).

Consideration of technical feasibility is critical to meeting this Congressional goal—the desired level of accuracy can only be met by OBD systems that are technically feasible to implement in the required timeframe.

EPA is proposing an OBD system that it believes is feasible and accurate, which minimizes false malfunction indications and needless repairs, and will gain consumer credibility and acceptance. It is a workable system that will lead to the repair of malfunctioning vehicles that contribute to air quality problems throughout the nation. EPA intends to monitor closely the development of OBD technology, consumer acceptance, and emission control strategies. As appropriate, EPA will revisit these issues and revise its OBD regulations.

2. Standardized Codes and Accessibility

The Act requires that OBD system information be accessible via standardized connectors, unrestricted and not requiring access codes or any device only available from the manufacturer. Further, the OBD system information must be usable without need for any unique decoding information or device. To satisfy these mandates, EPA is proposing that OBD systems conform to both uniform industry standards adopted through the Society of Automotive Engineers (SAE) and International Standards Organization (ISO) standards and be accessible with the use of a standard hand-held diagnostic tool.[5] In addition to "freeze-frame" information giving engine operating conditions at the time of the malfunction, the proposed rule requires the following information be provided over the standard link, if the information is available to the on-board computer: calculated load value, diagnostic trouble codes, engine coolant temperature, fuel control system status, fuel trim, fuel pressure, ignition timing advance, intake air temperature, manifold air pressure, air flow rate from the mass air flow meter, engine RPM, throttle position sensor output value, secondary air status, and vehicle speed. This information is also required by the OBD II regulation. In addition, the capability to perform bi-directional diagnostic control based on SAE specifications shall be available on demand through the serial port on the standardized data link connector.

As mentioned previously, this proposed rule requires at least one frame of information providing engine operating conditions at the time of malfunction. The Agency requests comment on whether more than one "freeze-frame" should be required, and whether freeze-frame information connected to misfire and fuel system malfunctions is sufficient or should the requirement be broadened to include all malfunctions.

3. Anti-Tampering Measures

EPA is proposing that manufacturers be required to protect the on-board computer from tampering. The method employed is left to the manufacturer's choice. Such methods could include soldering chips to their circuit boards, enclosing ("potting") the computer in a material such as polyurethane, or otherwise permanently sealing the computer housing. Write-protect features are required for flash memory systems. The final OBD regulation may refer to SAE standards #J2186 under development to meet CARB's OBD II requirement for write-protection.

The OBD system could be rendered incapable of appropriately detecting malfunctioning parts or systems if the computer were replaced or reprogrammed so that it ignored the system's sensors and always reported that the vehicle was functioning properly. The proliferation of aftermarket "performance chips" which may be installed in a vehicle to reset the engine operating parameters indicates that without anti-tampering measures, some owners may defeat the OBD system.

Today's proposal also requires manufacturers to use a single dashboard MIL to indicate all emission-related problems the manufacturer may choose to monitor. Manufacturers would continue to be allowed to install warning lights intended to alert the driver to safety problems or problems related to engine operation which could result in immediate damage such as low oil pressure or over temperature conditions. (Separate warning lights for engine temperature, oil level, and alternator performance will continue to be allowed). EPA is concerned that a proliferation of warning lights would lead to driver confusion. EPA does not expect manufacturers will, in addition, choose to monitor other engine-related components not included in the OBD system. An emission-related light separate from a light for other engine-

[5] See SAE standards ##J1850, J1877, J1892, J1930, J1962, J1978, J1979, J2008, J2012, J2186, J2187, and J2205, and ISO 9141 CARB in effect at the time of publication of this rule. Some of these SAE standards are in draft as of the time of publication of this rule. The final OBD regulations may require SAE standards identical to those currently in draft form, or revised standards should EPA concur with the revised standards in the event such revisions are made by SAE or CARB prior to promulgation of the final rule.

related problems might encourage some repair facilities to disconnect the emission-related light. EPA believes the requirement to have a single MIL for all emission-related problems is consistent with California's OBD II requirement.

To discourage tampering, the MIL would also be required to illluminate when the vehicle's ignition is in the "key-on" position each time the vehicle is started. This would facilitate in-use inspection to determine that the system is functioning. The MIL would go off after the engine is started unless a malfunction has been detected. Illumination of warning lights during key-on is already common practice in the auto industry.

Because repair personnel would be able to clear diagnostic codes using the standard tool, inspection and maintenance (I/M) lanes must have some way of ensuring that malfunction codes have not been cleared since the last OBD check of the vehicle's emission-related control systems. A readiness code would be required when the diagnostic system has completed all checks and determined that all monitored systems are functioning properly. As noted in the following section on Monitoring Frequency, this may require some extended vehicle operation to satisfactorily verify emission-related component or system performance. The readiness code should further discourage tampering with any part of the OBD system.

In addition, aftermarket parts must be fully compatible with the OBD system. Installation of aftermarket parts which prevent the OBD system from performing its proper function would be considered tampering. Questions regarding potential tampering due to installation of aftermarket parts would be considered in the same manner as EPA considers devices or actions which could affect emission performance.

4. Monitoring Frequency

EPA expects that the OBD system will evaluate component performance as often as possible. For example, misfire monitoring using a crank angle sensor can be performed continuously while the engine is running. On the other hand, the O_2 sensor can be evaluated over discrete time intervals whenever a particular vehicle operating condition is observed by the computer after closed-loop operation begins. EPA proposes requiring all components monitored by the OBD system to be fully evaluated at least once every trip. One CVS–72 driving cycle would qualify as a trip.

Manufacturers may determine a need to monitor emission-related components more frequently. For example, the potential for severe misfire which can cause thermal damage to the catalyst may necessitate continuous monitoring. Manufacturers should also consider the monitoring frequency necessary to reliably determine a malfunction has been detected. For example, catalyst performance assessment might require evaluation of several monitoring sequences.

5. MIL Illumination

The purpose of the MIL is to alert the vehicle operator to the need for maintenance or repair. As soon as the OBD system is able to reliably detect deterioration or a malfunction that could cause an emission increase above the threshold level, the MIL should illluminate to signal, at the earliest opportunity, the need for repair. Some current OBD designs routinely turn the MIL off when the ignition key is turned off and do not reilluminate the MIL when the vehicle restarts even though the emission-related problem has not been repaired. This can be confusing to the operator, perhaps inappropriately suggesting that the problem has gone away and service is not required. The operator might also question the reliability of the OBD system, believing that the MIL came on by mistake. Such confusion and misinterpretation of the need for maintenance would decrease the effectiveness of the OBD system. Consequently, EPA is proposing to require that the MIL remain illuminated during all periods of engine operation until the trouble codes stored in the on-board computer are cleared by a service technician or after repeated re-evaluation fails to detect a reoccurrence of the problem (see discussion following). This requirement would also ease integrating OBD system checks into I/M and other in-use enforcement programs.

As mentioned previously, the proposed regulations allow manufacturers to extinguish the MIL if no reoccurrence of the problem is detected. Manufacturers will need to determine the number of repeat driving operations necessary to confirm that the problem no longer exists and it would, therefore, be appropriate to extinguish the MIL and clear the computer of the suspect fault code. California's OBD II regulations allow the manufacturer to extinguish the MIL after two subsequent sequential driving cycles of similar operation in which a system fault did not recur for misfire and fuel system malfunctions and after three driving cycles for other malfunctions (CARB has proposed three driving cycles be required for all malfunctions, but this proposal has not yet been adopted). OBD II regulations allow the fault code to be cleared after forty (40) engine warm-up cycles if the same fault is not reregistered. EPA is considering adopting similar criteria which would serve as the minimum operation before extinguishing the MIL or clearing the computer of fault codes. Manufacturers may determine more extensive operation is appropriate for their particular vehicle designs.

In contrast to the current OBD II regulations, EPA sees no technical need or emission benefit in allowing the MIL to be extinguished in fewer repeat cycles for misfire and fuel system malfunctions than for other malfunctions. Indeed, due to the potentially severe emission impact resulting from misfire or fuel system malfunction, it is especially important to confirm with certainty that these problems no longer exist before extinguishing the MIL. Therefore, EPA proposes that manufacturers not be allowed to adopt OBD systems which extinguish the MIL in less than three subsequent sequential driving cycles which repeat the driving conditions under which the malfunction originally was detected.

Since a malfunction may only be detectable under specific driving situations, it is important these driving situations be repeated in verifying that the problem no longer exists. OBD II regulations set specific criteria for determining when the driving condition has been repeated in the case of misfire and fuel system monitoring. No similar driving cycle criteria are set for other malfunctions. However, EPA believes the driving cycle should be repeated for all types of malfunctions detected by the OBD system. For the purpose of this notice, EPA is proposing the criteria adopted in California for misfire and fuel system monitoring. Specifically, before extinguishing the MIL, the vehicle must be operated over two subsequent driving schedules which are simultaneously within ten (10) percent of the speed and load conditions which existed when the malfunction was first determined. Nevertheless, EPA requests comment on the need to set specific criteria in the regulations for determining when an operating condition has been repeated. EPA also requests recommendations as to what these criteria should be. EPA will consider adopting specific criteria in the final rule.

Concerning erasure of the fault codes, OBD II regulations similarly do not appear to require that specific operating conditions be repeated before erasing a fault code. As with MIL illumination, it

is essential the operating conditions be repeated before determining the problem no longer exists and the fault code is cleared. EPA requests comment on the need to establish minimum criteria for clearing the fault code and recommendations for such criteria. For the purpose of this proposal, EPA is adopting the same requirements as in the current OBD II regulations, i.e., erasing the fault code after 40 engine warm-up cycles if the same fault is not reregistered. EPA will consider adopting specific criteria for clearing the fault codes in the final rule.

Just as it is important that the MIL routinely illuminate when a problem exists, it is also important that the MIL be clearly worded to encourage repair. Current OBD systems use a phrase such as "Service Engine Soon." EPA believes this or similar wording effectively alerts the driver to the need for repair without specifically identifying the problem as uniquely related to emission control. (See IV. B. 3. Anti-Tampering Measures preceeding, for a discussion of the MIL and anti-tampering concerns.) EPA is proposing uniform wording but requests comment on the need for uniform MIL wording across the industry and, also, the most appropriate words to use. Further, comments are requested as to the difficulty individual manufacturers might have in incorporating uniform MIL wording. Should comments or other information made available to EPA support the need for uniform MIL wording, EPA proposes to adopt the words "Service Engine Soon" or such other similar wording which may be recommended and supported as more appropriate.

EPA proposes to require the MIL to blink continuously during periods of actual misfire. This is necessary to alert the driver to this high emitting and potentially catalyst damaging operating condition. Driver action, such as decreasing the acceleration rate, can at times alleviate the misfire. This proposal is consistent with OBD II. EPA requests comment as to whether it would be more appropriate to require the MIL to blink continuously only during periods of misfire which could cause catalyst damage, while less severe misfire conditions required only steady MIL illumination. EPA also requests comment on the need to specify the level of misfire at which potential catalyst damage is likely and, if necessary, what level of misfire should be specified in the final regulation as the minimum level required to be detected.

6. Repair Information Availability

In recognition of the importance of proper emission-related service and repairs, and the associated need for all persons engaged in the repairing and servicing of vehicles to have access to emission-related service and repair information, subsection 202(m)(5) of the Act was enacted. This subsection directs the Administrator to promulgate regulations which require manufacturers to

> provide promptly to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines, and the Administrator for use by any such persons, with any and all information needed to make use of the emission control diagnostics system prescribed under this subsection and such other information including instructions for making emission-related diagnosis and repairs. No such information may be withheld under section 208(c) if that information is provided directly or indirectly by the manufacturer to franchised dealers or other persons engaged in the repair, diagnosing, or servicing of motor vehicle engines * * *

Based on this directive, EPA is proposing regulations which would make emission-related service and repair information available to all automotive technicians and other persons engaged in the servicing and repairing of motor vehicles.

The purpose of the OBD system and emission-control systems is to reduce emission levels of various pollutants. For such systems to achieve projected levels of emission reductions, it will be essential that they be adequately maintained and repaired. This requires automotive technicians who possess the knowledge necessary to identify and repair improperly operating emission-related systems and components. This knowledge is acquired, in part, by having access to information on the operation and repair of such systems and related components.[6]

To date, automotive technicians employed by vehicle manufacturer franchisees have had access, through their employer, to needed emission-related service and repair information. The same has not been true for other individuals who repair and service vehicles. Some manufacturers do not make available to the public all the information needed to adequately service and repair motor vehicles. Further, when information is made available, it may be difficult to locate and time consuming to obtain.

It is especially important for independent technicians to have access to needed emission-related service and repair information, including training instructions. It has been estimated that independent technicians are responsible for conducting 80% of all repairs.[7] In addition, independent technicians are more likely to repair the vehicles which are the most likely to violate emission standards. This conclusion is the result of a recent study which demonstrated that (1) the level of excess emissions increases as a vehicle's mileage increases, and (2) the percentage of nondealer repairs increased and dealer repairs decreased as a vehicle's mileage increased.[8] Considering the large number of vehicles being serviced by independent technicians, it is essential that such individuals have access to adequate emission-related repair and service information.

The regulations proposed today are intended to preserve freedom of choice by consumers in where they obtain service and repair of emission-related systems. This can only be achieved by ensuring that all sectors of the automotive service industry have access to the information needed to perform such service and repairs.

The proposed regulations make needed emission-related service and repair information, as well as training instructions and materials, available to all persons engaged in the servicing and repairing of vehicles. In developing these regulations, EPA took into consideration draft recommendations [9] being developed by the SAE Vehicle Electrical/Electronics Systems Diagnostic Standards Committee (Committee). The recommendations were developed over the course of several meetings to which all members of the Committee were provided the opportunity to attend and participate. The Committee is comprised of representatives from more than 14 vehicle manufacturers, numerous equipment and information suppliers, and independent technicians. The draft document is still in review and revision has not yet undergone Committee vote.

To adequately fulfill the requirements of subsection 202(m)(5), the Committee determined that six issues needed to be addressed: (1) The type of information to be provided; (2) to whom the information should be made available; (3) how promptly the information should be made available; (4) the method of distribution of the information. (5) the

[6] To properly service and repair vehicles, automotive technicians require both access to needed information and training. Direct training is beyond the scope of this rulemaking; however, the availability of OEM training information and materials is covered by these proposed regulations.

[7] "Service Job Analysis," Hunter Publishing Co., 1984.

[8] "Survey of Vehicle Owners in the On-Board Diagnostics Program," Westat, Inc., July 18, 1990.

[9] SAE's draft of "Recommended Practice for the Application of the CAA of 1990 (section 202(m)(5)) (J2216)," as of July 25, 1991.

media through which information should be provided and the format in which it should be presented; and (6) cost of the information. After reviewing the Committee's draft recommendations, EPA has determined that this breakdown of issues is reasonable and presents a convenient method of discussing the regulations being proposed today.

Information. Subsection 202(m)(5) of the Act, as amended, requires manufacturers to make available any and all information needed to make use of the OBD system, as well as other information or instructions needed for making emission-related diagnosis and repairs, unless such information is protected by section 208(c) as a trade secret. Further, the Act provides that no emission-related information can be withheld under claim of trade secret if it is provided (directly or indirectly) by the manufacturer to franchised dealers or other persons engaged in the repair, diagnosing, or servicing of motor vehicles or motor vehicle engines.

Consistent with the Act, the proposed regulations require that "all information" needed to make emission-related repairs be made available to the automotive service industry. The scope of "all information" would include but not be limited to any service and repair information that an OEM provides to its authorized dealerships. It is clear that Congress intended that the definition of "all information" be sufficiently broad to insure that the information provided be adequate to allow effective repair of emission-related problems (this broad interpretation has not yet been discussed in the SAE deliberations). In some cases, this interpretation may mean that some manufacturers would need to provide additional information not currently provided to their franchised dealers. Such additional information could include information on the functional control strategy of the various systems and components affecting emissions. For example, all electronically controlled purge solenoids in the evaporative system have a series of criteria (e.g., time delay, minimum temperature, closed loop, etc.) that need to be met before the solenoid will allow purging to begin. Such information could be critical in repairing cars and allows mechanics to be able to understand the system so that they can perform effective repairs, without the sophisticated (and usually expensive) manufacturers' tools or access to diagnostic parts.

Another issue that needs to be addressed under "all information" is the issue related to indirect repairs. In the past, some manufacturers have chosen to address emissions or driveability problems caused by mechanical malfunctions or design problems by, for example, changing the computer calibration schedule to compensate for the problem, rather than fix the problem. Such indirect repairs, when they occur, are usually found in recall repair instructions and in technical service bulletins. In one case, rather than remachine a warped intake manifold, the manufacturer installed a richer calibration in the computer. Similar actions have been taken with leaky throttle body base gaskets. The problems arise when the mechanical (or direct cause) problem is corrected subsequent to the indirect repair. Such direct repairs are more likely to occur on higher mileage vehicles (probably beyond warranty or recall authority), and may be in combination with other major repairs. After the subsequent direct repair, the vehicle now may be a high emitter because of the rich calibration as a result of the indirect repair. The interpretation of "all information" would apply to such cases where an indirect repair could reasonably create a situation where a subsequent direct repair would result in high emissions. In these cases, the manufacturer would be allowed to implement the indirect repair (consistent with other provisions of the Act) provided that the repair instructions include instructions for proper repairs if the direct repair is performed subsequent to the indirect repair. In cases where such a scenario was not foreseen and the manufacturer subsequently becomes aware of such a problem that results in high in-use emissions, the manufacturer is obligated under the "all information" requirement of the Act to provide updated repair instructions to any person engaged in the servicing and repairing of motor vehicles.

EPA also recognizes the importance of having only legitimate OEM recalibrations performed on a vehicle. Therefore, EPA requests comment on the best mechanism for providing nonfranchised technicians with recalibration information necessary to perform such recalibrations.

Today's proposal also requires the vehicle's computer to uniquely identify the vehicle over the standard data link. Preferably, the identification would be the vehicle identification number (VIN), as currently done by GM. Such an identifier would be especially useful in decentralized I/M programs, allowing printout of the unique vehicle identification along with emission test results. This would allow EPA to track pattern failures and provide states the assurance that emission test results and vehicles are properly paired (thus minimizing potential cheating). Such vehicle identification could also be used to determine whether recall work had been conducted on vehicles within I/M areas.

Also being proposed is that the vehicle's computer identify the type of OBD system (OBD II, Federal OBD, etc.) on the vehicle, and the major systems monitored. This would allow an I/M inspector to, for example, simply check for stored codes indicating an EGR malfunction. Without the information indicating whether the EGR system is monitored, the inspector would not know whether the absence of EGR trouble codes meant the EGR system was operating properly or if the system was simply not monitored.

Finally, to provide service technicians with the information needed to determine that a component or system is operating correctly, EPA is proposing that manufacturers include information on the normal operating conditions for properly functioning emission-related components or systems. EPA requests comment on the need to adopt this requirement as part of these rules, the best way to accomplish this, and any difficulties (for example, significant burden to the manufacturer) that would arise.

If the Agency determines at any time that a manufacturer has failed to make the required information available, it will notify the manufacturer. At the manufacturer's request, EPA will meet with the manufacturer in an attempt to resolve the identified deficiencies. Failure by a manufacturer to provide the required information may result in a penalty of up to $25,000 a day.

Availability. In accordance with the Act, the proposed regulations require that information be provided to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines. Under this proposal, such persons would include, but not be limited to, tool and software manufacturers, aftermarket information providers, franchised dealerships, service suppliers (warehouse distributors, auto parts retailers, franchised retailers, and parts manufacturers and rebuilders), educational institutions, I/M administrators, vehicle manufacturers, service providers (independent service/repair garages, franchised repair outlets, and auto parts retailers with service bays), and individual owners/operators.

Timeliness. To be effective, information must be provided in a timely manner. For independent technicians this means having or having access to needed information when a vehicle is brought in for service.

To ensure that independent technicians have appropriate information when needed, the proposed regulations establish specific times within which manufacturers would be required to make available enhanced [10] and generic [11] service information and training information. The proposed regulations require enhanced service information to be made available to independent technicians within one month immediately following model introduction. Generic service information would have to be made available within 8 months immediately following model introduction or no later than the release of information to a manufacturer's franchised dealerships. This leaves a substantial time period during which many independent technicians may not have access to needed information. Therefore, the proposed regulations require that during the period between model introduction and the time the required information becomes accessible to independent technicians, each manufacturer, through an expeditious means available to its franchised dealers (e.g., hotline, regional service centers), make available to all independent technicians needed emission-related repair and service information.

The proposed regulations also require that preliminary generic and enhanced data stream information be made available to the automotive service industry three months immediately preceding model introduction. Final generic and enhanced data stream information would have to be released within three months immediately following model introduction. In addition, the proposed regulations require manufacturers to provide intermediaries [12] with all other emission-related service and repair information in a timely manner in order that their products or services be available to independent technicians when needed. To be timely, intermediaries would need to receive information within a time frame which would allow, where necessary, its conversion to an appropriate format, reproduction, notification, and distribution to independent technicians who may require the information. In all cases, the manufacturer retains full responsibility for compliance with section 202(m)(5) requirements. Failure of an intermediary to properly provide information does not relieve the manufacturer from responsibility to provide the information.

Distribution. Before information can be effective, individuals must know it is available and have access to it. Therefore, the proposed regulations require manufacturers to ensure that information covered by this section, whether distributed by the manufacturer or an intermediary, is reasonably accessible to all persons who service and repair motor vehicles. To qualify as reasonably accessible, the information must be available to independent technicians upon request without substantial delay. Further, manufacturers would be required to utilize reasonable means (e.g., trade journals and OEM catalogs) to make independent technicians aware that information covered by this section is available.

Media/Format. To be effective, the information required to be provided should be in (1) a format which can be readily understood, and (2) distributed through a medium which allows for prompt access and timely updating of materials. This requires tailoring the media and format to the type of information provided.

The CAAA require two types of information to be provided: (1) Information to make use of the OBD system and (2) other information, including instructions, for making emission-related diagnosis and repairs. All of the information required to be provided by these two types, except training information, can be distributed using the same format and media. Therefore, to facilitate distribution, the proposed regulations provide that the information is to be distributed as follows:

(1) *Training information:* The proposed regulations require manufacturers to make training information available, but allow them to make such information available through a medium of their choice. EPA expects that the medium selected would be the same as that used for franchisees (e.g., printed manuals, videotape, training classes).

(2) *Diagnostic/Repair Information:* Due to evolving computer technology and cooperation between the industry and other sectors of the automotive service industry, EPA expects the available media and format for this class of information to undergo substantial changes over the next several years. Therefore, the proposed regulations establish different media and format requirements for different time periods.

For model years 1994 through 1997, manufacturers would be permitted to use electronic or print media to distribute information. Terminology used in either print or electronic media would need to conform to the guidelines contained in SAEs' revised J1930, "Electrical/Electronic Systems Diagnostic Terms, Definitions, Abbreviations, and Acronyms." This recommended practice is required by CARB beginning in the 1993 model year for all service related information. After the 1997 model year, only electronic distribution would be require, while other modes of distribution would be allowed. Electronic distribution allows quicker access to information and is a more efficient means of updating materials. Comments are requested on the effective model year for providing electronic distribution, in particular how the available leadtime affects small manufacturers.

As to the type of format, the proposed regulations impose no requirements on manufacturers in model years 1994 and 1995. However, beginning in model year 1996, manufacturers would be required to use the format currently being developed by SAE. Entitled "Recommended Organization of Service Information" (J2008), this format establishes a recommended practice for organizing service information within an electronic data base. EPA expects that this format will be widely accepted throughout the auto industry. For those manufacturers choosing to provide direct digital communication with the service industry (e.g., by computer modem), the manufacturer, beginning in the 1996 model year, would need to provide for electronic data interchange following the guidelines in SAEs' draft J2187, "Remote Diagnostic/Service Communications."

Cost. In recognition of the costs incurred by independent technicians to acquire service and repair information for the wide variety of OEM service manuals, the proposed regulations require that such information be made available at a reasonable price (e.g., what could be expected if the suppliers of information were acting as competitors). In determining whether the price of information is reasonable, EPA would consider all relevant factors, including, but not limited to, the cost to the manufacturer of preparing and/or

[10] Enhanced service and repair information is specific for an original equipment manufacturer's (OEM) brand of tools and equipment.

[11] Generic service and repair information is not specific for an OEM's brand of tools and equipment.

[12] An intermediary is any individual or entity, other than an OEM, which provides service or equipment to automotive technicians.

providing the information, the type of information, the format in which it is provided, and the price charged by other manufacturers for similar information. Further, the proposed regulations require that when manufacturers provide the same exact information to independent technicians and dealerships, the price to independent technicians for such information would not exceed the lowest price charged to any of a manufacturer's authorized dealerships. EPA requests comment on whether the cost for information should be presumed reasonable in cases where manufacturers selling information directly to their dealers sell it to anyone else at the same price. EPA recognizes that some OEMs provide service manuals or other service and repair information to authorized dealerships as part of a franchise agreement. EPA is requesting comment on what information is needed to determine the reasonableness of the cost for such information which is not sold as a separate item to an authorized dealership, but is provided as part of a contractual agreement.

The proposed regulations are designed to prevent both monopoly pricing and attempts by manufacturers or other parties to impede the purchase of information by inflating prices. Manufacturers would be expected to exert reasonable effort to assure that all service and repair information is provided at a reasonable price. Manufacturers may distribute the required information directly or via an intermediary. Where an intermediary is used, fair and reasonable pricing can be achieved through (1) the use of licensing (royalty and/or sales) agreements between a manufacturer and an intermediary, and (2) where appropriate, the use of more than one intermediary to ensure competitive pricing in the marketplace.

The Agency believes that the successful accomplishment of the requirements for information availability could result in a market driven mechanism which provides the necessary information through commercial publication channels. EPA requests comments on the degree to which not copyrighting the required information could facilitate establishment of commercial publication channels. Further, would removing copyright restrictions be sufficient to demonstrate that the information is satisfactorily available?

7. Enforcement

Certification. Certification enforcement of the OBD requirements would be composed of four aspects: (1) Manufacturers would be required to submit documentation of OBD system design; (2) EPA would perform audit testing of emission data vehicles, fuel economy data vehicles, and assembly line vehicles; (3) EPA would evaluate results of in-use testing programs such as the in-use compliance and emission factors programs; and (4) EPA would evaluate compliance with information requirements.

Manufacturers would be required to provide EPA with sufficient documentation on the OBD system design to permit the Agency to perform a thorough evaluation of the effectiveness of the proposed OBD system. The Agency has determined that requiring specific monitoring designs or techniques is not necessary. The Agency encourages manufacturers to monitor particular components and systems with those strategies they determine to be the most effective in properly signaling malfunctions. Although the proposed regulations do not require that a manufacturer supply information which supports the decision not to monitor specific components or systems, the manufacturer must have such information available and EPA retains the right to access such information consistent with section 208 of the Act.

EPA is not proposing to require manufacturers as part of the certification program to routinely demonstrate via test data that their vehicles conform to these regulations. EPA expects to audit manufacturers' OBD designs by selectively evaluating individual designs over a wide range of potential malfunctioning conditions as described following. If a manufacturer's design fails this audit evaluation, the manufacturer will be denied certification for vehicles equipped with that OBD design. Due to this audit flexibility and the jeopardy the manufacturer has of failing an audit test if the OBD system is not properly designed, manufacturers should have sufficient incentive to properly design their OBD systems. Requiring each manufacturer to also supply test data over the full range of potential malfunctioning conditions and on each certification test vehicle would add hundreds of tests to the manufacturers' certification burden. Such an increase in certification burden on the industry appears unnecessary. EPA asks comment on the appropriateness of this proposal to not require manufacturer testing evaluating OBD systems on certification test vehicles.

During certification or fuel economy program audit testing by EPA, EPA could individually cause one or more of the following malfunctions on any emission data vehicle or fuel economy data vehicle. To evaluate a system's O_2 sensor, catalyst, or misfire monitoring, EPA could install or simulate a deteriorated O_2 sensor or catalyst or induce misfire. If the MIL illuminated and proper codes were set, the OBD system would comply with requirements to detect these malfunctions. If the MIL failed to illuminate, the OBD system would pass certification only if the increase in emissions due to the individual malfunction was less than the threshold level increases being established by this rulemaking.

During audit testing, EPA could electrically disconnect any emission-related component (one at a time) that directly or indirectly receives information or transmits information to the on-board computer, such as the auxiliary air system or engine coolant temperature sensor. The OBD system would pass certification if the MIL illuminated and proper codes were set for any electrical disconnection. Such electrical continuity audits could be done on any emission data vehicle, fuel economy data vehicle, or assembly line vehicle.

EPA also reserves the right to evaluate any pertinent data or information in deciding whether to grant a vehicle a certificate. In determining whether an OBD system should be certified, EPA may take into consideration information on the system's performance in actual use, including emissions and MIL illumination on in-use vehicles tested under the recall and emission factors programs or any other in-use testing program. Data from in-use vehicles would be particularly important in determining whether manufacturers would be allowed to "carryover" an OBD system from one model year to another.

This proposed certification program is consistent with the proposed requirement to mandate OBD monitoring for catalyst, oxygen sensor, and misfire problems. However, since the manufacturer has discretion on monitoring other components or systems for malfunctions or deteriorations, EPA will not presume these other components or systems will experience in-use problems and will not try to evaluate the impact of these potential problems during certification. The exception is electrical disconnection of components directly or indirectly receiving information from or transmitting information to the on-board computer. While EPA has not concluded such problems will necessarily occur,

electrical shorts and other such electrical problems are fairly common and, at times, difficult for the service technician to diagnose without the benefit of other information. Further, EPA believes it is relatively easy to design an OBD system capable of detecting these problems and, in fact, many manufacturer designs already do so. The cost of such monitoring is insignificant. This requirement seems appropriate to assure uniformity across the industry and to aid in the diagnosis of potential electrical problems.

In-Use Compliance. In-use enforcement of the proposed OBD regulations would focus on whether the OBD system detects problems that actually occur in use. In determining, under the provisions of section 207(c), the conformity of in-use vehicles with the OBD regulations, EPA would test any in-use vehicle, regardless of proper maintenance or use, as long as the vehicle's maintenance and use did not affect the proper functioning of the OBD system itself. Vehicles with detectable exhaust system leaks would first have these leaks repaired. Exhaust system leaks are not intended to be necessarily detectable by OBD. Since the exhaust emission test used to evaluate the emission performance of the vehicle does not measure the emissions from such leaks, EPA's evaluation of OBD performance will not penalize a manufacturer for exhaust system leaks. EPA would target in-use vehicles with high emissions and unilluminated MILs for further investigation of OBD system performance.

If an in-use vehicle with an unilluminated MIL were tested and shown to have high emissions, the problem or problems causing the high emissions would be diagnosed. If any single emission-related repair, regardless of whether the OBD system monitored for that malfunction, reduced emissions by an amount equal to or greater than a threshold level, the OBD system on that particular vehicle would be considered faulty. The malfunction would then be induced on other vehicles in the same design class by, for example, removing the malfunctioning component and installing it on the other vehicles. If the malfunction on an in-use vehicle caused an emissions increase greater than a threshold level without also causing MIL illumination, the OBD system as installed on that vehicle would be in violation of the requirements of today's proposed rule.

If a substantial number of vehicles violate the proposed OBD regulations, they could be recalled under section 207(c) for defective OBD systems and certification carryover of that OBD system design could be denied for future model years. In particular, if the malfunction found in use were not monitored by the system tested, future systems by the same manufacturer would be required to monitor for that malfunction, unless the manufacturer could demonstrate to the Administrator's satisfaction that the malfunction would not occur in subsequent model years.

Manufacturers have expressed concern that it may be inappropriate to require the recall of an OBD system in cases where the system fails to identify an emission-related component malfunction which occurs very infrequently. As one of the purposes of OBD is to identify random failures of emission control components which cause elevated emissions, EPA expects manufacturers to design OBD systems which detect isolated failures. However, it should be remembered that the Act requires that recall determinations be based on a failure to conform by a substantial number of vehicles in the class or category. In the case of an OBD system failing to identify an infrequent component failure, the OBD system, not the component, would be the subject of the recall and that recall would occur only if the determination were made that the "failure to identify" would occur on a substantial number of vehicles. Nevertheless, despite the intent to require detection of relatively infrequent component failures which result in exceedance of the threshold values, it is not EPA's intent to require recall of an OBD system if it fails to detect those problems that are so rare that they have an inconsequential emission impact on the in-use fleet. EPA requests comment on how best to distinguish and deal with extremely low frequency problems which, in aggregate, have inconsequential emission impact on the in-use fleet.

A recall to replace the defective component would occur only if the component were associated with the failure of a significant number of vehicles in the class to conform to applicable emission standards. However, EPA requests comments on the need to further clarify how extremely low frequency or unique malfunctions might be handled.

By requiring comprehensive OBD systems and assuring their performance at certification time, CARB's OBD II regulations help guarantee the OBD system is capable of detecting problems that might not occur until very high mileage, e.g. over 100,000 miles. EPA recognizes the need to assure appropriately functioning OBD systems at these high mileages. For catalyst and oxygen sensor deterioration or malfunction, misfire, and electrical disconnection, EPA's certification program similarly assures designs which should function appropriately and detect high mileage problems. For other potential problems, EPA's proposed program relies on manufacturer assessment of monitoring needs, backed up by EPA's in-use enforcement program. However, recognizing that EPA's recall testing authority appears to be limited to vehicles with a maximum of 75,000 accumulated miles, EPA requests comment on the need for alternative enforcement procedures to assure OBD systems appropriately detect problems at higher mileage. Specifically, comments are requested on the need to adopt a program similar to CARB's OBD II program which would require OBD monitoring, without manufacturer discretion, of a much broader list of potential in-use problems than catalyst, oxygen sensor, misfire and electrical disconnects. Since such an alternative program would limit manufacturer flexibility, information on the likely disadvantages of such an approach are also requested.

EPA's current in-use emission compliance program would continue to test properly maintained and used vehicles regardless of MIL illumination for compliance with existing regulations which require that vehicles conform to emission standards for their useful lives.

Repair Information Availability. The proposed rule requires manufacturers, in their application for certification, to describe how they would make information available in a manner which satisfies their regulatory responsibilities. EPA would review this plan and may require the manufacturer to revise its plan if, in the judgment of EPA, the manufacturer's plan would not assure information availability as required by the regulations. EPA may withhold certification until a satisfactory plan is received and approved by EPA. If, after certification, a manufacturer wishes to amend its plan, approval from EPA must be received prior to implementing the revised plan. EPA will monitor how manufacturers implement their approved plan for making repair information available. Pursuant to sections 203(a)(2) and 205 of the Act, as amended, failure of a manufacturer to make available information required by the proposed regulations, could subject the manufacturer to a civil penalty of up to $25,000 per day of violation.

EPA is concerned that, despite having a plan approved at the time of

certification, emission-related service information may not be adequately distributed or did not provide all information needed for effective repairs. This could occur for two reasons. First, an approved plan may not satisfy the statutory requirements when implemented. Second, the manufacturer may fail to implement all or part of an approved plan. If EPA determines that either of the situations have occurred, the Agency proposes to notify the manufacturer of this finding and will work with the manufacturer in an attempt to implement a plan which meets the statutory requirements. Failure of a manufacturer to implement a plan which satisfies the requirements of the Act may subject the manufacturer to a civil penalty of up to $25,000 per day commencing from the first day it was determined that the plan was deficient.

This enforcement protocol is intended to assure effective plans are designed and implemented for the dissemination and completeness of emission-related service information. EPA will make every effort to work with a manufacturer to assure plans are properly designed to satisfy the specific requirement of the regulations and the content of the statute. However, EPA expects it will not always be possible to determine the implementation success of a plan on the basis of its design. Therefore, the proposed rule allows both EPA and manufacturers the opportunity to revise a plan so as to improve its implementation.

Independent service technicians and others may have information which would be useful to EPA in determining whether emission-related service information was or will be appropriately available and sufficiently complete. At a meeting with interested parties held by EPA on April 19, 1991, to discuss the draft NPRM, it was suggested that independent technicians and their representative organizations be allowed the opportunity to review and comment on manufacturers, plans to distribute service and repair information prior to certification. EPA recognizes that such a review by independent technicians may be helpful in ensuring implementation of a satisfactory plan. However, EPA wants to ensure that a review procedure would not cause a delay in the certification process. Therefore, EPA is requesting comments on how to implement such a review procedure without affecting the timeliness of the certification process. EPA also requests comment on the best way to document service industry input on the effectiveness of the actual implementation of the plan.

8. Waivers

The CAAA of 1990 allow the Agency to waive the requirements of this rule for up to two model years for any class or category of vehicle for which compliance would be infeasible, consistent with corresponding regulations or policies adopted by CARB. In exercising this waiver authority, EPA will consider, in consultation with CARB, such factors as technical feasibility, lead time, and production cycles, including phase-in or phase-out of engines or vehicle designs and programmed upgrades of computers for needs other than OBD. EPA would not expect to grant a waiver based upon arguments of infeasibility if other manufacturers in a similar situation appear to be capable of satisfying the requirement. A petitioning manufacturer may be granted a waiver of some OBD provision of this rule even if another manufacturer appears capable of complying with the requirement if the petitioning manufacturer can demonstrate to the satisfaction of EPA that unique circumstances justify granting the request for the waiver. No specific deadlines for requesting a waiver are proposed. Rather, a manufacturer would request a waiver anticipating when it would need a decision and allowing for EPA review and decision.

Comments are requested concerning this general waiver provision, in particular the need for more specific waiver criteria or timing requirements. Specific recommendations for alternatives to this proposed waiver procedure are requested.

In the past, small volume manufacturers have had difficulty in complying with technology forcing regulations since the components they use are often obtained from outside sources (including large manufacturers). The need to obtain components for OBD systems from such sources may result in additional lead time constraints. Therefore, EPA requests comment on special considerations that might be appropriate in evaluating waiver requests from small volume manufacturers.

EPA proposes two specific implementation provisions which should ease the manufacturer's need to request waivers for either the 1994 or 1995 model year. First, EPA proposes to implement the evaporative emission OBD requirements coincident with the model year implementation of EPA's revised evaporative emission test procedures or the 1996 model year, whichever comes first. EPA is making this proposal based on the expectation that it would be prohibitively difficult for manufacturers to design an OBD system capable of monitoring the evaporative system for the 1994 and perhaps 1995 model years and then implement a significantly redesigned OBD system as soon as the 1995 or 1996 model years due to evaporative system redesign necessitated by the revised evaporative emission test procedures. Such a doubling of design effort would likely be costly. Further, insufficient lead time may be available to complete such a double design effort and put the resulting system into production. Adoption of this proposal would minimize manufacturer cost incurred in redesigning OBD systems if evaporative system design changes are adopted in response to the revised evaporative emission test procedures. At this time, the model year implementation of the revised evaporative emission test procedure is uncertain. Therefore, implementation of this specific proposal may result in delaying effectiveness of OBD evaporative emission monitoring requirements to the 1995 or 1996 model year. Comments are requested on the appropriateness of potentially delaying evaporative emission OBD requirements. EPA proposes to adopt this provision if comments support the need and difficulty in designing separate OBD evaporative monitoring systems as a result of changes to EPA's evaporative emission test procedures.

Second, EPA proposes to allow manufacturers to obtain Federal certification under the Federal OBD requirements for the initial model years of implementation by installing systems which satisfy CARB's OBD II requirements in place for those model years. The exact model years for which EPA will accept OBD II systems will be determined on the basis of comment to this proposal and further analysis by the Agency. This proposal would allow manufacturers to concentrate on designing one system to meet the OBD II requirements and installing that system nationwide in allowable model years without incremental testing and calibration development to assure compliance with EPA's proposed performance standards. Manufacturers have indicated they have been concentrating on designing OBD systems to meet CARB's OBD II rules. To simultaneously optimize to meet Federal performance requirements would, in the manufacturers' opinion, add substantial burden, especially in the near term. Manufacturers have stated that the certainty of a system designed

to California's OBD II rules being acceptable for nationwide compliance alleviates near term burden. However, for later model years, manufacturers face less burden and have greater flexibility to adjust their programs to meet regulatory requirements. Comments are requested on the appropriateness of accepting OBD II systems in the near term to ease the transition to complying with Federal requirements, including the potential benefits to the manufacturers, likely cost savings which would be realized by consumers, any concerns or potential problems of allowing such an option, and the date beyond which 100% Federal OBD compliance should be required.

In a draft NPRM which EPA made available for review, EPA had considered allowing OBD II systems to satisfy Federal requirements for the 1994 and 1995 model years. At a meeting held by EPA on April 19, 1991, to discuss the draft NPRM, Ford Motor Company suggested that EPA allow the use of OBD II systems as an alternative to OBD systems required by § 86.094–17 beyond the 1995 model year and delay 100% compliance with Federal OBD requirements until the year 2002. Ford argued that a significant manpower burden would be placed upon them by the 1996 deadline due to the need to develop two OBD systems concurrently.[13] The information presented was insufficient for EPA to conclude that 100% compliance with the Federal OBD requirements proposed today should appropriately be delayed until model year 2002. However, in response to Ford's specific proposal and the general support by other manufacturers, the Agency will consider allowing OBD II systems to fulfill Federal requirements under proposed § 86.094–17 for some period beginning with the 1994 model year [14] provided comments (including supporting data and analyses) merit a need and overall benefit of doing so.

Comments are requested on EPA's estimate of "application costs" in the RIA and whether there are additional incremental costs associated with perceived differences between the Federal and CARB requirements. Comments should include identification of specific aspects of the Federal program which differ from the CARB OBD II program and which result in a perception of significant increased burden on manufacturers. EPA will consider whether such differences can best be resolved through clarification or modification of the Federal proposal, or through extension of the option of allowing OBD II systems to satisfy Federal requirements. EPA requires additional, detailed information to discern how much of the perceived additional burden of the Federal rules is due to technical stringency differences with OBD II, product planning decisions internal to the manufacturer, or other aspects which might add burden. EPA also requests suggestions on alternatives to the option of extended Federal approval of OBD II systems which would similarly resolve concerns regarding the burden manufacturers would face in complying with both the CARB rules and Federal requirements. EPA will attempt to minimize burden giving due consideration to those aspects of the program which are expected to result in emission benefits via improved OBD systems.

Also, at the meeting of April 19, 1991, manufacturers suggested that EPA, upon granting a Federal waiver, accept an OBD I system as automatically satisfying Federal requirements. California requires manufacturers who cannot fully implement an OBD II system to at least implement OBD I. However, OBD I requires significantly less than either OBD II or the proposed Federal requirements. EPA believes there may be circumstances in which, by the 1994 model year, a manufacturer may be able to adopt improvements over those required by OBD I without significant technical difficulty and without incurring inappropriate production or other costs. In such a situation, the benefits of an enhanced OBD system might outweigh the incrementally increased costs over a system designed to meet OBD I requirements. Such an enhanced OBD system would likely also be acceptable to CARB, eliminating the concern that a separate system would have to be designed and installed in vehicles sold in the 49-states compared to systems installed in vehicles sold in California. Also, there may be circumstances in which a manufacturer satisfies OBD II requirements for vehicles sold in California, but cannot install the same system in their 49-state vehicles or otherwise fully comply with Federal requirements. In this latter case, it may also be inappropriate for EPA to just accept an OBD I quality system.

For these reasons, EPA is proposing to evaluate the acceptability of an OBD I system on a case-by-case basis. However, comments and information are requested on this issue. On the basis of this additional information and further study by EPA, the Agency may determine that an OBD I system is sufficient and a waiver from full compliance with the Federal OBD requirements is appropriate.

The waiver provisions under section 202(m)(2) of the Act pertain only to the OBD system and not to the information required to be provided by the manufacturer under section 202(m)(5). Further, since EPA expects this information would typically be available in some form, providing it in the manner proposed is not expected to result in undue burden to the manufacturer. Therefore, this proposal provides no waiver for complying with the requirements to provide OBD system information and emission-related service information to any person engaged in the service or repair of any 1994 or later model year LDV or LDT.

V. Discussion of Issues

A. Options Considered for Regulatory Approach

EPA considered several alternative regulatory strategies before deciding on the approach contained in today's proposed rule. These alternatives were (1) federal adoption of CARB's OBD II, (2) establishment of emission level thresholds which, if exceeded by a vehicle due to any single malfunction or combination of malfunctions, would trigger MIL illumination, (3) a voluntary program which would rely on in-use incentives to assure adequate OBD designs, and (4) establishment of an emission level threshold which, if exceeded by a vehicle due to any single malfunction would trigger MIL illumination. The proposed approach, that the system must detect a single malfunction which causes a change in emission performance greater than a given amount, is a variant of the fourth approach.

1. OBD II

CARB's path breaking OBD II rule, adopted in September 1989, was designed to force the development and widespread application of monitoring technologies that had not, in some cases, passed the concept stage. OBD II was prompted, in part, by the conclusion of CARB's staff that improved monitoring methods could more effectively detect malfunctions in some systems and that important emission-related systems

[13] Docket document number II–D–11, Ford submittal, April 19, 1991.

[14] Federal acceptance of certification to California OBD II requirements as meeting Federal requirements only applies in cases where California has a parallel requirement applicable to the given engine/fuel type. For example, California has no requirements for diesel engines; hence, there is no California OBD II to accept as meeting the Federal requirements pertaining to diesel engines.

were not monitored by OBD I.[15] OBD II contains strict requirements for monitoring each emission-related component. Manufacturers must obtain approval from CARB if they wish to employ a different method of monitoring a component from the method specified in the OBD II regulation. To demonstrate that their OBD system actually works, all manufacturers must submit one development vehicle each year for OBD evaluation and testing prior to obtaining a certificate for that model year. This preproduction focus helps assure that an effective OBD system is installed on each and every LDV.

While EPA recognizes the contribution of OBD II in encouraging the development of OBD systems, EPA also wishes to encourage manufacturers to develop and employ whatever monitoring strategies best target malfunctions occurring on vehicles in actual use which have significant emissions impact. EPA also wishes to provide the manufacturers with the flexibility to avoid the cost of installing OBD for a particular component by improving the design of that component so that it is less likely to malfunction or deteriorate in a manner which significantly affects emissions. Finally, EPA wishes to have the manufacturer take responsibility for determining which components or systems are likely to impact emissions due to malfunction or deterioration. Since vehicle designs are continuously evolving, EPA does not believe it can appropriately anticipate these problems when relying on data currently available to the Agency. In pursuing this goal of focusing attention on in-use performance, EPA is proposing to diverge from the OBD II rule in some respects.

EPA has set performance standards for OBD systems based on evaluation of the capabilities of the most promising monitoring methods currently in the advanced stages of development. However, EPA has not specified that these particular methods must be employed in all OBD systems. EPA wishes to encourage the development of innovative strategies that could monitor emission control components more accurately or cheaply. The flexibility to innovate is particularly important in a new, rapidly developing technology such as OBD. EPA is proposing not to require manufacturers to request special permission to use alternative monitoring strategies. As mentioned above, manufacturer flexibility can also be used to improve emission-related system design to eliminate in-use problems, perhaps obviating the need for OBD monitoring of certain components. As usual, EPA will conduct certification and in-use audits that target designs EPA believes are likely to be inadequate.

EPA's enforcement strategy is also significantly different from the approach followed by CARB. EPA believes that an enforcement strategy that stresses in-use testing is essential to achieve the federal OBD program's goal of reducing emissions from the in-use fleet and to ensure that the rule's design flexibility does not lead to systems that are not adequate or durable in the field. Nevertheless, certification enforcement will still be integral to the program, focusing on those components and systems most likely to malfunction in use, resulting in a significant emission impact.

EPA believes that this approach properly stresses the in-use performance of OBD systems while granting design flexibility to manufacturers. EPA believes that the systems installed on vehicles to comply with this proposed rule will be similar in scope and sensitivity to those installed to comply with OBD II. With the possible exception of evaporative system monitoring hardware, this proposed rule should not require any hardware not otherwise required by OBD II. In fact, the evaporative system monitoring hardware that may be required to satisfy this proposed rule should also allow manufacturers to better meet OBD II requirements.

Differences between this rule and OBD II are not intended to result in different OBD system designs between California and federal cars in the short term. Rather, these differences reflect a different approach in setting OBD requirements that should be complimentary to, not in conflict with, California's OBD II rule.

Commenters are requested to bring to EPA's attention aspects of its proposed rule that are incompatible with OBD II and would require the industry as a whole to develop two sets of OBD systems. Suggestions for resolving any inconsistencies are solicited.

2. Multiple Malfunction Emission Thresholds

EPA considered requiring an OBD system that could detect any malfunction or deterioration in any single component or combination of components that could cause exceedance of the emission standards. While this is a goal for future OBD systems, EPA has not proposed today an emission threshold equal to the standard. For several important faults such as catalyst deterioration and engine misfire, no monitoring method could accurately detect very minor problems. Attempts to detect minute deviations from optimal operation would likely lead to false malfunction determinations or, especially in the case of misfire, flagging of problems so minor that even the system's diagnostic capabilities could not help mechanics determine exactly what repair was necessary. An overly sensitive OBD system initially could cause drivers unnecessary anxiety and repair expense and would probably, over time, cause them to ignore the MIL. EPA believes that this result would be counter to the intent of Congress in establishing this law.

EPA's decision to pursue an OBD standard based on the detection of single malfunctions only was motivated by concerns for feasibility and false lights similar to those that led to the rejection of a threshold equal to emission standards. Monitoring technology is not sufficiently sensitive to be able to report to the computer the exact performance of all relevant components. Even if such monitoring technology were available, the computer capacity necessary to analyze the data to predict emissions would be prohibitively large, as would be the software development for the system. Any system that could analyze monitoring data from a few critical components would still be limited by the sensitivity of monitoring those components. A "hydrocarbon sniffer" (or "CO sniffer") in the exhaust system could detect small exceedances of the standard, whatever their cause, but would be of limited diagnostic assistance to a mechanic attempting to isolate very minor problems.

Notwithstanding these arguments, EPA intends to revisit the issue of multiple malfunction monitoring in the future, as more experience is gained with OBD systems.

3. Voluntary OBD

One manufacturer proposed a program which would not mandate any specific OBD system. Rather, installation of OBD systems capable of flagging emission problems would be encouraged via a modification of EPA's current in-use enforcement program. Under the proposed revision, manufacturer in-use compliance and, therefore, recall jeopardy would be limited to data from test vehicles which did not have their MIL illuminated and a problem code stored. EPA has rejected this option for four reasons.

[15] California Board Item #89-16-01.

First, it would significantly undercut EPA's ability to perform its mandate of discovering emission control system problems in particular vehicle classes. Manufacturers could escape responsibility for these problems simply by installing an OBD system that illuminated the MIL whenever the problem occurred.

Second, by exempting manufacturers from responsibility through recall for malfunctions that caused MIL illumination, and then requiring owners (at least in I/M areas) to bear the expense of repairing the vehicles, EPA would be transferring the burden of correcting faulty emission control system designs from manufacturers to individual owners. While EPA does not expect manufacturers would opt to design OBD systems which frequently indicated the need for repair, thus greatly burdening and irritating their customers, shifting this burden would be counter to Congress' intent in establishing EPA's recall authority.

Third, this proposal would not provide manufacturers with a genuine incentive to install monitoring systems that would detect the malfunctions that are the focus of this rule. Already, manufacturers do not face any recall liability for defects which do not affect a substantial number of vehicles in their class. Today's proposal is aimed at insuring the detection and repair of relatively infrequent, random defects that occur across the in-use fleet, but are not systematically common to a class of vehicles and, therefore, would not be grounds for recall.

Fourth, a truly voluntary program would appear to be precluded by the Act which mandates regulations requiring OBD. Thus, some changes to this option would be necessary so as to satisfy at least the minimum requirements of the Act. However, due to the other problems noted above, EPA has not pursued amending this option to make it minimally conform to the mandates of the Act.

4. Single Malfunction Emission Thresholds

EPA turned to fashioning an OBD rule based on maximum feasible detection of single faults on actual in-use vehicles. EPA initially considered establishing a grams per mile emission level that remained fixed throughout the life of a vehicle. EPA believes a fixed emission level threshold would not appropriately account for normal emission deterioration. Thus, setting the threshold at a level appropriate for low mileage vehicles would place an unreasonable burden on high mileage vehicles; a high mileage vehicle's MIL could illuminate when no malfunction exists due to normal emissions deterioration. Setting the threshold high enough to avoid this problem would make the threshold lax at low mileage where less deterioration has occurred. To avoid this problem EPA is proposing to use an additive threshold which is based on the impact of a malfunction on increased emissions. This method of determining exceedance of the threshold takes into account the impact of accumulated mileage on vehicle emissions.

B. Regulatory Approach

1. Emission Threshold

While the Act authorizes EPA to require OBD systems that detect any malfunction causing exceedance of an emission standard, EPA recognizes that the technology expected to be available in the near term will not be capable of detecting some small exceedances caused by relatively minor malfunctions. As discussed earlier and in detail in the following section on Technical Feasibility, EPA, CARB, and industry studies suggest that for most components, feasible monitoring technology will likely be limited to detecting malfunctions that could cause exhaust emissions to increase by no less than 0.2 g/mi HC, 1.7 g/mi CO, or 0.5 g/mi NOx. For catalyst deterioration and misfire detection, EPA expects the feasible monitoring technology to be limited to flagging problems which cause an increase in exhaust emissions of 0.4 g/mi HC, 3.4 g/mi CO, or 1.0 g/mi NOx.

EPA encourages manufacturers to adopt more sensitive monitoring techniques if they become available. However, EPA also recognizes that forcing manufacturers to adopt overly sensitive monitoring strategies which could generate a substantial number of false malfunction warnings could cause drivers unnecessary repair expense and undermine the credibility of dashboard warning lights. The Agency requests comment on whether the emission threshold defined above for enforcement strikes the proper balance between these concerns.

2. Heavy-Duty Vehicles

The Act authorizes EPA to require that OBD systems be installed on heavy-duty vehicles and engines. EPA is not proposing to exercise that authority under this rulemaking.

The Act provides EPA the discretion to adopt OBD regulations for heavy-duty vehicles and engines. EPA plans to consider this option at some future date and, if technically feasible and cost effective, may choose to propose regulations.

3. Diesel and Alternative Fueled Vehicles

In addition to gasoline fueled vehicles, today's proposed rule applies to light-duty diesel and alternative-fueled LDVs and LDTs to the extent component or system malfunction could similarly result in excessive increases in exhaust or evaporative emissions. However, the Agency recognizes that certain provisions of the rule may not apply to such vehicles. First, they may lack certain emission control components. For example, current light-duty diesels are not equipped with catalysts or oxygen sensors, components specifically required to be monitored by the Act. Second, based on engineering judgement, it does not appear that any technically feasible monitoring technique currently exists capable of detecting malfunctions of certain emission components, such as particulate traps commonly used in diesel vehicles. Therefore, at this time, EPA is proposing not to require monitoring of components or systems for their impact on particulate emissions.

However, EPA requires that, at a minimum, electrical continuity checks on emission control components providing input to or receiving output from the on board computer would be monitored. The manufacturer would be generally responsible to detect problems in vehicles operating on these other fuels which would result in exceedances of the exhaust or evaporative emission thresholds.

Such vehicles would be required to provide diagnostic information over a data link (when so equipped) consistent with the requirements for LDVs when the diesel or alternative-fueled LDV or LDT utilizes similar components or systems to gasoline-fueled LDVs or LDTs. In addition, diesel- and alternative-fueled LDV and LDTs would not be exempt from the information availability provisions of today's proposal.

EPA requests comment on any unique issues with technical feasibility, necessary leadtime, cost, and potential emission benefits of requiring OBD for diesel and alternative-fueled LDVs and LDTs.

4. Inspection and Maintenance (I/M)

EPA has not included specific guidelines on incorporation of OBD into I/M in this rule. This issue will be included in forthcoming regulations concerning enhanced I/M program requirements. However, at this time, EPA would like to solicit comments on incorporating into the OBD system radio

frequency transponders which could transmit fault codes and vehicle I.D. information to roadside receivers. Since the cost of installing such transponders in each new car has not been established by EPA, comments are requested concerning the cost and other considerations for both new car installation and post-production retro-fit installation. Information is also requested concerning any plans to offer such a device as a new car option or as an aftermarket device for consumers if it would make their I/M program check more convenient. Comments regarding the need to require a hook up point to facilitate post-production retrofit installation and the cost of such are requested. If adopted at some future date, this mechanism could enhance existing I/M programs by facilitating more continuous inspection of OBD systems on in-use vehicles. In this regard, EPA is requesting comments on whether each vehicle's OBD system should be constructed to include a plug or similar hook up to allow radio frequency transmitters to be added after vehicle construction. This would allow vehicles subject to I/M tests to be modified to make use of transponders.

C. Technical Feasibility

1. Overview

Over the decade of the 1980s, electronic controls gained increasing importance in the field of motor vehicles. Increasingly stringent emission and fuel economy standards required very tight control of critical engine parameters; electronic controls were the practical solution to this demand. Today, essentially every new passenger car and light truck has such controls and the number of parameters monitored and controlled continues to increase.

Initially, electronics were used to monitor and control air/fuel mixtures on gasoline engines. (Exhaust gas composition is monitored by an "oxygen sensor"; the ratio of fuel to air supplied by the carburetor or fuel injectors is adjusted for maximum efficiency and reduced emissions.) Gradually, other functions were transferred to electronic control. Today, many vehicles have electronically controlled ignitions which have no mechanical distributors. The spark coil is triggered by the computer, based on input from sensors monitoring engine speed, load, coolant temperature, and other factors. If spark knock is detected, the ignition timing can be automatically adjusted to eliminate it.

Computers have also opened the door to improved repairability. Because the computer receives information from many different sources, it has the potential to "know" when some of that information does not make sense. A simple example would be an engine temperature sensor. If the computer does not detect an increase in temperature several minutes after a cold start, some difficulty with the sensor or its wiring could be inferred. Under such a condition the operator would be informed by means of a "check engine" warning light and an identifying "trouble code" would be stored for later access by the service technician. Such technology is available on many new vehicles today.

Some vehicles are equipped with electronic computer controls that have various backup modes of operation. EPA has tested a General Motors vehicle with a 3.8 liter engine. When various faults were deliberately introduced, the computer system was able to detect the problem, illuminate the "Check Engine" light, set the appropriate trouble code, and revert to a backup mode of operation. Typically, acceptable emission control and vehicle performance were maintained even with the malfunctioning component; the computer was able to detect and compensate for the malfunction. A Ford vehicle with separate oxygen sensors on each bank of cylinders was able to rely on the "good" sensor when the other was disabled.

A detailed analysis of available monitoring strategies and issues is contained in the Technical Support Document for this rule available in the docket mentioned previously. The docket also contains the Technical Support Document for OBD II. The following discussion summarizes the major technical considerations. EPA requests comment on how intrusive testing (i.e., OBD monitoring strategies which require interuption of normal emission control systen1 operation) affects emission performance, and how this issue should best be handled.

2. Catalyst Failure Detection

EPA is proposing to require that the performance of the catalyst be monitored for a determination of catalyst failure, as opposed to monitoring potentially damaging operational modes, as some manufacturers have proposed. Monitoring catalyst performance, as opposed to only monitoring potentially damaging operating conditions, is important because:

(1) The catalyst can deteriorate for a number of reasons. For example, thermal degradation, catalyst poisoning, or mechanical failure can cause substantial efficiency loss. If an OBD system is designed only to detect operational modes which would lead to catalyst overheating, the system will not identify or detect efficiency loss due to non-thermal causes.

(2) While monitoring conditions that are potentially damaging to the catalyst can initially identify catalyst failure, any method that does not verify catalyst performance cannot determine whether the catalyst has been properly serviced.

EPA believes that the conversion and oxygen storage/release activity of the catalyst are a good indicator of how a catalyst is performing. Thus, EPA catalyst monitoring requirements and suggested compliance are based on the monitoring of these properties for a determination of catalyst performance.

Dual Oxygen Sensor Methods. Currently, the most promising methods for detecting catalyst failure use the dual oxygen sensor approach. This approach uses an additional oxygen sensor placed downstream of the catalyst. Catalyst performance is monitored with either direct observation of the downstream oxygen sensor or a comparison of the downstream oxygen sensor with the upstream oxygen sensor.

The principle of this approach lies in relating changes in the oxygen activity of the catalyst with the catalyst conversion efficiency. A catalyst with proper conversion and oxygen storage/release capabilities will oxidize the HC and CO, resulting in a downstream exhaust makeup of oxidized agents; the corresponding response pattern of an oxygen sensor placed downstream of the catalyst is a consistently "lean" signal from the sensor. Conversely, a catalyst which has lost a great deal of conversion activity will allow much of the untreated exhaust stream to pass through the catalyst. The resulting response wave pattern of a downstream oxygen sensor will reflect this, with more rich/lean switching corresponding to the fluctuations in the untreated exhaust. Dual oxygen sensor methods are based on correlating catalyst conversion activity with the difference in response patterns of the upstream and downstream oxygen sensors.

EPA and manufacturer data from dual oxygen sensor research suggest that the relationship between oxygen sensor comparison modes and catalyst conversion efficiency may, at least in some cases, more closely resemble a step function, rather than a direct linear correlation.

The implication of a stepwise relationship between oxygen sensor comparison modes and catalyst conversion efficiency is that dual oxygen sensor methods are more useful for the detection of gross losses in

catalyst activity rather than for a direct prediction of catalyst efficiency. Because of this, it is difficult to distinguish small losses in catalyst activity using the dual oxygen sensor method. However, EPA believes that this stepwise relationship will enable manufacturers to develop systems which can reliably detect catalysts which cause emissions greater than or equal to the proposed thresholds. EPA data suggests catalysts having an average HC conversion efficiency at or below 50 to 60% over the FTP can be flagged by such OBD systems. EPA believes catalysts with conversion efficiencies better than this will not result in emission increases greater than 0.4 g/mi HC, 3.4 g/mi CO, or 1.0 g/mi NOx. Thus, the dual oxygen sensor method is sufficient to meet the OBD requirements for catalyst monitoring being proposed today.

Detection of grossly deteriorated catalysts can occur with high confidence, and low error of commission, because of the drastic change that occurs in oxygen sensor modes in response to a catalyst with these types of losses in conversion activity.[16]

A critical issue for the use of dual oxygen sensor methods is the impact of deteriorated oxygen sensors on the accuracy of catalyst monitoring. A malfunctioning sensor may result in a misdiagnosis and a false code being stored by the OBD system. The pre-catalyst sensor is exposed to high temperatures and raw exhaust poisons, which can slow response time and lessen response amplitude. This may lead to a false diagnosis of catalyst failure on a system utilizing these sensor parameters for catalyst monitoring. The OBD monitoring system must be designed to detect sensor failure before the sensor is no longer able to accurately evaluate catalyst performance. Allowances and/or correction factors can be developed into the catalyst monitoring system to account for slight oxygen sensor deterioration. Two manufacturers have indicated that slight sensor deterioration would not have a significant impact on the catalyst monitoring capabilities of their system. At this time, EPA believes that oxygen sensor deterioration does not present a serious obstacle to the use of dual oxygen sensor methods for detecting catalyst deterioration.

[16] J. Koupal, M. Sabourin, and W. Clemmens, "Detection of Catalyst Failure on-Vehicle Using the Dual Oxygen Sensor Method," SAE Paper #910561, presented at the SAE International Congress and Exposition, February 1991.

Temperature Change Method. Another method which has been studied for monitoring catalyst conversion efficiency is the temperature change method. This method involves monitoring the temperature change across the catalyst and correlating this change with catalyst conversion efficiency. An advantage to this method is that it would introduce thermistors for diagnostic purposes which, although they are new additional equipment, are likely less expensive than oxygen sensors. Areas requiring further consideration with this method are the durability of these thermistors and their ability to operate under the high temperature conditions experienced in the catalyst. So far, studies have shown no discernible trends. However, at least one vehicle manufacturer has shown interest in developing this method.

Other Approaches. EPA recognizes that catalyst monitoring will present some technical challenges. Therefore, EPA solicits information on various causes of catalyst deactivation, possible means of prevention, and the likely overall impact on emissions if deactivation could be prevented. Although prevention of catalyst deterioration in lieu of monitoring has conceptual advantages, difficulties exist, such as: How many catalysts would fail despite such prevention techniques and how could proper operation of aftermarket catalysts be assured without monitoring. Furthermore, the CAAA requirement for OBD system monitoring of the catalyst would appear to preclude this option.

One possible approach to preventing catalyst deterioration would be to require that fuel to misfiring cylinders be shut off to prevent catalyst overheating. It appears that many vehicles will be equipped with sequential multipoint fuel injection to help meet future emission limits as well as for other reasons. For such vehicles, no additional hardware would be necessary to implement fuel shut-off during misfire. Commenters are requested to address whether fuel shutoff during misfire should be required for vehicles equipped with sequential fuel injection.

3. Oxygen Sensor Monitoring

The oxygen sensor is a critical part of the closed-loop fuel control system in vehicles. Three-way catalysts are most effective in converting the engine-out exhaust emittants when the exhaust stream is maintained in a narrow range near the stoichiometric condition (approximate air/fuel=14.7). The oxyen sensor voltage signal corresponds to the free oxygen present in the exhaust. The command computer monitors the oxygen sensor voltage to determine whether the air/fuel mixture is lean or rich of stoichiometry. The computer makes the appropriate correction in the amount of fuel delivered by the fuel delivery system. A properly functioning oxygen sensor will be able to respond both quickly and accurately to changes in the air/fuel ratio, enabling the fuel control system to maintain a narrow air/fuel operating window around stoichiometry and facilitating efficient catalyst conversion. Thus, proper operation of the oxygen sensor is critical to proper emission control.

For manufacturers using the oxygen sensor as part of the OBD system, the ability of the sensor to respond quickly and accurately will be critical for effective monitoring. A number of manufacturers have indicated to EPA that they plan to utilize the dual oxygen sensor method for catalyst failure detection. In this system, the pre-catalyst oxygen sensor, which is exposed to untreated exhaust, is more susceptible to contamination and thermal degradation than the oxygen sensor placed downstream of the catalyst. A dual oxygen sensor system which contains a deteriorated controlling oxygen sensor may incorrectly diagnose a catalyst as failed.

Oxygen sensor deterioration is characterized by a retardation of response characteristics including response rate, amplitude, and frequency. Specifically, oxygen sensor deterioration will result in a decrease in the rate at which the sensor will switch from lean to rich or rich to lean output voltage levels. As a result of this slowed response rate, both the amplitude range and frequency of the oxygen sensor response will decrease. EPA and manufacturer testing indicate that monitoring these response characteristics is adequate for a determination of sensor deterioration.

Some manufacturers may choose to monitor oxygen sensor performance by observing response characteristics during induced operating modes. For example, the lean to rich or rich to lean response rate can be accurately monitored using a short fuel cut during deceleration or steady-state conditions. However, monitoring response characteristics does not appear to require any induced condition. EPA data suggests that amplitude or switching frequency can be accurately monitored over steady-state or acceleration modes.

EPA and manufacturer data indicate that an oxygen sensor must be deteriorated substantially before emissions exceed the threshold levels

proposed in this notice. In this case, response characteristics of the oxygen sensor will have retarded significantly. Therefore, EPA believes that it is feasible for an OBD system to monitor some response characteristic of the oxygen sensor and detect deterioration before that deterioration results in exceedance of any emission beyond the proposed threshold levels. However, OBD systems which utilize the oxygen sensor to check other system performance might be more susceptible to oxygen sensor deterioration. For example, manufacturers using the comparison of an upstream and a downstream oxygen sensor for catalyst failure monitoring will have to be cognizant of the level of deteriorated oxygen sensor performance at which a significant decrease in OBD system accuracy occurs, even if oxygen sensor performance at this level will not directly result in exceedance of an emission standard.

4. Misfire Monitoring

The term misfire describes the occurrence of an incomplete combustion process within one or more cylinders. Misfire will occur when there is: (1) An abnormal fuel or air supply; (2) inadequate ignition spark; and/or (3) inadequate compression.

Two major reasons for identifying engine misfires are: (1) A misfire results in high exhaust concentrations of HC and CO and (2) a misfire can quickly cause the internal temperature of the catalyst to reach or exceed those levels that can cause irreversible damage. Both of these conditions can cause a vehicle to experience tailpipe emission non-compliance.

Three of the most commonly identified causes of misfire are secondary ignition system misfire, intake manifold leaks and fuel injector failure. As described in the Technical Support document to this rulemaking, tests conducted by EPA suggest that as little as 2–3% misfire (e.g., 2–3% of firing events resulting in misfire) can cause an otherwise properly functioning vehicle to exceed the HC emission standards. Significantly more severe misfire is required before catalyst overheating will occur. On the performance bench, when a misfire to a single cylinder due to either fuel shutoff or ignition shutoff was induced during testing, the sample catalyst's internal bed temperatures increased and stabilized in a temperature range where a catalyst can experience thermal deactivation over time. GM research modeled the relationship between the percentage of engine cylinders experiencing misfire with the stabilized catalyst bed temperature that occurred during such misfire operation.[17] At approximately 12% misfire, as occurs when one cylinder on a V-8 engine is experiencing total misfire, the catalyst bed temperature is predicted to stabilize around 1600 °F. The GM model predicts that catalyst bed temperatures caused by complete single catalyst misfire will range from about 1600 °F for an 8-cylinder engine to approximately 2000 °F for a 4-cylinder engine. Ford's research staff predicted that cumulative exposure to these elevated temperatures of approximately 15 to 30 minutes (depending on the exhaust air/fuel conditions during exposure) can substantially lower a catalytic converter's performance.[18]

As of this notice, three general methodologies have been presented to EPA which appear viable for compliance with the proposed misfire requirements. These are: (1) The crank angle velocity technique, (2) the crankshaft torque measurement detection technique, and (3) the use of individual cylinder sensors.

Crank Angle Velocity Technique. An approach which appears to have a significant potential for monitoring both engine misfire and identifying the individual cylinders that misfire is the crank angle velocity sensor technique developed by the University of Michigan Vehicular Electronic Laboratory [19] and perhaps others. Several manufacturers have indicated to EPA that they intend to use a crank angle sensor to comply with CARB's OBD II misfire requirements. They indicated that the identification of the misfiring cylinder(s) was feasible using this method and would be implemented in their system.

Crankshaft Torque Measurement Detection Technique. This technique was presented to EPA by a supplier which uses a proprietary miniature torque sensor that employs the principle of magnetostriction. Data were presented to EPA which indicated that a solitary misfire event was discernible from normal firing events in the laboratory during a variety of engine-dynamometer conditions. These conditions included no-load/low-load high-speed, and high-load high-speed operation. This supplier also provided a proprietary technical discussion as to how their sensor would not be as affected by road induced torque inputs as some sensors are reported to be. They indicated that testing and optimization is ongoing.

Individual Cylinder Sensor Techniques. EPA is aware of two techniques using individual cylinder sensors. The first, using individual cylinder oxygen sensors or thermocouples installed at each exhaust port, was evaluated by EPA. This detection method allows the OBD system to identify when multiple cylinder misfires are occurring and to identify the specific misfiring cylinder. The capability of identifying specific cylinders affords the computer the opportunity to take corrective action (i.e., shut off fuel to the offending cylinder).

Disadvantages of such an approach are the hardware cost associated with this technique and the reliability concerns presented by additional sensors. However, some manufacturers might incorporate exhaust port mounted oxygen sensors because the sensors could provide feedback to a system that could adjust the pulse width of individual fuel injectors. Adjustable pulse widths could provide additional benefits such as fuel economy or performance improvements.

The second technique using individual cylinder sensors was presented by a component supplier. It involves using in-cylinder pressure sensors for misfire detection. While the supplier had not developed a system using this technology, preliminary results from their work suggest that misfire clearly is detectable by this technology and a system incorporating these sensors would be capable of identifying individual misfiring cylinders.

5. Evaporative Emission Control System Monitoring

The evaporative emission control system collects evaporative emissions from the fuel system continuously, even when the vehicle is not operating. The amount of vapors collected is determined by a number of factors including ambient and fuel temperature, fuel vapor pressure, and recent driving patterns.

Ongoing EPA analyses of data from in-use vehicles that underwent evaporative system inspection by EPA in the last 4 to 5 model years show that approximately 10% failed vapor

[17] S.H. Oh, "Thermal Response of Monolithic Catalytic Converters During Sustained Engine Misfiring: A Computational Study", SAE paper no. 881591, Presented at the International Fuels and Lubricants Meeting and Exposition, Portland, OR, October, 1988.

[18] R.H. Hammerle, and C.H. Wu, "Effects of High Temperatures on Three-Way Automotive Catalysts," SAE Paper no. 840549, presented at SAE International Congress and Exposition, Detroit MI, February, 1984.

[19] W.B. Ribbens and G. "Rizzoni, Onboard Diagnostics of Engine Misfires," SAE paper no. 901768, presented at the 1990 SAE Passenger Car Meeting and Exposition, Dearborn, Michigan, September, 1990.

recovery system leakage tests and an additional 5% failed purge system checks. Based on EPA experience with larger data sets from earlier model years, as many as 40% of all production vehicles in the U.S. fleet may experience an evaporative system malfunction at some point in their lifetime.

Evaporative emission increases can result from malfunction of the vehicle's vapor recovery system, purge control system, or fuel control system. The vapor recovery system may experience failures such as a leaking gas cap or filler neck, a saturated or cracked canister, and deteriorated or disconnected hoses/lines. The purge control system may experience failures such as inoperative solenoids or valves and deteriorated or disconnected hoses/lines. Fuel system problems that can cause evaporative emission problems are leaking gaskets, fuel injectors, or fuel rails.

In most cases, evaporative emission failures occur due to purge activity loss or due to leaks in the vapor recovery system. Fuel system leaks are less frequent and are usually easy to detect because of driveability problems or noticeable odors. These system malfunctions cause evaporative emission failures during vehicle operation (running losses) and during engine-off conditions (diurnals and hot soaks).

EPA has proposed regulations concerning the revision of evaporative emission test procedures.[20] While these regulations will likely require the improvement of overall evaporative emission system designs, these improvements will most likely be in the form of increased canister capacity (via additional and/or larger canisters), more efficient purge strategies, and lower vapor pressure in the fuel tank. It is anticipated that these design improvements will greatly enhance the integrity and durability of the evaporative emission control system. However, even these new designs will not eliminate vapor recovery system leaks or purge system component failures which could result in high in-use evaporative emissions.

Therefore, EPA is proposing that manufacturers include evaporative emission system monitoring as part of the OBD system. The OBD system should detect a problem and illuminate the MIL when any leak or other malfunction of the vapor recovery or purge system has caused evaporative emissions of the vehicle to increase by an amount which would be equivalent to 2.0 grams per test or more.

An OBD system that can detect both purge activity loss and evaporative system leaks will be capable of tracking likely occurrences of both running loss and engine-off evaporative emissions. EPA has not yet finalized a test procedure or standard for running loss emissions. However, systems for the control of running loss emissions will be designed such that malfunctions likely to cause high running loss emissions (e.g., malfunctioning solenoid) would also result in high evaporative emissions. Consequently, EPA is proposing to verify OBD performance by testing vehicles over the revised evaporative emission test sequence, which includes measurement of running losses.

California's OBD II regulations require monitoring only the purge system. Thus, problems associated with the vapor recovery system could go undetected. At the time California adopted its OBD II regulations, it was unable to determine that an OBD system could be developed which monitored vapor recovery system performance. Thus OBD II was adopted with a limited scope of potential control.

Due to technical constraints, EPA also considered limiting the scope of these regulations to include only a functional check of the purge system. Such an option could not assure that vapor recovery system problems were detected or corrected. Also, a functional check of the purge system would not necessarily detect leaks in the purge system which could cause excess evaporative emissions. Finally, manufacturers have expressed concern with being able to determine when vapors should be present in the purge system. For example, under cold ambient conditions, insufficient vapors might be generated at the tank. A purge monitoring system which attempted to detect hydrocarbon flow under these conditions might incorrectly signal a system failure. A system which only detected air flow would not need vapors in the system; however, it could not detect major system problems such as disconnected hoses.

EPA has become aware of one system under development which seems to not only allow reliable monitoring of the purge system, but also of the vapor recovery system. Such a "total system" should be able to detect all malfunction problems which result in excess in-use evaporative emissions.

Several manufacturers are developing evaporative emission OBD systems that not only monitor purge activity, but are also capable of monitoring evaporative emission leaks which may result in excessive evaporative emission. One manufacturer is developing a system capable of monitoring positive and negative (vacuum) pressure in the evaporative emission control system. Components include a pressure/temperature sensor in the fuel tank, a solenoid on the fresh-air vent in the canister, and a two-way acting valve that vents-off excess pressure and lets in air during excess vacuum. During OBD monitoring, the OBD system energizes the solenoid and protection valve, shutting off both vents to the atmosphere, and opens the purge valve. This creates a negative pressure throughout the evaporative emission control system from the engine to the fuel tank. Leaks in the system, such as a disconnected hose, will cause a loss in negative pressure which can be detected by the pressure sensor.

EPA is currently performing tests to determine the sensitivity of this method to very small leaks in the evaporative emission control system. EPA is also addressing issues such as the effect of low pressure evaporative control systems on the resolution of this detection method, the effect of in-tank control valves on an OBD system's ability to monitor negative pressure throughout the entire evaporative emission system and the effect of vapor regeneration rate in the fuel tank due to returning fuel from the pressurized fuel system on the resolution of this detection method.

The current evaporative emission standard expects that systems will be designed to control all sources of fuel-related evaporative emissions. The 2.0 g/test standard provides a tolerance to allow for possible hydrocarbon sources other than fuel evaporation. Because the type of OBD system described above has not been fully evaluated, EPA is proposing an emission threshold which would allow evaporative emission due to a single type of control system problem to increase as much as the equivalent of 2.0 g on the evaporative emission test. Multiple leaks, for example, which would be detectable by the system would be grouped together and not treated individually in determining whether a 2.0 g/test increase was attributable to a single cause. Comments and data are requested on the appropriateness of the proposed threshold level.

EPA is also concerned about the rate of fuel vaporization versus the ability of the system to generate a vacuum. It may be possible, on high temperature days with a fuel of sufficiently high vapor pressure, for the fuel to vaporize at a

[20] 55 FR 1914 (January 19, 1990).

faster rate than the system's ability to create a vacuum. In such a case, the system's inability to create a vacuum may be interpreted as a leak within an otherwise properly operating system. The Agency has no data substantiating this concern and requests comments and supporting data either substantiating or refuting it. Comments should consider the Agency's regulations limiting vapor pressures of in-use fuels.

VI. Environmental Impact

The details of EPA's estimate of environmental impact are included in the Regulatory Impact Analysis to this rule which has been placed in the public docket. The following briefly summarizes that analysis.

The air quality benefits of the proposed rule are based on EPA models of the in-use fleet. Adjustments were made to account for trends in the fleet (e.g. higher percent of fuel injected designs are expected in the 1994–1996 models compared to now). Adjustment was also made anticipating the air quality benefit EPA expects from its proposed evaporative test procedure changes.[21] Different estimates were made for vehicles in areas expected to have I/M programs in place compared to non-I/M areas. EPA then assessed the likelihood of an OBD-induced repair occurring and the expected effect of such additional repairs on vehicle emission performance. These latter factors were based on studies specifically conducted by EPA in support of this rulemaking.[22] Because EPA has insufficient information to quantify the expected benefit, no emission benefit has been included for the impact of improved availability of emission-related service information. Comments are requested which would allow EPA to also quantify this benefit.

Since the environmental benefits occur over time, they were discounted at a 10% discount rate to put them in present value terms. The 10% discount rate is approved by the Office of Management and Budget (OMB) for performing cost/benefit analyses. Clearly, other discount rates may be applicable. The Agency has used both a 10% and a 3% discount rate in the past, and has included both discount rates in the Regulatory Impact Analysis for this proposal.

[21] 55 FR 1914 (January 19, 1990).

[22] See the report prepared by Westat, Inc., "Survey of Vehicle Owners in the On-Board Diagnostic Program, Final Report", July 18, 1990. Also, EPA report "Statistical Analysis of On-Board Diagnostics Repair Effectiveness Test Data". Both reports are in the docket to this proposed rule.

Applying the 10% discount rate yields the following estimate of per vehicle lifetime emission benefits due to the proposed OBD

TABLE I—LIFETIME EMISSIONS REDUCTIONS PER VEHICLE (POUNDS)

	HC	CO	NO_x
LDV			
Exhaust	20.7	216.4	15.4
Evaporative	14.3		
Total	35.0	216.4	15.4
LDT			
Exhaust	37.8	396.8	26.2
Evaporative	37.1		
Total	74.9	396.8	26.2

Air quality benefits were generated using the Agency's MOBILE4 Emission Factors Program. Separate emission factors were generated for I/M and non-I/M areas. The differences in emission factors between the baseline and OBD cases were multiplied by the vehicle miles traveled (VMT) for each year as projected by the Agency's fuel consumption model to determine the tons reduced. The tons reduced when compared to the baseline emissions for each given year as the fleet turns over are shown in Table II.

TABLE II—AIR QUALITY BENEFITS (TONS/YEAR (x10 ^{3}) AND PERCENTAGE REDUCTIONS OF HC, CO, AND NO_x)

	HC ton/yr	Percent	CO ton/yr	Percent	NO_x ton/yr	Percent
LDV						
Non-Attainment Areas:						
1995	0	0.0	0	0.0	0	0.0
2000	37	7.3	297	6.7	29	5.3
2005	126	23.5	1008	22.0	74	13.0
2010	201	35.3	1695	34.5	113	18.5
2015	258	42.0	2149	40.6	143	21.7
Nationwide:						
1995	0	0.0	0	0.0	0	0.0
2000	62	4.6	522	4.6	50	3.9
2005	210	14.9	1791	14.5	129	9.4
2010	293	19.5	2993	22.5	188	12.9
2015	420	26.0	3812	26.7	234	14.8
LDT						
Non-Attainment Areas:						
1995	0	0.0	17	0.6	2	0.7
2000	54	17.5	570	21.3	38	11.8
2005	125	38.1	1158	40.4	79	23.0
2010	182	50.0	1576	49.4	109	28.6
2015	220	54.2	1863	52.5	132	31.3
Nationwide:						
1995	0	0.0	41	0.5	5	0.7
2000	104	12.0	1162	14.9	86	10.5
2005	231	25.1	2320	28.1	168	19.2
2010	331	32.3	3008	33.1	225	23.4
2015	396	34.8	3544	35.1	271	25.3

VII. Economic Impact

A. Effect on Manufacturer Cost and Retail Price Equivalent (RPE)

To comply with many of the provisions made in today's proposal, specific equipment will be required on new vehicles. In addition to these equipment requirements, the need for increased computer size and computing demand will necessitate an expansion of computing capacity, memory, and input/output (I/O) capabilities for the on-board computer. Due to the nature of today's proposal and its basis on system performance without specific design requirements, manufacturers have considerable design flexibility. Therefore, it is difficult to develop cost estimates since a wide variety of approaches toward meeting compliance are available to the industry. The following discussion summarizes the impact on the retail price of a new vehicle imposed by today's proposal for what the Agency considers to be the most probable approach taken by industry to satisfy the proposed OBD requirements. The specific details of individual component costs are provided in the draft RIA which accompanies this proposed rulemaking and has been placed in the public docket. The following describes the types of costs and the methodology employed in determining the effect on retail price equivalent (RPE), the estimated impact on the purchase price of a new vehicle.

1. Component and Associated Hardware Costs

Based on the technical feasibility analysis, EPA identified the likely component and associated hardware (wiring, etc.) which could be necessary for a manufacturer to install to satisfy the proposed OBD requirements. These one-time costs for each of the components and associated hardware were then estimated. If EPA determined the necessary hardware would already be in place (i.e., not added due to these proposed OBD requirements) or that the incremental cost would be negligible, a zero dollar cost was assigned. These individual component and associated cost estimates are as

TABLE III—MANUFACTURER COMPONENT COST ESTIMATES [1]

Crankshaft Sensor	$10.00
Camshaft Sensor	10.00
Oxygen Sensor	20.00
Temperature/Pressure Sensor (EGR Monitor)	5.00
Pressure Sensor (Evaporative Monitor)	9.00
Solenoid (Evaporative Monitor)	5.00
Computer Chips	3-5
Microprocessor	3-6

[1] Costs include installation costs such as fittings and wiring.

EPA evaluated the likely vehicle designs and associated hardware which would be in place for the 1994 through 1996 model years without Federal OBD requirements. The incremental design impact of OBD on the 1994 through 1996 model year fleet was then estimated. The incremental design impact was used to predict the additional hardware and associated costs that the manufacturer would incur in building a fleet to conform to OBD requirements. This cost was averaged over the fleet to determine the following per vehicle hardware costs estimated for a typical manufacturer.

TABLE IV—WEIGHTED MANUFACTURER HARDWARE COSTS

Crankshaft Sensor	$4.70
Camshaft Sensor	1.85
Catalyst Monitor	16.20
EGR Monitor	2.50
Evaporative Monitor	14.00
Computer	16.50
Total	55.75

The estimated total component and associated equipment cost per vehicle to the manufacturer does not include a manufacturer markup for costs that are passed on to the consumer. EPA used a manufacturer markup of 19.2% or $10.70 per vehicle for component and associated equipment costs.

This hardware cost is based on a prediction of design trends through the 1996 model year. These design trends are used to estimate the incremental impact of these proposed OBD requirements. Although EPA expects these design trends would continue (for example, increasing use of downstream oxygen sensors and crank angle sensors), EPA has insufficient information to predict these trends beyond the 1996 model year. Consequently, EPA assumed no increase in the installation rate would occur. The incremental cost in these future years due to OBD, as estimated here by EPA, is overstated to the extent such equipment would have been more frequently installed anyway. EPA asks for comments and information which would help to better estimate design trends beyond the 1996 model year so as to more accurately estimate incremental OBD costs in these future years.

2. Research and Development Cost

Research and development costs constitute a one-time fixed cost to develop basic techniques for OBD. EPA has determined that the basic techniques necessary to meet California's OBD II regulations for exhaust emissions should be satisfactory for meeting Federal OBD regulations. No additional OBD techniques need to be developed. Consequently, manufacturers should incur no new research and development costs because of these proposed Federal OBD rules as they affect exhaust emissions. However, additional testing and calibration costs may be necessary and are estimated below under "application costs."

For evaporative emission control system monitoring, the Federal requirements may require development of monitoring systems different than required to meet California's OBD II rules. As discussed earlier in the Technical Feasibility section, a system identified by EPA which could satisfy the requirements being proposed today would use a pressure transducer and some other hardware to check for system leaks. EPA understands that at least two manufacturers plan to use a similar type of system to satisfy California's OBD II rules. To the extent other manufacturers pursue development of such a system for OBD II, no incremental research and development expense would be incurred by the manufacturers to meet the proposed Federal rules. EPA is uncertain how manufacturers will develop such systems to satisfy OBD II. However, such systems are not extraordinarily sophisticated and should not require significant research and development costs. Considering the wide applicability of such a monitoring system across a manufacturer's product line, the potential research and development cost for evaporative emission control system monitoring is expected to be negligible on a cost per vehicle basis.

3. Application Costs

Efforts to apply newly developed OBD techniques to meet these proposed Federal requirements will include additional engineering, emission and durability testing, and potential recalibration of the OBD system compared to what the manufacturer would otherwise have to do to meet California OBD II requirements. EPA has estimated application engineering costs at $5.20 per vehicle.

4. Warranty

OBD regulations are expected to flag the need for repairs covered by the manufacturer's warranty. The cost to the manufacturer for making these warranty [23] repairs (parts and labor) will occur over the life of the vehicle. They amount to $16.59 per LDV and $23.36 per LDT.

5. Total Manufacturer Cost

Summing the above costs gives a total cost to manufacturers of $77.87 per LDV and $84.64 per LDT.

6. Retail Price Equivalent

A manufacturer markup of 19.2% was then applied to hardware costs and a dealer markup of 5.7% was then applied to the sum of all the above costs, arriving at net RPE estimates of $93.62 per LDV and $100.78 per LDT.

B. Other Consumer Costs

EPA also estimated the cost incurred by a vehicle owner in getting vehicles repaired due to OBD detected problems. These costs include the increased repair costs due to repairs not covered by warranty.

Benefitting the consumer is the decrease in repair costs due to improved repair effectiveness for repairs done independent of OBD detection, in particular the reduced diagnostic time by repair technicians and the subsequent reduction in labor costs. If diagnostic time is reduced by ½ hour per repair due to the proposed OBD system, and labor costs are $45 per hour, the consumer savings can be significant over the course of a vehicle's lifetime during which several repairs may be done. Also, early repair can have fuel economy benefits associated with improved fuel economy resulting from emission control system repairs.[24] The benefit per gallon of fuel saved was estimated by the average retail price, not including taxes. EPA requests comment on whether this is the most appropriate estimate of the benefit of fuel saved. Specifically, some sources suggest the social benefit may be higher due to other costs of fuel consumption not reflected in the retail price of the fuel.[24a]

Consumer costs and savings are summarized below and are completely developed in the accompanying RIA. Items in parentheses represent savings to the consumer.

TABLE V—OTHER CONSUMER COSTS

	LDV	LDT
Repairs not covered by warranty	14.05	20.67
Repair effectiveness	[1](54.00)	(63.00)
Fuel economy effect	(13.65)	(28.39)
Total of other consumer costs	(53.60)	70.72

[1] Parentheses denote negative values.

C. Net Consumer Costs

Summing the RPE and other consumer costs results in an estimated lifetime net consumer cost of $40.01 per LDV and $30.03 per LDT for the proposed federal OBD requirements.

EPA has not been able to adequately quantify some potential cost savings not included in these estimates. Potential cost savings can accrue due to early repairs of malfunctions which, if left undetected and unrepaired, could result in the need for even more costly repairs in the future. Also, improved repair effectiveness should reduce the potential for a part to be unnecessarily replaced in attempting to fix a problem. Repair facilities should also benefit by improved availability of emission-related service information and the availability of generic tools for accessing and using the OBD system in problem diagnosis and repair. These service facility benefits could be passed along to the consumer in the form of lower repair costs. While none of these cost savings have been quantified, all should reduce the cost of OBD implementation. Other information is requested substantiating or allowing EPA to quantify these cost benefits.

VIII. Cost Effectiveness

Using the emission reduction and cost numbers referenced above, cost effectiveness values have been calculated to indicate the total cost per ton of pollutant reduced. Costs were apportioned across the pollutants which would likely be most affected by each aspect of the OBD system. For example, OBD costs for EGR monitoring were attributed to NO_x, whereas misfire detection would most likely have HC and CO reductions. Table VI summarizes the estimated cost effectiveness based on net consumer cost.

TABLE VI—OBD COST EFFECTIVENESS BASED ON NET CONSUMER COST ($/TON) [1]

	HC	CO	NO_x
LDV	1829	68	84
LDT	768	6	14

[1] Calculations use a 10% discount rate.

It is important to note the large impact the repair effectiveness savings have on the net consumer cost and, consequently, the cost effectiveness. Without these repair effectiveness savings, the cost effectiveness increases to $3429 per ton HC, $234 per ton CO, and $2422 per ton NO_x for LDVs, and $1329 per ton HC, $111 per ton for CO, and $1617 per ton NO_x for LDTs at a 10% discount rate. The total cost of the proposed rule would increase from $485 million to roughly $1.2 billion annually without the estimated consumer savings associated with repair effectiveness. While the repair effectiveness savings constitute what the Agency considers to be reasonable estimates, because of their large impact on net costs, specific comments are requested on the analysis used to generate these savings.

IX. Requests for Specific Comments

Specific comments are requested on the effects which enhanced I/M programs would have on the emission benefits of the proposed OBD systems. The emission benefits generated in the supporting analyses for this rule used the Agency's MOBILE4.0 emission factors model which contained no adjustments for the future existence of enhanced I/M programs. To the extent such I/M programs will identify super and high emitters, the emission benefits presented for OBD would likely change.

Specific comments are also requested regarding the repair effectiveness analysis used to estimate other consumer costs and savings. More specifically, data regarding the estimated ½ hour reduced diagnostic time per repair trip is requested.

Also requested is information regarding the percentage of engine-related repairs for which OBD would be expected to provide mechanic assistance. The Agency estimated this value at 21%. Upon analysis of other data sources, the Agency estimated that this value could be as high as 45%.[25]

[23] See RIA for discussion of which repairs are considered to be covered by warranty for this analysis.

[24] Green, K., "Cooperative Test Program Results: Implications for OBD," Memorandum to Robert Larson, U.S. EPA, December 20, 1990.

[24a] Green, D., Oak Ridge National Laboratory, "Quantifying the Costs and Benefits of Automotive Fuel Economy Improvement," presentation at the SAE Government/Industry meeting, Washington DC., May 16, 1991.

[25] Sherwood, Todd, "Percentage of Non-Damage Repairs Detectable by OBD," Memorandum to Rich Theroux, Office of Management and Budget, July 24, 1991.

Also requested are specific comments regarding the effects of OBD minus a Federal OBD rule. It is possible that manufacturers would have begun incorporating advanced OBD technology like that expected by today's proposal based on OBD's potential to improve in-use maintenance and customer satisfaction. The Agency requests comments on how such a natural influx of OBD technology would affect both the estimated costs and benefits of today's proposal.

X. Public Participation

A. Comments and the Public Docket

EPA welcomes comments on any aspect of this proposed rulemaking. All comments should be directed to the Air Docket, Docket No. A–90–35 (see "Addresses" above).

Commenters desiring to submit proprietary information for consideration should clearly distinguish such information from other comments to the greatest possible extent and label it as "Confidential Business Information." Submissions containing such proprietary information should be sent directly to the contact person listed above, and not to the public docket, to ensure that proprietary information is not inadvertently placed in the docket.

If a commenter wants EPA to use a submission labeled as confidential business information as part of the basis for a final rule, then a nonconfidential version of the document, which summarizes the key data or information, should be placed in the public docket. Information covered by a claim of confidentiality will be disclosed by EPA only to the extent allowed and by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies the submission when it is received by EPA, the submission may be made available to the public without further notice to the commenter.

B. Public Hearing

Anyone who wants to present testimony regarding this proposal at the public hearing (see "Dates") should, if possible, notify the contact person listed previously at least seven days prior to the opening day of the hearing. The contact person should be given an estimate of the time required for the presentation of the testimony and notification of any need for audio/visual equipment. Testimony can be scheduled by contacting the designated contact person. A sign-up sheet also will be available at the registration table the morning of the hearing for scheduling additional testimony.

EPA requests that approximately 50 copies of the statement or material to be presented be brought to the hearing for distribution to the audience. In addition, EPA would find it helpful to receive an advance copy of any statement or material to be presented at the hearing at least one week before the scheduled hearing date, in order to give EPA staff adequate time to review such material before the hearing. Such advance copies should be submitted to the contact person listed previously.

The official records of the hearing will be kept open for 30 days following the hearing to allow submission of rebuttal and supplementary testimony. All such submittals should be directed to the Air Docket, Docket No. A–90–35 (see "Addresses").

Mr. Richard D. Wilson, Director of the Office of Mobile Sources, is hereby designated Presiding Officer of the hearing. The hearing will be conducted informally, and technical rules of evidence will not apply. A written transcript of the hearing will be placed in the above docket for review. Anyone desiring to purchase a copy of the transcript should make individual arrangements with the court reporter recording the proceeding.

XI. Administrative Requirements

A. Administrative Designation

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement that a RIA be prepared. EPA has determined that this regulation is major; a draft RIA has been prepared and is available from the above address.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rulemaking.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 783.13) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC 20460 or by calling (202) 382–2740.

Public reporting burden for this collection of information is estimated to vary from 650 to 700 hours per response with an average of 675 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information. These estimates are an addition to the currently approved 15,850 hours per response for this collection.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Impact on Small Entities

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Analysis. EPA has determined that the regulations proposed today will not have a significant impact on a substantial number of small entities. This regulation will affect manufacturers of motor vehicles and motor vehicle engines, a group which does not contain a substantial number of small entities. Further, small motor vehicle manufacturers typically purchase emission control components developed by larger organizations. Finally, waivers are available to any manufacturer, including small manufacturers, that is unable to meet the requirements of this proposal in 1994 or 1995 model years. This waiver provision should assure that small manufacturers have adequate lead time to employ available technology.

This regulation will also positively affect independent repair shops and mechanics. The standardization requirements contained in the regulations proposed today will enhance the ability of independent mechanics to diagnosis and repair malfunctions.

Therefore, as required under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* I certify that this regulation does not have a significant impact on a substantial number of small entities.

XII. Authority

Statutory authority for the proposed emission standards is provided by sections 202(a), 202(m), 208(c) and 301(a) of the Clean Air Act, as amended, 42 U.S.C. 7521(a), 7521(m), 7542(c), and 7601(a).

List of Subjects in 40 CFR Part 86

Administrative practice and procedure, Air pollution control, Gasoline, Motor vehicles, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: September 4, 1991.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, part 86 of title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 86—CONTROL OF AIR POLLUTION FROM NEW AND IN-USE MOTOR VEHICLES AND NEW AND IN-USE MOTOR VEHICLE ENGINES: CERTIFICATION AND TEST PROCEDURES

1. The authority citation for part 86 is revised to read as follows:

Authority: Secs 202, 203, 205, 206, 207, 208, 215, 216, 301(a), Clean Air Act, as amended (42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7549, 7550, and 7601(a)), unless otherwise noted.

2. Section 86.094–2 is proposed to be amended by adding the following definitions in alphabetical order to read as follows:

§ 86.094–2 Definitions.

* * * * *

Enhanced service and repair information means information which is specific for an original equipment manufacturer's brand of tools and equipment.

* * * * *

Generic service and repair information means information which is not specific for an original equipment manufacturer's brand of tools and equipment.

* * * * *

Intermediary means any individual or entity, other than an original equipment manufacturer, which provides service or equipment to automotive technicians.

* * * * *

3. A new § 86.094–17 is proposed to be added to read as follows:

§ 86.094–17 Emission control diagnostic system for 1994 and later light-duty vehicles and light-duty trucks.

(a) All light-duty vehicles and light-duty trucks shall be equipped with an emission control diagnostic system capable of identifying, for each vehicle's useful life, the following types of deterioration or malfunction which could cause emission increases equal to or exceeding the following threshold levels as measured on the Federal Test Procedure:

(1) Catalyst deterioration before it results in an exhaust emission increase of greater than 0.4 g/mi HC, 3.4 g/mi CO, or 1.0 g/mi NOx;

(2) Engine misfire before it results in an exhaust emission increase of greater than 0.4 g/mi HC, 3.4 g/mi CO, or 1.0 g/mi NOx;

(3) Oxygen sensor deterioration before it results in an exhaust emission increase of greater than 0.2 g/mi HC, 1.7 g/mi CO, or 0.5 g/mi NOx;

(4) Any other deterioration or malfunction which occurs in actual use and results in an exhaust emission increase of 0.2 g/mi HC, 1.7 g/mi CO, or 0.5 g/mi NOx or which results in an evaporative emissions increase of 2.0 g/test.

(b)(1) All emission-related components connected to a computer shall, at a minimum, be monitored for circuit continuity. All components required by this section to be monitored shall be evaluated periodically, but no less frequently than once per EPA Urban Dynamometer Driving Schedule as defined in 40 CFR part 86, appendix I, paragraph (a), or similar trip.

(2) At a minimum the emission control diagnostic system shall monitor catalytic converters and oxygen sensors and shall detect misfiring cylinders.

(3) Oxygen sensor deterioration or malfunction which renders it incapable of performing its function as part of the OBD system shall be identified.

(c)(1) The emission control diagnostic system shall record code(s) indicating the status of the emission control system. Absent the presence of any fault codes, separate status codes shall be used to identify correctly functioning emission control systems and those emission control systems which need further vehicle operation to be fully evaluated. Fault codes shall be stored when deterioration or malfunction of the emission control system is detected; the fault code shall identify the type of malfunction.

(2) For a single misfiring cylinder, the fault code(s) shall identify the cylinder; multiple misfiring cylinders need not be identified if a distinct multiple misfire fault code is stored. For vehicles equipped with sequential fuel injection, fuel flow to the misfiring cylinders shall be shut off during periods in which misfire is occurring in excess of a level at which it must be detected.

(3) A fault code shall be stored when the emission control system reverts to a default or secondary mode of operation.

(4) The diagnostic system may erase a fault code if the same fault is not re-registered in at least 40 engine warm-up cycles, and the malfunction indicator light (see paragraph (d) of this section) is not illuminated.

(d) The emission control diagnostic system shall incorporate a malfunction indicator light (MIL) readily visible to the vehicle operator. When illuminated, it shall display "Check Engine," "Service Engine Soon," or a similar phrase. A vehicle shall not be equipped with more than one general purpose malfunction indicator light for emission-related problems; separate specific purpose warning lights (e.g. brake system, fasten seat belt, oil pressure, etc.) are permitted. The use of red for the OBD-related malfunction indicator light is prohibited.

(e) The MIL shall illuminate and remain illuminated when any of the conditions specified in paragraphs (a) and (b) of this section are met. The MIL shall blink under any period of operation during which engine misfire is occurring. The MIL shall also illuminate in the engine-run key position before engine starting or cranking and extinguish after engine starting if no malfunction has previously been detected. If a malfunction has previously been detected, the MIL may be extinguished if the malfunction does not reoccur under similar speed and load conditions on three consecutive trips and no new malfunctions are detected.

(f) *Available diagnostic signals.* (1) Upon detection of the first malfunction of any component or system, "freeze frame" engine conditions present at the time shall be stored in computer memory. Should a subsequent fuel system or misfire malfunction occur, any previously stored freeze frame conditions shall be replaced by the fuel system or misfire conditions (whichever occurs first). Stored engine conditions shall include, but are not limited to engine speed, open or closed loop operation, fuel system commands, coolant temperature, calculated load value, fuel pressure, vehicle speed, air flow rate, and intake manifold pressure if the information needed to determine these conditions is available to the computer. For freeze frame storage, the manufacturer shall include the most appropriate set of conditions to facilitate effective repairs. If the fault code causing the conditions to be stored is erased in accordance with paragraph (c) of this section, the stored engine conditions may also be erased.

(2) The following signals in addition to the required freeze frame information shall be made available on demand through the serial port on the standardized data link connector: Diagnostic trouble codes, engine coolant temperature, fuel control system status (closed loop, open loop, other), fuel trim (if equipped), ignition timing advance, intake air temperature, manifold air pressure (if equipped), engine RPM, throttle position sensor output valve (if equipped), secondary air status (upstream, downstream, or atmosphere; if equipped), calculated load value, and fuel pressure if the information needed to make these signals available is available to the computer. The signals shall be provided in standard units based on SAE specifications incorporated by reference in paragraph (h) of this section. Actual signals shall be clearly identified separately from default value or limp home signals. In addition, the capability to perform bi-directional diagnostic control based on SAE specifications shall be made available on demand through the serial port on the standardized data link connector per SAE specifications as referenced in paragraph (h) of this section.

(3) For all emission control systems for which specific on-board evaluation tests are conducted (catalyst, oxygen sensor, etc.), the results of the most recent test performed by the vehicle, and the limits to which the system is compared shall be available through the serial data port on the standardized data link connector per SAE specifications as referenced in paragraph (h) of this section.

(4) The vehicle identification number (VIN), the OBD requirements to which the vehicle is certified (i.e., California OBD I, California OBD II, or Federal OBD), and the major emission control systems monitored by the OBD system consistent with paragraph (h)(3) of this section, shall be available through the serial data port on the standardized data link connector per SAE specifications as referenced in paragraph (h) of this section.

(g) The emission control diagnostic system is not required to evaluate components during malfunction conditions if such evaluation would result in a risk to safety or component failure.

(h) The emission control diagnostic system shall provide for standardized access and conform with the following Society of Automotive Engineers (SAE) and ISO standards. The following ISO and draft SAE documents are incorporated by reference. This incorporation by reference [WILL BE SUBMITTED FOR APPROVAL] by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the ISO and the draft SAE documents may be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001. Copies may be inspected at Docket No. A–90–35 at EPA's Air docket (LE–131), room 1500 M, 1st Floor, Waterside Mall, 401 M Street, SW., Washington, DC, or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

(1) SAE J1850 "Class B Data Communication Network Interface" shall be used as the on-board to off-board communications protocol. Alternatively, ISO 9141–CARB "Road Vehicles Diagnostic Systems—CARB requirements for the interchange of digital information" may be used. All emission related messages sent to the J1978 scan tool (see paragraph(h)(2) of this section) over a J1850 data link shall use the Cyclic Redundancy Check and the three byte header, and shall not use inter-byte separation or checksums.

(2) Communication (without operator intervention to determine communication protocol) with diagnostic tools meeting the specifications of SAE J1978 "Generic Scan Tool."

(3) Basic diagnostic data (as specified in paragraph (f) of this section) shall be provided in the format and units in SAE J1979 "E/E Diagnostic Test Modes." Basic bi-directional diagnostic capability shall be available and be consistent with SAE J1979 messages and SAE J2205 Draft "Expanded Diagnostic Protocol for OBD II Scan Tool."

(4) Fault codes shall be consistent with SAE J2012 "Recommended Format and Messages for Diagnostic Trouble Codes," Part C.

(5) SAE J1962 "Diagnostic Connector."

(6) Limitation of Access—Any limitation of access to the diagnostic system shall be consistent with §§ 86.094–18 and 86.094–38(c). Access to vehicle calibration data, vehicle odometer, and keyless entry codes can be limited under the provisions of § 86.094–18.

(i) Upon application by the manufacturer, the Administrator may waive the requirements of this section for specific components of any class or category of light-duty vehicles or light-duty trucks for model years 1994 or 1995 (or both) if compliance would be infeasible or unreasonable considering such factors as, but not limited to, technical feasibility, lead time and production cycles, including phase-in or phase-out of engines or vehicle designs and programmed upgrades of computers. In its application the manufacturer must demonstrate that reasonable steps have been taken to comply with as many requirements of this section as practicable, given leadtime, product development cycles, and other constraints.

(j) For model years [TO BE DETERMINED], demonstration of compliance with California OBD II requirements shall satisfy the requirements of this section.

4. A new § 86.094–18 is proposed to be added to read as follows:

§ 86.094–18 Tampering prevention.

Any vehicle with emission control computer instructions shall include features to deter modification except as authorized by the manufacturer. Any reprogrammable computer codes or operating parameters must be resistant to tampering and the computer and any related maintenance instructions must conform to the provisions in SAE J2186 "E/E Data Link Security." A removeable calibration memory chip shall be potted or encased in a sealed container. The SAE J2186 documents are incorporated by reference. This incorporation by reference [WILL BE SUBMITTED FOR APPROVAL] by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of SAE J2186 may be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001. A copy may be inspected at Docket No. A–90–35 at EPA's Air docket (LE–131), room 1500 M, 1st Floor, Waterside Mall, 401 M Street, SW., Washington, DC, or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

5. Section 86.094–21 is proposed to be amended by adding and reserving paragraph (g) and by adding paragraphs (h) and (i) to read as follows:

§ 86.094–21 Application for certification.

* * * * *

(g) [Revised]

(h) For each engine family incorporating an emission control diagnostic system, the manufacturer shall submit the following information:

(1) Detailed written information fully describing the functional operation characteristics of the diagnostic system.

(2) The general method of detecting malfunctions for each emission-related component.

(3) A plan for making necessary service information available. Upon determination by EPA or the manufacturer that the submitted plan is not appropriately fulfilling its intent or

could better fulfill its intent, the opportunity shall exist to revise the plan to improve its implementation.

(i) The manufacturer shall describe provisions taken to prevent tampering with emission control computer instructions.

6. A new § 86.094–25 is proposed to be added to read as follows:

§ 86.094–25 Maintenance.

(a)–(c) [Reserved]

(d) For durability data vehicles equipped with an emission control diagnostic system, unscheduled maintenance shall only be performed if the malfunction is detected by the OBD system and the MIL is illuminated.

7. Section 86.094–30 is proposed to be amended by adding paragraphs (f) and (g) to read as follows:

§ 86.094–30 Certification.

* * * * *

(f) Emission control diagnostic service information plan.

(1) For any engine family having an emission control diagnostic system, the Administrator shall review the manufacturer's plan for making necessary service information available. Following review of the plan, the Administrator shall either:

(i) Approve the plan if it satisfies the requirements of this section and the intent of section 202(m)(5) of the Act, or

(ii) Require the manufacturer to revise the plan upon determination that it fails to comply with the requirements of this section or the intent of section 202(m)(5) of the Act.

(2) The Administrator shall withhold certification until the submitted plan is approved.

(3) If the Administrator determines at any time that either a manufacturer has failed to implement an approved plan or an approved plan fails to satisfy the requirements of this section or the intent of section 202(m)(5) of the CAA, he shall notify the manufacturer. At the manufacturer's request, the Administrator will meet with the manufacturer to attempt to resolve the identified deficiencies.

(4) A manufacturer may be subject to a penalty of up to $25,000 per day of violation for failure to make available the information required by this section.

(g) For engine families required to have an emission control diagnostic system, certification will not be granted if, for any test vehicle, the malfunction indicator light does not illuminate under any of the following circumstances:

(1) A catalyst is replaced with a deteriorated or defective catalyst resulting in an increase in emissions of greater than 0.4 g/mi HC or 3.4 g/mi CO or 1.0 g/mi NO_x on a normal temperature (20 to 30 °C) emission certification test.

(2) A misfire condition is induced resulting in an increase in emissions of greater than 0.4 g/mi HC or 3.4 g/mi CO or 1.0 g/mi NO_x on a normal temperature (20 to 30 °C) emission certification test.

(3) Any oxygen sensor is replaced with a deteriorated or defective oxygen sensor, or the operation of such a sensor is simulated, resulting in an increase in emissions of 0.2 g/mi HC or 1.7 g/mi CO or 0.5 g/mi NO_x on a normal temperature (20 to 30 °C) emission certification test.

(4) An emission-related component connected to a computer is electrically disconnected.

8. Section 86.094–35 is proposed to be amended by adding paragraph (i) to read as follows:

§ 86.094–35 Labeling.

* * * * *

(i) All light-duty vehicles and light-duty trucks shall comply with SAE Recommended Practices J1877 and J1892. SAE J1877 and J1892 are incorporated by reference. This incorporation by reference [WILL BE SUBMITTED FOR APPROVAL] by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001. Copies may be inspected at Docket No. A–90–35 at EPA s Air Docket (LE–131), room 1500M, lst Floor, Waterside Mall, 401 M Street, SW., Washington, DC, or at the office of the Federal Register, 1100 L Street, NW., Room 8401, Washington, DC.

9. A new § 86.094–38 is proposed to be added to read as follows:

§ 86.094–38 Maintenance instructions.

(a)–(f) [Reserved]

(g) *Emission control diagnostic service information.* (1) Manufacturers shall furnish or cause to be furnished to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines, or the Administrator upon request, any and all information including, but not limited to, service manuals, technical service bulletins, recall service information, data stream information, bi-directional control information, and training information, needed to make use of the OBD system; or such other information including instructions needed for making emission-related diagnosis and repairs unless such information is protected by section 208(c) as a trade secret. No such information may be withheld under section 208(c) of the Act if that information is provided (directly or indirectly) by the manufacturer to franchised dealers or other persons engaged in the repair, diagnosing, or servicing of motor vehicles or motor vehicle engines.

(2) Emission control diagnostic system and emission-related diagnosis and repair information not provided directly or indirectly by manufacturers to persons engaged in repairing or servicing of motor vehicles or motor vehicle engines, but needed by such persons to make emission-related diagnosis and repairs (e.g., functional control strategies, pin voltages at the breakout connector, etc.), shall be made available by manufacturers to intermediaries for distribution and/or conversion to an appropriate form as may be necessary to assure its timely use by persons servicing or repairing motor vehicles or motor vehicle engines.

(3) The manufacturer shall publish in factory service manuals a normal range for the calculated load value and mass air flow rate at idle and at 2500 RPM (no load, in neutral or park). If the total fuel command trim is made up by more than one source, all fuel trim signals shall be available.

(4) When information is provided through an intermediary, the manufacturer shall be responsible for ensuring that it is available to all persons engaged in the servicing and repairing of motor vehicles in accordance with the requirements of this section and the intent of section 202(m)(5) of the Act.

(5) When the same exact information is provided by a manufacturer to dealerships and independent technicians, the cost to independent technicians shall not exceed the lowest price at which it is provided to any authorized dealerships.

(6) All other information shall be made available to persons referred to in this section at a fair and reasonable price, as determined by the Administrator. In reaching a decision, the Administrator shall consider all relevant factors, including, but not limited to, the cost to the manufacturer of preparing and/or providing the information, the type of information, the format in which it is provided, and the price charged by other manufacturers for similar information.

(7) Any information which is not provided at a fair and reasonable price shall be considered unavailable.

(8) Manufacturers shall make enhanced service information available to independent technicians within 30

days immediately following model introduction.

(9) Manufacturers shall make generic service information available to independent technicians within 8 months immediately following model introduction.

(10) Manufacturers shall make preliminary generic and enhanced data stream information available at least three months immediately preceding model introduction.

(11) Manufacturers shall make final generic and enhanced datastream information available within three months immediately following model introduction.

(12) Prior to the availability of information required by paragraphs (g)(6) and (g)(7) of this section manufacturers shall provide a method, the same as or similar to that available to dealerships, through which independent technicians may obtain prompt and appropriate service and repair information.

(13) All other information which is needed (directly or indirectly) to service and repair emission-related systems or components of motor vehicles or motor vehicle engines shall be made available in a timely manner, as determined by the Administrator. In determining whether such information is provided in a timely manner, the Administrator shall consider all relevant factors, including, but not limited to, whether adequate time has been provided for conversion to an appropriate format, reproduction, and notification and distribution to independent technicians who require the information.

(14) The information required by this section shall be distributed in a manner which assures reasonable access without substantial delay, as determined by the Administrator, by any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines.

(15) The information required by this section. shall be provided as follows:

(i) Beginning with the 1994 model year, manufacturers may use electronic or print media to distribute information. Beginning in model year 1998, manufacturers may use electronic or print media to distribute information, but must make electronic media available.

(ii) Beginning with the 1994 model year, all service information and training instructions shall conform to the guidelines for common terms contained in SAE J1930 Revised "Electrical/Electronic Systems Diagnostic Terms, Definitions, Abbreviations, and Acronyms." J1930 is incorporated by reference. This incorporation by reference [WILL BE SUBMITTED FOR APPROVAL] by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and CFR part 51. Copies may be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001. Copies may be inspected at Docket No. A–90–35 at EPA's Air Docket (LE–131), room 1500 M, 1st Floor, Waterside Mall, 401 M Street, SW., Washington, DC or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

(iii) Beginning in model year 1996, manufacturers shall use the format specified in SAE's draft J2008 of recommended practices entitled "Recommended Organization of Service Information." J2008 is incorporated by reference. This incorporation by reference [WILL BE SUBMITTED FOR APPROVAL] by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001. Copies may be inspected at Docket No. A–90–35 at EPA's Air Docket (LE–131), room 1500M, 1st Floor, Waterside Mall, 401 M Street, SW., Washington, DC, or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

(iv) If a manufacturer provides direct digital communication with the service industry, the manufacturer shall support the guidelines in SAE J2187 Draft "Remote Diagnostic/Service Communications," beginning with the 1996 model year. J2187 is incorporated by reference. This incorporation by reference [WILL BE SUBMITTED FOR APPROVAL] but the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001. Copies may be inspected at Docket No. A–90–35 at EPA's Air Docket (LE–131), room 1500 M, 1st Floor, Waterside Mall, 401 M Street, SW., Washington, DC or at the Office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

(16) Manufacturers shall notify independent service facilities that information is available by appropriate means; for example, advertisement in trade publications.

(17) For purposes of paragraph (g) of this section, "person engaged in the repairing or servicing of motor vehicles or motor vehicle engines" includes, but is not limited to, intermediaries, tool and software manufacturers, aftermarket information providers, franchised dealerships, service suppliers (warehouse distributors, auto parts retailers, franchised retailers, and parts manufacturers and rebuilders), educational institutions, I/M administrators, vehicle manufacturers, service providers (independent service/repair garages, franchised repair outlets, and auto parts retailers with service bays), and individual owners/operators.

10. Section 86.095–30 is proposed to be amended by adding paragraphs (f) and (g) to read as follows:

§ 86.095–30 Certification.

* * * * *

(f) *Emission control diagnostic service information plan.* (1) For any engine family having an emission control diagnostic system, the Administrator shall review the manufacturer's plan for making necessary service information available. Following review of the plan, the Administrator shall either:

(i) Approve the plan if it satisfies the requirements of this section and the intent of section 202(m)(5) of the Act; or

(ii) Require the manufacturer to revise the plan upon determination that it fails to comply with the requirements of this section or the intent of section 202(m)(5) of the Act.

(2) The Administrator shall withhold certification until the submitted plan is approved.

(3) If the Administrator determines at any time that either a manufacturer has failed to implement an approved plan or an approved plan fails to satisfy the requirements of this section or the intent of section 202(m)(5) of the CAA, he shall notify the manufacturer. At the manufacturer's request, the Administrator will meet with the manufacturer to attempt to resolve the identified deficiencies.

(4) A manufacturer may be subject to a penalty of up to $25,000 per day of violation for failure to make available the information required by this section.

(g) For engine families required to have an emission control diagnostic system, certification will not be granted if, for any test vehicle, the malfunction indicator light does not illuminate under any of the following circumstances:

(1) A catalyst is replaced with a deteriorated or defective catalyst resulting in an increase in emissions of greater than 0.4 g/mi HC or 3.4 g/mi CO or 1.0 g/mi NO_x on a normal temperature (20 to 30 °C) emission certification test.

(2) A misfire condition is induced resulting in an increase in emissions of greater than 0.4 g/mi HC or 3.4 g/mi CO or 1.0 g/mi NO_x on a normal

temperature (20 to 30 °C) emission certification test.

(3) Any oxygen sensor is replaced with a deteriorated or defective oxygen sensor, or the operation of such a sensor is simulated, resulting in an increase in emissions of 0.2 g/mi HC or 1.7 g/mi CO or 0.5 g/mi NOx on a normal temperature (20 to 30 °C) emission certification test.

(4) An emission-related component connected to a computer is electrically disconnected.

11. Section 86.095–35 is proposed to be amended by adding paragraph (i) to read as follows:

§ 86.095–35 Labeling.

* * * * *

(i) All light-duty vehicles and light-duty trucks shall comply with SAE Recommended Practices J1877 and J1892. SAE J1877 and J1892 are incorporated by reference. This incorporation by reference [WILL BE SUBMITTED FOR APPROVAL] by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001. Copies may be inspected at Docket No. A–90–35 at EPA's Air Docket (LE–131), Room 1500M, 1st Floor, Waterside Mall, 401 M Street, SW., Washington, DC, or at the office of the Federal Register, 1100 L Street, NW., room 8401, Washington, DC.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 356 and 369

Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 356 and 369

[Docket No. 81N-0033]

RIN 0905-AA06

Oral Health Care Drug Products for Over-the-Counter Human Use; Amendment to Tentative Final Monograph to Include OTC Relief of Oral Discomfort Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the tentative final monograph (proposed rule) for over-the-counter (OTC) oral health care drug products by adding the conditions for which OTC relief of oral discomfort drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products and public comments on the advance notice of proposed rulemaking (published in the **Federal Register** of May 25, 1982; 47 FR 22712) to establish 21 CFR part 354 and after considering the tentative final monograph on OTC oral health care drug products (published in the **Federal Register** of January 27, 1988; 53 FR 2436). This proposal incorporates the rulemaking for OTC relief of oral discomfort drug products into the rulemaking for OTC oral health care drug products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by January 22, 1992. Written comments, objections, or requests for oral hearing on the combination of potassium nitrate and an anticaries active ingredient, identified in proposed § 356.26(h), by November 25, 1991. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 120 days for comments and objections instead of the normal 60 days. The agency is requesting comments and objections regarding proposed § 356.26(h) within a 60-day period so that the marketing status of a combination drug product containing potassium nitrate and an anticaries active ingredient can be determined in an expeditious manner. New data by September 24, 1992. Comments on the new data by November 24, 1992. Written comments on the agency's economic impact determination by January 22, 1992.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 25, 1982 (47 FR 22760), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC oral health care drug products, together with the recommendations of the Advisory Review Panel on OTC Oral Cavity Drug Products (Oral Cavity Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in the drug class. Interested persons were invited to submit comments by August 23, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by September 22, 1982.

In the **Federal Register** of July 30, 1982 (47 FR 32953), in response to a request for an extension of time, the comment period and reply comment period for OTC oral health care drug products were extended to November 22, 1982 and to December 22, 1982, respectively. In the **Federal Register** of December 28, 1982 (47 FR 57739), the reply comment period was extended to January 21, 1983.

The first part of the agency's proposed regulation, in the form of a tentative final monograph for OTC oral health care (anesthetic/analgesic, astringent, debriding agent/oral wound cleanser, and demulcent) drug products was published in the **Federal Register** of January 27, 1988 (53 FR 2436).

In the **Federal Register** of May 25, 1982 (47 FR 22712), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC relief of oral discomfort drug products, together with the recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (Dental Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by August 23, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by September 22, 1982.

In the **Federal Register** of July 30, 1982 (47 FR 32952), in response to a request for an extension of time, the comment period and reply comment period for OTC relief of oral discomfort drug products were extended to October 22, 1982 and to November 22, 1982, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Dental Panel were placed on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking on OTC relief of oral discomfort drug products, one drug manufacturers' association, one professional association, one consumer group, nine drug manufacturers, and two health care professionals submitted comments. Copies of the comments received are on public display in the Dockets Management Branch (address above) under Docket No. 80N-0228 and will be incorporated into Docket No. 81N-0033.

The Dental Panel was charged to review and evaluate dental and dental care drug products including agents for oral mucosal injury and agents for the relief of oral discomfort. Oral mucosal injury drug products are OTC preparations intended to relieve oral soft tissue injury by cleansing or promoting the healing of minor oral wounds or irritations (48 FR 33984). Agents for the relief of oral discomfort are OTC preparations to treat minor trauma or irritations of a transient nature to the gums or teeth (47 FR 22712 at 22717). The Oral Cavity Panel was charged to evaluate ingredients in OTC preparations intended for use for the temporary relief of symptoms due to minor irritations, inflammations, and other lesions of the mucous membranes of the oral cavity (47 FR 22760 at 22765). Because of the overlap between the rulemaking on OTC oral mucosal injury drug products and the rulemaking on OTC oral health care drug products, the agency incorporated that part of the oral mucosal injury rulemaking that includes oral wound cleansers into the tentative final monograph for OTC oral health care drug products published in the **Federal Register** of January 27, 1988 (53 FR 2436). Likewise, because the ingredients reviewed as relief of oral discomfort agents and the ingredients

reviewed as oral health care drug products are indicated for similar therapeutic purposes in the same area (i.e., the oral cavity), in this document, the agency is proposing to combine the two rulemakings into the rulemaking on OTC oral health care drug products (21 CFR part 356). Accordingly, the advance notice of proposed rulemaking to establish 21 CFR part 354 is being merged into the rulemaking to establish 21 CFR part 356. The intent of the combined rulemaking is to identify those ingredients that are generally recognized as safe and effective in temporarily relieving the symptoms associated with minor oral wounds or other irritations of the mouth, gums, or teeth. Combining these two rulemakings into one will result in more consistent labeling on these OTC drug products intended for topical use in the oral cavity and in less confusion for the manufacturers of these drug products and for the consumer.

FDA is issuing the tentative final monograph for OTC oral health care drug products in several segments. This document amends the first segment that addressed OTC oral health care anesthetic/analgesic, astringent, debriding agent/oral wound cleaner, and demulcent drug products (published in the **Federal Register** of January 27, 1988; 53 FR 2436). A subsequent segment of the tentative final monograph on OTC oral health care drug products will contain the agency's responses to comments regarding oral health care antimicrobial drug products and comments on the drug or cosmetic status of certain oral health care ingredients and claims. This segment will be published in a future issue of the **Federal Register**. Another segment will address comments received in response to the advance notice of proposed rulemaking that results from the agency's call-for-data for antiplaque ingredients published in the **Federal Register** of September 19, 1990 (55 FR 38560).

The advance notice of proposed rulemaking, which was published in the **Federal Register** on May 25, 1982 (47 FR 22712), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated as a "tentative final monograph." In this tentative final monograph (proposed rule) to amend part 356 (proposed in the **Federal Register** of January 27, 1988; 53 FR 2436), FDA states for the first time its position on the establishment of a monograph that includes OTC relief of oral discomfort drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC oral health care drug products and will include relief of oral discomfort drug products.

This proposal constitutes FDA's tentative adoption of the Dental Panel's conclusions and recommendations on OTC relief of oral discomfort drug products, as modified on the basis of the comments received and the agency's independent evaluation of that report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above) either under Docket No. 80N–0228 or 81N–0033. All information on file under Docket No. 80N–0228 is being incorporated into Docket No 81N–0033. These modifications are reflected in the following summary of the comments and FDA's responses to them.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC relief of oral discomfort drug products (47 FR 22712), the agency suggested that the conditions included in the monograph (Category I) be effective 6 months after the date of publication of the final monograph in the **Federal Register** and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 6 months after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to these drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling

and reformulate their products and have them in compliance in the marketplace.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of January 30, 1973 (38 FR 2781) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking for OTC relief of oral discomfort drug products. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

A. General Comments on Relief of Oral Discomfort Drug Products

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464 at 9471 to 9472) and in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–698 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. One comment was vitally concerned about certain aspects of the Dental Panel's report and recommended monograph because, if these recommendations are adopted as substantive rulemaking, the firm's ability to stay in business would be drastically affected. Although agreeing that OTC drugs should be generally recognized as safe and effective and not misbranded, the comment was concerned that the direction taken by that Panel and the agency would eliminate competitive differences between OTC drug products available in the marketplace. The comment argued that these differences, which appear small and inconsequential by scientific standards, are of vital importance to the consumer and also help maintain our economic system. The comment further argued that any system of review that forces all marketed products to be equal in composition and claims is to the advantage of firms that can afford to do the most advertising.

The comment named four of its OTC drug products that would be affected by the Dental Panel's recommendations and stated that these four products represent about two-thirds of the company's total sales. The comment stated that, if required, these four drug products could be reformulated and relabeled, but at an increased cost to the company as well as to the consumer. The comment added that it would be prepared to document these costs at the appropriate time. The comment claimed that, unlike larger companies, its firm is not equipped to do product testing and that it is not easy to get dental people or dental schools to perform tests at a reasonable price on products such as those manufactured by the company.

In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of the combined economic impacts of the entire OTC drug review. Based on this assessment, the agency has determined that no OTC drug review rule, including this proposed rule on drug products for the relief of oral discomfort, is a major rule as defined by Executive Order 12291. Nor is any one OTC drug review rule likely to have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act. The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act. However, the assessment did recognize the possibility that some individual monographs might have a significant impact on small firms. Therefore, the assessment included a discretionary regulatory flexibility analysis that identified ways of reducing burdens on small firms. The agency invited public comment in the advance notice of proposed rulemaking (47 FR 22712) regarding any impact this rulemaking would have on OTC drug products for the relief of oral discomfort. Comments were to be accompanied by appropriate documentation. Although comments were received on this matter, no documentation was submitted with this or other comments that would alter the determination reached by the agency in the economic assessment that there is no legal basis for any preferential waiver, exemption, or tiering strategy for small firms compatible with the public health requirements of the Federal Food, Drug, and Cosmetic Act (the act). In this proposal the agency is again inviting public comment on the economic impact of the rule.

The agency recognizes that some changes in the current manufacturing and marketing practices of OTC drug products for the relief of oral discomfort may result if the Dental Panel's recommendations are fully implemented. In reformulating a number of OTC drug products for the relief of oral discomfort to comply with the final monograph, there will be fewer active ingredients used and, consequently, some of the differences among these products will disappear from the marketplace. However, some product differences in active and inactive ingredients will remain. In addition, under the agency's revised labeling policy for OTC drug products, some labeling variations concerning claims will be allowed. (See comment 12 below.) Firms will continue to be permitted to market competitive OTC drug products for the relief of oral discomfort that either comply with the conditions of the monograph or are the subject of an approved new drug application.

3. One comment objected to the Dental Panel's recommendation that beeswax should not be included as an inactive ingredient in products intended for use in an open tooth cavity for the relief of toothache (47 FR 22712 at 22726). The comment contended that the Panel's position that beeswax, because of its occlusive properties, exposes the consumer to unnecessary risks was based on opinion and not on data. The comment added that the Panel was not charged with reviewing inactive ingredients and that, instead of condemning beeswax, the Panel should have expressed its concern and recommended that a study of occlusivity be conducted.

The comment submitted many consumer letters and two in vitro studies in support of the safety of beeswax as an inactive ingredient in toothache relief products (Ref. 1). The consumer letters contained complaints about the reformulation of a toothache product from one that contains beeswax to one that conforms to the Dental

Panel's recommendations and does not contain beeswax. The comment stated that consumer response to the reformulated product was highly unfavorable, unlike the almost completely favorable response to the beeswax formulation. The product was subsequently reformulated to the beeswax formulation in order to maintain this product on the market.

The first submitted study involved an apparatus for measuring the in vitro transfer of air pressures of 25, 50, 75 and 100 millimeters of mercury from the apex of the tooth, through a root canal that was packed with cotton, to an open tooth cavity that was packed with "toothache gum" containing beeswax. The purpose was to show that the gum formulation does not hinder the transfer of gas pressure and therefore is not occlusive. The second in vitro study was designed to measure the ability of C^{14}-glucose in an artificial saliva mixture to migrate from the bottom of a tooth cavity through "toothache gum" containing beeswax that was packed into the tooth cavity. The comment stated that the results of the studies show that beeswax does not hinder the flow of soluble materials into and out of tooth cavities and, except at very low pressures, does not hinder the transfer of gas pressure. The comment contended that these studies demonstrating the safety of using a "toothache gum" containing beeswax in an open tooth cavity negate the Panel's "opinion" that beeswax would prevent the escape of gases and fluids from a degenerating pulp.

The agency agrees with the Dental Panel that it is inappropriate to use inactive ingredients that will form an occlusive barrier in drug products for the relief of toothache in an open tooth cavity. The Panel believed, and the agency concurs, that any occlusive agent such as beeswax should not be included in such products because "the use of occlusive agents * * * in a tooth cavity * * * exposes the consumer to unnecessary safety risks." The Dental Panel reasoned that "any agent which acts as a physical barrier and does not permit the escape of fluids and gases from a degenerating pulp * * * may result in increased pain and possible spread of infection." (See 47 FR 22712 at 22726.)

The agency finds that the submitted in vitro data described above cannot be extrapolated to a vital or partially vital tooth set in a bony socket surrounded by soft tissue in an otherwise healthy patient where the bacterial flora of the saliva is constantly changing. Therefore, in the agency's judgment the submitted data are inadequate to support the safety of including beeswax as an inactive ingredient in drug products for the relief of toothache. The agency concludes that in this situation clinical studies are necessary to demonstrate safety and effectiveness of the product. Such studies could be very short in duration.

The OTC drug review is an active, not an inactive, ingredient review, and the Dental Panel's recommendations concerning inactive ingredients in toothache relief drug products are not included in this document. However, agency regulations in § 330.1(e) (21 CFR 330.1(e)) state that one of the conditions under which OTC drug products are generally recognized as safe and effective is that the product contain "only suitable inactive ingredients which are safe * * * and do not interfere with the effectiveness of the preparation." The agency is concerned that occlusive inactive ingredients such as beeswax may compromise the safe use of products for the relief of toothache not only because they may prevent the escape of fluid and gases from a degenerating tooth pulp, but also because they can form temporary fillings that would encourage the consumer to significantly delay treatment by a dentist.

To support this position, the agency notes that several of the consumer complaints about the comment's reformulation of its product to one that does not contain beeswax were based on the consumer's inability to use the product to delay or completely avoid seeking professional help in resolving the underlying condition that caused the toothache. The agency believes that a toothache relief product in a dosage form that lends itself to the formation of a temporary filling that allows a consumer to self-treat an open tooth cavity on a long-term basis provides an unwarranted opportunity for consumers to misuse such products. In regulating drug products for the relief of toothache that are subject to the final monograph, the agency will consider whether beeswax, or any other inactive ingredient that lends itself to the formation of a temporary filling, compromises the safe use of toothache products by preventing the escape of fluid and gases from a degenerating tooth pulp. If the agency makes such a determination, appropriate regulatory action will be taken.

The agency's comments and evaluation of the data are on file in the Dockets Management Branch (address above) (Ref. 2).

References

(1) Comment No. C00006, Docket No. 80N-0228, Dockets Management Branch.

(2) Letter from W.E. Gilbertson, FDA, to B.L. Pritz, Grandpa Brands Company, coded LET17, Docket No. 80N-0228, Dockets Management Branch.

B. Comments on Specific Relief of Oral Discomfort Drug Products

4. One comment from a professional association stated that the association recognizes the use of benzocaine and butacaine sulfate as safe and effective for OTC use as analgesics for the oral mucosa, but does not recognize the effectiveness of phenolic preparations for that use.

The association's view of benzocaine and butacaine sulfate for use as oral mucosal analgesics is in agreement with the Dental Panel's Category I recommendation (47 FR 22712 at 22757 to 22758). The Dental Panel concluded that penolic preparations of 0.25 to 1.5 percent phenol and phenolate sodium, if used as directed, are safe and effective as oral mucosal analgesics for the relief of oral discomfort (47 FR 22739 to 22740). The Oral Cavity Panel also reviewed 0.5 to 1.5 percent phenol and phenolate sodium (47 FR 22760 at 22814 to 22815) and recognized the safety and effectiveness of these ingredients as OTC anesthetic/analgesics for topical use on the mucous membranes of the mouth and throat.

In this amendment, the agency is proposing to include oral mucosal analgesics in the anesthetic/analgesic therapeutic category proposed in the first segment of the tentative final monograph for OTC oral health care drug products. (See Part II. paragraph B.5. below.) The ingredients and labeling for oral health care anesthetic/analgesics included in this amendment reflect the agency's evaluation of both Panels' recommendations.

After evaluating both Panels' recommendations regarding the effectiveness of phenol for topical use on the mucous membranes of the mouth and throat, the agency concurs with the Panels' conclusions that phenol is an effective oral mucosal analgesic. Further, the comment did not submit any data or other information to support its position that phenol is not effective as an oral mucosal analgesic nor did it offer any criticism of the data used by the Panel to support the effectiveness of phenol as an oral mucosal analgesic.

The Dental Panel recommended a phenol concentration range of 0.25 to 1.5 percent for use as an oral mucosal analgesic, whereas the Oral Cavity Panel recommended 0.5 to 1.5 percent

for anesthetic/analgesic drug products. Based on the available information concerning OTC drug products containing phenol, the agency is proposing that the minimum concentration of phenol for use as an oral mucosal analgesic be 0.5 percent rather than 0.25 percent for the following reasons: (1) The data reviewed by the Dental Panel concerning 0.25 percent phenol consist of a study that only lists 0.25 percent phenol in a table of topical anesthetic drugs "which were partially or totally ineffective" as providing "numbness (incomplete)" in clinical testing that involved the application of a painful electrical stimulus to the tip of the tongue (Ref. 1), and (2) other references state that phenol possesses topical anesthetic activity at a concentration of 0.5 percent (Refs. 2 and 3). Therefore, the agency concurs with the Oral Cavity Panel's recommendation and is proposing in this amendment that the concentration range of phenol used as an oral mucosal analgesic be 0.5 to 1.5 percent.

For teething preparations, however, the agency is proposing to limit the concentration to 0.5 percent phenol because no data for other concentrations of teething preparations were submitted to the Dental Panel or to the agency. Because the first segment of the tentative final monograph for OTC oral health care drug products did not address teething preparations, the agency is including directions for use of teething preparations in § 356.52(d)(7)(iii) of this amendment. (See comment 36 below.)

References

(1) Adriani, J., et al., "The Comparative Potency and Effectiveness of Topical Anesthetics in Man," *Clinical Pharmacology and Therapeutics*, 5:49–62, 1964.

(2) "AMA Drug Evaluations—1980," 4th Ed., American Medical Association, Chicago, p. 1022, 1980.

(3) Martindale, W., "The Extra Pharmacopeia," 26th Ed., The Pharmaceutical Press, London, p. 202, 1972.

5. Three comments objected to the Dental Panel's recommendation that benzocaine be placed in Category III as an agent for the relief of toothache. All of the comments referred to a recent published study in which benzocaine was tested as an agent for the temporary relief of toothache, and each comment contained a short summary of the results of this study (Ref. 1). Two of the comments felt that the data submitted to the Panel in support of the effectiveness of benzocaine as a toothache remedy were better than the data for eugenol, which the Panel placed in Category I.

One comment believed that there was a discrepancy between the standard of effectiveness used to evaluate eugenol and the standard used to evaluate benzocaine and other ingredients. The comment stated that the Panel did not provide any reason why benzocaine is not an effective toothache relief agent, but simply stated that "there are insufficient data to establish effectiveness of benzocaine after application into a tooth cavity, as an agent for the relief of toothache, at the 2- to 20-percent concentrations" (47 FR 22712 at 22730). The comment contended that the amount of evidence in its submissions to the Panel (Refs. 2, 3, and 4) was sufficient to support the effectiveness of benzocaine and requested that the agency place benzocaine in Category I as an agent for the relief of toothache pain, based on these submissions and the additional study by Sveen, Yaekel, and Adair (Ref. 1). One comment felt that the data in support of benzocaine as a toothache relief agent in a gel dosage form should be extended to benzocaine in a poultice dosage form. The comment felt that in the absence of evidence to the contrary, a poultice should deliver the drug as well, if not better than a gel, because it will not wash away easily with saliva. A fourth comment agreed with the Panel's Category III categorization of benzocaine preparations based on the lack of efficacy data.

The agency has reviewed the effectiveness data on eugenol (Refs. 5 through 9) that were submitted to the Dental Panel and has determined that the data are insufficient to place eugenol in Category I as a toothache remedy (see comment 7 below). Therefore, in this tentative final monograph the agency is proposing that eugenol be classified in Category III as an agent for the relief of toothache.

The agency has also reviewed the comment's data plus other data (Refs. 2, 4, 5, 6, and 10 through 14) submitted to the Panel in support of the effectiveness of benzocaine as an agent for the relief of toothache and agrees with the Panel's Category III classification. The submissions contained data from animal studies that showed benzocaine to be a safe and effective topical anesthetic. However, there were no clinical data to demonstrate benzocaine's effectiveness in reducing pain due to a cavity in a tooth. The data submitted to the Panel were sufficient to establish benzocaine as a Category I oral mucosal analgesic, but inadequate to establish its effectiveness as an agent for the relief of toothache.

The agency has reviewed the study by Sveen, Yaekel, and Adair (Ref. 1), cited by three of the comments as evidence of the effectiveness of benzocaine, and concludes that it does not provide sufficient evidence to reclassify benzocaine to Category I as an agent for the relief of toothache. In the study, 49 patients who had a toothache resulting from dental caries were given either a gel dosage form containing 7.5 percent benzocaine or a placebo gel without any medication. Of the 24 patients receiving the gel containing benzocaine, 20 (83 percent) were reported to be relieved of pain with an average onset time of 3.7 minutes. The placebo gel gave relief to 16 percent of the 25 patients who received it.

One of the major problems with this study involves the inadequate documentation of efficacy measurements, i.e., the rating scales used to measure pain intensity and relief are not defined. No details are given of the actual scales used by the investigator to determine the pain intensity or the period of time that actual relief was experienced. The results only indicate that relief or no relief was obtained. Paragraph 6 of the methods and materials section of this study indicates that the data were collected by an investigator who visually examined the patient's tooth, applied the benzocaine or placebo gel to the tooth and surrounding gingiva, and filled in the patient record form recording any changes in the relief of the toothache. However, no details are given of the actual scales used to measure baseline pain intensity or pain relief, e.g., visual analog scales or rating scales for pain intensity and pain relief. Assuming a 2-point pain relief category scale, as implied by Table II (Ref. 1), the actual relief experienced could have been trivial (slight relief) to substantial (complete relief). Additionally, the details regarding the duration of pain relief are inadequate. For the placebo group, the investigator mentioned that some subjects experienced pain relief for 1 or 2 minutes, and four patients felt pain relief for more than 10 minutes. For the benzocaine group, however, the investigator did not determine the duration of pain relief at all.

Another problem is the lack of assurance that levels of pain and other patient characteristics affecting a response were comparable between the test and control groups at baseline. The article did not compare the two treatment groups for baseline pain intensity and for use of aspirin, codeine, or other analgesic medications. It is possible that the difference between treatment groups regarding pain relief is attributable to differences between the

two groups in baseline levels of these two factors. It is important that the control and test groups have comparable levels of pain severity at baseline because the degree of pain relief is usually correlated with initial pain intensity.

The randomization procedure for the distribution of the medication was unorthodox. It consisted of the investigator randomly selecting a tube of medication from a box containing an equal number of active and placebo tubes. This procedure is subject to possible bias by the investigator, especially if the contents of the tubes were not carefully disguised. Any knowledge of the identity of the specific medication that a given patient has received would have likely influenced the investigator's collection of data from the patient, and hence made the evidence much weaker. The use of a random number list or card-shuffling technique to assign medication in a random fashion to consecutively recruited patients would have been simple and scientifically more desirable.

Under the results section (paragraph 4) of this study (Ref. 1), it is indicated that some subjects disliked the taste of "the applied substance." It is conceivable that the benzocaine may have imparted a distinctive taste to the gel that would have enabled both the patient and the investigator to identify the tubes of medication containing active drug. This would invalidate the results of this study, especially in light of the randomization procedure used.

In summary, the results of this study, as summarized in Table II (Ref. 1), provide some evidence for a pain-relieving effect for benzocaine gel when applied as described in the article. The study design, however, was flawed and as a result the study is not adequate to support the reclassification of benzocaine from Category III to Category I as an agent for the relief of toothache. The two most critical problems with this published study involve the poor documentation of efficacy measurements, e.g., the absence of scales for determining pain relief and duration of relief, and the lack of assurance that levels of pain and other patient characteristics affecting the response were comparable in the two groups at baseline. In any future studies, the nature of the scales used and the patients' reports of relief should be well defined in order to determine the magnitude of the clinical effect. The "blindness" of the study should be clarified by examination of the taste of benzocaine gel in comparison to its vehicle.

Based on its review of data submitted to the Dental Panel and the article by Sveen, Yaekel, and Adair (Ref. 1) submitted with the comments, the agency is classifying benzocaine in Category III as an agent for the relief of toothache in this amendment. If additional data from well-designed clinical studies that show benzocaine to be an effective toothache pain remedy are received, the agency will consider reclassifying benzocaine in Category I as an agent for the relief of toothache. At that time, the acceptable dosage forms for benzocaine would be determined.

References

(1) Sveen, O.B., M. Yaekel, and S.M. Adair, "Efficacy of Using Benzocaine for Temporary Relief of Toothache," Oral Surgery, Oral Medicine, Oral Pathology, 53:574–576, 1982.
(2) OTC Volume 080048.
(3) OTC Volume 080114.
(4) OTC Volume 080255.
(5) OTC Volume 080003.
(6) OTC Volume 080081.
(7) OTC Volume 080034.
(8) Summary Minutes of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, 5th Meeting, October 10 and 11, 1973, in OTC Volume 08APA2.
(9) Summary Minutes of the Advisory Review Panel of OTC Dentifrice and Dental Care Drug Products, 14th Meeting, October 16 and 17, 1974, in OTC Volume 08APA2.
(10) OTC Volume 080017.
(11) OTC Volume 080055
(12) OTC Volume 080191.
(13) OTC Volume 080214.
(14) OTC Volume 080258.

6. One comment noted that its submissions of data to the Dental Panel concerning products containing water-soluble chlorophyllin are listed in the Panel's report under the heading "Submissions by Firms" (47 FR 22712 at 22714), but that water-soluble chlorophyllin is not mentioned in the report. The comment stated that although chlorophyllin has been classified primarily as a wound healing agent, its mode of action has not been conclusively defined and the literature indicates that it produces beneficial effects not necessarily explainable by its wound-healing properties. According to the comment, dental and medical reports consistently refer to relief of discomfort as a result of topical administration of chlorophyllin and, in this capacity, the ingredient is acting as an analgesic in that it produces a lessening of sensibility to pain.

The comment contended that the Dental Panel defined "analgesic" so narrowly that the definition excludes chlorophyllin as well as other pain relievers such as aspirin and adrenocorticosteroid hormones. Stating that the Panel defined an "analgesic (topical)" as "an ingredient used in drug products for surface application to provide temporary relief of discomfort by an anesthetic or analgesic effect" (47 FR 22716), the comment argued that the Panel dealt solely with ingredients with an anesthetic effect and did not include any ingredients with an "analgesic" effect in its review.

The comment added that a broader interpretation of what constitutes a topical analgesic is contained in the advance notice of proposed rulemaking for OTC external analgesic drug products, which reads: "Some drugs exert analgesic effects by eliminating a painful stimulus. These agents reduce swelling of the tissues or they neutralize noxious chemical substances that are released by trauma, an infection, or another process" (44 FR 69768 at 69777). The comment believed that the drugs so described could include chlorophyllin because the clinical studies submitted indicate that chlorophyllin provides patients with relief of oral discomfort. The comment concluded by requesting that water-soluble chlorophyllin be included in a broadened category of "oral mucosal analgesics" or in an added category of "miscellaneous agents for the relief of oral discomfort" so as to ultimately achieve Category I status.

The agency acknowledges that the comment did submit data regarding water-soluble chlorophyllin to the Dental Panel for review and that, although submissions concerning chlorophyllin are listed in the Panel's report on OTC drug products for the relief of oral discomfort, this ingredient is not discussed in that document. Because the data in the submissions dealt primarily with the wound-healing effects of chlorophyllin, it appears that the Panel reviewed this ingredient only as an oral wound-healing agent in its report on OTC oral mucosal injury drug products (published in the **Federal Register** of November 2, 1979; 44 FR 63270 at 63286). Reference to the comment's submissions in the list of submissions appearing in the relief of oral discomfort drug products report appears to have been an error that occurred as a result of the Panel's one large report subsequently being subdivided into three separate reports (i.e., anticaries, oral mucosal injury, and relief of oral discomfort).

The agency does not agree with the comment that the Dental Panel's definition of "analgesic" is so narrow that it would exclude pain relievers such as aspirin and adrenocorticosteroid hormones. The Panel's discussion of oral

mucosal analgesics (47 FR 22712 at 22736) did not include those pain relievers because no data were submitted to the Panel regarding the use of such drugs as oral mucosal analgesics. Because the Dental Panel's definition of "analgesic" is broad enough to include any analgesic ingredient regardless of its mechanism of action, the agency does not see any reason to change that definition.

The agency agrees with the statement in the external analgesic drug products report that "some drugs exert analgesic effects by eliminating a painful stimulus. These agents reduce swelling of the tissues or they neutralize noxious chemical substances that are released by trauma, an infection, or another process" (44 FR 69768 at 69777). However, the agency does not consider the submitted data adequate to demonstrate that chlorophyllin is an analgesic that acts in this manner. The data contain little information on the analgesic effect of chlorophyllin (Ref. 1). The data consist of many studies on the wound-healing effects and deodorizing properties of chlorophyllin, but only part of one article in the submissions deals with the analgesic effect of chlorophyllin (Ref. 2). That article contains a number of summarized clinical reports in which patients with various dental problems, e.g., extractions, gingivitis, stomatitis, and pyorrhea, were treated with a chlorophyllin preparation. The studies were conducted primarily to evaluate the healing effect of chlorophyllin; however, some observations were made regarding chlorophyllin's effect on pain.

The agency finds the clinical reports inadequate to demonstrate the analgesic effectiveness of chlorophyllin because there are insufficient details regarding the study designs; no information is given as to how or under what conditions the studies were conducted; the studies were not well-controlled or blinded; there was no recorded measurement of the condition of the subjects at baseline; and no information was given as to how relief of pain was evaluated. Therefore, in this amendment, the agency is not including chlorophyllin in an added category of "miscellaneous agents for the relief of oral discomfort," but is proposing that water-soluble chlorophyllin be classified as a Category III ingredient for use as an oral mucosal analgesic.

References

(1) OTC Volumes 080043 and 080168.

(2) Taraporvala, P.V., "A Preliminary Report on Therapy with Chlorophyll (Chloresium) in Dentistry," Journal of the Indian Medical Profession, 4:1905–1911, 1957.

7. One comment agreed with the Dental Panel's decision to place eugenol in Category I as an agent for the relief of toothache. Three other comments questioned the Panel's decision to place eugenol in Category I for this use. One of the comments stated that the Panel was apparently aware of the capacity of eugenol to damage viable tooth pulp when it advised that eugenol should be recommended only when there is "persistent, throbbing pain," because intermittent pain might "indicate that the pulp is still viable, and eugenol may compromise the pulp vitality in that case" (47 FR 22712 at 22728). The comment stated that a lay person with a toothache might not be readily able to distinguish the intermittent pain of a viable tooth; thus, eugenol has the potential for harmful effects unless used under professional supervision, is not an appropriate product for self-medication, and should not be permitted for OTC sale. Another comment contended that there was a danger with eugenol in that consumers may misuse it, in spite of adequate warnings on the label, by applying it in an open cavity from which a filling has been lost. The comment stated that because it is known that eugenol is an irritant, one cannot be assured that this problem can be avoided.

Two of the comments questioned the effectiveness data that the Dental Panel accepted for eugenol. One comment noted that the Panel stated that well-controlled, published studies on the effectiveness of eugenol for the relief of toothache are not available, and that the Panel considered the options of acknowledged experts in endodontics, who, however, did not agree with each other on the advisability of making eugenol available to the consumer as an OTC toothache remedy (47 FR 22728). The comment did not believe that the Panel's reliance on the opinion of experts in endodontics, as well as the published opinions of other experts that eugenol is a dental analgesic or has a topical anesthetic effect, is sufficient under OTC drug regulations (21 CFR 330.10(a)(4)(ii)) to establish the effectiveness of eugenol. The comment contended that the conflict of the expert opinion, as is evident from the Panel's own statement, should indicate that eugenol is not generally recognized as safe and effective and should not have been placed in Category I. The other comment contended that the Panel's Category I recommendation on eugenol was actually made with no data to prove effectiveness.

The agency has reviewed the information submitted to the Dental Panel (Refs. 1 through 5) and the data and information cited by the Panel (47 FR 22728) regarding the effectiveness of eugenol. The agency has determined that no data from any clinical studies involving eugenol were submitted to the Panel (47 FR 22728). The Panel recommended a Category I classification of eugenol for the following reasons: (1) The drug's long history of use in periodontal dressing and as a toothache remedy, (2) a belief that there is a need for an OTC toothache relief product for consumers, and (3) the opinion of an expert in endodontics that eugenol be retained for OTC toothache remedies (Ref. 4). A second expert called by the Panel stated that toothache remedies are basically not effective in correcting the cause of the toothache and only offer pain relief as a result of a placebo effect (Ref. 5). This expert questioned the consumer's ability to determine whether the toothache is of pulpal or periapical (dentinal) origin, i.e., whether there is irreversible damage to a tooth with a persistent, throbbing pain or reversible damage with a quick, sharp pain occurring as a response to stimuli such as heat or cold.

The agency does not find sufficient evidence to exist to establish general recognition of the effectiveness of eugenol as a toothache remedy within the requirements of the OTC drug regulations (21 CFR 330.10(a)(4)(ii)). There is a need for controlled clinical investigations that demonstrate the effectiveness of eugenol used for the relief of toothache. Therefore, the agency is reclassifying eugenol as an agent for the relief of toothache from Category I to Category III in this amendment.

References

(1) OTC Volume 080003.

(2) OTC Volume 080034.

(3) OTC Volume 080181.

(4) Summary Minutes of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, 5th meeting, October 10 and 11, 1973, OTC Volume 08APA2.

(5) Summary Minutes of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, 14th meeting, October 16, and 17, 1974, OTC Volume 08APA2.

8. Four comments cited a number of published studies (Refs. 1 through 10) to support the effectiveness of 5 percent potassium nitrate as a Category I tooth desensitizer. Some of these studies were cited in the Panel's report (Refs. 1 and 2); one was submitted to the Panel, but not cited in its report (Ref. 3); and one was submitted to the Panel, reviewed as unpublished data, and published subsequently (Ref. 4). Some of the

studies were published after the Panel completed its work and thus were not available to the Panel (Refs. 5 through 10). One comment cited five of these studies as the basis that a professional association used to recognize the usefulness and safety of a toothpaste containing 5 percent potassium nitrate for the relief of pain and discomfort from dentinal hypersensitivity (Refs. 1 through 4, and 9).

One comment requested that the Category III classification of 5 percent potassium nitrate be reexamined on the basis of the "file record" and the new data submitted by the comment (Ref. 11). The comment submitted two new clinical studies and copies of four clinical studies that were submitted by another comment (Ref. 12). The comment maintained that "substantial evidence, as defined in 21 U.S.C. 355, consisting of adequate and well-controlled investigations" clearly exists for a toothpaste containing 5 percent potassium nitrate in a compatible base. The comment maintained that no further studies on potassium nitrate are necessary because abundant clinical support is available to demonstrate the safety and effectiveness of potassium nitrate as a tooth desensitizing agent.

Another comment submitted five new, unpublished studies involving 254 subjects experiencing dentinal hypersensitivity (Ref. 12). The comment maintained that these studies demonstrate the effectiveness of 5 percent potassium nitrate in relieving dentinal sensitivity.

The agency has reviewed the data and concludes that there are sufficient data from two well-controlled clinical studies and three supportive studies to establish the effectiveness of 5 percent potassium nitrate as a tooth desensitizer.

In one study (Ref. 13), the effectiveness of two 5-percent potassium nitrate toothpastes was evaluated using methods recommended by the Dental Panel (47 FR 22712 at 22756 to 22757) in a placebo-controlled, 12-week, double-blind, 3-way parallel comparative study of 60 subjects. The hypersensitivity levels of the subject were assessed by two objective methods (i.e., thermal stimulus and tactile stimulus) and by subjective response. Reductions in tooth hypersensitivity caused by the two potassium nitrate dentifrices and by the placebo dentifrice (the dentifrice base without the potassium nitrate) were measured at the 2-week, 4-week, 8-week, and 12-week intervals. The reductions caused by the potassium nitrate dentifrices were compared statistically to the reductions caused by the placebo dentifrice at each time interval. When evaluated subjectively at 4 weeks, the two potassium nitrate dentifrices caused mean reductions in hypersensitivity of 42 and 41 percent, and the placebo dentifrice caused a mean reduction in hypersensitivity of 16 percent; at 8 weeks, the two potassium nitrate dentifrices caused mean reductions in hypersensitivity of 50 and 61 percent, and the placebo dentifrice caused a mean reduction in hypersensitivity of 23 percent; at 12 weeks, the two potassium nitrate dentifrices caused mean reductions in hypersensitivity of 75 and 69 percent, and the placebo dentifrice caused a mean reduction of 34 percent. When the decrease in hypersensitivity was assessed thermally by responses to a cold air blast (60 pounds per square inch (psi), 70 °F) from an air syringe, the two potassium nitrate dentifrices caused mean reductions in hypersensitivity of 46 percent (statistically significant) and 32 percent (not statistically significant) at 4 weeks, and the placebo caused a 27-percent reduction in hypersensitivity; at 8 weeks, the two potassium nitrate dentifrices caused mean reductions in hypersensitivity of 52 and 56 percent compared to a 33-percent reduction caused by the placebo; and at 12 weeks, the potassium nitrate dentifrices caused 74 and 70 percent reductions in mean hypersensitivity scores compared to a 48-percent reduction in hypersensitivity caused by the placebo. When the decreases in hypersensitivity were measured by responses to the tactile stimulation of a No. 23 dental probe, the two potassium nitrate dentifrices caused reductions in mean hypersensitivity scores of 46 and 52 percent at 4 weeks compared to the 24-percent reduction caused by the placebo; at 8 weeks, the two active ingredient dentifrices caused mean reductions of 72 and 67 percent, compared to the 36-percent reduction caused by the placebo; and at 12 weeks, the potassium nitrate products caused mean reductions of hypersensitivity of 87 and 82 percent compared to a 54-percent reduction caused by the placebo. Except where noted above, the reductions in tooth hypersensitivity caused by the active ingredient products were statistically significantly greater than the reductions caused by the placebo ($p. \leq .05$).

In a second study (Ref. 14), the effectiveness of a 5-percent potassium nitrate dentifrice and a 10-percent strontium chloride dentifrice were evaluated with a placebo in a 12-week, double-blind, 3-way comparative study of 45 subjects. The hypersensitivity responses were assessed by thermal stimulus and by subjective responses. Reductions in tooth hypersensitivity were measured at the 2-week, 4-week, 8-week, and 12-week intervals. When the decrease in mean hypersensitivity scores was assessed thermally by responses to a cold air blast (60 psi at 70 °F) from an air syringe, the potassium nitrate dentifrice caused a 31-percent reduction at 2 weeks compared to a 11-percent reduction caused by the placebo. The reduction in hypersensitivity assessed thermally and caused by the potassium nitrate dentifrice increased at each time interval to a 81-percent reduction in mean hypersensitivity scores at 12 weeks compared to a 14-percent reduction caused by the placebo. When the decrease in tooth hypersensitivity was assessed subjectively, the 5-percent potassium nitrate dentifrice caused a 34-percent reduction from baseline scores at 2 weeks, and the placebo caused a 4-percent reduction. This reduction in hypersensitivity caused by the potassium nitrate dentifrice increased at each interval to 79 percent at 12 weeks compared to a 32-percent reduction caused by the placebo dentifrice at 12 weeks. The 5-percent potassium nitrate dentifrice caused reductions in tooth hypersensitivity that were statistically significantly greater than the reductions caused by the placebo at all time intervals ($p \leq .05$).

In a third clinical study (Ref. 15), the desensitizing effect of a 5-percent potassium nitrate dentifrice was compared with a placebo dentifrice using a double-blind, placebo-controlled, 8-week study of 32 subjects. The subjects were restricted to individuals who complained of hypersensitivity following periodontal surgery. The hypersensitivity levels were assessed by measuring the subjects' response to a thermal stimulus (i.e., a 1-second blast of cold air, 60 psi, 70 °F± 3 °F) from an air syringe and by subjective evaluation. Subjectively, 78.6 percent of the subjects using the potassium nitrate dentifrice reported improvement at 4 weeks compared to 18.2 percent of the subjects using the placebo who reported improvement. At 8 weeks, 92.9 percent of the subjects using the potassium nitrate dentifrice reported improvement, and 54.5 percent of the subjects using the placebo reported improvement. When the decrease in mean hypersensitivity scores was assessed by measuring the responses to thermal stimulus, the potassium nitrate dentifrice caused a 57-percent decrease in hypersensitivity in 4 weeks. This decrease was significantly greater than the 32-percent decrease caused by the placebo ($p=.03$). At 8 weeks, although the 65-percent decrease in hypersensitivity caused by the

potassium nitrate dentifrice was not significantly greater than the 48-percent reduction associated with the placebo at the $p = .05$ level, it was significant at the $p = .1$ level and is thus supportive of effectiveness.

In addition to the above clinical studies of 8 or 12 weeks duration, two 4-week studies are supportive of the tooth desensitizing claim for 5 percent potassium nitrate (Refs. 4 and 16). In one study (Ref. 4), the effectiveness of a 5-percent potassium nitrate dentifrice was evaluated on 27 subjects in a double-blind, parallel, comparative study. Hypersensitivity levels were measured by the response to an electrical stimulus (pulp stethoscope), a thermal stimulus (cold air blast of 60 psi, 70 °F), and by subjective analysis. At 2 weeks, the potassium nitrate dentifrice caused a significantly greater desensitizing effect than the placebo ($p \leq .01$) for all three stimuli. This effect increased with continued use of the desensitizing agent during the 4 weeks of treatment and was consistently greater than the effect caused by the placebo ($p \leq .05$). Subjective data demonstrated that 92 percent of the subjects using the potassium nitrate dentifrice and 21 percent of the subjects using the placebo reported relief at the end of 4 weeks.

The other 4-week study (Ref. 16) was a double-blind, 3-way comparative, parallel study of 60 subjects that compared the effectiveness of a 5-percent potassium nitrate dentifrice, a 10-percent strontium chloride dentifrice, and a placebo dentifrice. Hypersensitivity levels were measured by the response to an electrical stimulus (pulp stethoscope), a thermal stimulus (cold air blast of 60 psi, 70 °F), and by subjective evaluation. After 2-weeks use and continuing through 4-weeks use, the 5-percent potassium nitrate dentifrice caused reductions in tooth hypersensitivity that were statistically significantly greater than the placebo reductions at all time intervals ($p < .05$). These results were observed for all three stimuli.

The agency is also aware of a 12-week, double-blind clinical study using 75 subjects in which the effectiveness of two commercially available 5 percent potassium nitrate dentifrices was compared to a placebo (Ref. 21). Hypersensitivity reduction was assessed by a thermal stimulus (1-second blast of cold air, 60 psi, 65 to 70 °F), a tactile stimulus (dental explorer No. 23), and by subjective evaluation. The scores from all three methods showed a gradual reduction in tooth sensitivity from baseline to each of the succeeding time intervals, but there were no statistically significant differences between either of the potassium nitrate dentifrices and the placebo.

Regarding the safety of potassium nitrate, the agency is aware that recent publications in the scientific literature have expressed concern that nitrates may be involved in the production of certain forms of cancer (i.e., gastric and liver cancer) when used at relatively low concentrations on a chronic basis (Refs. 17 through 20). Ingested nitrates can be converted in the oral cavity and the stomach to nitrites, which in turn can lead to endogenous nitrosation in the stomach; however, the extent and significance of the conversion of nitrate to nitrite in the body is not clear. Although, at this time, the data in the scientific literature do not justify changing the safety classification of potassium nitrate, the agency invites comments on this issue.

Based upon the evaluation of the available studies, the agency is proposing in this amendment to reclassify 5 percent potassium nitrate from Category III to Category I as a tooth desensitizer. Directions for using the dentifrice are discussed in comment 38 below.

The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Refs. 22 and 23).

References

(1) Hodosh, M., "A Superior Desensitizer—Potassium Nitrate," *Journal of the American Dental Association*, 88:831–832, 1974.

(2) Stark, M.M., et al., "Rationalization of Electric Pulp-Testing Methods," Oral Surgery, Oral Medicine, Oral Pathology, 43:598–606, 1977.

(3) Green, B.L., M.L. Green, and W.T. McFall, "Calcium Hydroxide and Potassium Nitrate as Desensitizing Agents for Hypersensitive Root Surfaces," Journal of Periodontology, 48:667–672, 1977.

(4) Tarbet, W.J., et al., "Clinical Evaluation of a New Treatment for Dentinal Hypersensitivity," Journal of Periodontology, 51:535–540, 1980.

(5) Tarbet, W.J., et al., "Home Treatment for Dentinal Hypersensitivity: A Comparative Study," Journal of the American Dental Association, 105:227–230, 1982.

(6) Council on Dental Therapeutics, "Desensitizing Dentifrice," Journal of the American Dental Association, 104:410, 1982.

(7) Council on Dental Therapeutics, "Evaluation of Denquel Sensitive Teeth Toothpaste," Journal of the American Dental Association, 105:80, 1982.

(8) Green, M.L., and B.L. Green, "Calcium Hydroxide: An Effective Desensitizing Agent," Dental Hygiene, 52:280–285, 1978.

(9) Tarbet, W.J., et al., "An Evaluation of Two Methods for the Quantitation of Dentinal Hypersensitivity," Journal of the American Dental Association, 98:914–918, 1979.

(10) Tarbet, W.J., et al., "The Pulpal Effects of Brushing with a 5 Percent Potassium Nitrate Paste Used for Desensitization," Oral Surgery, Oral Medicine, Oral Pathology, 51:600–602, 1981.

(11) Comment No. C00011, Docket No. 80N–0228, Dockets Management Branch.

(12) Comment No. C00012, Docket No. 80N–0228, Dockets Management Branch.

(13) Axelrod, S., and S. Minkoff, "Desensitizing Dentifrice Study," draft of unpublished study, Comment No. C00011, Docket No. 80N–0228, Dockets Management Branch.

(14) Axelrod, S., and S. Minkoff, "Desensitizing Toothpaste, Long Term Safety and Effectiveness" (Study DDR 15–78), draft of unpublished study, Comment Nos. C00011 and C00012, Docket No. 80N–0228, Dockets Management Branch.

(15) Stolman, J., and G. Silverman, "Desensitizing Toothpaste, Post Periodontal Surgery-Hypersensitivity" (Study DDR 13–80), draft of unpublished study, Comment No. C00012, Docket No. 80N–0228, Dockets Management Branch.

(16) Goldman, P., and G. Silverman, "Desensitizing Toothpaste" (Study DDR 16–78), draft of unpublished study, Comment Nos. C00011 and C00012, Docket No. 80N–0228, Dockets Management Branch.

(17) Hartman, P.E., "Overview: Nitrate Load in the Upper Gastrointestinal Tract—Past, Present, and Future," Banbury Report 12: Nitrosamines and Human Cancer, 1982, Cold Spring Harbor Laboratory.

(18) Lijinsky, W., R. Kovatch, and C. Riggs, "Altered Incidences of Hepatic and Homopoietic Neoplasms in F344 Rats Fed Sodium Nitrate," Carcinogenesis, 4:1189–1191, 1983.

(19) Mirvish, S.S., "The Etiology of Gastric Cancer," Journal of the National Cancer Institute, 71:631–647, 1983.

(20) Weisburger, J.H., "Role of Fat, Fiber, Nitrate and Food Additives in Carcinogenesis: A Critical Evaluation and Recommendations," Nutrition and Cancer, 8:47–62, 1986.

(21) Manochehr-Pour, M., M. Bhat, and N. Bissada, "Clinical Evaluation of Two Potassium Nitrate Toothpastes for the Treatment of Dental Hypersensitivity," Periodontal Case Reports, 6:25–30, 1984.

(22) Letter from W.E. Gilbertson, FDA, to S. Most, Block Drug Company, Inc., coded LET008, Docket No. 80N–0228, Dockets Management Branch.

(23) Letter from W.E. Gilbertson, FDA, to D. Smith, Vicks Research Center, Richardson-Vicks Inc., coded LET009, Docket No. 80N–0028, Dockets Management Branch.

9. Two comments recommended that 10 percent strontium chloride be placed in Category I as a tooth desensitizing ingredient. The comments maintained that the effectiveness of 10 percent strontium chloride is supported by several adequate and well-controlled studies (Refs. 1 through 7), some of which were submitted to the Dental

Panel. One of these studies (Ref. 3) was submitted to the Panel as unpublished material and was published after the Panel was disbanded. One comment maintained that the Panel did not appear to challenge the design of the studies that were submitted, but rather questioned the results of the studies based upon the variability of the findings. The comment asserted that the variability was due to the different study designs utilized, as well as the known differences in individual responses to effective desensitizer dentifrice products. The comments also submitted a recently published study to support the effectiveness of strontium chloride as a tooth desensitizer (Ref. 8).

One of the comments submitted six additional clinical studies (Refs. 9 through 14) which have become available since the Panel disbanded. The comment mentioned that these new studies were conducted according to the Panel's recommended guidelines. The comment also submitted a statistical reanalysis of one of the studies submitted to the Panel (Ref. 15) and a statistical analysis of the combined data (Ref. 16) of two of the submitted clinical studies. In addition, the comment included testimonials from four experts who all stated that in their opinion, "* * * 10% strontium chloride hexahydrate in a desensitizing dentifrice is a safe and effective agent for the treatment of dentinal hypersensitivity" (Ref. 17). The comment maintained that "substantial evidence" as defined in 21 U.S.C. 355, "consisting of adequate and well-controlled investigations," clearly exists to support classification of 10 percent strontium chloride as a Category I tooth desensitizer.

A comment from a professional association concurred with the Dental Panel's Category III classification of strontium chloride as a tooth desensitizer. However, another comment, submitted to the agency at a later date, pointed out that on March 30, 1984, one commercially available 10-percent strontium chloride hexahydrate dentifrice was accepted by the association as a safe and effective desensitizing dentifrice (Ref. 18).

The agency has reviewed all of the submitted data and does not agree with the comments that the data are sufficient to classify strontium chloride in Category I as a tooth desensitizer. The agency agrees with the Panel's evaluation of the studies it reviewed (47 FR 22712 at 22755). The Panel stated that these studies were conflicting and inconclusive, and lacked early, consistent, favorable, and statistically significant results.

The statistical reanalysis by Wolf (Ref. 15), of a study that Uchida et al. (Ref. 3) had previously submitted to the Panel, compared the effectiveness of a 10-percent strontium chloride dentifrice to the effectiveness of a placebo dentifrice in relieving postperiodontal surgical hypersensitivity to mechanical stimuli, compressed air blast, and cold water. A subjective assessment of the degree of hypersensitivity for each stimulus was recorded. The published study by Uchida et al (Ref. 3) reported on data from 60 subjects, whereas the statistical reevaluation of the study by Wolf reported on data from 72 subjects. This discrepancy is not explained. The reanalysis of the data demonstrated that when evaluated for sensitivity to air and cold water stimuli, a significantly greater number of treatment subjects reported excellent improvement at weeks 2, 4, and 8 when compared to the number of placebo subjects reporting excellent improvement. The number of teeth sensitive to these stimuli was also reported to be significantly reduced. No significant differences in sensitivity to the mechanical (scratch) stimulus were observed between the treatment group and the placebo group at any time period. The agency notes that no raw data were submitted with the reanalysis, making it difficult to determine exactly which results were analyzed to establish the significant differences observed between treatments, and the statistical methods used to analyze the data were not well described. Additionally, the agency believes that the mean sensitivity score per subject, rather than using individual teeth, should be the fundamental unit for analysis because the teeth within a patient's mouth cannot be treated as uncorrelated units. Therefore, the agency concludes that neither the published study by Uchida et al. (Ref. 3) nor Wolf's reanalysis of the data (Ref. 15) provides adequate support for the effectiveness of strontium chloride as a tooth desensitizer.

One study by Singh (Ref. 9) was an 8-week, double-blind, controlled clinical study involving the responses of 60 subjects with postperiodontal surgical hypersensitivity to tactile (No. 23 dental probe), and thermal ("gentle burst of compressed air") stimuli. Although the data demonstrated that in all instances the reduction in hypersensitivity observed in subjects using the active dentifrice exceeded that observed in subjects using the placebo dentifrice, only one significant difference was noted. At 8 weeks, a statistically significant superiority of the strontium chloride dentifrice over the placebo dentifrice was reported via a reduction in the number of teeth responding to thermal stimulation. However, because the analyses based on the number of teeth are inadequately described, the validity of the results cannot be determined. All other analyses of measurements resulted in statistical nonsignificance.

Another study by Simring and Collins (Ref. 10) was a 12-week, double-blind, three-way, placebo-controlled investigation of 75 subjects evaluating the effectiveness of a 10-percent strontium chloride dentifrice and a 5-percent potassium nitrate dentifrice in relieving functionally occurring and postperiodontal surgical hypersensitivity. (For a discussion of the effectiveness of potassium nitrate as a tooth desensitizer, see comment 8 above.) The subjects' responses to tactile stimulation (No. 23 dental probe) and thermal stimulation (an unquantified burst of compressed air) were assessed. The study failed to provide evidence of effectiveness. Statistical significance was demonstrated for only 7 out of 120 statistical tests. No significant improvement was observed when the mean sensitivity scores per subject were the units of analysis. Significant improvement could be demonstrated in two tests when individual teeth were used as the fundamental units of analysis. However, as in the Singh study discussed above, the agency does not consider analyses based upon sensitivity scores of individual teeth to be valid. In the other five significant statistical tests, the strontium chloride dentifrice was significantly better than the potassium nitrate dentifrice but not significantly better than the placebo. The agency concludes that these results do not demonstrate or support the effectiveness of strontium chloride as a tooth desensitizer.

In a statistical analysis, Wolf (Ref. 16) combined the data from the study by Singh (Ref. 9) and the study by Simring and Collins (Ref. 10). When the data were combined, no significant differences in tactile total pain scores between the strontium chloride dentifrice and the placebo dentifrice were observed. Significant differences in favor of the strontium chloride dentifrice were noted for the number of teeth reacting to tactile stimuli at 8 weeks ($p < 0.05$). Significant differences in thermal sensitivity total pain scores were observed in favor of the strontium chloride dentifrice at weeks 4 and 8 ($p < 0.05$). Significant differences in the number of teeth responding to thermal stimuli were observed in favor of the

strontium chloride dentifrice at 4 weeks ($p < 0.05$) and at 8 weeks ($p < 0.01$). However, the agency concludes that this pooled analysis is not valid. There is no evidence that these studies were designed with any prior intent to combine the data. Additionally, for some unexplained reason, only the results from 26 of 39 available patients from the Simring study were combined with the results of the Singh study.

A third study by Silverman and Goldman (Ref. 11) was a 4-week, double-blind, three-way, comparative, parallel study of 60 subjects that assessed the effectiveness of a 10-percent strontium chloride dentifrice, a 5-percent potassium nitrate dentifrice, and a placebo dentifrice as tooth desensitizing agents. The subjects' responses to electrical stimulus (pulp stethoscope) and thermal stimulus (1 second blast of cold air, 60 psi at 70 °F) were measured and analyzed. Subjective evaluations were also recorded and analyzed. The 10-percent strontium chloride dentifrice was shown to be significantly better than the placebo at only one time point and by only one method of measurement (i.e., pulp stethoscope stimulus results at week four). Although the results of this study support the desensitizing effectiveness claim for potassium nitrate (see comment 8 above), they do not support the desensitizing effectiveness claim for strontium chloride.

Another study by Silverman (Ref. 12) evaluated the effectiveness of a 10-percent strontium chloride dentifrice in a 12-week, double-blind, placebo-controlled, comparative study of 90 subjects with hypersensitive teeth. Hypersensitivity levels were assessed at 2-week intervals by thermal stimulus (1-second blast of cold air, 60 psi at 70 °F), tactile stimulus (No. 23 dental probe), and subjective response. The strontium chloride dentifrice caused decreases in hypersensitivity, beginning at the 2d week and increasing continuously until the 12th week; however, these decreases in dentinal hypersensitivity were statistically significantly greater than the decreases in dentinal hypersensitivity caused by the placebo ($p \leq .05$) only at the 12-week assessment period for thermal stimuli and subjective response. The agency concludes that this study does not support the effectiveness of 10 percent strontium chloride as a tooth desensitizer.

In the fifth study by Axelrod and Minkoff (Ref. 13), the desensitizing effectiveness of a 10-percent strontium chloride dentifrice and a 5-percent potassium nitrate dentifrice was compared to a placebo dentifrice in a 12-week, double-blind, 3-way comparative study of 45 subjects with dentinal hypersensitivity. Hypersensitivity was assessed thermally (1-second blast of cold air, 60 psi at 70 °F) and evaluated subjectively. Although the results of this study clearly support the effectiveness of potassium nitrate (see comment 8 above), they do not as clearly support the effectiveness of strontium chloride. When measured thermally, the strontium chloride caused a significantly greater reduction in hypersensitivity than the placebo at 4 weeks ($p = .05$), 8 weeks ($p = .01$), and 12 weeks ($p = .01$). However, the subjective response scores for strontium chloride showed no significantly greater decreased in hypersensitivity than for the placebo dentifrice. The agency believes that these data are partially supportive of the effectiveness of strontium chloride as a tooth desensitizer.

Another study by Axelrod and Minkoff (Ref. 14) is partially supportive of the effectiveness of strontium chloride as a tooth desensitizing ingredient. The desensitizing effectiveness of a 10-percent strontium chloride dentifrice was evaluated in a 12-week, double-blind, parallel, comparative study of 61 subjects with dentinal hypersensitivity. Hypersensitivity levels were assessed by thermal (thermally controlled cold air stream) and tactile (Yeaple Probe) stimuli and by subjective evaluation. When hypersensitivity was measured thermally, the strontium chloride dentifrice caused significantly greater reductions in hypersensitivity than the placebo at 8 weeks ($p = .02$) and at 12 weeks ($p = .0001$) but not at 2 or 4 weeks. When measured tactilely, the strontium chloride dentifrice caused significantly greater reductions in hypersensitivity than the placebo at 12 weeks ($p = .02$) but not at any other time period. When assessed subjectively, the strontium chloride dentifrice caused significantly greater reductions in hypersensitivity than the placebo at 4 weeks ($p = .004$), 8 weeks ($p < .001$), and 12 weeks ($p < .001$).

A study by Johnson, Zulgar-Nain, and Koval (Ref. 8) was also submitted in support of the effectiveness of 10 percent strontium chloride. The object of the study was to evaluate an "electro-ionizing" toothbrush for the treatment of dentinal hypersensitivity. Only incidentally was the desensitizing effect of strontium chloride tested. Strontium chloride used with the "electro-ionizing" brush without a battery produced significantly more desensitization at 12 weeks than did the stannous fluoride dentifrice used with the "electro-ionizing" brush without a battery. However, the results of a subjective questionnaire, in which the subjects were asked to note a decrease in hypersensitivity, failed to demonstrate significant improvement when strontium chloride was used. The agency concludes that this study cannot be used to support the effectiveness of 10 percent strontium chloride as a tooth desensitizer.

The agency believes that two of the submitted studies (Refs. 13 and 14) are partially supportive but do not provide sufficient evidence of the effectiveness of 10 percent strontium chloride as a tooth desensitizer. Moreover, based on the overwhelming predominance of nonsignificant improvement in dentinal hypersensitivity observed in the submitted studies, the agency is classifying strontium chloride in Category III as a tooth desensitizer in this amendment.

The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 19).

References

(1) Pusso-Carrasco, H., "Strontium Chloride Toothpaste—Effectiveness as Related to Duration of Use," Pharmacology and Therapeutics in Dentistry, 1:209–215, 1971.

(2) Hernandez, F., et al., "Clinical Study Evaluating the Desensitizing Effect and Duration of Two Commercially Available Dentifrices," Journal of Periodontology, 43:367–372, 1972.

(3) Uchida, A., et al., "Controlled Clinical Evaluation of a 10% Strontium Chloride Dentifrice in Treatment of Dentin Hypersensitivity Following Periodontal Surgery," Journal of Periodontology, 51:578–581, 1980.

(4) Shapiro, W.B., et al., "Controlled Clinical Comparison Between a Strontium Chloride and a Sodium Monofluorophosphate Toothpaste in Diminishing Hypersensitivity," Journal of Periodontology, 41:523–525, 1970.

(5) Graf, H., "Sensodyne Clinical Trials," draft of unpublished study in OTC Volume 080224, Dockets Management Branch.

(6) Blitzer, B., "A Consideration of the Possible Causes of Dental Hypersensitivity: Treatment by a Strontium Ion Dentifrice," Periodontics, 5:318–321, 1967.

(7) Shapiro, W.B., R.S. Kaslick, and A.I. Chasens, "The Effect of a Strontium Chloride Toothpaste on Root Hypersensitivity in a Controlled Clinical Study, "Journal of Periodontology, 41:702–703, 1970.

(8) Johnson, R.H., B.J. Zulgar-Nain, and J.J. Koval, "The Effectiveness of an Electro-Ionizing Toothbrush in the Control of Dentinal Hypersensitivity," Journal of Periodontology, 53:353–359, 1982.

(9) Singh, S., "Strontium Chloride Dentifrice Study," draft of unpublished study, Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(10) Simring, M., and J.F. Collins, "Desensitizing Dentifrice Study, Final

Report," draft of unpublished study, Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(11) Silverman, G., and P. Goldman, "Desensitizing Toothpaste," (DDR study No. 16–78), draft of unpublished study, Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(12) Silverman, G., "Desensitizing Dentifrice Study," draft of unpublished study, Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(13) Axelrod, S., and S. Minkoff, "Desensitizing Toothpaste," (DDR Study No. 15–78), draft of unpublished study, Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(14) Axelrod, S., and S. Minkoff, "Desensitizing Dentifrice Study (10% Strontium Chloride Hexahydrate)," draft of unpublished study, Comment No. C00018, Docket No. 80N–0228, Dockets Management Branch.

(15) Wolf, E.H., "Statistical Summary of a Controlled Clinical Evaluation of a 10% Strontium Chloride Dentifrice in Treatment of Dentin Hypersensitivity Following Periodontal Surgery," draft of unpublished study, Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(16) Wolf, E.H., "Statistical Analysis of Combined Data From Postperiodontal Surgery Subjects in Strontium Chloride Dentifrice Studies Conducted at FDU and UFla," draft of unpublished study, Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(17) Comment No. C00010, Docket No. 80N–0228, Dockets Management Branch.

(18) Comment No. C00018, Docket No. 80N–0228, Dockets Management Branch.

(19) Letter from W.E. Gilbertson, FDA, to S. Most, Block Drug Company, Inc., coded LET13, Docket No. 80N–0228, Dockets Management Branch.

C. Comments on Dosages for Relief of Oral Discomfort Drug Products

10. One comment expressed concern about what it considered the Dental Panel's arbitrary judgment that only concentrations of 85 to 87 percent eugenol are effective as agents for the relief of toothache. The comment contended that lower concentrations of eugenol are also effective for this use, but stated that because of its limited resources, other companies would have to conduct studies to demonstrate the effectiveness of concentrations of eugenol below 85 percent for the relief of toothache.

The Dental Panel's Category I classification of 85 to 87 percent eugenol for the relief of toothache was based on the opinion of experts in endodontics as well as published opinions of other experts that eugenol is a dental analgesic or has a topical anesthetic effect (47 FR 22712 at 22728). The agency, however, does not agree with the Panel's conclusion regarding 85 to 87 percent eugenol and is placing eugenol for the relief of toothache in Category III in this tentative final monograph (see comment 7 above). The Panel also concluded that concentrations of less than 85 percent eugenol may be effective because 85 to 87 percent eugenol is recognized as effective (47 FR 22734). However, because no supportive effectiveness data were available, these lower concentrations of eugenol were placed in Category III. The agency concurs with the Panel's classification of these lower concentrations of eugenol. Other than data on a combination product containing benzocaine (5 percent) and eugenol (less than 85 percent), the comment did not submit any data in support of the effectiveness of concentrations of eugenol at less than 85 percent (see comment 44 below), nor did any other comment submit data that demonstrate the effectiveness of these lower concentrations. Therefore, eugenol as an agent for the relief of toothache at concentrations less than 85 percent remains in Category III.

11. Three comments disagreed with the Dental Panel's Category III classification of phenol in concentrations up to 1.5 percent for the relief of toothache resulting from an open tooth cavity. The comments referred to a statement in the Panel's report in which two acknowledged research experts in endodontics cited phenol's capacity to damage odontoblasts by increasing the permeability of dentinal tubules (47 FR 22712 at 22734). The experts further stated that although phenol may stop pain, its potential to produce pulp damage warrants its elimination from toothache preparations. Citing the minutes of the 5th and 15th Panel meetings in support of their position, the comments stated that the placement of phenol in Category III for safety was based on the Panel's misunderstanding of the presentations made by the two experts (Refs. 1 and 2). The comments contended that the experts were actually referring to the damaging effects of phenol when used at high concentrations and that such effects would not occur with concentrations of 0.5 to 1.5 percent. The comments concluded that phenol concentrations from 0.5 to 1.5 percent will not irritate dental pulp, are safe for use in products for the relief of toothache, and should be placed in Category I for safety.

The agency has reviewed the references cited by the comments and acknowledges that some parts of the discussion concerning the damaging effects of phenol to the pulp, dentin, and dentinal tubules dealt with high concentrations of phenol. However, it cannot be determined from the minutes of the Panel's meetings (Refs. 1 and 2) exactly what concentrations of phenol were being discussed in all cases. The Panel pointed out that there is evidence that some concentrations of phenol can cause irreversible pulp damage (47 FR 22734), and there are no available data demonstrating that phenol in low concentrations is safe for application into an open tooth cavity. In view of the uncertainty regarding the maximum safe concentration of phenol to use as a toothache relief agent for application into an open tooth cavity, the agency agrees with the Panel's conclusion that phenol in concentrations up to 1.5 percent be placed in Category III. The agency invites the submission of data to support the safety and effectiveness of phenol for this use.

References

(1) Ellison, R., presentation to the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, Summary Minutes of 5th Meeting, October 10 and 11, 1973, in OTC Volume, 08APA2.

(2) Bender, I. B., presentation to the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, Summary Minutes of 14th Meeting, October 16 and 17, 1974, in OTC Volume 08APA2. (See appendix II of the minutes of the 15th Meeting, December 4 and 5, 1974.)

D. Comments on Labeling for Relief of Oral Discomfort Drug Products

12. Noting its continued opposition to the exclusivity policy, one comment stated that FDA should not prohibit the use of alternative OTC labeling terminology to describe indications, if that terminology is truthful, not misleading, and intelligible to the consumer. The comment's views on this subject were presented in oral and written testimony submitted to FDA in connection with the September 29, 1982, FDA hearing on the exclusivity policy. A second comment supported the position of the first comment, stating that severely limited wording for indications should be avoided.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall

neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g).

In this amendment to the tentative final monograph for OTC oral health care drug products, supplemental language relating to indications has been proposed and captioned as *Other Allowable Statements.* Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final monograph stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph. However, the agency has decided that, because these additional terms have been reviewed by FDA, they should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under the monograph.

13. Three comments disagreed with the Dental Panel's recommendation that the name and quantity of each inactive ingredient be listed in the labeling of OTC drug products for the relief of oral discomfort. One comment stated that a list of inactive ingredients in the labeling would be meaningless, confusing, and misleading to most consumers. The comments noted that the act and present regulations do not require that the inactive ingredients of OTC drug products be included on a label and argued that the Panel's recommendation to list these ingredients in descending order of quantity poses additional problems because labels would have to be changed as quantities of inactive ingredients change.

The agency agrees that the Federal Food, Drug, and Cosmetic Act (the act) does not require the identification of all inactive ingredients in the labeling of OTC drug products. Section 502(e) of the act (21 U.S.C. 352(e)) requires that all active ingredients and certain other ingredients, whether included as active or inactive, be disclosed in the labeling. The act also limits the requirement for stating the quantity of ingredients in OTC drug products to those specifically mentioned in section 502(e). Although the act does not require the disclosure of all inactive ingredients in the labeling of OTC drug products, the agency agrees with the Panel that listing of inactive ingredients in OTC drug product labeling would be in the public interest. Consumers with known allergies or intolerances to certain ingredients would then be able to identify substances that they may wish to avoid.

The Nonprescription Drug Manufacturers Association (NDMA) (formerly known as The Proprietary Association), the trade association that represents approximately 85 OTC drug manufacturers who reportedly market between 90 and 95 percent of the volume of all OTC drug products sold in the United States, has established guidelines (Ref. 1) for its member companies to list voluntarily inactive ingredients in the labeling of OTC drug products. Under another voluntary program begun in 1974, the member companies of NDMA have been including the quantities of active ingredients on OTC drug labels. The agency is not at this time proposing to require the listing of inactive ingredients in OTC drug product labeling. However, the agency commends these voluntary efforts and urges all other OTC drug manufacturers to similarly label their products.

Reference

(1) "Voluntary Codes and Guidelines of the OTC Medicines Industry," The Nonprescription Drug Manufacturers Association, Washington, 1991, in OTC Volume 13BTFM.

14. One comment stated that excessive labeling requirements, especially when products are packaged in small containers, would increase consumer cost. The comment requested that only essential information be required on the label.

The agency has reviewed the Dental Panel's recommended labeling and, whenever possible, has revised the labeling so that only information essential for the safe and effective use of the drug is required. The agency believes that the labeling proposed in this amendment is necessary to assure proper and safe use of these OTC drugs by the public. Accordingly, the agency recommends that when any OTC drug product is packaged in a container that is too small to contain all of the required labeling, the product be enclosed in a carton or be accompanied by a package insert that contains the information complying with the monograph. The labeling provisions in 21 CFR Part 201 (e.g., §§ 201.10(i), 201.15, 201.60, 201.61, and 201.62) address various requirements for labeling drugs including drugs packaged in containers too small to accommodate a label with sufficient space to bear all the information required for compliance with various regulations. In those instances where an OTC relief of oral discomfort drug product is packaged in a container that is too small to include all of the required labeling, the product can be enclosed in a carton or be accompanied by a package insert that contains the information complying with the monograph. Manufacturers are also encouraged to print a statement on the product container label, carton, or package insert suggesting that the consumer retain the carton or package insert for complete information about the use of the product when all the required labeling does not appear on the product container label.

The NDMA has recently promulgated guidelines for industry to consider when examining product labels for readability and legibility (Ref. 1). These guidelines are designed to assist manufacturers in making the labels of OTC drug products as legible as possible. The agency commends this voluntary effort and urges all OTC drug manufacturers to examine their product labels for legibility.

Reference

(1) "Points for Consideration in Examining Product Labels for Readability and Legibility," The Nonprescription Drug Manufacturers Association, Washington, April 10, 1990, in OTC Volume 13BTFM, Docket No. 80N–0228, Dockets Management Branch.

15. Two comments concerned the following statements from the Dental Panel's discussion under part C, Labeling for OTC Drug Products for the Relief of Oral Discomfort: "The label should include a clear statement of the usually effective minimum and, where applicable, maximum dose (or concentration if more appropriate) per time interval. If dosage varies with the consumer's age, the directions should be broken down by age groups" (47 FR 22712 and 22719). One comment stated that the wording should be modified to include a gel dosage form and suggested the following wording: "The manufacturer should provide clear instructions as to how the drug should be used including where applicable a minimum and maximum dose, time interval of use and child dosage form if applicable." The other comment

maintained that FDA regulations do not require such labeling, particularly with respect to topical dosage forms. The comment stated that such a requirement would confuse the patient and make it difficult to market a product. The comment requested that the agency clarify that such labeling will not be required.

The agency believes that the Dental Panel's discussion cited above is consistent with agency regulations in 21 CFR 201.5 and § 330.10(a)(4)(v) regarding the labeling of OTC drug products. Directions for use of OTC drug products should be clear, direct, and provide the user with sufficient information to permit safe and effective use of the product. The agency agrees with the Panel that minimum and/or maximum dosages (or concentrations if appropriate), time intervals for doses, and special pediatric labeling, if necessary, are important for proper usage by the consumer. The agency believes that requiring such labeling on OTC drug products for the relief of oral discomfort is neither excessively restrictive nor apt to be so confusing to the consumer that marketing of a product would be precluded or hindered. In addition, the agency points out that the Panel's statement (47 FR 22719) was intended as a general, not a specific, recommendation, and the wording is comprehensive enough to encompass all possible dosage forms including gels. Therefore, the agency is not amending the Panel's report as requested and, in this amendment to the tentative final monograph, is proposing directions for use consistent with the Panel's discussion and existing agency regulations.

16. Four comments objected to the Dental Panel's definition of an agent for the relief of toothache as "an ingredient used for the temporary relief of pain arising as a result of an open tooth cavity." One comment believed that the indication for agents for the relief of toothache should reflect the use of these products for pain "due to" or "associated with" toothache, but should not be limited to instances in which the pain is "throbbing" and "persistent." Two comments stated that pain described as a toothache may be due, among other causes, to cracked or defective fillings, foreign or external objects caught between the teeth or between the teeth and gums, excessive plaque or calculus (calcified tooth deposits), cracks in the dental enamel, or trauma to the jaws or gums. Two of the comments thought the definition was too restrictive and ignored mucosal (gingival) pain, which is generally considered by the lay public to be a "toothache." One comment proposed the following definition: "An ingredient used for the temporary relief of pain due to an open tooth cavity or pain arising from an aching tooth." Another comment suggested that the definition should be broadened as follows: "An oral discomfort agent for the temporary relief of: 'Toothache due to open cavity' or 'Pain arising from an aching tooth'." In support of extending toothache claims to pain not associated with an open tooth cavity, this comment and another comment contended that a survey of 966 people (Ref. 1) demonstrated that consumers do not limit their definition of toothache pain to "pain arising from an open tooth cavity," but use the same word "toothache" generically to describe any pain in or about the mouth, jaw, and gums, as well as the teeth. One comment added that topical analgesics, such as benzocaine and phenol, are safe and effective for the temporary relief of "toothache," even if the pain is not due to an "open tooth cavity" and the dental pulp is not irreversibly damaged. Another comment objected to the Panel's not including a claim for pain associated with toothache among the claims for oral mucosal analgesics. The comment requested that a claim for the temporary relief of pain, commonly referred to as "toothache pain" as differentiated from pain due to an open tooth cavity, be placed in Category I for oral mucosal analgesic ingredients.

The Dental Panel began its general discussion of agents for the relief of toothache by describing the significance of an open cavity in a tooth (47 FR 22712 at 22725). A normal, healthy tooth contains a layer of protective enamel directly above a layer of dentin. The dentin encloses the soft tissues of the pulp, which are very susceptible to any irritation occurring in a cavity. Irritation causes inflammation leading to either a reversible or an irreversible stage of pulp disease. A tooth in the irreversible stage is characterized by a persistent, throbbing pain. If the pain is intermittent, rather than persistent, the pulp damage may be reversible.

The Dental Panel limited the definition of an agent for the relief of toothache to ingredients for the temporary relief of throbbing, persistent toothache resulting from a cavity. The Panel based its definition on the assumption that, in general, agents that have historically been used for the relief of toothache are irritating to viable dental pulp and should only be used on a tooth with irreversible pulp damage. Such agents should not be used on a tooth with reversible pulp damage, i.e., a tooth with intermittent pain, because the agent could exacerbate the condition and cause the tooth to die. (Although the Panel placed eugenol in Category I as an ingredient for the relief of toothache, the agency is placing the ingredient in Category III for such use and, consequently, there are no Category I ingredients for the relief of toothache in this document. See comment 7 above.)

The agency has received other comments which have requested a Category I indication for benzocaine as an agent for the relief of toothache (see comment 5 above). The Dental Panel placed benzocaine in Category III as an agent for the relief of toothache. The Panel considered benzocaine safe, but the available data were insufficient to show that benzocaine was effective in relieving toothache pain after application into a tooth cavity (47 FR 22712 at 22730). The agency has reviewed both the data submitted to the Panel and additional data submitted in response to the Panel's report and finds that the data do not support the reclassification of benzocaine from Category III to Category I as an agent for the relief of toothache. Although benzocaine is far less caustic than eugenol, it is not effective as an anodyne when instilled into a cavity in a tooth with irreversible pulp damage. Benzocaine is more effective in relieving pain when it is applied to the oral mucosa.

The agency has reviewed the results of the consumer survey (Ref. 1) which two comments contended showed that toothache pain should not be restricted to pain associated with an open tooth cavity. The agency finds that this survey shows that the American public uses the word "toothache" in a generic sense to indicate pain in or about the mouth, jaw, and gums, as well as the teeth, but that it does not support extending a toothache claim to pain that is not associated with an open tooth cavity. Of the 82 percent of the respondents who reported ever having had a toothache, 65 percent had their toothache caused by a tooth problem, i.e., pain caused by a cavity (41 percent), tooth decay (16 percent), or a cracked filling (8 percent). When asked the location of the pain experienced during their last toothache, only 26 percent reported the pain as located in the tooth itself. The survey did not adequately address consumers' ability to determine whether the pain is due to a toothache. In fact, the survey indicates that there is a great difference between consumers' perception of the location of the "toothache" pain and the actual cause of the pain. Because consumers who self-diagnose pain in or

about the mouth are often unable to determine the exact location of the cause of the pain, it is important that OTC drug products contain the proper indications to assist them in selecting the correct product. Therefore, the agency believes that it is important that the definition and indications for these products be restricted to pain associated with an open tooth cavity, a condition readily recognizable to consumers, to ensure proper use of these products.

With respect to the other comments' contention that oral mucosal analgesics are effective in relieving "toothache," oral mucosal analgesics are indicated for such conditions as the relief of pain due to minor irritation or injury of soft tissue of the mouth but have not been shown to be effective in relieving "toothache" due to a cavity. In the survey submitted by the comment, the majority of respondents who had "pain associated with a toothache" actually had a problem with a tooth, e.g., a cavity or decay. It would be inappropriate for an oral mucosal analgesic to have an indication for the relief of "pain associated with a toothache" when the pain is caused by a problem with the tooth itself and not the surrounding soft tissue. Therefore, the agency agrees with the Dental Panel that agents for the relief of toothache should be restricted to ingredients placed in a tooth cavity to relieve throbbing, persistent pain resulting from an open cavity in the tooth. Moreover, oral mucosal analgesics that relieve pain arising from an injury to adjacent soft tissue should not be indicated for the relief of pain due to a problem inherent to a tooth. Accordingly, the agency does not accept the comments' request to change the definition of an agent for the relief of toothache or to place in Category I for oral mucosal analgesic ingredients a claim for the temporary relief of pain, commonly referred to as "toothache pain" as differentiated from pain due to an open tooth cavity.

Reference

(1) Comment No. C00007, Docket No. 80N-0228, Dockets Management Branch.

17. One comment objected to the Dental Panel's recommendation that the labeling of OTC drug products for the relief of oral discomfort indicate the principal intended action of each active ingredient (47 FR 22712 at 22718). The comment indicated that if a statement of general pharmacological activity is present, a statement of principal intended action of active ingredients would often be simply redundant and that the use of pharmacological terms describing principal intended actions might be confusing to some consumers.

The agency agrees in part and disagrees in part with the comment. The comment is correct in stating that if a statement of general pharmacological activity is present, then a statement of principal intended action of active ingredients would likely be redundant. The agency has reviewed the Panel's recommendation and believes that the Panel was simply recommending that each product for the relief of oral discomfort bear a statement of identity in accord with 21 CFR 201.61, which the Panel cited at 47 FR 22718. This recommendation for OTC drug products for the relief of oral discomfort is consistent with the labeling for all OTC drug products in that 21 CFR 201.61 requires the statement of identity to be in terms of the established name of the drug, if any, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. The regulation further requires that such statements shall employ terms descriptive of general pharmacological category(ies) or principal intended action(s); and cites as examples the terms "antacid," "analgesic," "decongestant," "antihistaminic," etc. The agency is designating and proposing one or more terms such as these as the "statement of identity" for the various product classes included in this tentative final monograph after considering the Panel's recommendations and other suggested terms submitted in the comments. (See comment 18 below.)

18. Two comments objected to the Dental Panel's recommended "Statement of identity" for tooth desensitizers in § 354.65(a). The comments believed the recommended term "tooth desensitizer" is overly restrictive, not adequately descriptive, and potentially confusing to consumers because it could conceivably mislead them by incorrectly suggesting a new use for these products, such as toothache relief or oral analgesia. The comments suggested that other terms such as "toothpaste for sensitive teeth" or "desensitizing toothpaste" should be permitted. One of the comments added that the term "desensitizing toothpaste" had been used for over 20 years for one of its products, has had wide acceptance, and is readily understood. A third comment objected to the Panel's restrictiveness in proposing to allow only one statement of identity in the labeling of tooth desensitizer drug products. The comment argued that FDA should allow manufacturers the alternatives set forth in existing agency regulations regarding the statement of identity for OTC drug products (21 CFR 201.61), which state that the label shall include the established name of the drug, if any, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. If the drug is a combination that has no established name, the requirement may be satisfied by placing a prominent and conspicuous statement of the general pharmacological action(s) of the combination or its principal intended action(s), in terms that are meaningful to laymen.

The agency agrees with the comments that the term "tooth desensitizer" may be misleading to consumers because it may suggest to them that the product can be used for purposes other than its intended use, e.g., as a toothache remedy or an oral analgesic. The agency has reviewed the labeling of tooth desensitizer drug products and agrees that other descriptive terms could be used. The agency believes that the most descriptive term would be that the product is a toothpaste (or dental gel) for sensitive or hypersensitive teeth. The agency believes that the term "desensitizing toothpaste" is similar to "tooth desensitizer" in that it may suggest to consumers that the product can be used for conditions other than the treatment of sensitive teeth, e.g., the relief of toothache. As the Dental Panel explained in its general discussion of agents used to treat "hypersensitive" (ultrasensitive) teeth (47 FR 22712 at 22749), hypersensitivity in teeth develops when the dentin is exposed to the environment of the oral cavity. The dentin, which contains the sensory mechanism of the tooth, can become ultrasensitive to various stimuli such as temperature change, mechanical stimuli, and certain chemicals. Because the development of hypersensitive teeth is complex and may occur for many different reasons, e.g., erosion or abrasion of calcified structures, the diagnosis of this condition should be made by a dentist.

It is important that products containing tooth desensitizing ingredients be clearly labeled for this purpose and not mistakenly used to treat other conditions involving the teeth or gums. Thus, the agency is proposing in this amendment that the statement of identity recommended by the Panel in § 354.65(a) (which appears in § 356.62(a) in this proposal) be revised as follows: The labeling of the product contains the established name of the drug, if any, and identifies the product as a (insert dosage

form, e.g., "toothpaste" or "dental gel") "for" (select one of the following: "sensitive" or "hypersensitive") "teeth."

19. Referring to agents for the relief of toothache, one comment disagreed with the Dental Panel's Category II classification of labeling claims such as "stops pain," "soothes sore gums," and "alleviates pain" (47 FR 22712 at 22730) and any claims that such a product "provides soothing relief." the comment asserted that it failed to understand why such terms are considered too vague and maintained that the terms are useful to the consumer and should be allowed, as long as the product's label contains accepted indications for use as recommended by the Panel in § 354.50(b).

The Panel stated in its report that indications for the use of an "agent for the relief of toothache should be simply and clearly stated and should provide the user with a reasonable expectation of results to be anticipated from use of the product" (47 FR 22719). The agency believes that the term "stops" on the label of agents for the relief of toothache could be misleading and subject to misinterpretation by consumers. The claim "stops pain" implies that pain will not resume and does not provide the consumer with a reasonable expectation of the duration of relief provided by an OTC drug product. Therefore, the agency agrees with the Panel's Category II classification of the labeling claim "stops pain."

The agency believes that the term "soothing" is a product attribute describing certain physical and chemical qualities of an OTC drug product. However, such product attributes are not indications for use, but merely factual statements related to product performance. The agency has no objection to the use of terms describing certain physical and chemical qualities of a drug, as long as these terms do not imply that any therapeutic effect might occur, are true and not misleading, and are distinctly separated from labeling indications. Terms describing a product's characteristics (e.g., color, odor, flavor, and feel) may appear in the labeling for the consumer's information. The agency concludes that it is not necessary to include terms such as these in this amendment.

The agency believes that "alleviates" is an acceptable term, and manufacturers should have the option to use this term in the indications for toothache relief drug products. The agency is therefore proposing to revise the Panel's recommended indication for relief of toothache drug products as follows: "Temporarily" (select one of the following: "alleviates" or "relieves") "throbbing, persistent toothache due to a cavity until a dentist can be seen."

The agency is not proposing any Category I agents for the relief of toothache in this amendment. Consequently, the agency is not including labeling for agents for the relief of toothache in this document. In the even that an ingredient for the relief of toothache reaches monograph status (Category I), the agency will include labeling, as discussed above, in the final monograph.

20. Two comments disagreed with the Dental Panel's placement of certain claims in Category II, specifically, "For temporary relief of cavity toothache" (47 FR 22712 at 22730 and 22742), "* * * [R]elief from toothache due to cavities," "Eases pain due to cavities * * *" (47 FR 22730), and "Temporary relief for toothache due to cavities" (47 FR 22742). Noting that the Panel placed these claims in Category II because the claims could be considered "misleading and unsupported by scientific data" (47 FR 22730), one comment maintained that some of these claims are simply alternative ways of stating claims that the Panel placed in Category I or are statements that merely describe the product's action. The second comment argued that the claims "For temporary relief of cavity toothache" and "Temporary relief for toothache due to cavities" are within the acceptable parameters of the Panel's recommended indication for agents for the relief of toothache in § 354.50(b) (47 FR 22758). The comment added that, in light of the agency's announced intention to ease the so-called OTC "Exclusivity Rule," published in the **Federal Register** of July 2, 1982 (47 FR 29002), these claims should be classified as Category I.

Two of the above labeling claims, "* * * [R]elief from toothache due to cavities" and "Eases pain due to cavities * * *," when evaluated by the Panel, included the term "fast." For a discussion of terms that refer to the onset of action of the drug, such as "fast." (See comment 25 below.)

The Panel recommended the following indication for agents for the relief of toothache: "For the temporary relief of throbbing, persistent toothache due to a cavity until a dentist can be seen." The agency agrees with the Panel regarding the importance of emphasizing that eugenol, if it should become a Category I ingredient for the relief of toothache, should only be used when "throbbing, persistent pain" exists. (See comment 21 below.) In its general discussion of agents for the relief of toothache and its discussion of eugenol (47 FR 22712 at 22725 to 22727), the Panel stated that irritating substances (e.g., eugenol) should only be applied to a nonviable tooth with irreversible damage (characterized by throbbing, persistent pain) because the application of an irritating substance is likely to further injure a viable tooth that has reversible damage (characterized by intermittent pain).

The agency considers the claims proposed by the comments as not providing consumers sufficient information for the safe and effective use of these products because the claims do not include the definitive terms "throbbing" and "persistent." For this reason, and irrespective of the easing of the exclusivity policy (see comment 12 above), the agency concludes that these claims are not suitable alternative ways of stating the claim proposed by the Panel for agents for the relief of toothache, nor are they statements describing the product's action. Although the claims proposed by the comment might be appropriate for nonirritating agents for the relief of toothache, no such agents are currently classified in Category I. (See comment 21 below.) The agency will further consider such claims should a nonirritating agent for the relief of toothache attain Category I status. At this time, however, because there are no Category I ingredients for the relief of toothache, the agency is not including any "relief of toothache" claims in this amendment. In the event that an ingredient for the relief of toothache reaches monograph status (Category I), the agency will include the Panel's recommended indication in the final monograph.

21. Two comments requested that the indication recommended by the Dental Panel in § 354.50(b), "for the temporary relief of throbbing, persistent toothache due to a cavity * * *," be limited to 85 to 87 percent eugenol and not extended to apply to any ingredient that may be classified in Category I in the future. One of the comments stated that limiting the use of toothache remedies to teeth with persistent, throbbing pain is unnecessary for nonirritating ingredients such as benzocaine. The comment maintained that patients cannot readily assess their own level of pain and that they will desire relief regardless of the level of pain. Stating that there are instances when a consumer desires relief from a toothache that is causing less than persistent, throbbing pain and contending that the labeling proposed by the Panel would discourage the use of these products in such instances, the comment maintained that there were no facts to support such a stringent

requirement for a drug as safe as benzocaine.

The agency recognizes that all ingredients that may become Category I agents for the relief of toothache may not be irritating and harmful to a viable dental pulp. The Panel described the types of toothache pain that differentiate between a viable dental pulp and a nonviable dental pulp. It stated that intermittent toothache pain indicates that the dental pulp is still viable and that persistent, throbbing pain indicates that the dental pulp is no longer viable (47 FR 22712 at 22728). The Panel recommended an indication for throbbing, persistent toothache for eugenol, the only agent for the relief of toothache that it put in Category I ingredient, because it is known to be irritating and potentially harmful to viable dental pulp (47 FR 22727). The agency, however, disagrees with the Panel's Category I classification of eugenol used for the relief of toothache. Therefore, in this amendment, the agency is placing eugenol in Category III and is not including any labeling for ingredients for the relief of toothache (see comment 7 above). If eugenol is upgraded to monograph status (Category I), the agency will include the Panel's recommended indication for eugenol in the final monograph.

The agency recognizes that the Panel recommended the same indication, i.e., the persistent, throbbing pain, for all Category III active ingredients for the relief of toothache. Other ingredients may be safe for use in a viable tooth when the toothache pain is not persistent and throbbing. Therefore, the agency agrees with the comment that the indication "for the temporary relief of throbbing, persistent toothache" would not be necessary for such ingredients. If any Category III ingredient for the relief of toothache is upgraded to Category I, and if sufficient data are submitted to the agency demonstrating that the ingredient does not further damage irritated, but viable, dental pulp, the agency will consider an appropriate indication that provides for the safe use of the ingredient.

22. One comment believed that terms for oral mucosal analgesics such as "helps comfortable adjustment" and "unaccustomed use," which the Dental Panel placed in Category II, should be allowed as Category I if used in conjunction with a Category I claim such as "for the temporary relief of pain due to minor irritation of soft tissue due to dentures or orthodontic appliances."

The Panel placed terms such as "helps comfortable adjustment" and "unaccustomed use" in Category II on the basis that they are vague and not definitive of the condition for which relief is sought (47 FR 22712 at 22742). The Panel listed four indications that it felt adequately describe the conditions for which an oral mucosal analgesic should be used (47 FR 22740). All of these indications concern the "temporary relief of pain" due to various conditions, such as minor irritation caused by dentures or injury of soft tissue of the mouth. The Panel did not believe that these Category I indications would be improved by the addition of terms such as "helps comfortable adjustment" or "unaccustomed use," which are not directly related to conditions causing pain. The agency concurs with the Panel and thus rejects the comment's contention that these Category II terms should be allowed in an indication if used in conjunction with a Category I claim.

23. One comment objected to the Dental Panel's recommended requirement in § 354.55(b)(1)(iv) that the indication for use of an oral mucosal analgesic for the relief of pain due to canker sores carry the statement "when the condition has been previously diagnosed by a dentist." The comment stated that canker sores are mucosal lesions commonly diagnosed by consumers, are generally self-limiting, and seldom lead to complications. The comment added that requiring an individual to seek professional advice prior to treatment of a canker sore with proven safe and effective local anesthetics is not in the best interest of the consumer. The comment requested that § 354.55(b)(1)(iv) be revised to read as follows: "For the temporary relief of pain due to canker sores."

In the tentative final monograph for OTC oral mucosal injury drug products (48 FR 33984 at 33989), the agency discussed the self-treatment of canker sores with OTC drug products. The agency stated that, because the term "canker sores" has been used in the labeling of marketed OTC drug products for many years, consumers have a general understanding of the term and do not require a professional diagnosis by a dentist before using an OTC drug product to cleanse a canker sore. Additionally, in the first segment of the tentative final monograph for OTC oral health care drug products (53 FR 2436 at 2458), the agency proposed the following indication for oral health care anesthetic/analgesics in § 356.55(b)(2): "For the temporary relief of pain associated with canker sores." Because oral mucosal analgesics are being combined with oral health care anesthetic/analgesics in this amendment (See part II. paragraph B.5. below), the indication proposed in § 356.55(b)(2) will apply to oral mucosal analgesic ingredients. The indication appears in § 356.52(b)(2) in this amendment. The agency believes that this proposed indication responds to the concerns expressed by the comment.

24. Referring to oral mucosal analgesic drug products, one comment disagreed with the Dental Panel's Category II classification of the labeling claims "For * * * temporary relief of pain and soreness due to minor irritation of teeth and gums," "For * * * effective relief of sore gums," and "For * * * temporary relief of minor mouth or gum soreness" (47 FR 22712 at 22742). The comment maintained that these claims are simply alternative ways of stating claims that the Panel placed in Category I or are statements that describe the product's action. The comment recommended that these Category II claims be moved to Category I.

The above labeling claims, when evaluated by the Panel, included the terms "quick," "rapid," and "fast." For a discussion of terms such as these that refer to the onset of action of the drug, see comment 25 below. The Panel classified the first two claims mentioned by the comment in Category II because, based on the available evidence, it concluded that the claims are misleading and unsupported by scientific data (47 FR 22742). The third claim was also classified in Category II because the Panel judged this claim to be "too vague" and recommended that "it must be more specific" (47 FR 22742).

The agency concurs with the Panel and further considers the comment's version of the first cited claims, "For * * * temporary relief of pain and soreness due to minor irritation of teeth * * *," to be unacceptable because the Category I indications for oral mucosal analgesics do not include relief of pain and soreness due to irritation of teeth. Oral mucosal analgesics are intended for use on soft tissues, and the agency concludes that a claim related to irritation of teeth is not acceptable for products containing ingredients in this class.

In the tentative final monograph for OTC oral mucosal injury drug products, published in the **Federal Register** of July 26, 1983 (48 FR 33984), the agency proposed to replace the phrase "oral soft tissues" with the phrase "mouth and gums." The agency believes that the phrase "oral soft tissues" lacks precise meaning for most consumers and that the phrase "mouth and gums" will be more readily understood by consumers. Therefore, in this amendment, the agency is proposing to revise the indications recommended by the Dental

Panel in § 354.55(b)(1)(i) and (iii) and § 354.55(b)(3) by using the phrase "mouth and gums" instead of "soft tissues," "soft tissue of the mouth," or "oral tissues." Because of the similarities between oral mucosal analgesics and oral health care anesthetic/analgesic ingredients, the agency is proposing in this amendment to combine the two categories. (See part II. paragraph B.5. below.) Therefore, the agency is also proposing to combine these revised indications for oral mucosal analgesics and the indications for oral health care anesthetic/analgesics proposed by the agency in § 356.55(b) of the first segment of the tentative final monograph for OTC oral health care drug products and to include these revised and combined indications in § 356.52(b) of the amended tentative final monograph.

25. One comment expressed concern that all claims which state that a product provides "fast," "quick," or "rapid" relief have been placed in Category II. The comment stated that such claims should be Category I for any product containing benzocaine because, as the Dental Panel noted, benzocaine "has an almost immediate onset of action" (47 FR 22712 at 22738). Claiming that the effect is well known and is evidenced in the scientific literature, the comment expressed its belief that a claim that a product containing benzocaine provides "fast," "quick," or "rapid" temporary relief of toothache pain is founded in scientific fact and should be allowed. A second comment contended that terms such as "fast" and "quick" are not inherently misleading and should therefore be permitted in the labeling of products that can demonstrate such onset of action through scientific data.

As with all OTC drug products, relief of oral discomfort drug products containing benzocaine are expected to achieve their intended results within a reasonable period of time. However, the specific period of time within which relief of oral discomfort drug products achieve these results is not related in a significant way to the safe and effective use of the products. Accordingly, terms such as "fast," "quick," or "rapid" would not signal any property that is important to the safe and effective use of these products and these terms are outside the scope of the OTC drug review and will not be addressed in this amendment. For other classes of products in the OTC drug review, however, statements relating to time of action may properly fall within the list of terms covered by the monograph.

Excluding such terms from the monograph does not imply that they cannot appear in the labeling of a product provided they meet the provisions in section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Such terms will be evaluated by the agency in conjunction with normal enforcement activities relating to that section of the act. Moreover, any term that is outside the scope of the monograph, even though it is truthful and not misleading, may not appear in the boxed area of the labeling entitled "FDA Approved Uses" or "FDA Approved Information" and may not detract from such required information. (See comment 12 above.)

26. Three comments objected to the Dental Panel's Category II classification of the claim "Builds increasing protection against painful sensitivity to cold, heat, sweet, sour, or contact," and claims that imply a superiority in onset of action, such as "quicker," "more quickly," and "faster" for tooth desensitizing ingredients (47 FR 22712 at 22751). The comments maintained that these claims should be classified in Category I if they are supported by adequate scientific documentation.

One comment stated that because improving sensitivity scores with time is commonplace in the various chemical investigations of tooth desensitizing ingredients, the claim "Builds increasing protection * * *." is valid. The comment maintained that the Panel's reasoning that "This Claim implies a slow mechanism of action." (47 FR 22751) is irrelevant to the claim's validity. However, another comment stated that daily use of a tooth desensitizing product for a period of weeks does show a decrease in hypersensitivity and that, accordingly, there is indeed a slow mechanism of action seen in the therapeutic responses to tooth desensitizing ingredients during a study. Therefore, the comment stated that the claim "Builds increasing protection * * *." is valid and important information.

Regarding claims that imply a superiority in onset of action, such as "quicker," "more quickly," and "faster," one comment maintained that if data demonstrate that one agent relieves sensitivity in 1 week whereas another agent relieves sensitivity in 3 weeks, the first agent is obviously therapeutically "faster" than the second. The comment contended that this is important consumer protection information that should be encouraged when supported by sound scientific data.

The OTC drug review establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. Two principal conditions examined during the review are allowable ingredients and allowable labeling. FDA has determined that it is not practical—in terms of time, resources, and other considerations—to set standards for all labeling found in drug products. Accordingly, OTC drug monographs regulate only labeling related in a significant way to the safe and effective use of covered products by lay persons. OTC drug monographs establish allowable labeling for the following items: Product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action.

The agency believes that the claim "Builds increasing protection against painful sensitivity to cold, heat, sweet, sour, or contact" is related to the therapeutic effectiveness of the drug product and is derived from data concerning the mechanism of drug action. Data submitted to the agency in support of the effectiveness of potassium nitrate as a tooth desensitizer (Refs. 1 and 2) indicate that the desensitizing effectiveness of potassium nitrate increases with time, up to 12 weeks. For example, in a 12-week study by Axelrod and Minkoff (Ref. 3), subjects using a dentifrice containing potassium nitrate showed the following subjective decreases in sensitivity: 15 percent at 2 weeks, 42 percent at 4 weeks, 50 percent at 8 weeks, and 75 percent at 12 weeks. The subjects showed comparable decreases in sensitivity when their tactile responses and cold air responses were measured. (See comment 8 above.)

The agency believes that these results indicate that potassium nitrate's effectiveness as a tooth desensitizer is cumulative and that such information should be available to consumers because it might take 2 or 3 weeks before significant therapeutic relief is obtained from the use of a potassium nitrate dentifrice. Therefore, the agency agrees with the comments that the claim "Builds increasing protection * * *." is appropriate for tooth desensitizers such as potassium nitrate, which at this time is the only Category I tooth desensitizer. Therefore, in this amendment, the agency is proposing the following additional indication in § 356.62(b)(2): "Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact."

However, the agency believes that unspecified periods of time, such as

"quicker," "more quickly," or "faster," implying prompt relief are not related in a significant way to the safe and effective use of tooth desensitizers and thus are outside the scope of the OTC drug review. As with all OTC drug products, tooth desensitizers are expected to achieve their intended results within a reasonable period of time. As discussed above, it might take 2 or 3 weeks before significant therapeutic relief is obtained from the use of potassium nitrate dentifrice. Therefore, terms such as "quicker," "more quickly," or "faster" do not seem to be appropriate for OTC tooth desensitizers. For other classes of products in the OTC drug review, such as bronchodilators, statements relating to onset of action may properly fall within the list of terms covered by the monograph.

The agency emphasizes that even though terms such as "quicker," "more quickly," or "faster" are outside the scope of the OTC drug review for this class of products, they are subject to the provisions in section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Such terms will be evaluated by the agency in conjunction with normal enforcement activities relating to that section of the act.

Moreover, any term that is outside the scope of the review, even though it is truthful and not misleading, may not appear in any portion of the labeling required by the monograph and may not detract from such required information. However, statements and terms outside the scope of the monograph may be included elsewhere in the labeling, provided they are not false or misleading.

References

(1) Comment No. C00011, Docket No. 80N–0228, Dockets Management Branch.

(2) Comment No. C00012, Docket No. 80N–0228, Dockets Management Branch.

(3) Axelrod, S., and S. Minkoff, "Desensitizing Dentifrice Study, 1981," draft of unpublished study, Comment No. C00011, Docket No. 80N–0228, Dockets Management Branch.

27. One comment indicated that excessive warning statements should be avoided. It claimed that to preface consumer advice that does not concern life-threatening, or even dangerous, situations with the word "warning" simply encourages the reader to ignore labeling which should be read.

The agency agrees that excessive warning statements should be avoided. For example, the Dental Panel's recommended warning "Children under 12 years of age should be supervised in the use of this product" is not included in the warnings section of this proposal because the statement appears in the directions for use. However, concerning the use of the term "warning," section 502(f)(2) of the act (21 U.S.C. 352(f)(2)) provides, in part, that any marketed drug must bear in labeling "* * * such adequate warnings * * * as are necessary for the protection of users * * *."Furthermore, § 330.10(a)(4)(v) of the OTC drug regulations (21 CFR 330.10(a)(4)(v)) requires that the labeling of OTC drug products include "* * * warnings against unsafe use, side effects, and adverse reactions * * *." Thus, the agency concludes that it is insufficient to limit statements in the "Warnings" section of the labeling to life-threatening or highly dangerous situations only. OTC labeling must also warn against unsafe use of the product and alert consumers of possible side effects even if not likely to be life-threatening or highly dangerous. The agency encourages consumers to read fully all warnings information because the statements included in this section of the labeling are considered important to the proper safe use of the product.

28. A number of comments objected to the warning "Do not swallow" that was recommended by the Dental Panel for all drugs for the relief of oral discomfort. Several comments stated that oral mucosal analgesics and agents for the relief of toothache are placed on the gums or in a tooth and therefore it would be difficult for the patient not to swallow some of the drug. Moreover, the comments argued that because the drugs have been found safe for use in the mouth, such a requirement is illogical and unnecessary. The comments also stated that this warning could unnecessarily alarm consumers and cause them to believe that swallowing even small quantities of the product would result in substantial harm. One comment believed that consumers might misinterpret the warning to mean that one should totally refrain from the act of swallowing rather than to refrain from swallowing excessive amounts of the product. Another comment stated that the warning should not be required for tooth desensitizers because such products are used by adults, who do not appreciably ingest identifrices. The comment added that this warning should be reserved for conditions where there is a reasonable basis for concern based on the safety record of the ingredient or on the use pattern.

The agency agrees with the comments that the warning "Do not swallow" is not needed for drug products included in this rulemaking for the relief of oral discomfort. The agency believes that products such as oral mucosal analgesics, agents for the relief of toothache, and oral mucosal protectants that are directly applied in small amounts to small areas of the oral mucous membranes or to the teeth (e.g., as a liquid or gel) do not require such a warning. These products are not intended to be used in large amounts in the mouth, and the small amount of drug that an individual would undoubtedly swallow would cause no harm. Therefore, the agency will not include the warning "Do not swallow," which was recommended by the Panel for agents for the relief of toothache, oral mucosal analgesics, and oral mucosal protectants in §§ 354.50(c)(1)(iv), 354.55(c)(1)(iii), and 354.60(c)(3), respectively. However, for oral mucosal analgesics formulated as a mouthwash (oral rinse), the agency believes that the directions for use of the product should state that the product should be spit out after rinsing. The agency is including the wording "* * * and then spit out" in the directions for mouthwashes (oral rinses) in § 356.52(d)(1)(i), (d)(2)(i), (d)(4)(i), (d)(5)(i), (d)(6)(i), (d)(7)(i)(A) and (B), and (d)(8)(i) of this proposal.

Both tooth desensitizers and fluoride dentifrices are used in the same manner, i.e., brushed on the teeth with a toothbrush and then spit out. The Panel did not recommend and the agency did not propose a warning concerning the avoidance of swallowing for fluoride dentifrices because these products have a long history of safe use (see the advance notice of proposed rulemaking for OTC anticaries drug products published in the **Federal Register** of March 28, 1980 (45 FR 20666 at 20682) and the tentative final monograph for OTC anticaries drug products published in the **Federal Register** of September 30, 1985 (50 FR 39854 at 39864)). Accordingly, the agency believes that such a warning is not warranted for tooth desensitizer drug products. In addition, as stated by the comment, tooth desensitizers are recommended for adult use and not for children under 12 years of age, thus there is little likelihood that the intended population would ingest the product. The Dental Panel stated that, even in children aged 3 to 6 years, the large majority swallow less than 0.5 gram of toothpaste per brushing (47 FR 22712 at 22751). Adults could be expected to swallow even less. For these reasons, the agency is not including in this proposal the warning regarding swallowing that was recommended by the Panel for tooth desensitizer drug products in § 354.65(c)(2).

29. One comment objected to the Dental Panel's statement in 47 FR 22712

at 22726 that "most toothache remedies are very caustic preparations which will burn the oral mucosa" insofar as it purports to apply to benzocaine. The comment noted that benzocaine, as stated by the Panel, "is one of the more widely used and safest topical anesthetics found in OTC preparations" (47 FR 22737). The comment added that the Panel found the irritancy and sensitivity incidence of benzocaine were at levels of other commonly used drugs (47 FR 22738), and that the Panel did not believe a warning as to that effect was required for the ingredient. The comment requested that, should benzocaine be placed in Category I, the "irritation" warning recommended by the Panel in § 354.50(c)(1)(iii) should not apply to products containing benzocaine.

The Dental Panel's statement referred to by the comment was part of a general discussion on toothache remedies. It is not clear in the discussion to what preparations the Panel was referring. It is possible that the Panel was referring to eugenol, which it stated is known to be very caustic (47 FR 22727). In addition, the Penal described this statement as pertaining to "most," not "all," toothache remedies. The agency believes that the Panel did not intend for the statement to apply to benzocaine because the Panel stated elsewhere in its report that the incidence of benzocaine irritancy equals that of other commonly used drugs and is less than that of the more frequently used sensitizer (47 FR 22738).

The "irritation" warning in § 354.50(c)(1)(iii) referred to by the comment states, "If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly." This statement was proposed as a general warning required for all Category I ingredients in all classes of drug products for the relief of oral discomfort (i.e., agents for the relief of toothache, oral mucosal analgesics, oral mucosal protectants, and tooth desensitizers). The warning statement does not refer to any specific ingredient, but rather refers to the condition that is being treated. If the condition does not improve or if it worsens, the consumer is instructed to seek professional treatment. Therefore, the agency does not accept the comment's claim that the warning statement is not applicable to benzocaine.

As discussed in comment 5 above, benzocaine remains in Category III as an agent for the relief of toothache in this amendment. However, even if sufficient effectiveness data are submitted to reclassify benzocaine to Category I, the agency will still require the general warning statement recommended by the Panel in § 354.50(c)(1)(iii) of its report or a similar warning.

30. Three comments objected to many of the warnings proposed by the Dental Panel for tooth desensitizer drug products in § 354.65(c). Objecting to the warning in § 354.65(c)(1) that states, "Do not continue use beyond 2 weeks except under supervision of a dentist." All of the comments argued that 2 weeks is not an adequate trial period for the use of tooth desensitizers because the effectiveness of desensitizing agents may not be apparent after only 2 weeks of regular use. Two of the comments maintained that about 50 percent of the population does not regularly visit or have access to a dentist and, as a result, makes use of OTC medications. These comments stated that, in the absence of a dental recommendation, 4 weeks, rather than 2 weeks, is a more realistic trial period for the use of a tooth desensitizer. The comments stated that they were aware of the Panel's concern that a diagnosis of hypersensitivity may not accurately be made without professional advice, but contended that the majority of sufferers could make the association between inciting factors and the symptoms of hypersensitivity. One comment recommended that the agency combine § 354.65 (c)(1) and (c)(4) to read as follows: "If relief is not apparent after 4 weeks of regular use or if the intensity of pain increases, see your dentist, as this may indicate a serious dental problem." The other two comments suggested that § 354.65(c)(1) be revised to read as follows: "Do not continue use beyond 4 weeks in the absence of relief except as directed by a dentist. When used on a daily basis, a decrease in sensitivity should occur within the first 2 weeks and greater improvement will occur as regular use continues."

One comment requested that proposed § 354.65(c)(5), which states "See your dentist as soon as possible whether or not relief is obtained," be revised to read as follows: "If relief is not apparent after 4 weeks of regular use or if the intensity of pain increases, see your dentist, as this may indicate a serious dental problem." The comment maintained that if sensitivity is effectively reduced after 4 weeks, it is unnecessary for the consumer to consult a dentist. However, the comment added that if sensitivity is not reduced after 4 weeks, a dentist should be consulted as soon as possible because a dental problem may be present. One comment recommended replacing §§ 354.65 (c)(4) and (c)(5) with the following "Caution" statement: "Caution: Sensitive teeth may require professional attention. See your dentist if the problem persists or if irritation occurs." The other comment recommended a similar statement: "Caution: Sensitive teeth may require professional attention. See your dentist if the problem persists." Both comments contended that the two warnings proposed by the Panel (§ 354.65 (c)(4) and (c)(5)) are excessively and unnecessarily alarming and that the same purpose could be accomplished in a less alarming manner by using a caution statement similar to one recommended above.

The agency agrees with the comments that, when treating dental hypersensitivity with a tooth desensitizer, 4 weeks is a more reasonable trial period than 2 weeks. Clinical data submitted to the agency in support of the Category I status of potassium nitrate as a tooth desensitizer clearly demonstrate that hypersensitivity may be reduced after 2 weeks treatment, but the reduction increases steadily and is more apparent after 4 weeks treatment. (See comment 9 above.)

Although all of the comments maintained that hypersensitivity can be self-diagnosed and self-treated by the consumer, the agency believes that a professional diagnosis is necessary before using a tooth desensitizer for longer than 4 weeks. Dental hypersensitivity may have many causes including faulty restorations, cracked teeth, or infected dental pulp (47 FR 22712 at 22750). Because none of these conditions would be helped by a tooth desensitizer (47 FR 22750), the agency believes that a dentist's evaluation and treatment is necessary before using a tooth desensitizer for longer than 4 weeks. The agency agrees with the Panel that tooth desensitizers should be available as OTC drug products for temporary use until a dentist can be seen or for longer use under professional supervision (47 FR 22749). However, because hypersensitivity may be caused by conditions that require treatment by a dentist, the agency concludes that 4 weeks is an adequate period of time for a consumer to use a tooth desensitizer without professional advice even if the condition appears to improve.

The agency believes that the two warnings recommended by the Panel in §§ 354.65 (c)(4) and (c)(5) can be combined with the warning recommended in § 354.65(c)(1) and simplified into one warning which is proposed in § 356.62(c) as follows: "Sensitive teeth may indicate a serious

problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or doctor." The agency has determined that the signal word "warning" rather than the word "caution" will be used routinely in OTC drug labeling that is intended to alert consumers to potential safety problems. Therefore, the word "warning" will be used for the above statement in this proposal.

31. One comment objected to the Dental Panel's warnings recommended for tooth desensitizers in § 354.65(c)(3), "Children under 12 years of age should be supervised in the use of this product." The comment stated that the oral toxicity of these products is very low based on the amount of product used for normal daily toothbrushing (of which only 5 to 10 percent is actually ingested) or even if the entire tube were inappropriately ingested. The comment suggested that because tooth desensitizers present a minimal health risk to children upon ingestion during normal use and because dentinal hypersensitivity is primarily an adult condition, the warnings in §§ 354.65 (c)(2) and (c)(3) are not appropriate for tooth desensitizers and should be deleted.

Three comments recommended that the agency delete the Panel's recommended warning in § 354.65(c)(6), which states "If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly." Two comments contended that irritation, fever, and infection are not relevant to the condition of, or the products available for, sensitive teeth. Two comments suggested that this warning was unnecessarily alarming, and one of them added that the warning would contribute to the consumer's negation of label precautions because of their excessive use in unwarranted situations.

All three comments suggested that the Panel's recommended warning in § 354.56(c)(7), which states "Do not exceed recommended dosage," be deleted because dentifrice products have a universally accepted, standard method of use and that their safety, as a class, makes such a warning unnecessary. Two comments stated that the proposed warning appeared excessive for the dentifrice product category and should properly be reserved for those products that require it so as to avoid diluting the impact of the message, while one comment added that it is not possible or necessary to establish a "recommended dosage" for dentifrices.

The agency agrees with the comments that §§ 354.65 (c)(3), (c)(6), and (c)(7) are not necessary for the safe use of a tooth desensitizer drug product. The toxicity of the Category III tooth desensitizing agents discussed in the Panel's report is low (47 FR 22712 at 22751 to 22756) and products containing these ingredients are not likely to be used to any great extent by children under 12. Based upon the new directions proposed by the agency for tooth desensitizers stating that a dentist be consulted for use in children under 12 (see comment 38 below), the agency concludes that the warning "Children under 12 years of age should be supervised in the use of this product" is redundant.

The agency reviewed the Panel's evaluation of tooth desensitizing ingredients (47 FR 22750) and did not find any discussion that the consumer should consult a dentist or physician if fever, irritation, or infection are present. The agency does not consider fever, irritation, and infection as being related to dental hypersensitivity and, therefore, does not believe that a warning for the consumer to consult a dentist or physician if those symptoms are present is necessary on a tooth desensitizing drug product.

The agency concludes that the Panel's recommended warning in § 354.65(c)(7) "Do not exceed recommended dosage" can be deleted. The agency believes that consumers know how to use a dentifrice and that it is unnecessary as well as impractical to establish a recommended dosage for a dentifrice.

Therefore, the agency is not including the Panel's recommended §§ 354.65 (c)(3), (c)(6), and (c)(7) in this amendment.

32. Several comments disagreed with certain aspects of the directions (§ 354.50(d)) recommended by the Dental Panel for agents for the relief of toothache (47 FR 22712 at 22758). Noting that the proposed directions specify that the medication should be placed on a cotton pledget, the comments maintained that a cotton pledget is impractical for use with a gel, which is placed directly into a tooth cavity without cotton. Therefore, the directions should be modified to make it clear that they do not apply to gel formulations. One comment stated that the directions should be limited to eugenol (85 to 87 percent).

One comment argued that the directions that restrict use of a toothache relief medication to 1 minute not more than four times daily are inconsistent with the Panel's recommended testing requirements for these drugs, which state that the cotton pledget moistened with medication should be removed after 5 minutes. The comment added that the limitation on the frequency of application is impractical and unnecessary for this class of products, and that use of the drug should depend on patient requirements.

The agency acknowledges that the directions recommended by the Panel in § 354.50(d) may not be appropriate for all ingredients and/or formulations (such as gels). The directions (regarding use of a cotton pledget and limitation of use to 1 minute not more than four times daily) were written for products containing 85 to 87 percent eugenol, the only ingredient classified by the Panel as a Category I toothache relief agent. Eugenol can irritate oral mucous membranes; therefore, it is necessary to place eugenol on a cotton pledget in order to confine the drug to the tooth cavity, and prevent its spread to the oral tissues. Likewise, the 1-minute time limitation is necessary to prevent irritation. Eugenol is classified in Category III in this amendment (see comment 7 above). Because there are no Category I ingredients for the relief of toothache, no labeling for this use is included in this document. However, in the event that eugenol reaches monograph status, the agency is proposing to clarify part of the directions for eugenol to instruct the consumer to remove the cotton pledget. The revised directions would be as follows: "* * * Moisten a cotton pledget with 1 or 2 drops of medication and place in the cavity for approximately 1 minute and then remove * * *." As discussed below, if other ingredients for the relief of toothache are reclassified to Category I, the agency will propose directions that are appropriate for those ingredients.

The Panel recommended that eugenol be used not more than four times a day (47 FR 22712 at 22728). The comment did not submit any data in support of a more frequent interval of using eugenol; therefore, the agency has no basis for changing the Panel's recommendation. The agency also points out that products to relieve toothache are intended to be used only for a short time until a dentist can be seen. These products may provide some temporary relief, but the underlying cause of the toothache remains untreated. Unrestricted use of such products may tend to cause an individual to postpone a necessary visit to the dentist. Therefore, the agency believes that it is in the consumer's best interest for toothache relief agents to

have a limitation on their frequency of use.

33. One comment contended that the age limitations in the Panel's proposed dosage for benzocaine as an agent for the dental relief of toothache are in error (47 FR 22712 at 22730). The comment stated that the Panel must have intended that this drug be limited to use in individuals 12 years and older rather than the "2 years of age and older" as stated in the Panel's proposed dosage.

The agency does not believe that the Panel intended to limit the use of benzocaine to individuals 12 years of age and older in its proposed dosage for this ingredient as a toothache relief agent (47 FR 22730).The Panel recommended that agents for the relief of toothache are appropriate for use in children under 12 years of age when it stated that eugenol could be used in children 2 years of age and older (47 FR 22758). The Panel also determined that products containing benzocaine are safe for use in children under the age of 12 years when it recommended directions for the use of benzocaine as a teething preparation in infants 4 months of age or older (47 FR 22738).

The comment did not submit any data or present any rationale for limiting the use of benzocaine as an agent for the relief of toothache to individuals 12 years of age and older. Therefore, the agency concludes that the Panel's proposed dosage for benzocaine for use as an agent for the relief of toothache in children 2 years of age and older is appropriate and does not need to be revised.

34. One comment requested that a gel dosage form be included in the Dental Panel's proposed dosage for benzocaine for use as an agent for the relief of toothache (47 FR 22712 at 22730). The comment also explained that the use of a cotton pledget would not be appropriate for applying benzocaine in a gel dosage form to an open tooth cavity.

The agency believes that a gel dosage form may be appropriate for benzocaine used as an agent for the relief of toothache and agrees that the use of a cotton pledget to apply benzocaine in a gel dosage form to an open tooth cavity would not be necessary. However, the ingredient benzocaine remains in Category III for use as an agent for the relief of toothache in this amendment. (See comment 5 above.) Until sufficient data are submitted to reclassify this ingredient to Category I for use to relieve toothache pain, the agency is not able to proposed directions that would address the dosage form to be used.

35. One comment objected to the Dental Panel's recommendation that products containing butacaine sulfate be packaged in single-use units to contain no more than 30 milligrams (mg) of butacaine sulfate each with no more than six units per package (47 FR 22712 at 22719). The comment stated that to repackage its butacaine sulfate dental ointment (currently marketed as a 4-percent ointment in ¼ and 1 ounce (oz) tubes) to comply with the Panel's recommendations would create a number of problems, all contributing to increased production costs. The comment added that its present collapsible tube supplier has stated that it is not possible to provide a tube for only 0.75 g of this drug product and thus it would be necessary to change the package style. The comment stated that due to the characteristics of this product, the best packaging alternative available is a "form-fill-seal" pouch, for which suitable material needs to be identified. In addition, the comment stated that the size of the pouch, which needs to be determined, may be too small to permit printing of the required labeling, so that separate closures would have to be provided. The comment claimed that it did not have the capability in-house to solve those problems and, thus, the firm would be required to use a contract packager.

As an alternative to the Panel's proposed single-use unit package, the comment recommended that its currently marketed 1-oz tubes be discontinued and the package of six ¼-oz tubes be maintained. Each ¼-oz tube would provide 10 applications per tube using a 2-inch ribbon per application because the firm had determined in its laboratory that 30 mg is obtained by using this amount of its ointment from the ¼-oz tube. Thus, the comment recommended that the statement "apply not more than a two inch ribbon" be added to the directions section of the labeling for these products. The comment added that its product has been marketed for over 40 years with few reports of adverse reactions over the last 31 years, none of which were of a serious nature, and contended that its recommended packaging and directions for products containing butacaine sulfate rationally resolve the problem of package size limitations.

The agency has reviewed the adverse reaction reports that have been submitted for dental products containing butacaine sulfate (Ref. 1). A total of three adverse reactions have been reported. These reports do not support the Panel's recommendation to package and label 4 percent butacaine sulfate in single-use units containing no more than 0.75 g of the product with no more than six units per package. One woman had an allergic reaction to the drug which would not be unusual for a "caine" type of local anesthetic. Because of such allergic reactions, the Panel recommended, and the agency is proposing, the warning "Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other 'caine' anesthetics." One man experienced edema and developed an ulcer in the mouth while using the drug. This marketing history of only three relatively mild adverse reactions while butacinae sulfate has been marketed in a dental ointment without package size limitations supports the comment's contention that package size limitations supports the comment's contention that package size limitations are not necessary for the safe marketing of OTC drug products containing this ingredient. Therefore, the agency is not proposing package size limitations for butacaine sulfate in this tentative final monograph and is revising the directions for use for these products to delete reference to single-use packaging.

The agency is also deleting the Panel's warnings recommended specifically for butacaine sulfate in § 354.55(c)(4) of its proposed monograph because the information in these warnings is included in the directions for use for these products in § 356.52(d)(3) of this proposal. The Dental Panel's recommended direction "do not use more than one unit at a time (each unit to contain no more than 30 milligrams)" contains the substance of the comment's suggested phrase "apply not more than a two inch ribbon" without being product specific. Because the size of the opening of a particular container and the consistency of a particular drug product will affect the amount of drug delivered in a given "ribbon"-size of the product, the agency is revising the directions to require a dosage of 30 mg butacaine sulfate per application which is relevant to all drug products regardless of their consistency or the size of the package opening. The agency is also revising the directions for butacaine sulfate for clarity and to conform with the format of other OTC drug monographs to read "For products containing butacaine sulfate identified in § 356.12(c)—The product contains 30 milligrams butacaine sulfate per dosage unit. Adults: Apply (manufacturer should state specific amount of product that contains 30 milligrams butacaine sulfate) to the affected area. Do not apply again for at least 3 hours. do not use more than three applications in 24 hours unless directed by a dentist or doctor. Children under 12 years of age: Consult a dentist or doctor."

Reference

(1) Department of Health and Human Services, Food and Drug Administration, "Annual Adverse Reaction Summary Listing," pertinent pages for the years 1976 through 1990, in OTC Volume 13BTFM, Docket Number 80N–0228, Dockets Management Branch.

36. One comment objected to the Dental Panel's limitation of phenol-containing oral mucosal analgesic products to two categories, i.e., teething preparations and dental rinses. The comment stated that the other two Category I oral mucosal analgesics, benzocaine and butacaine sulfate, do not share this limitation. The comment expressed concern that products containing phenol would be restricted to a liquid dosage form, such as a dental rinse only, while products containing benzocaine and butacaine sulfate could be marketed in dosage forms other than dental rinses, such as sprays and gels. The comment stated that sprays and gels have been used for a long time by consumers and professionals for treating conditions requiring topical analgesia, that the Panel did not provide reasons why phenol was limited to teething preparations and dental rinses, and that, without scientific justification for this limitation, the tentative final monograph should provide for the continued use of phenol-containing sprays and gels.

Some of the ingredients, including phenol preparations, evaluated by the Dental Panel in its report on OTC relief of oral discomfort drug products were also evaluated by the oral Cavity panel in its report on OTC oral health care drug products (47 FR 22760) and by the agency in the first segment of the tentative final monograph for OTC oral health care drug products (53 FR 2436). Because of the similarities and overlap between these two rulemakings, the agency has decided to combine them. (See part II. paragraph B.1. below.) Therefore, the agency is amending the tentative final monograph for OTC oral health care drug products to include the ingredients and indications reviewed by the Dental Panel as OTC drug products for the relief of oral discomfort. Oral mucosal analgesic ingredients are being included as oral health care anesthetic/analgesic ingredients. (See part II. paragraph B.5. below.) The agency proposed directions for phenol preparations in § 356.55(d)(6)(i) (A) and (B) and § 356.55(d)(6)(ii) of the tentative final monograph for OTC oral health care drug products that provide for solid and nonsolid dosage forms and for direct application as well as for use as a mouthwash (oral rinse) (53 FR 2436 at 2459). The agency believes that these proposed directions answer the comment's concerns.

Because the first segment of the tentative final monograph for OTC oral health care drug products did not address teething preparations, the agency is amending the recommended directions for phenol preparations by adding the following directions for use in § 356.52(d)(7)(iii) of this proposal: "For products intended for use as a teething preparation, the product is an aqueous solution or suspension containing phenol or phenolate sodium equivalent to 0.5 percent phenol. For infants and children 4 months to under 12 years of age: Apply to the affected area. Use up to 6 times daily or as directed by a dentist or doctor."

37. One comment made several recommendations regarding the directions for use recommended by the Dental Panel for phenol preparations. It stated that the Panel's recommended directions for the use of phenol-containing oral mucosal analgesics fail to consider the differences in the appropriate dosage limitations between dental rinses and other dosage forms. The comment agreed with the Dental Panel's recommendation that the total daily dosage of phenol be limited to a maximum of 600 mg for adults and children 12 years of age and older, adding that this limitation is consistent with the maximum daily dosage for phenol-containing lozenges recommended by the Oral Cavity Panel (47 FR 22760 at 22928). However, the comment indicated that the Dental Panel's phrasing of the directions in § 354.55(d)(4) may lead one to believe that the daily dosage limitation applies to the amount of product that is used as a rinse rather than the amount of active ingredient that may be potentially ingested. The comment emphasized the importance of recognizing that the actual amount of product ingested represents only a small portion of the amount of liquid placed in the oral cavity. To support its statement, the comment submitted a number of studies concerning the volume of mouthrinse used under unsupervised conditions (Ref. 1), the maximum absorption of phenol (Ref. 2), and the duration of anesthesia (Refs. 3 through 6). Based on these studies, the comment stated that the maximum amount of phenol absorbed during rinsing of the mouth with a preparation containing 1.4 percent phenol is 12 percent; the maximum duration of anesthesia is 2 hours; and the mean volume of liquid used by the subjects to rinse the oral cavity is 16.5 milliliters (mL). According to the comment, if this volume of rinse is used every 2 hours "around-the-clock," the maximum amount of phenol ingested (348 mg) is well below the 600-mg limit recommended by both the Dental Panel and the Oral Cavity Panel for adults and children 12 years of age and older.

The comment also stated that age has no influence on the duration of topical anesthesia and that a dose frequency of every 2 hours is also appropriate for children 6 to 12 years of age. The comment suggested a volume limitation of 15 mL for this age group and stated that rinsing with 15 mL of 1.4 percent phenol every 2 hours "around-the-clock" could result in a maximum absorption of 25 mg of phenol per dose, which would not exceed the 300-mg total daily dose limit recommended by the Dental Panel for children 6 to under 12 years of age.

The comment further contended that the Dental Panel unnecessarily restricted the dose frequency for phenol-containing oral mucosal analgesic solutions to a maximum of six times per day. As an alternative, the comment recommended that the maximum single dosage for adults be set at 50 mg every 2 hours, stating that a 50-mg dose used at 2-hour intervals would comply with the maximum daily dosage of 600 mg phenol recommended by the Dental and Oral Cavity Panels. The comment submitted data to support its recommendations (Refs. 1 through 6). For children 6 to under 12 years of age, the comment stated that the maximum single dose should not exceed 25 mg of phenol with a 300-mg maximum daily dosage of phenol. The comment noted that these maximum dosage limits represent the quantity of phenol ingested and that it is highly unlikely that a consumer would use a product "around-the-clock" (for 24 hour), but if this did occur, the total daily dosage would still be within the acceptable safety limits.

The comment requested that § 354.55(d)(4) be revised to read as follows:

(4)(i) *For products containing phenol identified in § 354.12(c).* "Apply to (spray on) the affected area. Repeat every two hours if necessary."

(ii) *For products containing phenol identified in § 354.12(c) when used as a dental rinse.* "Rinse the affected area for approximately 15 seconds then expel remainder. Repeat every two hours if necessary."

Some of the ingredients, including phenol preparations, evaluated by the Dental Panel in its report on OTC relief of oral discomfort drug products were also evaluated by the Oral Cavity Panel in its report on OTC oral health care drug products (47 FR 22760) and by the agency in the first segment of the tentative final monograph for OTC oral

health care drug products (53 FR 2436). Because of the similarities and overlap between these two rulemakings, the agency has decided to combine them. (See part II. paragraph B.1. below.) Therefore, the agency is amending the tentative final monograph for OTC oral health care drug products to include the ingredients and labeling reviewed by the Dental Panel as OTC drug products for the relief of oral discomfort. In this amendment, the agency is proposing to include oral mucosal analgesic ingredients and labeling in the anesthetic/analgesic sections of the oral health care drug products tentative final monograph. (See comment 36 above.)

The agency addressed many of the comment's concerns in the first segment of the tentative final monograph for OTC oral health care drug products and proposed directions for phenol preparations in § 356.55(d)(6)(i) (a) and (b) and § 356.55(d)(6)(ii) (53 FR 2436 at 2459). The agency discussed the following concerns expressed by the comment: for adults and children 12 years of age and over and for children ages 6 to under 12, a maximum daily dosage of phenol of 600 mg and 300 mg, respectively (53 FR 2440 and 2441); a 2-hour dosage frequency for the solid dosage form (10 to 50 mg of phenol) and for dosage forms other than solid (0.5 to 1.5 percent phenol) (53 FR 2440 and 2441); no restriction of rinsing volume for adults and children 12 years of age and over; a proposal for a 10 mL restriction of rinsing volume for children 6 to under 12 years of age (53 FR 2455); a rinsing time of at least 15 seconds for both adults and children 6 years of age and over; for direct application for adults and children 2 years of age and older, to allow the products to remain in place for at least 15 seconds (53 FR 2455), and to change the term "expel remainder" to "spit out" (53 FR 2438).

The agency believes that the above-referenced discussions and the proposed directions for phenol preparations in § 356.55(d)(6)(i) (a) and (b) and § 356.55(d)(6)(ii) in the first segment of the tentative final monograph for OTC oral health care drug products answer the comment's concerns.

The agency has reviewed the Dental Panel's recommended term "dental rinse" used in § 354.55(d)(4) and is proposing to change the term to "mouthwash (oral rinse)" in order to better describe the use of the product and to be consistent with the agency proposal in the first segment of the tentative final monograph for OTC oral health car drug products.

References

(1) Yankell, S.L., M.M. Dolan, and J. Pauls, "Mouthrinse Use Patterns," Journal of Preventive Dentistry, 5:28, 1978.

(2) Davis, C.S., "Oral Mucosal Absorption of Phenol from Chloraseptic Mouthwash and Gargle," draft of unpublished study, Comment C00013, docket No. 80N–0228, Dockets Management Branch.

(3) Young, J.R., "Use of Phenol Anesthetic Spray for Pain Relief," E.E.N.T. Digest, 30:51–60, 1968.

(4) Braunlin, E.A., "Evaluation of an Antiseptic, Anesthetic Solution," Journal of the National Medical Association, 56:151–152, 1964.

(5) Bronsky, D.A., To Evaluate the Efficacy of Both Chloraseptic Solution and Chloraseptic Lozenges When Used to Relieve the Gingival and Buccal Mucosal Discomfort Associated with Orthodontic Braces," draft of unpublished study, Comment C00014, Docket No. 80N–0033, Dockets Management Branch.

(6) Blum, B., "Clinical Evaluation of an Anesthetic Mouthwash," The New York State Dental Journal, 26:419–421, 1960.

38. Three comments objected to the directions proposed by the Dental Panel for tooth densensitizers in § 354.65(d). One comment stated that the sentence "For children under 2 years of age there is no recommended dosage except under the advice and supervision of a dentist or physician," is unnecessary. The comment reasoned that children under 2 years of age, whose teeth are erupting through the gum, would not use a densensitizing toothpaste because neither gingival recession nor periodontitis would be present for the period of time necessary to cause gum recession or tooth erosion which lead to dentinal hypersensitivity. The comment added that the statement "Children under 12 years of age should be supervised in the use of this product," is likewise unnecessary in the directions because the oral toxicity of tooth desensitizers is low, and only 5 to 10 percent of the toothpaste is ingested during actual brushing. The comment maintained that because dental hypersensitivity is primarily an adult condition, a health risk to children resulting from ingestion of a tooth desensitizer is highly unlikely under conditions of normal use. The other two comments stated that the directions are excessively wordy, considering the familiarity of users with the product category. They recommend the following directions: "Use in place of your regular toothpaste or as your dentist directs. Consult your dentist for use by children under 12 years of age."

The agency agrees with the comment that dental hypersensitivity is primarily an adult condition, that directions for use by children are unnecessary, and that these drug products need not be used in children unless directed by a dentist or doctor. Additionally, data submitted to the agency in support of the effectiveness of potassium nitrate as a tooth desensitizer (Refs. 1 and 2) (see also comment 8 above) indicate that at least a 1-inch strip of dentifrice should be used twice a day for optimum effectiveness. Based on the studies conducted, the consumer should be instructed to brush thoroughly for at least 1 minute so that the potassium nitrate is applied to all sensitive areas of the teeth. Further, because of the sensitivity of the teeth, the agency believes that it should be suggested to consumers that a soft bristle toothbrush be used to apply the dentifrice. Therefore, in this tentative final monograph, the agency is proposing in § 356.62(d) that the directions for tooth desensitizers read as follows: "Adults and children 12 years of age and older: Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Children under 12 years of age: consult a dentist or doctor."

References

(1) Comment No. C00011, Docket No. 80N–0228, Dockets Management Branch.

(2) Comment No. C00012, Docket No. 80N–0228, Dockets Management Branch.

39. One comment requested that the oral mucosal analgesic portion of the tentative final monograph include a section on professional labeling. The comment noted that the Dental Panel classified certain indications for oral mucosal analgesics in Category II, specifically post-extraction pain and the pain of a gingivectomy. The comment agreed with the Panel that these indications are inappropriate for consumer labeling, but maintained that they are legitimate uses of local anesthetics by the dental professional. Requesting that the agency develop and include in the tentative final monograph acceptable labeling indications for use only in promotion to professionals, the comment suggested that such legitimate indications include claims for relief of pain associated with gingivectomy, insertion of immediate dentures, pericoronitis, aphthous ulcers, infectious stomatitis, Vincent's infection, tooth extraction and other oral surgery, and for preinjection topical anesthesia.

The agency believes that some of tne comment's suggested indications for products containing topical anesthetic/

analgesic (oral mucosal analgesic) ingredients could be included in the professional labeling section of the monograph. The Dental Panel found that a combination of a topical anesthetic/analgesic and a denture adhesive is a rational combination because it may enable a denture wearer to benefit from the analgesic action, while the adhesive helps to secure the dentures, and both actions increase the comfort of the user (47 FR 22712 at 22721). The Panel stated that immediate dentures (dentures that are placed in the mouth immediately following the extraction of the natural teeth as part of the surgical procedure), particularly, may be uncomfortable or painful in some instances. The Dental Panel recommended benzocaine, butacaine sulfate, and phenol preparations (phenol and phenolate sodium) as Category I oral mucosal analgesics, but not for these professional uses.

Ship, Williams, and Osheroff (Ref. 1) report that topical anesthesia has been used, in dentistry, prior to injection of anesthetic drugs and for suppression of the gag reflex in oral manipulations. They studied the anesthetic potency and duration of effect of topically applied dyclonine hydrochloride when compared with lidocaine hydrochloride and four antihistamines. Test solutions were applied with cotton-tipped applicator sticks or as a mouth wash to affected areas. Fifteen patients with severe, recurrent aphthous stomatitis were evaluated over a 6-month period. The results showed excellent depth of anesthesia when 0.5 to 5 percent dyclonine hydrochloride was compared with 5 percent lidocaine hydrochloride. The mean duration of anesthesia was 45 minutes for dyclonine hydrochloride with onset occurring in 4 to 8 minutes. No perceptible differences were noted in the depth of anesthesia produced by the various concentrations tested. No adverse reactions were reported. The mean duration of anesthesia was 30 minutes for lidocaine hydrochloride, with onset occurring in 3 to 8 minutes.

Ping, White, and Spear (Ref. 2) discussed the use of dyclonine hydrochloride to control the severe gag reflex which they considered necessary to facilitate intraoral dental radiographs. Dyclonine hydrochloride was used in more than 300 patients during a 16-month period. Patients rinsed their mouths with 0.5 to 1 percent dyclonine solution for 40 seconds and then expectorated. After a short period of time, full mouth periapical dental radiographs were taken with complete absence of the gag reflex. No appreciable increase in the effectiveness of the more concentrated dyclonine solution could be detected. Patients rinsing their mouths with dyclonine solution before intraoral radiographs experienced every little discomfort, resulting in better radiographs. The authors noted that, in prosthodontics, the gag reflex also presents frequent problems during the making of impressions. The authors reported that dyclonine mouth rinses gave excellent results, but only a few patients were studied. However, the extent and duration of anesthesia were considered unnecessarily extensive for the average case. The agency lacks sufficient data to ascertain whether anesthetic/analgesic drugs like dyclonine are currently used in prosthodontic procedures and invites comments and data on such use.

Adriani and Zepernick (Ref. 3) compared the potency and effectiveness of dyclonine hydrochloride with other topical anesthetics in man by using electrical current delivered by a nerve stimulator. Their procedure involved quantitating the amount of electric current needed to elicit a response after the topical application of 1 percent dyclonine hydrochloride to a mucosal surface. Several surfaces were studied, with the tip of the tongue used for most studies because of its sensitivity, accessibility, and production of the most consistent results. When the duration and effectiveness were considered on a milligram for milligram basis in the study, the results showed good depth of anesthesia when 1 percent dyclonine hydrochloride was compared with 4 percent lidocaine and 6 percent hexylcaine. The authors specifically mentioned that 1 percent dyclonine hydrochloride is an effective topical anesthetic that does not have adverse systemic responses characteristic of other local anesthetics.

Based on the above data, the agency believes that dyclonine hydrochloride can be used for the relief of discomfort in patients with an excessive gag reflex when having impressions of the teeth made or during intraoral radiography and for preinjection topical anesthesia under the supervision of a dentist or physician. However, the agency lacks adequate data to support the use of dyclonine hydrochloride for the relief of pain associated with gingivectomy, insertion of immediate dentures, or tooth extraction and the use of benzocaine, butacaine sulfate, or phenol preparations (phenol and phenolate sodium) for any of the above uses. Accordingly, the agency is amending the section on professional labeling that was proposed for oral anesthetic/analgesic ingredients in the first segment of the tentative final monograph for OTC oral health care drug products, § 356.80, to enable manufacturers to provide health care professionals with information about the additional indications for products containing the ingredient dyclonine hydrochloride. However, these indications cannot be used on the consumer labeling of the product because consumers cannot self-diagnose and self-treat these conditions.

The agency is proposing the following indications for products containing dyclonine hydrochloride in the professional labeling section of this amendment: "For the temporary relief of discomfort in patients with an excessive gag reflex when having impressions of the teeth made or during intraoral radiography" and "For use as a pre-injection topical anesthetic on the oral mucosa."

Concerning the comment's suggested claims for relief of pain associated with "other oral surgery," the agency does not find a sufficient basis to include this indication in the professional labeling for topical anesthetic/analgesic drug products. The agency believes that the term "other oral surgery" is ambiguous and could imply that these topical products may have an anesthetic effect on deeper tissues than would be affected by the superficial anesthetic effect of topical anesthetic/analgesic drug products.

In the first segment of the tentative final monograph for OTC oral health care drug products, the agency determined that anesthetic/analgesic drug products can be used for the relief of pain associated with tonsilitis, pharyngitis, stomatitis, and throat infections which first must be diagnosed by a dentist or doctor (53 FR 2436 at 2438 and 2439). Therefore, "stomatitis" is included in this amendment as a professional indication for oral anesthetic/analgesic ingredients. Likewise, the agency believes that the pain associated with Vincent's infection (necrotizing ulcerative gingivitis or trench mouth) could be alleviated by OTC anesthetic/analgesic ingredients after diagnosis by a dentist or doctor. Therefore, the agency is amending the professional labeling in § 356.80(a) to include "Vincent's infection."

Regarding the conditions of "aphthous ulcers" (canker sores) and "pericoronitis" (inflammation of the gingiva surrounding the crown of a partially erupted tooth, i.e., teething pain) mentioned by the comment, the Panel recommended these as OTC indications in § 354.55(b), and the agency has determined that these conditions are self-diagnosable and self-

treatable. Accordingly, the agency is proposing the OTC indication "For temporary relief of pain associated with canker sores" for all Category I oral mucosal analgesic ingredients and the OTC indication "For the temporary relief of sore gums due to teething in infants and children 4 months of age and older" only for benzocaine and phenol, for the reasons discussed above. (See comments 23 and 36 above.)

References

(1) Ship, I. I., A. F. Williams, and B. J. Osheroff, "Development and Clinical Investigation of a New Oral Surface Anesthetic for Acute and Chronic Oral Lesions," Oral Surgery, Oral Medicine, and Oral Pathology, 13:630–636, 1960.

(2) Ping, R. S., J. G. White, and L. B. Spear, "Dyclonine Hydrochloride as a Topical Anesthetic in Dentistry," Oral Surgery, Oral Medicine, and Oral Pathology, 10:623–626, 1957.

(3) Adriani, J., and R. Zepernick, "Clinical Effectiveness of Drugs Used for Topical Anesthesia," Journal of the American Medical Association, 188:711–716, 1964.

E. Comments on Combination Drug Products

40. Several comments objected to the Dental Panel's Category III classification of combinations containing two agents for the relief of oral discomfort from the same pharmacotherapeutic group, but with different mechanisms of action (47 FR 22712 at 22722). The comments contended that this Category III classification is inconsistent with recommendations made by the Topical Analgesic Panel and the Oral Cavity Panel that a combination of the topical analgesics phenol and benzocaine be Category I. Noting that phenol has a slow onset but a long duration of action as a topical analgesic, and that benzocaine has a rapid onset but a short duration of action as a topical analgesic, the comments argued that these differing pharmacologic activities for benzocaine and phenol supplement one another. Two of the comments added that further testing of the combination of these ingredients is unwarranted because both ingredients have well-defined actions. The comments requested that the combination of phenol and benzocaine be a Category I combination for use as an oral mucosal analgesic.

The agency agrees with the comments that the combination of benzocaine and phenol can be classified Category I for the relief of oral discomfort. In the first segment of the tentative final monograph for OTC oral health care drug products (53 FR 2436 at 2450 and 2451), the agency determined that the combination of benzocaine and phenol (i.e, oral anesthetic/analgesic ingredients) conforms to the requirements in 21 CFR 330.10 and to the agency's guidelines for OTC drug combination products (Ref. 1) and proposed Category I status. Because oral mucosal analgesics (e.g., benzocaine and phenol) are being combined with oral anesthetic/analgesics (See Part II. paragraph B.5 below), the combination of benzocaine and phenol is likewise proposed as Category I in this amendment.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

41. Two comments stated that the Panel's Category II classification of combinations containing more than two Category I dentifrice and dental care agent active ingredients in section II. Paragraph D.6.e. of the May 25, 1982 advance notice of proposed rulemaking (47 FR 22712 at 22721) conflicts with the Panel's Category I classification of a three-ingredient combination containing an oral mucosal protectant, an oral mucosal analgesic, and an oral antiseptic (47 FR 22720 to 22721). One of the comments recommended that the agency make an exception for this particular three-ingredient combination and modify the Panel's recommendations accordingly. The second comment suggested that there be no limit to three active ingredients in combination and that combinations of two or more active ingredients be permitted provided they are sound and can be shown to be of value.

The agency agrees with the second comment that three-ingredient combinations need not be limited provided they are supported by adequate data. Moreover, FDA agrees that no fixed limit need be placed upon the number of active ingredients in a combination product if it can be shown to be a rational, safe, and effective combination with a suitable target population. This position is consistent with the FDA policy for OTC drug combination products in 21 CFR 330.10(a)(4)(iv) and with the guidelines for OTC drug combination products (Ref. 1). The various panels placed certain two- and three-ingredient combination products in Category I because data were presented to support their safety and effectiveness. Regardless of the number of ingredients, the agency will consider any combination for Category I that meets the regulation and guidelines mentioned above. The proposed allowable combinations are listed in § 356.20 of the amendment.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products, September 1978," Docket No. 78D–0322, Dockets Management Branch.

42. One comment stated that part of the Dental Panel's rationale for placing the combination of an oral mucosal protectant and a denture adhesive in Category II was not totally accurate. The Panel had stated that the thickness of the film of the protectant would interfere with the fit of the dentures (47 FR 22712 at 22722). The comment, however, explained that the film would probably not be thick enough to interfere with denture fit and suggested that a more appropriate rationale would be that the oral mucosal protectant "is not needed because the denture already covers the wound."

The agency agrees with the Panel's rational that the oral mucosal protectant would interfere with the action of the denture adhesive and that the added thickness of the protectant would interfere with the fit of dentures. The agency also accepts the comment's suggested rationale that the oral mucosal protectant is not needed in a product intended for use with dentures because the denture already covers the wound.

43. One comment disagreed with the Dental Panel's Category III classification for the combination of an oral mucosal protectant with an oral mucosal analgesic claiming a prolonged duration of action (47 FR 22712 at 22722 to 22723). The comment stated that the Panel was not aware that the prolonged action of benzocaine in an oral mucosal protectant paste had been documented. The comment briefly summarized: (1) the reported persistence of mucosal anesthesia by benzocaine when dissolved in an emollient dental past (Ref. 1), (2) the safety and effectiveness of this combination (Ref. 2), and (3) the prolonged retention of the paste in various parts of the mouth (Refs. 3, 4, and 5). Stating that the "oral mucosal protectant paste" with benzocaine is a marketed product that has been "Accepted" by the American Dental Association's Council on Dental Therapeutics since 1973, the comment added that a "prolonged action" claim is approved for advertising in the Journal of the American Dental Association and submitted a copy of the advertisement (Ref. 6). The comment concluded by strongly urging FDA to reverse the Dental Panel's position on the

"prolonged duration of action" claim for this marketed oral mucosal paste containing benzocaine and to reclassify this claim to Category I for this combination.

The agency has evaluated the data submitted by the comment and concludes that they are not sufficient to support the claim of a prolonged analgesic action for benzocaine when combined with an oral mucosal protectant. Some of the data (Refs. 3, 4, and 5) indicate that the duration of maintenance of the protectant paste in various regions of the mouth averaged 1 to 2 hours, depending on the region of the mouth to which the paste was applied. A wide range of times has been reported—from 10 minutes to 24 hours (Ref. 5). However, benzocaine was not included in the paste in these studies.

In one study in which benzocaine was included in the paste (ref. 1), the investigator reported that the onset of anesthesia, for the investigated group, varied between 10 to 20 minutes and persisted for 1 to 2 hours, but benzocaine in a nonprotectant paste was not included in the study. Therefore, there is no way of determining from this study whether the use of the protectant paste prolonged the duration of action of the benzocaine. In the other study in which benzocaine was included in the protectant paste (Ref. 2), the effectiveness of the benzocaine-protectant paste combination was compared with the effectiveness of the protectant paste alone in reducing the pain and discomfort associated with lesions of the oral mucosa. The results showed that the combination product was significantly more effective than the protectant paste in reducing the pain caused by the mucosal lesions.

While the results support the effectiveness of benzocaine as a Category I oral mucosal analgesic (which is the conclusion that the Panel reached), they do not demonstrate "prolonged duration of action" of the combination product compared with the oral mucosal analgesic without an oral mucosal protectant. Thus, the submitted studies are inadequate because they do not demonstrate that the combination of ingredients prolongs the analgesic effect of the oral mucosal analgesic. Studies must be designed and conducted to test the duration of the analgesic effect of the combination against its oral mucosal analgesic component alone in a nonprotectant vehicle, thus establishing that the oral mucosal protectant prolongs the duration of action of the oral mucosal analgesic.

The agency notes that the marketed protectant paste discussed in the studies (Refs. 1 through 5) was submitted to the Oral Cavity Panel (Ref. 7), but was not submitted to the Dental Panel for evaluation as a drug for the relief of oral discomfort. The ingredients in the paste, i.e., pectin, gelatin, and sodium carboxymethylcellulose in a plasticized hydrocarbon gel of 5 percent polyethylene in mineral oil, were not evaluated by the Oral Cavity Panel as oral mucosal protectants. The pectin and gelatin were evaluated as demulcents (47 FR 22760 at 22916 to 22919), and the sodium carboxymethylcellulose and plasticized hydrocarbon gel (polyethylene in mineral oil) were considered inactive ingredients (47 FR 22764). Thus, none of these ingredients is generally recognized as a safe and effective oral mucosal protectant.

Concerning the advertisement submitted by the comment, the acceptance of an advertisement for an OTC drug product in a scientific journal cannot be interpreted as signifying that the OTC drug or any claim made for it is generally recognized as safe and effective by the agency. The Federal Trade Commission has the primary responsibility for regulating OTC drug advertising. FDA does, however, regulate OTC drug advertising that constitutes labeling under the act. For an OTC drug to be generally recognized as safe and effective and not misbranded, the advertising for the drug product must satisfy the FDA regulations in § 330.1(d) (21 CFR 330.1(d)), which state that the advertising may prescribe, recommend, or suggest the drug's use only under the conditions stated in the labeling.

In conclusion, the agency concurs with the Panel and is proposing that the combination of an oral mucosal protectant with an oral mucosal analgesic claiming a prolonged duration of action for the analgesic be classified as Category III.

References

(1) Gaynor, H.M., "Clinical Investigation of the Use of Benzocaine in Orabase," Journal of Connecticut State Dental Association, 42:112–116, 1968.

(2) Stallard, R.E., N. Hiep, and A.K. ElGeneidy, "Safety and Effectiveness of Orabase with Benzocaine," draft of unpublished study, Comment No. C00016, Docket No. 80N–0228, Dockets Management Branch.

(3) Morgan, P.S., "An Oral Adhesive Vehicle in the Postoperative Care of Dental Extractions," Texas Dental Journal, 78:3–7, 1960.

(4) Kutscher, A.H., et al., "A New, Long-Lasting Vehicle for the Application of Drugs to the Oral Mucous Membranes," Journal of the American Dental Association, 62:40–43, 1961

(5) Parker, D. A. S., "Clinical Trial of an Oral Adhesive Paste," Australian Dental Journal, 13:197–200, 1968.

(6) Comment No. C00016, Docket No. 80N–0228, Dockets Management Branch.

(7) OTC Volume 130004.

44. One comment disagreed with the Dental Panel's recommendation that a combination drug product containing benzocaine and eugenol be placed in Category III for the relief of toothache. The comment submitted data from two short studies and claimed that the results confirm that a combination of benzocaine and eugenol in a beeswax dosage form is effective as a toothache remedy (Ref. 1). The comment acknowledged that no statistical evaluation of the data was performed and that, because of limited resources, the studies would not be expanded to a full clinical evaluation. Based on the data presented, the comment requested that the combination of benzocaine and eugenol be categorized as generally recognized as safe and effective as an agent for the relief of toothache.

The agency has reviewed the data from the two studies and has determined that insufficient information is provided to evaluate the results of the studies. There is inadequate information concerning the conditions under which the studies were conducted, the methods used to randomly allocate the test and control medications, and the category scales for determining pain intensity. In addition, the design of the studies was inadequate for determining that the combination is equal to or better than each of the active ingredients used alone at its therapeutic dose. The activity of the combination was only tested against a placebo preparation that consisted of the gum base without any active ingredients. The effectiveness of the combination should also have been tested against each individual ingredient separately in order to determine the contribution of each individual ingredient to the combination's activity. When the study was expanded to include an experimental formulation containing eugenol, the eugenol was present at twice the concentration contained in the combination product. These data are not adequate to establish effectiveness of the combination product.

The agency concurs with the Dental Panel's Category III recommendation for the combination of benzocaine and eugenol and is so classifying that combination in this tentative final monograph. The Panel placed benzocaine in Category III as an agent for the relief of toothache on the basis of insufficient effectiveness data (47 FR

22712 at 22730), and adequate data have not been presented to establish that benzocaine is effective in relieving toothache pain (see comment 5 above). Although the Panel placed eugenol in Category I for the relief of toothache, the agency has determined that the data are inadequate to demonstrate the effectiveness of eugenol for this use and is placing it in Category III (see comment 7 above). The agency invites the submission of data from well-designed, adequately-controlled studies that show benzocaine or eugenol as single active ingredients or in combination with each other are effective in reducing toothache pain.

Reference

(1) Comment C00006, Docket No. 80N–0228, Dockets Management Branch.

45. One comment expressed concerns about the categorization of the combination of benzocaine and capsicum and the combination of oxyquinoline, benzocaine, and capsicum for use in a dental poultice for the temporary relief of noncavity toothache.

The agency agrees with the Dental Panel that the combination of an oral mucosal analgesic (benzocaine) and a counterirritant (capsicum) is Category III for the relief of noncavity toothache pain (47 FR 22712 at 22722). The agency also agrees with the Panel's Category I classification of benzocaine (5 to 20 percent for use as an oral mucosal analgesic (47 FR 22725 and 22757 to 22758) and its Category III classification of capsicum, equivalent to 0.01 to 0.02 percent capsaicin, for use on intact (normal) oral mucosa as a counterirritant for the relief of toothache (47 FR 22731). The Panel stated that "If a Category III active ingredient or other condition is present in a combination product containing no Category II ingredient or labeling, the combination is classified as Category III" (47 FR 22722).

In addition, the requirements for OTC combination drug products, set forth in § 330.10(a)(4)(iv) (21 CFR 330.10(a)(4)(iv)) state that "an OTC drug may combine two or more safe and effective ingredients and may be generally recognized as safe and effective * * *." Category II or Category III active ingredients are not permitted in a Category I combination product. Therefore, if benzocaine is used as an oral mucosal analgesic in combination with a Category III ingredient (capsicum), the resulting combination is classified as a Category III product. One product containing benzocaine and capsicum was submitted to the Dental Panel. However, the submissions did not contain adequate data for the individual ingredients nor any data for the combination product (Refs. 1 and 2). Furthermore, the comment did not submit any new data to support the effectiveness of the combination of benzocaine and capsicum for the relief of noncavity toothache.

The agency has reviewed the labeling of the product containing benzocaine, capsicum, and oxyquinoline that was submitted to the Panel (Ref. 3) and determined that the benzocaine is included in the product as an oral mucosal analgesic, the capsicum as a counterirritant, and the oxyquinoline as an antimicrobial (antiseptic). The agency is proposing that this combination of ingredients in a dental poultice dosage form for the relief of noncavity toothache be placed in Category II. The Dental Panel classified combination products containing a counterirritant and an oral antiseptic (e.g., oxyquinoline) in Category II because it found no rationale for a combination product containing a counterirritant and an oral antiseptic (47 FR 22712 at 22722).

The Dental Panel deferred the review of oxyquinoline as an antiseptic to the Advisory Review Panel on OTC Oral Cavity Drug Products (47 FR 22715). The Oral Cavity Panel classified oxyquinoline in Category III as an antimicrobial ingredient for topical use on the mucous membranes of the mouth and throat because of insufficient safety data and no data from controlled in vivo studies on its effectiveness as a broad-spectrum antimicrobial agent (47 FR 22760 at 22880 to 22881). Despite the Oral Cavity Panel's Category III recommendation for oxyquinoline as a single ingredient, the agency concurs with the Dental Panel's recommendation that the combination of a counterirritant and an oral antiseptic should be in Category II. A counterirritant should be applied only "on intact (normal)" oral mucosa (47 FR 22731). Because no infection should be present at the site of use, no antiseptic is necessary. Accordingly, the agency is proposing that the combination of oxyquinoline, benzocaine, and capsicum be classified as Category II.

References

(1) OTC Volume 080191.
(2) OTC Volume 080214.
(3) OTC Volume 080003.

46. Expressing concern about the status of chlorobutanol in its company's toothache relief product that contains a combination of eugenol and chlorobutanol, one comment stated that consumers have commented favorably on the product. The comment contended that long time public usage and acceptance should be considered in the evaluation of such products and that small companies should not be expected to conduct elaborate tests on their products to prove effectiveness.

Although the Dental Panel placed eugenol in Category I for the relief of toothache (47 FR 22712 at 22727), the agency has determined that the data are inadequate to demonstrate the effectiveness of eugenol for this use and is placing it in Category III in this document (see comment 7 above). Chlorobutanol was not reviewed by the Panel. In the company's submission to the Panel (Ref. 1), chlorobutanol hydrous (chloroform derivative) was listed as an active ingredient on the product's label; however, chlorobutanol was not listed in the typed list of active ingredients in the submission nor were data submitted on chlorobutanol for any use. Thus, the Panel did not consider this ingredient to be an active ingredient and did not classify it. Adequate data demonstrating safety and effectiveness are necessary to support the use of this ingredient in toothache relief products. Without such data, the agency considers chlorobutanol a Category II ingredient for the relief of toothache.

FDA's standards for the effectiveness of OTC drugs in 21 CFR 330.10(a)(4)(ii) state that marketing experience and testimonials alone are not adequate proof of effectiveness, which is to be demonstrated by clinical studies. With regard to the comment's concern about impacts of testing on small manufacturers, this issue is discussed in comment 2 above.

Reference

(1) OTC Volume 080003.

47. One comment requested that a combination dentifrice containing 5 percent potassium nitrate and an acceptable Category I fluoride be classified as Category I for the combined indication of tooth desensitizing and dental caries control, provided that the product satisfies the Laboratory Testing Profile (LTP) criteria required for fluoride-containing anticaries dentifrices. Stating that data submitted to the agency adequately support a Category I classification of potassium nitrate as a tooth desensitizer, the comment maintained that a potassium nitrate/fluoride combination fully agrees with the criteria for Category I combinations cited by the Dental Panel in its report on OTC drug products for the relief of oral

discomfort (47 FR 22712 at 22720). Those criteria are as follows:

Two Category I active ingredients from different pharmacotherapeutic groups may be combined to treat different symptoms concurrently if each Category I active ingredient is present within its established dosage range; the combination is rational; there is a significant target population that suffers the concurrent symptoms; and the combination is as safe and as effective as each individual active ingredient used alone.

The comment noted the Category I status of fluorides for use in dentifrices for the prevention of dental caries and the major significance to the field of dental health of the effectiveness of the fluoride ion in lowering the incidence of dental caries. The comment maintained that a combination product containing a desensitizing agent and an anticaries agent would benefit those consumers who must use a desensitizing dentifrice because the combination would permit continued topical fluoride administration while the consumer is building and maintaining resistance to dental hypersensitivity. The comment added that the target population for the combination dentifrice consists of all consumers who have hypersensitive dentin, which is about 12 percent of the United States adult (18 or over) population or more than 19 million people.

Stating that it was unaware of any synergistic toxicity that could arise from the combination of fluoride and potassium nitrate, the comment maintained that the fluoride/potassium nitrate combination drug product should be as safe as the single ingredient dentifrices. The comment submitted toxicological data to confirm the safety of the combination product formulation (Refs. 1 and 2).

The comment maintained that the effectiveness of potassium nitrate as a desensitizing ingredient would not be expected to be diminished in the presence of fluoride. Citing the Merck Index, the comment noted that potassium nitrate is a very soluble inorganic salt, 1 g dissolving in 2.8 mL water (Ref. 3). Therefore, the comment contended that potassium nitrate would readily dissolve and saturate saliva to provide bioavailable nitrate at a level adequate for therapeutic effect, regardless of the presence of fluoride in the formula. The comment submitted in vitro data to support the bioavailability of the nitrate ion in dentifrices containing fluoride and potassium nitrate (Ref. 1). The comment also submitted two human dental hypersensitivity clinical studies (Refs. 4 through 7) to support its contentions regarding the effectiveness of the potassium nitrate/fluoride combination drug product.

The comment noted that the LTP's recommended by the Dental Panel in its report on OTC anticaries drug products (45 FR 20660 at 20677 to 20681) can be used to demonstrate the effectiveness of the fluoride ingredient in a fluoride/potassium nitrate combination drug product in place of extensive clinical testing. The comment submitted data to support the bioavailability of the fluoride ion in a fluoride/potassium nitrate combination dentifrice (Refs. 1 and 2) and data pertaining to the remineralization enhancement of teeth by dentifrices containing potassium nitrate and fluoride in combinations (Ref. 8).

The comment also submitted statements from four experts, including three former members of the Dental Panel, who reviewed the material submitted to the FDA by the comment and concluded that two currently available dentifrices containing potassium nitrate in combination with fluoride are generally recognized as safe and effective and not misbranded for the prevention of dental caries and the treatment of dentinal hypersensitivity (Ref. 9).

The comment recommended that FDA revise the Panel's recommendation in § 354.20, "Permitted combinations of active ingredients," by adding paragraph (f) as follows: "(f) Potassium nitrate 5% tooth desensitizer as identified in section 354.16 and any generally recognized as safe and effective fluoride-containing anticaries drug product."

The agency is proposing a Category I classification for potassium nitrate as a tooth desensitizing ingredient in this document (see comment 8 above), and has proposed a Category I classification for several fluoride ingredients as anticaries agents in the tentative final monograph for OTC anticaries drug products published in the **Federal Register** of September 30, 1985 (50 FR 39854 at 39872).

The agency agrees with the comment that a combination dentifrice containing 5 percent potassium nitrate and a Category I fluoride is a rational combination. Furthermore, the agency concludes that the submitted data support the safety and effectiveness of this combination.

The first study (Refs. 4, 5, and 6) was a 12-week, double-blind, 3-way comparative parallel investigation of one dentifrice containing 5 percent potassium nitrate combined with 0.76 percent sodium monofluorophosphate, one dentifrice containing 5 percent potassium nitrate alone, and one dentifrice base with no active ingredients (the placebo). The study was designed to measure the effect of these dentifrices on hypersensitive teeth. The primary study parameters were subjective assessments by the participants, tactile sensitivity scores (measured by the Yeaple probe device), and recorded responses to a preset cold air stimulus (a 1-second blast of air at 60 pounds per square inch and 65 to 70 °F from an air syringe). A total of 68 subjects with dentinal hypersensitivity were randomly assigned to one of the three groups and subsequently completed the 12-week course of treatment. Following baseline assessments, the subjects were observed at intervals of 2, 4, 8, and 12 weeks. Mean scores of all groups demonstrated progressive improvement throughout the 12 weeks of the trial. Improvement in scores occurred more rapidly with the two test dentifrices than with the placebo. By the end of the 12-week study period, the scores of those subjects using the potassium nitrate/sodium monofluorophosphate and the potassium nitrate dentifrices were roughly equivalent and significantly better than those of the subjects using the placebo dentifrice ($p \leq 0.001$). However, the study failed to compare the effects of the combination product against the desensitizing effects of sodium monofluorophosphate dentifrice alone. Thus, this study does not eliminate the possibility that fluoride preparations, which the Dental Panel classified as Category III tooth desensitizers (47 FR 22712 at 22751), are potentially effective for hypersensitivity treatment and that the sodium monofluorophosphate contributes to the desensitizing effect of the combination drug product.

The second study (Refs. 5, 6, and 7) was designed as a 12-week, 4-way, parallel, double-blind trial of four treatment dentifrices. One dentifrice contained 5 percent potassium nitrate and 0.76 percent monofluorophosphate, one contained 5 percent potassium nitrate as the single active ingredient, one contained 0.76 percent sodium monofluorophosphate as the single active ingredient, and the placebo dentifrice was composed of the dentifrice base with no active ingredients. As in the first study, the primary effectiveness parameters were subjective assessments by the participants, tactile sensitivity scores, and cold air stimulus scores. However, although the first study measured a subjective response to a preset blast of

cold air, the cold air scores in the second study were based upon incremental tolerance to a thermally adjusted stream of increasingly cooler air. A total of 60 subjects completed the study. As in the previous study, the potassium nitrate/sodium monofluorophosphate and the potassium nitrate dentifrices demonstrated similar levels of effectiveness in reducing tooth hypersensitivity. At the 2-week interval, both tactile and cold air scores for groups receiving the potassium nitrate containing dentifrices showed greater improvements than did corresponding scores for either the sodium monofluorophosphate or the placebo dentifrices. By the fourth week, the subjective assessments also demonstrated the greater effectiveness of the potassium nitrate products.

Although the tooth hypersensitivity scores of all groups decreased throughout the period of the trial, subjective, tactile, and cold air scores indicated that the potassium nitrate and the potassium nitrate/sodium monofluorophosphate dentifrices provided greater benefit than did the sodium monofluorophosphate or placebo dentifrices. Results of statistical tests of 12-week differences in mean subjective and tactile scores indicated highly significant differences ($p<0.01$) in favor of the potassium nitrate containing dentifrices when compared to the placebo. Tests of the cold air scores, however, in spite of noted differences, did not demonstrate the same high level of statistical significance ($p=0.08$ for the pairwise comparison of the potassium nitrate/sodium monofluorophosphate dentifrice against the placebo, and $p=0.05$ for the potassium nitrate dentifrice compared to the placebo). Subjective and tactile score comparisons at the 12-week interval of the potassium nitrate/sodium monofluorophosphate and the potassium nitrate dentifrices against the sodium monofluorophosphate dentifice were highly significant ($p<0.01$), while p-values for the 12-week cold air score comparisons of the sodium monofluorophosphate dentifrice and the two potassium nitrate products were somewhat higher (0.06 against the potassium nitrate/sodium monofluorophosphate dentifrice, and 0.04 versus the potassium nitrate dentifrice). The statistical tests indicated that there was no difference at week 12 in comparisons of the group scores of the sodium monofluorophosphate dentifrice versus the placebo and of the potassium nitrate/sodium monofluorophosphate dentifrice versus the potassium nitrate dentifrice.

These two studies produced consistent results indicating that the potassium nitrate/sodium monofluorophosphate and the potassium nitrate dentifrices are more effective tooth desensitizers than a placebo dentifrice and that the two test dentifrices provided similar therapeutic effects over a 12-week test period. The second study, in which an additional group received the fluoride dentifrice, demonstrates that after 12 weeks there is very little desensitizing benefit derived from either the placebo or the sodium monofluorophosphate dentifrice. Results from both studies indicate that the benefit derived from the two potassium nitrate products (with and without the sodium monofluorophosphate) is nearly the same, and results from the second study demonstrate that the difference in benefit derived from the sodium monofluorophosphate product compared to the placebo is not statistically significant after 12 weeks of continuous use. This evidence supports the conclusion that sodium monofluorophosphate does not contribute substantially to the effective, 12-week desensitizing relief derived from the combination dentifrice containing potassium nitrate and sodium monofluorophosphate.

When evaluating ingredients for their tooth desensitizing effectiveness, the Dental Plan considered fluoride preparations, including sodium fluoride, sodium monofluorophosphate, and stannous fluoride, as a group. It stated that "Since the availability of the fluoride ion is similar in all these preparations, it would suggest that the effectiveness data are also related in a similar manner" (47 FR 22712 and 22752). Therefore, the agency believes that since monofluorophosphate does not contribute to the desensitizing effect of the potassium nitrate/sodium monofluorophosphate dentifrice, other Category I fluoride ingredients would likewise not contribute to the desensitizing effect of a combination desensitizing/anticaries dentifrice.

Regarding the anticaries effectiveness of the sodium monofluorophosphate portion of this combination dentifrice, in its report on OTC anticaries drug products published in the **Federal Register** of March 28, 1980, the Dental Panel recommended LTP's Category I anticaries ingredients in dentifrice formulations (45 FR 20666 at 20677). The Panel stated that the extensive amount of testing of anticaries dentifrices, which has included laboratory animal testing and clinical testing, allows prediction as to which dentifrice formulations will be effective. The Panel concluded that, if certain analytic and biologic tests are conducted on new formulations and acceptable test values are achieved, clinical testing of those formulations is not required. The analytic tests recommended by the Panel were theoretical total fluorine determination, available fluoride ion determination, pH, and specific gravity. The Panel also recommended that fluoride dentifrices meet the requirements of two of the following biologic tests: (1) Enamel solubility reduction; (2) fluoride uptake by enamel; and (3) animal caries reduction.

Because these LTP's represented a new concept with many technical issues yet to be resolved, they were not included in the Panel's proposed monograph or in the agency's first segment of the tentative final monograph on OTC anticaries drug products published in the **Federal Register** on September 30, 1985 (50 FR 39854). Instead, the agency held an open public meeting on September 26 and 27, 1983, regarding unresolved technical issues concerning the LTP's and reopened the administrative record to include the proceedings of the public meeting and to allow comments on matters raised at the meeting. In the second segment of the tentative final monograph for OTC anticaries drug products published in the **Federal Register** of June 15, 1988 (53 FR 22430), the agency considered information generated at the public meeting and in comments and stated that the requirement of lengthy clinical trials to demonstrate anticaries effectiveness of fluoride dentifrices is no longer warranted. Having determined that demonstration of the availability of the fluoride ion in the formulation and satisfaction of the biological testing requirements are the most important testing criteria for predicting the effectiveness of a fluoride dentifrice, the agency stated that appropriate laboratory testing is adequate to assure the effectiveness of fluoride dentifrices containing Category I ingredients. The agency proposed that fluoride dentifrices meet or exceed the soluble fluoride ion level specified for each particular fluoride ingredient listed in the monograph and meet the test requirements of any two of the biological tests recommended by the Dental Panel in its report (53 FR 22435). However, the agency has not evaluated the comments received to date on this proposal.

The agency believes that a dentifrice product containing an ingredient included in the anticaries monograph, i.e., sodium fluoride, sodium monofluorophosphate, or stannous fluoride, that satisfies the requirements of the LTP's has demonstrated anticaries effectiveness. Therefore, the agency has tentatively determined that the LTP's could be used to demonstrate the anticaries effectiveness of the fluoride in any combination dentifrice containing 5 percent potassium nitrate and a Category I fluoride ingredient. The agency is not currently aware of any chemical evidence predictive of an interaction between potassium nitrate and any Category I fluoride ingredient that would alter the bioavailability or effectiveness of either ingredient. In addition, based upon the available evidence, the agency also believes that the combination of 5 percent potassium nitrate and a Category I fluoride ingredient does not decrease the safety of either of the individual active ingredients. Such a combination would provide rational concurrent therapy for a significant target population when used under adequate directions for use and warnings against unsafe use. Therefore, an acceptable dentifrice containing 5 percent potassium nitrate and any Category I fluoride ingredient in combination would need to meet the requirements of the final monographs for OTC anticaries drug products and for OTC relief of oral discomfort drug products.

The agency is therefore proposing to include the combination of 5 percent potassium nitrate and any Category I fluoride ingredient labeled for the relief of hypersensitive teeth and for the prevention of dental caries as Category I in this amendment to the tentative final monograph for OTC oral health care drug products.

The agency notes that no OTC drug advisory review panel considered this combination. In accordance with the agency's Compliance Policy Guide 7132b.16 (which describes the agency's enforcement policy regarding the marketing of OTC combination drug products not reviewed by an OTC drug advisory review panel) (Ref. 10), this specific combination may not be marketed until the Commissioner states by notice in the **Federal Register** that the combination has been tentatively determined to be generally recognized as safe and effective and that OTC marketing of the combination will be permitted under specified conditions. Before marketing may begin, the comment period must have ended and another **Federal Register** notice must have been published setting forth the agency's determination concerning marketing before publication of the final rule. The comment period for this document is 120 days. However, the agency is requesting comments and objections regarding the combination of potassium nitrate and fluoride in a dentifrice drug product in a shorter period of 60 days so that the marketing status of such a combination drug product can be determined in an expeditious manner. Any such marketing that might be allowed, pending issuance of the final monograph, is subject to the risk that the Commissioner may adopt a different position in the final monograph that could require relabeling, recall, or other regulatory action.

The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 11).

References

(1) Comment No. C00009, Docket No. 80N-0228, Dockets Management Branch.

(2) Comment No. C00017, Docket No. 80N-0228, Dockets Management Branch.

(3) "The Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, 1976, p. 992.

(4) Silverman, G., "Desensitizing Dentifrice Study," draft of unpublished paper, coded LET004, Docket No. 80N-0228, Dockets Management Branch.

(5) Comment No. SUP003, Docket No. 80N-0228, Dockets Management Branch.

(6) Comment No. SUP004, Docket No. 80N-0228, Dockets Management Branch.

(7) Comment No. SUP002, Docket No. 80N-0228, Dockets Management Branch.

(8) Letter with attachments from Block Drug Co., Inc., to W.E. Gilbertson, FDA, coded LET005, Docket No. 80N-0228, Dockets Management Branch.

(9) Comment No. SUP, Docket No. 80N-0228, Dockets Management Branch.

(10) "OTC Drugs—General Provisions and Administrative Procedures for Marketing Combination Products," Food and Drug Administration Compliance Policy Guidelines, 7132b.16, OTC Volume 13BTFM.

(11) Letter from W.E. Gilbertson, FDA, to S. Most, Block Drug Company, Inc., coded LET0010, Docket No. 80N-0228, Dockets Management Branch.

48. Referring to the table summarizing the Dental Panel's categorization of active ingredients (47 FR 22712 at 22725), where the combination of sodium fluoride, strontium chloride, and edetate disodium is listed as a Category II tooth desensitizer, one comment suggested that sodium fluoride and strontium chloride be deleted from this item in this table. The comment stated that edetate disodium is the Category II ingredient and that the combination becomes Category II because of the use of edetate disodium.

The Panel reviewed a combination drug product containing 0.44 percent sodium fluoride, 10 percent strontium chloride, and the chelating agent edetate disodium (Ref. 1), and stated that the purpose of the edetate disodium in this drug product was to maintain the ingredients sodium flouride and strontium chloride in solution by chelating the strontium and preventing the formation of insoluble strontium chloride (47 FR 22750). [In reviewing the data submitted to the Panel (Ref. 1), the agency has determined that the Panel's report erroneously stated strontium chloride at page 22750, and that it should have stated strontium fluoride.] The Panel listed edetate disodium as an inactive ingredient (47 FR 22715) and did not review this ingredient as a single active ingredient. The Panel listed both sodium fluoride and strontium chloride as active ingredients (47 FR 22715), reviewed each of these ingredients as tooth desensitizers (47 FR 22751), and placed both ingredients in Category III. The Panel also placed combinations of two tooth desensitizers in Category III (47 FR 22722).

Because the presence of the inactive ingredient edetate disodium is crucial to maintain the integrity of the combination drug product containing sodium fluoride and strontium chloride, the agency considers edetate disodium a pharmaceutical necessity in this product and concludes that it was appropriate for the Panel to review this product as a separate specific combination. The agency also agrees with the Panel's Category II determination that this specific combination drug product is unsafe for OTC use because the 0.44 percent sodium fluoride concentration represents a safety risk without proven benefit as a tooth desensitizer (the Panel had recommended 0.22 percent sodium fluoride dentifrice as safe for daily use as an anticaries agent (45 FR 20666 at 20682)) and because the chelating properties of the inactive ingredient edetate disodium may cause decalcification of teeth (47 FR 22750). The agency believes that the Panel's intent to place sodium fluoride and strontium chloride as single ingredients in Cagetory III, to place the combination of 0.44 sodium fluoride and 10 percent strontium chloride containing edetate disodium in Category II, and to place combinations of two tooth desensitizers in Category III is clearly stated in the Panel's report and that modification of the Panel's summary table is unnecessary.

Reference

(1) OTC Volume 080010.

F. Comments on Testing Guidelines

49. Two comments requested that the Dental Panel's "Data Required for Evaluation" guidelines (47 FR 22712 at 22756) be reconsidered. The comments felt that some of the protocol requirements were inappropriate, unrealistic, unachievable, obsolete, or in variance with widely accepted methodology. Specific changes were suggested.

The agency has not addressed specific testing guidelines in this document. In revising the OTC drug review procedures relating to Category III, published in the **Federal Register** of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. Therefore, the specific changes suggested by the comments are not being addressed in this document. The revised procedures also state the time in which test data must be submitted for consideration in developing the final monograph. (See also part II. paragraph A.2. below.)

50. Several comments objected to seven aspects of the Dental Panel's recommended testing guidelines for reclassifying agents for the relief of toothache in Category I as follows:

(1) The criteria for the selection of patients, specifically the limitation of patient selection to only those with severe pain or only those between the ages of 20 and 50 years; the comments stated that patients of any age should be allowed to participate in the study.

(2) The requirement of a positive control in the testing guidelines; the comments stated that the only Category I ingredient that could be used as a positive control is eugenol, an aromatic, and that use of this ingredient as a positive control is impractical and would not allow adequate blinding of a study.

(3) The use of a sequential analysis design for the testing of agents for the relief of toothache; the comments stated that such a design is impractical because it requires the pairing of patients to receive two different treatments within as short a period of time as possible, not to exceed 1 day. Because patients with toothaches are difficult to obtain, the comments argued that, in many instances, less than two patients with toothache will be seen in a clinic during 1 day.

(4) The method of data analysis; one comment contended that the data collected in a study should be analyzed by standard statistical methodology rather than the statistical methodology used in sequential analysis because, in studying a toothache relief drug product, the investigator cannot normally use the same individual for two different products.

(5) The blinding technique; one comment stated that the Panel's recommendation that, as a blinding technique, eugenol be placed on the tongue of all patients when this ingredient is used as a control in testing would serve no useful purpose and would only confuse the patients.

(6) The Panel's recommendation that the relief of pain last "at least 20 minutes" before the treatment is considered effective; the comments stated that shorter periods of relief from pain are significant and should be considered adequate to demonstrate effectiveness.

(7) The Panel's recommendation that pain be measured as "tolerable" or "intolerable;" one comment stated that it has been standard practice in testing to use pain scales with more than two points of pain discrimination which reliably measure pain reduction. The comment contended that the use of a reliable pain scale would obviate the need to follow the Panel's recommendations to pair patients with the same pain intensity over a short time interval.

Several comments also objected to four aspects of the Panel's recommended testing guidelines for upgrading a Category III tooth desensitizer to Category I as follows:

(1) The Panel's criteria for selecting patients, specifically that each of the three studies should include persons with the same type of sensitivity and that at least one of the three studies must be on persons with Type I sensitivity, defined as hypersensitivity due to periodontal surgery. The comments urged deletion of the requirement that a minimum of 6 weeks pass following periodontal surgery before patients who underwent such surgery are admitted as subjects in a study; also, the comments requested that the selection of patients be made on the presence of subjective pain of dentinal hypersensitivity and on the basis of sound professional judgment. One comment was not aware of any data that suggest that the condition of dentinal hypersensitivity differs depending on its cause (e.g., cervical erosion, abrasion, gingival recession, periodontal surgery) and urged the agency to confine the focus of testing to the condition of dentinal hypersensitivity and not to its causes. The comments objected to the Panel's recommendation that persons selected for test and placebo trials should be of the same sex and be reasonably similar in age, in number of sensitive teeth, and in the mean sensitivity score (47 FR 22712 at 22756). The comments argued that adding sex and age pairing requirements and pairing subjects with teeth having near-identical hypersensitivities unduly compound the problem of timely completion of clinical investigations utilizing large numbers of subjects. The comment contended that hypersensitivity does not appear to be correlated with either patient age or sex.

(2) The requirement of a paired sequential study design (47 FR 22756). The comments were opposed to a paired sequential design for these studies and suggested that sex, age, and sensitivity equivalence for test and placebo trials be specified for groups of patients in study designs other than paired sequential analysis. The comments recommended that persons selected for test and placebo trials should be reasonably similar in the mean sensitivity score so far as is practical.

(3) The Panel's recommendation that teeth which may be included in the study be limited to incisors and premolars in both arches as well as recommendations concerning how many teeth should be examined during each patient evaluation. One comment recommended deleting the requirement that all teeth be examined each time after the initial examination establishes which teeth are sensitive and which are not and urged that only the hypersensitive teeth should be evaluated on subsequent examinations. Also, the comment felt that molars should be allowed to be included in the study if the investigator is able to identify one or more of them as hypersensitive teeth.

(4) The Panel's recommendation that in studies involving tooth desensitizers both the test and placebo materials must be indistinguishable regarding taste, consistency, and appearance (47 FR 22756). The comments believed that the requirement for the placebo to be "indistinguishable" from the active ingredient is unreasonable and suggested terminology used in the tentative final monograph for OTC antiperspirant drug products (47 FR 36492 at 36500). The comments recommended the use of the terms "as similar as possible" to replace "indistinguishable" and the addition of the phrase "as judged by sensory evaluation procedures" to the guidelines.

Comments on the testing guidelines for reclassifying agents for the relief of toothache and for reclassifying tooth desensitizer objected to the Panel's recommendation that three investigators at three separate institutions, preferably academic institutions, should perform studies required to upgrade a Category III ingredient to Category I (47 FR 22756). Two comments believed this requirement is unnecessary because one multiclinical, double-blind study or two separate studies are sufficient to prove efficacy. One comment recommended that the requirement for the number of studies should be consistent with FDA's traditional rule that two well-controlled clinical studies are adequate for demonstrations of efficacy. Two comments believed that "the limitation to an academic setting" was unduly restrictive and should be deleted. The comments felt that flexibility should be allowed for the use of clinics or private practices which can mobilize adequate numbers of patients and demonstrate clinical experience suitable for these studies.

The comments concluded that certain of the testing guideline requirements are inappropriate and unachievable, that others are not realistic or representative of the present state of the art, and that the goal of demonstrating effectiveness can be properly realized by other clinically acceptable protocols. The comments requested that other acceptable procedures should be allowed.

The agency has not addressed specific testing guidelines in this document. In revising the OTC drug review procedures relating to Category III, published in the **Federal Register** of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols and the number of studies needed to upgrade Category III conditions to Category I. The revised procedures also state the time in which test data must be submitted for consideration in developing the final monograph. (See also Part II. paragraph A.2. below.) Thus, under the current agency approach, acceptable procedures other than those recommended by the Dental Panel may be allowed.

51. Two comments objected to the Dental Panel's recommendation that a cross-over design be used for studies to demonstrate the effectiveness of an agent for the relief of toothache (47 FR 22712 at 22735) for the following reasons: (1) It would be difficult or impossible to utilize the same patient for a second drug treatment if the first drug treatment relieved the patient's toothache; and (2) ethically, the patient's toothache should be professionally treated as soon as possible. The comments requested that the agency delete this requirement for testing agents for the relief of toothache.

The Panel's recommended testing guidelines are not being included in this proposal. (See comments 49 and 50 above.) The Panel recommended that a sequential analysis study design be used to demonstrate the effectiveness of agents for the relief of toothache. The agency believes that the comments may have misinterpreted the Panel's recommendation. A sequential analysis design does not involve multiple test treatments of the same patient as is required by a cross-over study design. In a sequential analysis design, patients are paired randomly over a time interval that is as short as possible. Each patient of the pair receives only one test treatment. One patient receives one type of treatment and the second patient receives the other type of treatment. The results obtained from treating each of the patients in the pair are then used as the unit of comparison for the two different treatments. Successive pairs of patients are sequentially analyzed until statistically significant differences between the two treatments are achieved. The agency concludes that the Panel's recommended testing guidelines for agents for the relief of toothache would not require a cross-over testing design.

52. Regarding the Dental Panel's recommended testing guidelines for agents for the relief of toothache (47 FR 22712 at 22736), one comment stated that the mode of application of toothache relief drugs should not be specified because the method of application will depend on the ingredient and/or formulation. Another comment stated that the testing procedures should allow for the use of other dosage forms as appropriate. The comment further stated that because a consumer cannot always be expected to find his or her tooth cavity, it is more practical to apply the ingredient to the total tooth surface; therefore, clinical studies should be designed to support the efficacy of agents for the relief of toothache for use in and around the tooth.

In the revision of the OTC drug review procedures relating to Category III, published in the **Federal Register** of September 29, 1981 (46 FR 47730) and clarified April 1, 1983 (48 FR 14050), the agency advised that, regarding testing procedures, tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. (See also Part II. paragraph A.2. below.) The Panel did provide for testing a gel dosage form in its testing guidelines (47 FR 22736), but the agency recognizes that the Panel's recommended testing procedures do not include all possible methods of application and dosage formulations. The agency will consider the use of any appropriate testing procedure even though it may differ from that recommended by the Panel. The Panel's testing criteria are considered to be recommendations to the agency; however, test designs that are used in studies submitted in support of the safety and effectiveness of Category III conditions are evaluated on their own merits rather than on how well they meet the Panel's requirements. Thus, when Category III ingredients are tested for safety and/or effectiveness and subsequently upgraded to Category I, the agency will propose directions for use that are consistent with the manner of application used in the testing procedures. If clinical studies demonstrate the safety and efficacy of agents for the relief of toothache for use in and around the tooth, directions for such use will also be included in the monograph.

II. The Agency's Tentative Conclusions and Adoption of the Dental Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of ingredient categories

The agency has reviewed all claimed active ingredients submitted to the Dental Panel, as well as other data and information available at this time, and has made some changes in the categorization of relief of oral discomfort active ingredients recommended by the Panel. As a convenience to the reader, the following list is included as a summary of the categorization of relief of oral discomfort active ingredients recommended by the Panel and the proposed categorization by the agency.

Active ingredients	Panel	Agency
1. *Agents for the relief of toothache* [1]		
Benzocaine	III	III
Benzyl alcohol	III	III
Butacaine sulfate	III	III
Capsicum (as a counterirritant).	II	II
Capsicum (for use in an open tooth cavity).	II	II
Cresol	III	III
Creosote	III	III
Eugenol (85 to 87 percent).	I	III
Eugenol (1 to 84 percent).	III	III
Menthol	II	II
Methyl salicylate	II	II
Phenol preparations (phenol and/or phenolate sodium):	III	III
Thymol preparations (thymol and thymol iodide).	III	III
2. *Oral mucosal analgesics (Topical anesthetics):*		
Benzocaine	I	I
Benzyl alcohol	III	I
Butacaine sulfate	I	I
Camphor	II	II
Chlorophyllin (water-soluble).	Not reviewed	III
Cresol	III	III
Methyl salicylate	II	II
Phenol preparations (phenol and/or phenolate sodium).	I	I
Thymol preparations (thymol and thymol iodide).	III	III
3 *Oral mucosal protectants:*		
Benzoin preparations (benzoin tincture and compound benzoin tincture).	I	I
Myrrh, fluidextract	III	III
4 *Tooth desensitizers:*		
Citric acid and sodium citrate in poloxamer 407 (Pluronic F-127 gel).	III	III
Fluoride preparations (sodium fluoride, sodium monofluorophosphate, and stannous fluoride).	III	III
Formaldehyde solution.	III	III
Potassium nitrate	III	I
Sodium fluoride (0.44 percent); strontium chloride, and edetate disodium (in combination).	II	II
Strontium chloride	III	III

[1] The Panel recommended that beeswax should not be included as an inactive ingredient in products intended for use in an open tooth cavity, and the agency concurs.

2. Testing of Category II and Category III conditions

The Panel recommended testing guidelines for agents for the relief of toothache (47 FR 22712 at 22735) and for tooth desensitizers (47 FR 22712 at 22756). The agency's position regarding the Panel's testing guidelines is discussed in comments 49, 50, and 51 above. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any relief of oral discomfort ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Dental Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows.

1. The Dental Panel was charged to review and evaluate dental and dental care drug products including agents for oral mucosal injury and agents for the relief of oral discomfort. Oral mucosal injury drug products are OTC preparations intended to relieve oral soft tissue injury by cleansing or promoting the healing of minor oral wounds or irritations (48 FR 33984 at 33984). Agents for the relief of oral discomfort are OTC preparations to treat minor trauma or irritations of a transient nature to the gums or teeth (47 FR 22712 at 22717). The Oral Cavity Panel was charged to evaluate ingredients in OTC preparations intended for use for the temporary relief of symptoms due to minor irritations, inflammations, and other lesions of the mucous membranes of the oral cavity (47 FR 22760 at 22765). Because of the overlap between the rulemaking on OTC oral mucosal injury drug products and the rulemaking on OTC oral health care drug products, the agency incorporated that part of the oral mucosal injury rulemaking that includes oral wound cleansers into the first segment of the tentative final monograph for OTC oral health care drug products published in the Federal Register of January 27, 1988 (53 FR 2436). Likewise, because the ingredients reviewed as relief of oral discomfort agents and the ingredients reviewed as oral health care drug products are indicated for similar therapeutic purposes in the same area (i.e., the oral cavity), in this document, the agency is merging the advance notice of proposed rulemaking for OTC relief of oral discomfort drug products into the tentative final monograph for OTC oral health care drug products (proposed as 21 CFR part 356). The intent of the combined rulemaking is to identify those ingredients that are generally recognized as safe and effective in temporarily relieving the symptoms associated with minor oral wounds or other irritations of the mouth, gums, or teeth. Combining these two rulemakings into one will result in more consistent labeling on the OTC drug products intended for topical use in the oral cavity and in less confusion for the manufacturers of these drug products and for the consumer.

2. The agency is not including § 354.1 "Scope" of the Dental Panel's recommended monograph for relief of oral discomfort drug products in this proposal because the proposed "Scope" (§ 356.1) of the tentative final monograph for OTC oral health care drug products adequately covers all oral health care drug products including relief of oral discomfort drug products.

3. So that the definition of an oral health care drug will include agents for relief of oral discomfort, the agency is proposing to amend § 356.3(a) of the tentative final monograph for OTC oral health care drug products by adding the words "gums," and "teeth," and the phrase "minor irritations of the gums" to read as follows: "A drug product applied topically for the proper care of the oral cavity, including the temporary relief of symptoms of the gums, teeth, mouth, and throat, for example, minor irritation of the gums, occasional mouth soreness, or minor sore throat."

The agency is also adding a definition for the term "dentifrice" in § 356.3(h) of the definition section of this proposal.

In this proposal, the agency is incorporating the definitions found in § 354.3 of the Dental Panel's recommended monograph for OTC relief of oral discomfort drug products into § 356.3 of the amended tentative final monograph for OTC oral health care drug products. However, the agency is not including the definitions for an "agent for the relief of oral discomfort" or for an "oral mucosal analgesic" found in § 354.3(a) and § 354.3(c), respectively, of the Dental Panel's recommended monograph for relief of oral discomfort drug products. The definition for an "oral health care drug" in § 356.3(a) has been revised to include agents for the

relief of oral discomfort. (See part II. paragraph B.3. above.) Oral mucosal analgesic ingredients are being included in this amendment as anesthetic/analgesic ingredients, and the definition for an "anesthetic/analgesic" in § 356.3(c) of this amendment adequately defines this therapeutic group. Individual definitions are renumbered accordingly.

4. Although the Dental Panel classified 85 to 87 percent eugenol in Category I as an agent for the relief of toothache, the agency has determined that the data are inadequate to demonstrate effectiveness of this ingredient and reclassified the ingredient in Category III for this use. (See comment 7 above.)

5. In this proposal, the agency is not including the agents for the relief of toothache that were recommended by the Dental Panel in § 354.10 of its monograph. Section 356.10 of this proposed monograph is reserved for agents for the relief of toothache should any be classified in Category I in the future.

6. The agency is including oral mucosal analgesics, § 354.12 of the Dental Panel's recommended monograph, in the therapeutic category of OTC oral health care anesthetic/analgesics in § 356.12 of this proposal. Some of the same ingredients (i.e., benzocaine, benzyl alcohol, and phenol) were reviewed as oral mucosal analgesics by the Dental Panel and as anesthetic/analgesics by the Oral Cavity Panel. Oral mucosal analgesics and anesthetic/analgesics are intended for the temporary relief of pain caused by minor irritations or injuries of the oral mucosa. Therefore, the agency believes that these ingredients should be considered to be one therapeutic category. In this proposal, to eliminate duplication and overlap, the agency is proposing to combine the indications, warnings, and directions recommended in § 354.55 for oral mucosal analgesics by the Dental Panel with the indications, warnings, and directions proposed by the agency for anesthetic/analgesics in § 356.55 of the first segment of the tentative final monograph for OTC oral health care drug products. The combined indications, warnings and directions for anesthetic/analgesic active ingredients are found in § 356.52 of this proposal. Additionally, the term "oral mucosal analgesic" is replaced by the term "anesthetic/analgesic" in this proposal.

7. The Dental Panel classified benzyl alcohol in Category III as an oral mucosal analgesic (47 FR 22712 at 22743 to 22744). The Oral Cavity Panel classified benzyl alcohol in Category I as an anesthetic/analgesic it its report (47 FR 22760 at 22809 to 22810), and the agency agreed with the Category I classification in the first segment of the tentative final monograph for OTC oral health care drug products (53 FR 2436). Therefore, in this proposal, the agency is including benzyl alcohol as a Category I anesthetic/analgesic in § 356.12(b).

8. Although butacaine sulfate was not reviewed by the Oral Cavity Panel, the Dental Panel classified it as a Category I oral mucosal analgesic, § 354.12(b). The agency agrees with the Dental Panel's Category I classification and is, therefore, including butacaine sulfate in this proposal in 356.12(c) as an anesthetic/analgesic.

9. The agency is including oral mucosal protectants, § 354.14 of the Dental Panel's proposed monograph, in § 356.20 of this proposal.

10. The agency is including 5 percent potassium nitrate as a Category I tooth desensitizer in § 356.22 of this amendment. (See comment 8 above.)

11. The section containing package size limitations, § 354.18 of the Dental Panel's recommended monograph, is being revised and is included in this amendment in § 356.24. The agency is not including the package size limitations for butacaine sulfate that were recommended by the Dental Panel in § 354.18(a) of its report. Additionally, the agency is revising the directions for use for butacaine sulfate by deleting any reference to single-use packaging. (See comment 35 above.)

12. The Dental Panel classified several combination drug products in Category I and included them in § 354.20 of its proposed monograph at § 354.20. The agency is deferring consideration of recommended § 354.20(b), (c), and (d) to the antimicrobial segment of the rulemaking for OTC oral health care drug products because these recommended combinations all contain antimicrobial ingredients. The agency is proposing to add the Dental Panel's remaining Category I combinations in 354.20 (a) and (e) to the combinations proposed by the agency in § 356.20 of the first segment of the tentative final monograph for OTC oral health care drug products and to include the combinations in this amendment in § 356.26.

13. Because oral mucosal protectants are not indicated for use in sore throat, the agency concludes that when anesthetic/analgesic ingredients are combined with oral mucosal protectants, the indication for anesthetic/analgesics in § 356.52(b)(1), "For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat," should not be used. The agency also notes that the indication in § 356.52(b)(7), "For products containing * * * when used in denture adhesive products * * *," is not applicable to combination products containing anesthetic/analgesics and oral mucosal protectants because the Panel stated in its report that the use of an oral mucosal protectant in a denture adhesive is irrational (47 FR 22712 at 22722). Therefore, the agency is proposing to include in § 356.66, "Labeling of combination drug products," the following: "For permitted combinations [of oral mucosal protectants and anesthetic/analgesics] identified in § 356.26(c). Any or all of the indications in § 356.52(b)(2), (b)(3), (b)(4), (b)(5), and (b)(6) should be used."

14. The agency has reviewed data and information submitted in support of the safety and effectiveness of a dentifrice containing fluoride (sodium monofluorophosphate) and potassium nitrate for the claims of prevention of cavities and tooth desensitization and has determined that the data are sufficient to demonstrate the effectiveness of this combination. Furthermore, the agency has determined that any Category I fluoride may be used in combination with potassium nitrate as long as the product demonstrates anticaries effectiveness. Therefore, in this proposal, the agency is proposing a Category I classification for the combination of any Category I fluoride ingredient and potassium nitrate used for the prevention of cavities and tooth desensitization. (See comment 47 above.)

15. The warning "Children under 12 years of age should be supervised in the use of this product" in §§ 354.50(c)(1)(vi), 354.55(c)(2) and (c)(4)(i), 354.60(c)(5), and 354.65(c)(3) of the Dental Panel's recommended monograph is not included in the warnings sections of this proposal because the statement appears in the directions for use for all products formulated as mouthwashes (oral rinses). (See comments 27 and 31 above.)

16. The agency is not including in this proposal the warning "Do not swallow" that was recommended by the Dental Panel in §§ 354.50(c)(1)(iv), 354.55(c)(1)(iii), 354.60(c)(3), and 354.65(c)(2). However, for anesthetic/analgesics formulated as mouthwashes (oral rinses), the agency is including the wording "* * * and then spit out" in the directions in §§ 356.52(d)(1)(i), (d)(2)(i), (d)(4)(i), (d)(5)(i), (d)(6)(i), (d)(7)(i)(a) and (d)(7)(i)(b), and (d)(8)(i) of this proposal. (See comment 28 above.)

17. The labeling for agents for the relief of toothache recommended by the Dental Panel in § 354.50 is not being included in this proposal. Section 356.50 in this proposal is reserved for the labeling of agents for the relief of toothache in the event that any ingredients are classified in Category I in the future.

18. The agency is not including in this proposal the Dental Panel's recommended statement of identity for oral mucosal analgesics in § 354.55(a). Oral mucosal analgesics are included as part of the therapeutic category identified as anesthetic/analgesics in § 356.52 (see Part II, paragraph B.5. above), and the statement of identify proposed by the agency in § 356.52(a) is sufficient.

19. The agency is proposing to revise the indications recommended by the Dental Panel in § 354.55(b)(1)(i) and (b)(1)(iii) and § 354.55(b)(3) by using the phrase "mouth and gums" instead of "soft tissues," "soft tissue of the mouth," or "oral tissues." The agency is including the revised indications in § 356.52(b)(3), (b)(5), and (b)(7) of this proposal. (See comment 24 above.)

20. Because canker sores do not require professional diagnosis before self-treatment, the agency is not including in this proposal the indication recommended by the Dental Panel in § 354.55(b)(1)(iv). The indication proposed in § 356.55(b)(2) of the first segment of the tentative final monograph for OTC oral health care drug products is being included in this amendment in § 356.52(b)(2). (See comment 23 above.)

21. The warnings recommended for oral mucosal analgesics by the Dental Panel in § 354.55(c)(1)(i) and (c)(1)(ii) are not being included in this proposal. The agency believes that the intent of those warnings is fulfilled by the warnings proposed for anesthetic/analgesics by the agency in § 356.55(c)(1) and (c)(2) of the first segment of the tentative final monograph for OTC oral health care drug products and is proposing those warnings for anesthetic/analgesic ingredients in § 356.52(c)(1) and (c)(2).

22. The agency is not including in this proposal the warnings recommended specifically for butacaine sulfate by the Dental Panel in § 354.55(c)(4) because the information in these warnings is included in the revised directions for use of butacaine sulfate in § 356.52(d)(3) of this proposal. (See comment 35 above.)

23. The directions for use of benzocaine proposed by the agency in § 356.55(d)(1) and (d)(2) of the first segment of the tentative final monograph for OTC oral health care drug products are being included in this proposal in § 356.52(d)(1)(i) and (d)(1)(ii) as directions for use of benzocaine. The directions recommended for benzocaine by the Dental Panel in § 354.55(d)(1) have been slightly revised by the agency and are being included in this proposal as the directions in § 356.52(d)(1)(iii) for using benzocaine in a teething preparation.

24. The agency is revising the directions recommended by the Dental Panel for butacaine sulfate in § 354.55(d)(2) to eliminate the reference to package size limitations. The agency is including the revised directions in § 356.52(d)(3) of this proposal. (See comment 35 above.)

25. The agency is proposing that the minimum effective concentration of phenol for use as an oral health care anesthetic/analgesic be 0.5 percent rather than 0.25 percent as recommended by the Dental Panel and is including the minimum effective concentration of 0.5 percent in § 356.52(d)(7) of this proposal. (See comment 4 above.)

26. As a result of combining oral mucosal analgesics and oral health care anesthetic/analgesics, the agency is not including the directions for use of phenol as an oral mucosal analgesic recommended by the Dental Panel in § 354.55(d) (3) and (d)(4). The directions proposed for use of phenol as an anesthetic/analgesic by the agency in the first segment of the tentative final monograph for OTC oral health care drug products in § 356.55(d)(6)(i) (a) and (b) and § 356.55(d)(6)(ii) are being proposed in § 356.52(d)(7)(i) and (d)(7)(ii). (See comment 36 above.)

27. The agency is proposing to limit the concentration of phenol in teething preparations to 0.5 percent phenol. Additionally, the agency is proposing to revise the direction it proposed in § 356.55(d)(6) of the first segment of the tentative final monograph for OTC oral health care drug products by adding directions for the use of teething preparations and including those directions in § 356.52(d)(7)(iii) of this proposal. (See comments 4 and 36 above.)

28. The agency is including in §§ 356.52(d)(1)(iv), (d)(3)(ii), and (d)(7)(iv) of this proposal the directions for the use of benzocaine, butacaine, and phenol in dental adhesives that were recommended by the Dental Panel in § 354.55(d)(5).

29. The agency is including in § 356.60 of this proposal the labeling recommended by the Dental Panel for oral mucosal protectants in § 354.60.

30. The agency is proposing to revise the indication recommended by the Dental Panel for oral mucosal protectants in § 354.60(b)(4) "For protecting recurring canker sores when the condition has been previously diagnosed by a dentist" by deleting the phrase "when the condition has been previously diagnosed by a dentist." The agency has determined that canker sores do not require professional diagnosis before self-treatment. (See comment 23 above and part II. paragraph B.21. above.) The revised indication is included in § 356.60(b)(4) of this proposal.

31. The agency has determined that the wording of the warning proposed in the first segment of the tentative final monograph for OTC oral health care drug products in § 356.70(c) for debriding agents/oral wound cleansers is also appropriate for oral mucosal protectants. Therefore, the agency is proposing to combine §§ 354.60(c)(1) and (c)(2) of the Dental Panel's recommended monograph into the following revised warning for oral mucosal protectants (included in this amendment in § 356.60(c)(1)): "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly."

32. The agency is revising the labeling recommended for tooth desensitizers by the Dental Panel in § 354.65 and is including the revised labeling in § 356.62 of this proposal.

33. The agency is proposing that the statement of identity for tooth desensitizer drug products recommended by the Dental Panel in § 354.65(a) be revised to provide a choice of dosage forms and a choice between the words "sensitive" and "hypersensitive." (See comment 18 above). The revised statement of identity is included in § 256.62(a) of this proposal.

34. In order to clarify and shorten the language of the monograph the agency has revised the indication recommended by the Dental Panel for tooth desensitizers in § 354.65(b) as follows: "Helps reduce painful sensitivity of the teeth to cold, heat, acids, sweets, or contact." The revised indication is included in § 356.62(b)(1) of this proposal.

35. Because the desensitizing effect of potassium nitrate has been demonstrated to be cumulative, the agency is proposing in this amendment that the following additional indication for tooth desensitizers be included in § 356.62(b)(2): "Builds increasing protection against painful sensitivity of

the teeth to cold, heat, acids, sweets, or contact." (See comment 26 above.)

36. The agency is combining and simplifying the warnings recommended for tooth desensitizers by the Dental Panel in § 354.65(c)(1), (c)(4), and (c)(5) into one warning "Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or doctor." The agency is proposing to include the revised warning in § 356.62(c) of this proposal. (See comment 30 above.)

37. Because the agency does not consider fever, irritation, and infection to be related to dental hypersensitivity, the warning recommended for tooth desensitizers by the Dental Panel in § 354.65(c)(6) is not being included in this proposal. Additionally, the agency is not including the warning recommended by the Dental Panel in § 354.65(c)(7), "Do not exceed recommended dosage," in this amendment. (See comment 31 above.)

38. The agency has revised the directions for use for tooth desensitizers recommended by the Dental Panel in § 354.65(d) and is proposing to include these revised directions for use in § 356.62(d) of this proposal. (See comment 38 above.)

39. The agency is proposing new § 356.66, "Labeling of Combination Drug Products" in which labeling specific to combination drug products containing oral health care ingredients is described.

40. The agency is proposing to include professional labeling for products containing dyclonine hydrochloride in § 356.80(b). The agency is also amending the professional labeling proposed in § 356.80(a) of the first segment of the tentative final monograph for OTC health care drug products to include "Vincent's infection." (See comment 39 above.)

41. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and other applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." That option is proposed in § 356.48(a).

42. Combining the rulemaking for relief of oral discomfort drug products with the rulemaking for oral health care drug products resulted in the redesignation of many section and paragraph numbers. As a convenience to the reader, the following chart is included to show how all of the section and paragraph numbers have been redesignated.

REDESIGNATED SECTION AND PARAGRAPH NUMBERS OF THE TENTATIVE FINAL MONOGRAPH FOR ORAL HEALTH CARE DRUG PRODUCTS AMENDED BY ADDING THE INGREDIENTS AND LABELING FROM THE RULEMAKING FOR RELIEF OF ORAL DISCOMFORT DRUG PRODUCTS

Paragraph number in this amended TFM for oral health care drug products	Paragraph number in the TFM for oral health care drug products (53 FR 2436)	Paragraph number in the ANPR for relief of oral discomfort drug products (47 FR 22712)
356.3(a)	356.3(a)	
356.3(b)		354.3(a)
356.3(c)	356.3(b)	354.3(b)
		354.3(c)
356.3(d)	356.3(c)	
356.3(e)	356.3(d)	
356.3(f)	356.3(e)	
356.3(g)	356.3(f)	
356.3(h)	356.3(g)	
356.3(i)	356.3(h)	
356.3(j)		354.3(d)
356.3(K)		354.3(e)
356.10 (reserved).		354.10
356.12(a)	356.10(a)	354.12(a)
356.12(b)	356.10(b)	
356.12(c)		354.12(b)
356.12(d)	356.10(c)	
356.12(e)	356.10(d)	
356.12(f)	356.10(e)	
356.12(g)	356.10-(f)	354.12(c)
356.12(h)	356.10(g)	
356.14	356.14	
356.16	356.16	
356.18	356.18	
356.20(a)		354.14(a)
356.20(b)		354.14(b)
356.22 (reserved).		354.16
		354.18(a)
356.24		354.18(b)
356.26(a)	356.20(a)	
356.26(b)	356.20(b)	
356.26(c)		354.20(a)
		354.20(b)
		354.20(c)
		354.20(d)
356.26(d)		354.20(e)
356.26(e)	356.20(c)	
356.26(f)	356.20(d)	
356.26(g)	356.20(e)	
356.26(h)		
356.48(a)	356.50(a)	
356.48(b)	356.50(b)	
356.50 (reserved).		354.50
		354.55(a)
356.52(a)	356.55(a)	
356.52(b)(1)	356.55(b)(1)	
356.52(b)(2)	356.55(b)(2)	
354.55(b)(1)(iv)		
356.52(b)(3)		354.55(b)(1)(i)
356.52(b)(4)		
354.55(b)(1)(ii)		
356.52(b)(5)		
354.55(b)(1)(iii)		
356.52(b)(6)		354.55(b)(2)
356.52(b)(7)		354.55(b)(3)

REDESIGNATED SECTION AND PARAGRAPH NUMBERS OF THE TENTATIVE FINAL MONOGRAPH FOR ORAL HEALTH CARE DRUG PRODUCTS AMENDED BY ADDING THE INGREDIENTS AND LABELING FROM THE RULEMAKING FOR RELIEF OF ORAL DISCOMFORT DRUG PRODUCTS—Continued

Paragraph number in this amended TFM for oral health care drug products	Paragraph number in the TFM for oral health care drug products (53 FR 2436)	Paragraph number in the ANPR for relief of oral discomfort drug products (47 FR 22712)
356.52(c)(1)	356.55(c)(1)	
356.52(c)(2)	356.55(c)(2)	
		354.55(c)(1)(i)
		354.55(c)(1)(ii)
		354.55(c)(1)(iii)
356.52(c)(3)		354.55(c)(1)(iv)
		354.55(c)(2)
356.52(c)(4)		354.55(c)(3)
		354.55(c)(4)
356.52(c)(5)		354.55(c)(5)
356.52(c)(6)		354.55(c)(6)
356.52(d)(1)(i)	356.55(d)(1)(i)	354.55(d)(1)
356.52(d)(1)(ii)	356.55(d)(1)(ii)	
356.52(d)(1)(iii)		
356.52(d)(2)(i)	356.55(d)(2)(i)	
356.52(d)(2)(ii)	356.55(d)(2)(ii)	
356.52(d)(3)		354.55(d)(2)
356.52(d)(4)	356.55(d)(3)	
356.52(d)(5)	356.55(d)(4)	
356.52(d)(6)	356.55(d)(5)	
356.52(d)(7)(i)(a)	356.55(d)(6)(i)(a)	
356.52(d)(7)(i)(b)	356.55(d)(6)(i)(b)	354.55(d)(4)
356.52(d)(7)(ii)	356.55(d)(6)(ii)	
356.52(d)(7)(iii)		354.55(d)(3)
356.52(d)(7)(iv)		354.55(d)(5)
356.52(d)(8)	356.55(d)(7)	
356.54	356.65	
356.56	356.70	
356.58	356.75	
356.60(a)		354.60(a)
356.60(b)		354.60(b)
356.60(c)(1)		354.60(c)(1)
356.60(c)(1)		354.60(c)(2)
		354.60(c)(3)
356.60(c)(2)		354.60(c)(4)
		354.60(c)(5)
356.60(d)		354.60(d)
356.62(a)		354.65(a)
356.62(b)(1)		354.65(b)
356.62(b)(2)		
356.62(c)		354.65(c)(1)
		354.65(c)(2)
		354.65(c)(3)
356.62(c)		354.65(c)(4)
356.62(c)		354.65(c)(5)
		354.65(c)(6)
		354.65(c)(7)
356.62(d)		354.65(d)
356.66	356.78	
356.80(a)	356.80(a)	
356.80(b)		
356.80(c)	356.80(b)	

The agency is also designating proposed subpart D of the monograph as subpart C and is placing the labeling sections under subpart C.

43. For an active ingredient to be included in an OTC drug final monograph, it is necessary to have publicly available sufficient chemical information that can be used by all

manufacturers to determine that the ingredient is appropriate for use in their products. Most of the active ingredients that the Dental Panel and the Oral Cavity Panel classified as Category I are standardized and characterized for quality and purity and are included in official compendia. Alum, benzocaine, benzyl alcohol, carbamide peroxide, compound benzoin tincture, dyclonine hydrochloride, gelatin, glycerin, hydrogen peroxide, menthol, pectin, phenol, salicyl alcohol, sodium bicarbonate, and zinc chloride are included as articles in the current United States Pharmacopeia (U.S.P.) or National Formulary (Ref. 1). Although benzoin tincture was included as an article in U.S.P. XV (Ref. 2), it is not included in the current U.S.P. The remaining ingredients (i.e., butacaine sulfate, elm bark, hexylresorcinol, potassium nitrate, and sodium perborate monohydrate) are not adequately characterized.

The agency believes that it would be appropriate for interested parties to develop with the United States Pharmacopeial Convention appropriate standards for the quality and purity of the oral health care ingredients that are not already included in official compendia. In this tentative final monograph, butacaine sulfate, elm bark, hexylresorcinol, potassium nitrate, and sodium perborate monohydrate are proposed in Category I. However, should interested parties fail to provide necessary information so that appropriate standards may be established, these ingredients will not be included in the final monograph. The same standards should also be developed for any Category II or III ingredients for which data are submitted for inclusion in the final monograph.

References

(1) "United States Pharmacopeia XXII—National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, 1989, pp. 41, 147, 150, 223 to 224, 485, 611, 663, 821, 1021, 1061, 1236, 1252, 1462, 1906, and 1932.

(2) "United States Pharmacopeia XV," United States Pharmacopeial Convention, Inc., Washington, p. 91, 1955.

The agency is proposing to remove the existing warning and caution statement recommended in § 369.20 for "toothache preparations." That statement reads "For temporary use only until a dentist can be consulted." If ingredients for the relief of toothache are included in the final monograph, the existing statement in § 369.20 will be superseded by the requirements of the final monograph on OTC oral health care drug products (part 356, subpart C). If ingredients for the relief of toothache are not included in the final monograph, products containing these ingredients will need a new drug application for marketing, and there will be no need for the existing statement to appear in § 369.20.

III. Recent Developments

A. Additional Warning(s) for Products Indicated for Relief of Sore Throat

In March 1990, the agency became aware of four reports from the United Kingdom (U.K.) of life threatening pharyngeal spasm that were related to a phenol-containing OTC oral spray used for the symptomatic relief of sore throat (Ref. 1). All cases occurred when people who may have had epiglottitis used the anesthetic/analgesic oral spray. One person died, with the cause of death listed as acute epiglottitis. The only difference in the formulation between the OTC drug product used in the U.K. and a similar product marketed in the United States (U.S.) is that the drug product used in the U.K. contains 0.0145 percent tartrazine as a coloring agent, and the drug product marketed in the U.S. has not contained tartrazine since 1980. The manufacturer of the product informed the agency that the British Committee on Safety of Medicines (CSM) was reconsidering the future marketing of the phenol-containing OTC drug product (Ref. 2).

Subsequently, the CSM permitted continued marketing of the phenol-containing OTC oral spray so long as certain labeling changes were made in both consumer and professional labeling (Ref. 3). The revised labeling states that (1) the product is not for use in children under 12 unless recommended by a doctor; (2) the product should not be used and a doctor consulted if there is a difficulty in breathing, if breathing is noisy, or if there is a severe difficulty in swallowing; and (3) the product should not be used without consulting a doctor if sore throat is severe, has lasted for more than 2 days, or is accompanied by high fever, headache, nausea, or vomiting.

The agency requested information from the company on any serious adverse drug experience reports that it had received from consumers in the U.S., regarding either anaphylactic-like reactions or swelling of the throat or larynx area leading to difficulty in breathing related to the use of the phenol-containing OTC oral health care drug product. The company conducted a review of its data base for the years 1963 to 1990, found a total of 18 reports, and submitted these reports to the agency (Refs. 4 and 5). The reports indicated that adverse reactions occurred both with and without tartrazine in the product. The company also provided the agency with U.S. drug experience reports, specifically anaphylactic-like reactions or swelling of the throat or larynx area resulting in difficulty in breathing, for its OTC drug products indicated for sore throat that contain anesthetic/analgesic ingredients other than phenol (i.e., mentol and benzocaine) (Ref. 5).

The agency contacted manufacturers of the major brands of OTC oral health care drug products containing Category I anesthetic/analgesic ingredients (i.e., benzocaine, benzyl alcohol, dyclonine hydrochloride, hexylresorcinol, menthol, phenol, and salicyl alcohol) (Ref. 6). In addition, the agency contacted the manufacturer of a major brand of an OTC oral health care drug product containing tartrazine (Ref. 6). FDA requested these manufacturers to provide any reports received regarding airway obstruction or anaphylactic-type reactions associated with these products.

The agency has analyzed the information received along with information already in its spontaneous reporting system. Duplicative reports, i.e., industry reports identical with FDA reports, were excluded. A case was included in this analysis only if there was documentation of swelling of the throat, larynx, or epiglottis and/or respiratory difficulty. Reports in which it was noted that the product became lodged in the throat resulting in mechanical obstruction of the airway were not included. The agency has documented 4 cases involving benzocaine, 3 cases involving benzyl alcohol, 38 cases involving dyclonine hydrochloride, 3 cases involving hexylresorcinol, 3 cases involving menthol, 24 cases involving phenol, and 0 cases involving salicyl alcohol. In some cases, only one anesthetic/analgesic ingredient was involved; in others, more than one anesthetic/analgesic ingredient was involved. In addition, the agency has documented nine cases involving tartrazine in combination with a Category III antimicrobial ingredient (i.e., cetylpyridinium chloride). In three of these cases, the product also contained benzyl alcohol. In two of the cases, the product also contained benzocaine (Ref. 6).

The manufacturer of the phenol-containing OTC oral spray discussed above recently informed FDA (Ref. 7) that it intends to enhance the warning statement currently proposed for anesthetic/analgesic ingredients in the tentative final monograph for OTC oral

health care drug products (53 FR 2436 at 2458) on all dosage forms of its OTC oral health care drug products containing any anesthetic/analgesic ingredient and indicated for the relief of sore throat. The manufacturer included a synopsis and evaluation of adverse experience reports involving OTC oral health care anesthetic/analgesic drug products and a review of the characteristics of epiglottitis.

The manufacturer stated that the most prevalent symptoms of epiglottitis are sore throat (often severe), dysphagia (difficulty in swallowing), fever, and dyspnea (difficulty in breathing). It noted that two of the four symptoms (i.e., severe sore throat and fever) are already addressed in the warning proposed by the agency in the OTC oral health care tentative final monograph (53 FR 2436 at 2458), as follows: "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly * * *." The manufacturer noted that this warning does not refer to dysphagia or dyspnea. With regard to dysphagia, the manufacturer stated that preliminary research indicates that there is considerable consumer confusion with respect to difficulty in swallowing. Typically, consumers equate the discomfort or pain of swallowing that accompanies even a minor sore throat with difficulty in swallowing. Patients with epiglottitis, however, frequently experience dysfunction of the epiglottis that does not allow them to swallow normally. The manufacturer stated that consultations with otolaryngologists indicated that when consumers do experience true difficulty in swallowing, as is exhibited by an inability to swallow their own saliva (as can occur with epiglottitis), they are extremely unlikely to use an OTC oral anesthetic/analgesic. The manufacturer, therefore, concluded that the addition of "difficulty in swallowing" to the warning statement for OTC oral health care anesthetic/analgesic drug products would not convey a clear or meaningful message to consumers, but rather it would likely prevent the appropriate use of such products.

However, the manufacturer maintained that dyspnea or difficulty in breathing is well understood by the consumer. Therefore, although specialists in otolaryngology have advised that adult epiglottitis patients experiencing such symptoms are unlikely to use any OTC sore throat product, the manufacturer believes that the addition of this symptom to the warning statement adds a further measure of assurance that OTC oral health care anesthetic/analgesic drug products will not be used in inappropriate situations.

The manufacturer concluded that the currently proposed warning statement for OTC oral health care drug products (see above) could be clarified by making a few simple changes, thereby providing further assurance that such OTC drug products will not be misused. The manufacturer proposed a revised warning as follows:

> If sore throat is severe, or is accompanied by difficulty in breathing, or persists for more than 2 days, do not use and consult a doctor promptly. If sore throat is accompanied by or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your doctor or dentist promptly.

The manufacturer further stated that it intends to phase in this enhanced warning statement on all of its oral anesthetic/analgesic drug products as current labeling inventory is exhausted (Ref. 7).

The agency believes that the number of adverse event reports involving either anaphylactic-like reactions or swelling of the throat or larynx area leading to difficulty in breathing and related to the use of oral health care drug products indicated for relief of sore throat symptoms demonstrates the need for labeling to highlight this potential problem. Epiglottitis is a severe, rapidly progressive infection of the epiglottis and surrounding tissues that may be quickly fatal because of sudden respiratory obstruction by the inflamed structures (Ref. 8). Its incidence is highest in children 2 to 5 years of age, but it may occur at any age. Sore throat, hoarseness and, usually, high fever develop abruptly in a previously healthy child. The patient should be hospitalized immediately if epiglottitis is suspected (Ref. 7). The agency believes that the labeling on all OTC oral health care products indicated for use in relieving the symptoms of sore throat should alert consumers to the possibility that they may need immediate medical attention if certain symptoms are present. However, at this time, the agency is not including such language in this tentative final monograph, but instead is requesting comment on how best to convey such information to consumers.

There are several questions that need to be addressed. The warning statement proposed in §§ 356.52(c)(1), 356.54(c), and 356.58(c)(1) of this amendment for ingredients indicated for use in relieving the symptoms of sore throat (i.e., anesthetic/analgesics, astringents, and demulcents) is as follows: "If sore throat is severe, persists for more than 2 days, is accompanied by or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly * * *." The agency seeks comment on whether "difficulty in breathing," "noisy breathing," or "difficulty in swallowing" should be added to this warning. If so, how should the warning be worded to best alert consumers to these potential problems?

The agency notes that the warning statement required by the CSM for the phenol-containing oral spray discussed above states that the product is "Not to be used by children under 12 years of age unless recommended by a doctor." The directions for use being proposed in this amendment indicate that children under 12 years of age should be supervised in the use of liquid dosage forms. Solid dosage forms may be used by adults and children 2 years of age and older without supervision, except for phenol-containing products, which may only be used by adults and children 6 years of age and older. Because the incidence of epiglottitis is highest in children aged 2 to 5 years (Ref. 8), the agency seeks comment on whether the use of products indicated for the relief of sore throat should now also be limited to adults and children over a certain age e.g., 6 or 12 years.

Finally, the agency would like comment on whether any revised warning statements should apply only to products containing anesthetic/analgesic ingredients, or should such warning statements apply to any OTC drug product that is indicated for treating a sore throat. The agency believes that any revised warning statement should apply to any OTC oral health care drug product used to treat a sore throat.

Based on comments received, if necessary, the agency will propose revised labeling for OTC oral health care drug products indicated for the relief of soar throat in an amendment to this tentative final monograph.

References

(1) Letter from M. D. Young, The Procter & Gamble Co., to M. D. Tyson, FDA, dated March 2, 1990, in OTC Volume 13BTFM.

(2) Minutes of Meeting between Richardson-Vicks, Inc., The Procter & Gamble Co., and FDA, dated March 5, 1990, in OTC Volume 13BTFM.

(3) Letter from R. A. Stolt, Richardson-Vicks, Inc., to D. Barash, FDA, dated June 15, 1990, in OTC Volume 13BTFM.

(4) Letter from R. A. Stolt, Richardson-Vicks, Inc., to D. Barash, FDA, dated March 9, 1990, in OTC Volume 13BTFM.

(5) Letter from R. A. Stolt, Richardson-Vicks, Inc., to D. Barash, FDA, dated August 2, 1990, in OTC Volume 13BTFM.

(6) Summary of Adverse Reaction Reports Regarding Airway Obstruction/Anaphylactic-type Reactions Associated with Oral Health Care Anesthetic/Analgesic Products, Food and Drug Administration, March 11, 1991, in OTC Volume 13BTFM.

(7) Letter from R. A. Stolt, Richardson-Vicks, Inc., to W. E. Gilbertson, FDA, dated February 19, 1991, in OTC Volume 13BTFM.

(8) "Acute Epiglottitis," in "The Merck Manual of Diagnosis and Therapy," ed. by R. Berkow and A. J. Fletcher, Merck, Sharp & Dohme Research Laboratories, Rahway, NJ, 1987, pp. 2020 and 2021.

B. Artificial Saliva Drug Products

The agency has recently become aware of several currently marketed artificial saliva drug products that are indicated for use as mouth moisteners and oral lubricants for individuals with permanent or temporary salivary gland disfunction (i.e., xerostomia). These preparations are designed to mimic natural saliva both chemically and physically (Ref. 1). They usually consist of an aqueous solution containing a thickening agent, a humectant, and electrolytes usually found in saliva. Their consistency approaches that of normal saliva, and their electrolyte levels are adjusted to approximate those of natural saliva (Ref. 2). They do not stimulate saliva production and, thus, must be considered as replacement therapy, not as a cure for xerostomia (Ref. 1).

Xerostomia, a condition in which saliva production is severely limited or completely arrested, has a various etiology and may be either temporary or permanent depending upon the cause (Ref. 2). Temporary xerostomia is often a side effect caused by the administration of various classes of drugs (e.g., antihistamines, decongestants, diuretics, and antihypertensives). The condition disappears when drug therapy ceases. Permanent xerostomia may be caused by exposure of the salivary glands to radiation therapy for the treatment of malignant neoplasms of the head or neck, or it may be a symptom of an autoimmune disease such as Sjogren's syndrome. The adverse effects of chronic xerostomia include stomatitis, burning tongue, reduced denture wearing time, difficulty in swallowing and speaking, disturbed sleep patterns, rampant caries, and periodontal disease (Refs. 1 and 2).

The agency believes that artificial saliva products could be potentially useful for individuals suffering from either temporary or permanent xerostomia. However, no submissions were made to the Panel or the agency regarding these products, nor is the agency aware of any specific data that would establish general recognition of safety and effectiveness. Therefore, the agency invites specific data and information regarding the use of artificial saliva drug products. After review and evaluation of the data submitted, the agency will consider artificial saliva drug products for inclusion in the final monograph for OTC oral health care drug products.

References

(1) Baker, K. A., "Oral Health Products," in "Handbook of Nonprescription Drugs," 9th Ed., American Pharmaceutical Association, Washington, 1990, pp. 667, 668, and 679.

(2) "Accepted Dental Therapeutics," 39th Ed., American Dental Association, Chicago, 1982, pp. 52, 53, 54, and 324.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC relief of oral discomfort drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC relief of oral discomfort drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC relief of oral discomfort drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by January 22, 1992. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) 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 evironmental impact statement is required.

Interested persons may, on or before January 22, 1992, submit to the Dockets Management Branch written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. Written comments, objections, or requests for oral hearing on the combination of potassium nitrate and an anticaries active ingredient, identified in § 356.26(h), by November 25, 1991. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before January 22, 1992. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before September 24, 1992, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before November 24, 1992. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on November 24, 1992. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects

21 CFR Part 356

Labeling, Oral health care drug products, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 356 (as proposed in the **Federal Register** of May 25, 1982 (47 FR 22712) and the **Federal Register** of January 27, 1988 (53 FR 2436)) and 21 CFR part 369 be amended as follows:

1. Part 356 is revised to read as follows:

PART 356—ORAL HEALTH CARE DRUG PRODUCTS FOR OVER-THE COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

356.1 Scope.
356.3 Definitions.

Subpart B—Active Ingredients

356.10 Agents for the relief of toothache.
356.12 Anesthetic/analgesics.
356.14 Astringents.
356.16 Debriding agent/oral wound cleansers.
356.18 Demulcents.
356.20 Oral mucosal protectants.
356.22 Tooth desensitizers.
356.24 Package size limitations.
356.26 Permitted combinations of active ingredients.

Subpart C—Labeling

356.48 Labeling of oral health care drug products.
356.50 Labeling of drug products for the relief of toothache.
356.52 Labeling of anesthetic/analgesic drug products.
356.54 Labeling of astringent drug products.
356.56 Labeling of debriding agent/oral wound cleanser drug products.
356.58 Labeling of demulcent drug products.
356.60 Labeling of oral mucosal protectant drug products.
356.62 Labeling of tooth desensitizer drug products.
356.66 Labeling of combination drug products.
356.80 Professional labeling.

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

Subpart A—General Provisions

§ 356.1 Scope.

(a) An over-the-counter oral health care drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 356.3 Definitions.

As used in this part:

(a) *Oral health care drug.* A drug product applied topically for the proper care of the oral cavity, including the temporary relief of symptoms of the gums, teeth, mouth, and throat, for example, minor irritation of the gums, occasional mouth soreness, or minor sore throat.

(b) *Agent for the relief of toothache.* An ingredient used for the temporary relief of pain arising as a result of an open tooth cavity.

(c) *Anesthetic/analgesic.* A substance applied topically to an epithelial surface (e.g., skin or mucous membrane) that relieves pain without necessarily abolishing other sensations (analgesic) or a substance applied topically that completely blocks pain receptors resulting in a sensation of numbness and abolition of response to painful stimuli (anesthetic).

(d) *Anhydrous glycerin.* An ingredient that may be prepared by heating glycerin U.S.P. at 150 °C for 2 hours to drive off the moisture content.

(e) *Astringent.* An agent that causes contraction of the tissues or arrest of secretions by coagulation of proteins on a cell surface.

(f) *Debriding agent/oral wound cleanser.* A nonirritating agent which causes or assists in the removal (physically or chemically) of foreign material or devitalized or contaminated tissue from or adjacent to a minor oral wound or a traumatic or infected lesion to expose surrounding healthy tissue and does not delay wound healing.

(g) *Demulcent.* A bland, inert agent that soothes and relieves irritation of inflamed or abraded surfaces such as mucous membranes.

(h) *Dentifrice.* A substance used with a toothbrush to clean the accessible surfaces of the teeth. It is an abrasive-containing dosage form for delivering an active ingredient to the teeth.

(i) *Mouthwash (oral rinse).* A solution used for rinsing the mouth, not necessarily for medicinal purposes.

(j) *Oral cavity (mouth).* The cavity of the mouth and associated structures, including the cheeks, palate, oral mucosa, glands where ducts open into it, the teeth, and the tongue.

(k) *Oral mucosal protectant.* An ingredient which is a pharmacologically inert substance which forms an adherent, continuous, flexible, or semirigid coating when applied to the oral mucous membranes. The coating protects the irritated area from further irritation due to the activity of oral structures.

(l) *Tooth desensitizer.* An ingredient which acts on the dentin to block perception of those stimuli which are usually not perceived by subjects with normal teeth but which are perceived by patients with dental hypersensitivity.

Subpart B—Active Ingredients

§ 356.10 Agents for the relief of toothache.

§ 356.12 Anesthetic/analgesics.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § 356.52(d).

(a) Benzocaine.
(b) Benzyl alcohol.
(c) Butacaine sulfate.
(d) Dyclonine hydrochloride.
(e) Hexylresorcinol.
(f) Menthol.
(g) Phenol preparations (phenol and/or phenolate sodium).
(h) Salicyl alcohol.

§ 356.14 Astringents.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § 356.54(d).

(a) Alum.
(b) Zinc chloride.

§ 356.16 Debriding agent/oral wound cleansers.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § 356.56(d).

(a) Carbamide peroxide in anhydrous glycerin.
(b) Hydrogen peroxide.
(c) Sodium bicarbonate.
(d) Sodium perborate monohydrate.

§ 365.18 Demulcents.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § 356.58(d):

(a) Elm bark.

(b) Gelatin.

(c) Glycerin.

(d) Pectin.

§ 356.20 Oral mucosal protectants.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient in § 356.60(d).

(a) Compound benzoin tincture, U.S.P. XIX.

(b) Benzoin tincture, U.S.P. XV.

§ 356.22 Tooth desensitizers.

The active ingredient of the product consists of potassium nitrate when used within the dosage limits and in the dosage form established in § 356.62(d).

§ 356.24 Package size limitations.

Products containing benzoin preparations identified in § 356.20 should be packaged in well-closed containers in a quantity of 30 milliliters or less.

§ 356.26 Permitted combinations of active ingredients.

(a) Any single anesthetic/analgesic active ingredient identified in § 356.12 may be combined with any single astringent active ingredient identified in § 356.14.

(b) Any single anesthetic/analgesic active ingredient identified in § 356.12 may be combined with any single demulcent active ingredient identified in § 356.18.

(c) Any single oral mucosal protectant active ingredient identified in § 356.20 may be combined with any single anesthetic/analgesic active ingredient identified in § 356.12.

(d) Any single anesthetic/analgesic active ingredient identified in § 356.12 may be combined with any generally recognized safe and effective denture adhesive.

(e) Benzocaine identified in § 356.12(a) may be combined with menthol identified in § 356.12 (f).

(f) Benzocaine identified in § 356.12(a) may be combined with phenol preparations identified in § 356.12 (g).

(g) Oral health care and cough-cold combinations. See § 341.40 of this chapter.

(h) Potassium nitrate identified in § 356.22 may be combined with any single anticaries active ingredient identified in § 355.10(a) of this chapter.

Subpart C—Labeling

§ 356.48 Labeling of oral health care drug products.

(a) The word physician may be substituted for the word doctor in any of the labeling statements in this part.

(b) Indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this part, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

§ 356.50 Labeling of drug products for the relief of toothache.

§ 356.52 Labeling of anesthetic/analgesic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral anesthetic," an "oral anesthetic/analgesic," or an "oral pain reliever."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed below:

(1) "For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat."

(2) "For the temporary relief of pain associated with canker sores."

(3) "For the temporary relief of pain due to minor irritation or injury of the mouth and gums."

(4) "For the temporary relief of pain due to minor dental procedures."

(5) "For the temporary relief of pain due to minor irritation of the mouth and gums caused by dentures or orthodontic appliances."

(6) *For products containing benzocaine identified in § 356.12(a) or phenol identified in § 356.12(g) when used as anesthetic/analgesics for teething pain.* "For the temporary relief of sore gums due to teething in infants and children 4 months of age and older."

(7) *For products containing any ingredient identified in § 356.12 when used in denture adhesive products.* "For the temporary relief of pain or discomfort of the mouth and gums due to dentures."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For all products containing any ingredient identified in § 356.12 labeled with only the indication in § 356.52(b)(1) or with the indication in § 356.52(b)(1) plus any of the indications in § 356.52(b)(2), (b)(3), (b)(4), (b)(5), (b)(6), or (b)(7).* "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly."

(2) *For all products containing any ingredient identified in § 356.12 labeled with any of the indications in § 356.52(b)(2), (b)(3), (b)(4), (b)(5), (b)(6), or (b)(7) but not with the indication in § 356.52(b)(1).* "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly."

(3) "Do not exceed recommended dosage."

(4) *For all products containing any ingredient identified in § 356.12 (a) and (c).* "Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other 'caine' anesthetics."

(5) *For all products labeled with the indication identified in § 356.52(b)(6).* "Fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your doctor."

(6) *For all products containing any ingredient identified in § 356.12 when used in denture adhesive products.* "See your dentist as soon as possible."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing benzocaine identified in § 356.12(a)*—(i) *For dosage forms other than solid, the product is a 5- to 20-percent solution or suspension.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around in the mouth, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains 2 to 15 milligrams benzocaine.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(iii) *For products intended to be used as teething preparations, the product is a 5- to 20-percent solution or suspension.* Apply to the affected area not more than four times daily or as directed by a dentist or doctor. For infants under 4 months of age there is no recommended dosage or treatment except under the advice and supervision of a dentist or doctor.

(iv) *For denture adhesive products the product contains 5 to 20 percent benzocaine.* Apply on area of denture that comes in contact with sore gums.

(2) *For products containing benzyl alcohol identified in § 356.12(b)*—(i) *For dosage forms other than solid, the product is a 0.05- to 10-percent solution or suspension.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains 100 to 500 milligrams benzyl alcohol.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(3) *For products containing butacaine sulfate identified in § 356.12(c)*—(i) *The product contains 30 milligrams butacaine sulfate per dosage unit.* Adults: Apply (manufacturer should state specific amount of product that contains 30 milligrams butacaine sulfate) to the affected area. Do not apply again for at least 3 hours. Do not use more than three applications in 24 hours unless directed by a dentist or doctor. Children under 12 years of age: Consult a dentist or doctor.

(ii) *For denture adhesive products the product contains 30 milligrams butacaine sulfate per dosage unit.* Apply on area of denture that comes in contact with sore gums.

(4) *For products containing dyclonine hydrochloride identified in § 356.12(d)*—(i) *For dosage forms other than solid, the product is a 0.05- to 0.10-percent solution or suspension.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains 1 to 3 milligrams dyclonine hydrochloride.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(5) *For products containing hexylresorcinol identified in § 356.12(e)*—(i) *For dosage forms other than solid, the product is a 0.05- to 0.1-percent solution or suspension.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains 2 to 4 milligrams hexylresorcinol.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(6) *For products containing menthol identified in § 356.12(f)*—(i) *For dosage forms other than solid, the product is a 0.04- to 2-percent solution or suspension.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains 2 to 20 milligrams menthol.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(7) *For products containing phenol preparations identified in § 356.12(g)*—(i) *For dosage forms other than solid, the product is an aqueous solution or suspension containing phenol or phenolate sodium equivalent to 0.5 to 1.5 percent phenol*—(A) *For direct application.* Adults and children 2 years of age and older: Apply to the affected area, allow to remain in place for at least 15 seconds and then spit out. Use every 2 hours or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(B) *For use as a mouthwash (oral rinse).* Adults and children 12 years of age and older: Gargle or swish around the mouth for at least 15 seconds and then spit out. Use every 2 hours or as directed by a dentist or doctor. Children 6 to under 12 years of age: Apply 10 milliliters to the affected area, gargle, or swish around the mouth for at least 15 seconds and then spit out. Use every 2 hours or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 6 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product (lozenge or tablet) contains phenol or phenolate sodium equivalent to 10 to 50 milligrams phenol.* Adults and children 12 years of age and older: Allow the product (lozenge or tablet) to dissolve slowly in the mouth. May be repeated every 2 hours or as directed by a dentist or doctor. Children 6 to under 12 years of age: Allow product (lozenge or tablet) to dissolve slowly in the mouth. May be repeated every 2 hours, not to exceed 300 milligrams phenol in 24 hours, or as directed by a dentist or doctor. Children under 6 years of age: Consult a dentist or doctor.

(iii) *For products intended for use as a teething preparation, the product is an aqueous solution or suspension containing phenol or phenolate sodium equivalent to 0.5 percent phenol.* For infants and children 4 months to under 12 years of age: Apply to the affected area. Use up to 6 times daily or as directed by a dentist or doctor.

(iv) *For denture adhesive products, the product contains phenol or phenolate sodium equivalent to 0.5 to 1.5 percent phenol.* Apply on area of denture that comes in contact with sore gums.

(8) *For products containing salicyl alcohol identified in § 356.12(h)*—(i) *For dosage forms other than solid, the produce is a 1- to 6-percent solution or suspension.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product.

Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains 50 to 100 milligrams salicyl alcohol.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

§ 356.54 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral astringent."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For temporary relief of occasional minor irritation, pain, sore mouth, and sore throat."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings": *For all products containing any ingredient identified in § 356.14.* "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing alum identified in § 356.14(a), the product is a 0.2- to 0.5-percent aqueous solution.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(2) *For products containing zinc chloride identified in § 356.14(b), the product is a 0.1- to 0.25-percent aqueous solution.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

§ 356.56 Labeling of debriding agent/oral wound cleanser drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral debriding agent" or an "oral debriding agent/oral wound cleanser."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed below: (1) "Aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth."

(2) "For temporary use in cleansing minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums."

(3) "For temporary use to cleanse canker sores."

(4) *Other allowable statements.* In addition to the required information specified in paragraphs (a), (b), (c), and (d) of this section, the labeling of the product may contain any of the following statements, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(i) "Assist in the removal of foreign material from minor wounds."

(ii) "Physically removes debris from minor oral wounds."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings": *For all products containing any ingredient identified in § 356.16.* "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing carbamide peroxide identified in § 356.16(a), the product is a 10- to 15-percent solution in anhydrous glycerin*—(i) *For direct application.* Adults and children 2 years of age and older: Apply several drops directly to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For use as a mouthwash (oral rinse).* Adults and children 2 years of age and older: Place 10 to 20 drops onto tongue. Mix with saliva. Swish around in the mouth over the affected area for at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(2) *For products containing hydrogen peroxide identified in § 356.16(b), the product is a 3-percent aqueous solution*—(i) *For direct application.* Adults and children 2 years of age and older: Apply several drops to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For use as an oral rinse.* Adults and children 2 years of age and older: Mix with an equal amount of warm water. Swish around in the mouth over the affected area for at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(3) *For products containing sodium bicarbonate identified in § 356.16(c).* Adults and children 2 years of age and older: Prepare a solution by mixing ½ to 1 teaspoon in ½ glass (4 ounces) of water. Swish around in mouth over affected area for at least 1 minute and then spit out. Use up to four times daily or as directed by a dentist or doctor. Children under 12 should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(4) *For products containing sodium perborate monohydrate identified in § 356.16(d).* Adults and children 6 years of age and older: Dissolve 1.2 grams of sodium perborate monohydrate in 1 ounce (30 milliliters) of warm water. Use immediately. Swish solution around in the mouth over the affected area or gargle for at least 1 minute and then spit it out. Do not swallow. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Consult a dentist or doctor for use in children under 6 years of age.

§ 356.58 Labeling of demulcent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral demulcent."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For temporary relief of minor discomfort and protection of irritated areas in sore mouth and sore throat."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing elm bark identified in § 356.18.* "If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly."

(2) *For products containing glycerin identified in § 356.18(c).* "Do not use full strength. Dilute with two or three volumes of water."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing elm bark identified in § 356.18(a), the product is 10 to 15 percent elm bark in a solid dosage form.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(2) *For products containing gelatin identified in § 356.18(b)*—(i) *For dosage forms other than solid, the product is a 5- to 10-percent solution or suspension containing a sufficient quantity of gelatin to form a semi-solid state.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around in the mouth, or allow to remain in place for at least 1 minute and then spit out. Use as needed or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains a sufficient quantity of gelatin to form a solid state.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

(3) *For products containing glycerin identified in § 356.18(c).* Adults and children 2 years of age and older: Apply a solution containing glycerin diluted with 2 or 3 parts of water to the affected area. Gargle, swish around in the mouth, or allow to remain in place for at least 1 minute and then spit out. Use as needed or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of this product. Children under 2 years of age: Consult a dentist or doctor.

(4) *For products containing pectin identified in § 356.18(d)*—(i) *For dosage forms other than solid, the product is a solution or a gel containing a sufficient quantity of pectin to form a semi-solid state.* Adults and children 2 years of age and older: Apply to the affected area. Gargle, swish around in the mouth, or allow to remain in place for at least 1 minute and then spit out. Use as needed or as directed by a dentist or doctor. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or doctor.

(ii) *For solid dosage forms, the product contains a sufficient quantity of pectin to form a solid state.* Adults and children 2 years of age and older: Allow product to dissolve slowly in the mouth. May be repeated as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

§ 356.60 Labeling of oral mucosal protectant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "oral mucosal protectant."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed below:

(1) "Forms a coating over a wound."

(2) "Protects against further irritation."

(3) "For temporary use to protect wounds caused by minor irritations or injury."

(4) "For protecting recurring canker sores."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly."

(2) "Do not exceed recommended dosage."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions": *For products containing compound benzoin tincture or benzoin tincture identified in § 356.20(a) and (b), the product is compound benzoin tincture, U.S.P. XIX or benzoin tincture, U.S.P. XV.* Adults and children 6 months of age and older: Dry the affected area. Saturate a cotton applicator with medication. Apply the undiluted medication directly to the affected area. Do not use more often than every 2 hours. Children under 6 months of age: Consult a dentist or doctor.

§ 356.62 Labeling of tooth desensitizer drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a (insert dosage form, e.g., "toothpaste" or "dental gel") "for" (select one of the following: "sensitive" or "hypersensitive") "teeth."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed below:

(1) "Helps reduce painful sensitivity of the teeth to cold, heat, acids, sweets, or contact."

(2) "Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact."

(c) *Warnings.* The labeling of the product contains the following warning under the heading "Warnings." "Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or doctor."

(d) *Directions.* The labeling for products containing potassium nitrate identified in § 356.22, as a 5 percent dentifrice, contains the following information under the heading "Directions": Adults and children 12 years of age and older: Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Children under 12 years of age: Consult a dentist or doctor.

§ 356.66 Labeling of combination drug products.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each active ingredient in the combination drug product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable over-the-counter (OTC) drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs, unless otherwise stated below.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC drug monographs or listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. In addition to the required information identified above in this section, the labeling of the combination drug product may contain any of the "other allowable statements" (if any) that are identified in the applicable monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(1) *For permitted combinations identified in § 356.26(c).* Any or all of the indications in § 356.52(b)(2), (b)(3), (b)(4), (b)(5), and (b)(6) should be used.

(2) *For permitted combinations identified in § 356.26(g).* The indications in § 341.85(b)(4) of this chapter should be used.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

§ 356.80 Professional labeling.

(a) The labeling of products containing oral health care anesthetic/analgesic active ingredients identified in § 356.12 provided to health professionals (but not to the general public) may contain the following indication: "For the temporary relief of pain associated with" (select one or more of the following conditions: "tonsilitis," "pharyngitis," "throat infections," "Vincent's infection," or "stomatitis.")

(b) The labeling of products containing dyclonine hydrochloride identified in § 356.12(d) provided to health professionals (but not to the general public) may contain the following indications:

(1) "For the temporary relief of discomfort in patients with an excessive gag reflex when having impressions of the teeth made or during intraoral radiography."

(2) "For use as a preinjection topical anesthetic on the oral mucosa."

(c) The labeling of products containing oral health care debriding agent/oral wound cleanser active ingredients identified in § 356.16 provided to health professionals (but not to the general public) may contain the following indication: "For temporary use in the cleansing of gum irritation due to erupting teeth (teething)."

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

2. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.20 [Amended]

3. In subpart B, § 369.20 *Drugs; recommended warning and caution statements* is amended by removing the entry for "TOOTHACHE PREPARATIONS."

Dated: July 1, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-22749 Filed 9-23-91; 8:45 am]

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Part IV

Environmental Protection Agency

40 CFR Parts 85 and 86

Air Pollution Control and Emission Standards for New Motor Vehicles, Urban Buses, and Heavy-Duty Engines; Proposed Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 85 and 86

[AMS-FRL-3996-3]

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Particulate Emission Regulations for 1993 Model Year Buses, Particulate Emission Regulations for 1994 and Later Model Year Urban Buses, Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses, Test Procedures for Urban Buses, and Oxides of Nitrogen Emission Regulations for 1998 and Later Model Year Heavy-Duty Engines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: Today's notice of proposed rulemaking relates to urban buses, heavy-duty diesel engines (HDDEs) used in urban buses, and all heavy-duty engines (HDEs), all of which are required by the Clean Air Act (CAA) as amended in 1990. First, for the 1993 model year, EPA proposes to expand the applicability of the current 0.10 gram per brake horsepower-hour (g/bhp-hr) particulate matter (PM) standard for urban bus engines to a broader group of HDEs used in other types of buses. Second, EPA proposes a new PM standard of 0.05 g/bhp-hr for 1994 and later model year HDDEs used in urban buses. Third, EPA proposes two alternative performance standards for HDDEs used in urban buses whose engines are rebuilt or replaced after January 1, 1995, applicable to 1993 and earlier model year urban buses. Fourth, EPA proposes to retain the current heavy-duty transient test procedure for emission testing of urban bus engines. As proposed, these items would reduce the ambient levels of particulate matter in urban areas.

In addition to the bus standards listed above, today's notice also proposes a separate 4.0 g/bhp-hr oxides of nitrogen (NOx) standard for all 1998 and later model year HDEs. The proposed standard is expected to reduce the nationwide NOx inventory by two percent when fully implemented.

DATES: Written comments on this proposal will be accepted until November 8, 1991.

EPA will hold a public hearing on this Notice of Proposed Rulemaking on October 9, 1991.

Further information on the public hearing and the submission of comments can be found under "Public Participation" in the "Supplementary Information" section of today's notice.

ADDRESSES: Interested parties may submit written comments (in duplicate if possible) to Public Docket No. A–91–28 at the address listed below.

The public hearing will be held at the EPA Motor Vehicle Emissions Laboratory, 2565 Plymouth Road, Ann Arbor, MI, and will begin at 9 a.m. A court reporter will be present to make a written transcript of the proceedings and a copy will be placed in the public docket following the hearing.

Materials relevant to this proposed rulemaking are contained in Public Docket A–91–28. This docket is located in room M–1500, Waterside Mall (Ground Floor), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Dockets may be inspected from 8 a.m. until 12 noon, and from 1:30 p.m. until 3 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Philip N. Carlson, Emission Control Technology Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, Michigan 48105, Telephone: (313) 668–4270.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

Various emission standards for both diesel-fueled and gasoline-fueled heavy-duty engines have been in effect since the early 1970's. Since that time, EPA has continued to promulgate more stringent emission standards for heavy-duty engines as well as adopting a new test procedure for certification. The current heavy-duty transient test procedure replaced a 13-mode steady-state test procedure for all certification testing in the 1985 model year.

EPA promulgated the first particulate matter (PM) standards for heavy-duty diesel engines (HDDEs) on March 15, 1985 (50 FR 10605). The PM standards promulgated in that rule were set at 0.60 grams per brake horsepower hour (g/bhp-hr) for 1988 through 1990 model year HDDEs, 0.25 g/bhp-hr for 1991 through 1993 model year HDDEs, and 0.10 g/bhp-hr for 1994 and later model year HDDEs. In addition, HDDEs used in urban buses were required to meet the 0.10 g/bhp-hr PM standard beginning with the 1991 model year. For emission regulation purposes, EPA has defined an urban bus to be a heavy heavy-duty diesel-powered passenger-carrying vehicle with a load capacity of fifteen or more passengers and intended primarily for operation within the confines of a city or greater metropolitan area. The EPA definition also lists typical physical characteristics of urban buses. (See 40 CFR 86.091–2.)

The American Public Transit Association (APTA) petitioned EPA to delay the 0.10 g/bhp-hr urban bus PM standard until the 1994 model year to coincide with the implementation of the 0.10 g/bhp-hr standard for all other HDDEs. However, before EPA was able to take final action on the APTA petition, Congress took up the issues raised in that petition as part of the debates regarding amendments to the CAA. As a result, section 202(f) of the CAA as amended delays the 0.10 g/bhp-hr urban bus PM standard until the 1993 model year, with a PM standard of 0.25 g/bhp-hr for 1991 and 1992 model year urban buses. EPA issued a separate notice of proposed rulemaking for the interim PM standard for 1991 and 1992 model year urban buses on May 29, 1991 (56 FR 24242) and is currently in the process of developing the final rule.

B. Requirements of the Amended Clean Air Act

Today's proposal is designed to implement several requirements of the CAA as amended. These requirements are as follows:

1. 1993 Model Year Bus PM Standard

Section 202(f) [1] of the CAA as amended establishes a 0.10 g/bhp-hr standard for buses other than those subject to standards under section 219. The Act does not define the class "buses".

2. 1994 and Later Model Year Urban Bus PM Standard

Section 219(b) of the amended CAA requires EPA to adopt a 0.05 g/bhp-hr PM standard for 1994 and later model year urban buses. However, if EPA determines that 0.05 g/bhp-hr is not technologically achievable, taking into account durability, costs, lead time, safety, and other relevant factors, EPA must relax the PM standard to no more than 0.07 g/bhp-hr.

3. Urban Bus Retrofit/Rebuild Requirements

Section 219(d) of the CAA requires that EPA develop regulations governing 1993 and earlier model year urban bus engines which are rebuilt or replaced

[1] Section 207(b) of the Clean Air Act Amendment of 1990 amends section 202 of the Act by adding a new section 202(f). However, the current section 202(f) in the CAA was not omitted by the amendments. Section 202(f) will be used in this NPRM to refer solely to the new subsection added by section 207(b) of the amendments.

after January 1, 1995. EPA can set an emission standard or an emission control technology requirement for the affected engines. This program is to apply in Metropolitan Statistical Areas (MSAs) and Consolidated Metropolitan Statistical Areas (CMSAs) with 1980 populations of 750,000 or greater.

4. Urban Bus Test Procedure

Section 219(e) of the amended CAA requires that testing procedures for urban buses reflect actual operating conditions.

5. 1998 and Later Model Year Heavy-duty Engine NOx Standard

Section 202(a)(3)(B)(ii) of the amended Clean Air Act requires EPA to adopt a 4.0 g/bhp-hr NOx standard for all 1998 and later model year gasoline-fueled and diesel-fueled heavy-duty engines.

II. Description of Proposal

The following section describes EPA's proposals. For a more detailed analysis and discussion of issues related to these proposed requirements the reader is directed to the Regulatory Support Document (RSD) associated with this proposal. A limited number of copies of the RSD are available from the contact person listed above and a copy has been placed in the public docket for this rulemaking.

A. 1993 Model Year Bus PM Standard

Section 202(f) of the amended CAA specifies a 1993 particulate standard of 0.10 g/bhp-hr for "buses other than those subject to standards under section 219". Section 219 of the CAA provides standards "applicable to urban buses for the model year 1994 and thereafter." Current regulations at 40 CFR 86.091–11 provide for a 0.10 g/bhp-hr particulate standard for urban buses (heavy heavy-duty buses intended primarily for intra-city uses) in 1993. The term "buses" is not defined in the CAA or by EPA regulations.

EPA believes the most straightforward reading of section 202(f) is that Congress intended to include more than pre-1994 urban buses in its scope. In effect, "buses" as used in that section includes more than urban buses.

Section 202(f) differs from prior versions in the House and Senate bills in that these previous bills used the term "urban bus" and were clearly limited to urban buses. Congress failed to use this term in section 202(f) and instead used the more general term "buses". The plain meaning of this term and the importance of giving meaning to all parts of the provision leads EPA to believe this change in terminology reflects an apparent intention to broaden the scope of the provision.[2]

The CAA defines "urban bus" in section 219(f) by reference to EPA's regulatory definition. At the same time, Congress failed to define the term "bus". Lacking a definition in the Act, EPA believes the best interpretation of the term is to include buses that are similar to urban buses. Although there is clearly considerable flexibility in how broadly EPA might define "buses", there is no clear indication Congress intended to include all possible buses in the scope of section 202(f), from small shuttle buses to large inter-city passenger buses. Without more indication of Congressional intent, EPA believes the best course may be to define "bus" to include, in addition to urban buses, those buses which use the same class of engines as urban buses (normally heavy heavy-duty diesel engines) and are capable of being centrally fueled.

In arriving at this conclusion, EPA has considered three options for the application of the 1993 model year 0.10 g/bhp-hr PM standard. The first option considered would continue applying the standard to only urban buses. However, EPA is not proposing this option today because it does not appear to reflect Congressional intent.

The second option considered is that identified initially above. In addition to applying the standard to existing urban buses, this second option would also apply the standard to those buses which use heavy heavy-duty engines and are capable of being centrally fueled. A possible variation on the second option, suggested by industry and which EPA is considering but not proposing, would be identical with the further restriction that the only additional buses covered (besides existing urban buses) would be those buses which use the same engine models as urban buses and are capable of being centrally fueled. The third option considered would begin applying the standard broadly to all categories of buses, including inter-city buses, shuttle buses, and school buses.

EPA proposes only the second option while inviting comment on the first and third options and any other possible options. EPA believes the second option is consistent with the intent of the CAA and that it would minimize potential disruption in the design and production of engines, particulate traps and chassis, as discussed below.

EPA does not believe the difference in environmental impact between the three options will be dramatic. Any broadening of the definition will only have an effect for one year because, as stated above, all heavy-duty engines are required to meet a 0.10 g/bhp-hr PM standard in 1994 except for engines used in urban buses for which a new PM standard is proposed today. In addition, the maximum number of new buses covered by the above options is not large compared to the total number of heavy-duty vehicles.[3] The technological and economic issues discussed below may further reduce the environmental impact of the option chosen.

The bus engines which would be included in the second and third options considered for this proposal have not received the same particulate control development attention as urban buses. Engine manufacturers make their plans based in part on emissions regulations. The standards which existed prior to the CAA amendments required urban bus engines to meet a 0.10 g/bhp-hr standard in 1991 while other heavy duty engines were given until 1994 to meet this standard. The two year delay in the 0.10 g/bhp-hr standard for urban bus engines is due in part to engine manufacturers who argued that the standard would not be economically feasible for urban buses until 1993. Thus a revamping of the development schedule may be required if the manufacturers are to meet the lower particulate standard for additional buses in 1993. However, to the extent that banked emission credits might be available, they might ease the impact of including any additional buses under the 0.10 g/bhp-hr PM standard for the 1993 model year.

Various other parties may be affected by the new requirements. The makers of the particulate trap systems which enable buses to meet the lower particulate level have based their planning on a 0.10 g/bhp-hr standard for 1994 model year heavy-duty vehicles generally. It may be difficult for them to meet production goals a year earlier for a broader group of buses. Additionally, the makers of coaches, into which the engines will be placed, may not be prepared to put trap-equipped engines into their coaches in 1993; there may be packaging problems in some cases. Finally, it is unlikely that school districts

[2] Interpreting "buses" to mean "urban buses" leaves no independent meaning for the statutory phrase "for model years prior to 1994" as "(urban) buses other than those subject to standards under section 219" would already specify pre-1994 model year urban buses.

[3] There are about 3000 heavy heavy-duty bus engines sold per year for use in urban buses; about 800 more of these engines are sold for use in other buses. EPA also requests information on the numbers and types of buses which would be included in each of the options presented above, the engines used in them, and whether they are currently centrally fueled.

and others who could be affected by the expanded standard have scheduled resources to cover the cost of buses which will meet the 0.10 g/bhp-hr standard in 1993. EPA invites comment from trap system manufacturers, coach manufacturers, school districts and others on how their plans might be affected by the inclusion of additional buses under the 1993 standard.

An additional issue which may affect bus coach manufacturers is their vulnerability to interruptions in orders. If the broader inclusion of bus engines under the 1993 standard were to limit model availability, and if that in turn prompted bus operators such as school districts to pre-buy or postpone purchase of buses in 1993, bus manufacturers could experience a severe economic impact. EPA invites comments from all parties on this possible scenario.

An additional problem affecting end users of buses is the availability of fuel appropriate to 1993 buses. In order to ensure that low sulfur fuel would be available when heavy-duty engines generally were required to meet the 0.10 g/bhp-hr PM standard, EPA promulgated regulations (See 55 FR 34119, August 21, 1990) which limit the sulfur content to 0.05 weight percent in on-highway diesel fuel beginning October 1, 1993. The sulfur content allowed in diesel certification fuel was also set as part of that rulemaking. Engines sold in the 1991 through 1993 model years will be certified using 0.10 weight percent sulfur fuel, reflecting the average fuel sulfur level expected to be used during those vehicles' useful lives. Beginning with the 1994 model year, the certification fuel sulfur content will be 0.05 weight percent, matching that of commercial diesel fuel.

Since reducing the amount of sulfur in diesel fuel generally reduces particulate emission levels (specifically, the sulfate fraction of particulate), manufacturers of HDDEs other than urban bus engines have been designing their 1994 model year engines to meet a 0.10 g/bhp-hr PM standard on a certification fuel with a 0.05 weight percent sulfur content. Under the second and third options, the broader group of 1993 model year bus engines would be required, along with urban buses, to meet the 0.10 g/bhp-hr PM standard using a 0.10 weight percent sulfur test fuel. This could potentially make compliance more difficult if manufacturers of these additional bus engines had planned for 0.05 weight percent fuel to be available for their engines required to meet the 0.10 g/bhp-hr PM standard. The limited applicability of EPA's second option to only buses capable of being centrally fueled, as urban buses currently are, is designed to help resolve this problem; operators of such buses should be capable of obtaining lower sulfur fuel in bulk quantities.[4]

As stated above, EPA requests comment on the three options described above, including comment on the legal bases for each option. The proposed regulations in today's notice include regulatory language for the proposed option. Should public comments and data support a different option, regulations would be constructed in a similar fashion. In addition, EPA requests comment on the feasibility of diesel engines used in buses generally meeting the 0.10 g/bhp-hr standard in 1993, including specific technical information about how compliance in 1993 would differ from compliance in 1994.

EPA is not proposing any changes to the heavy-duty averaging, trading and banking program for 1993. However, EPA requests comment as to how the averaging, trading and banking program should be applied to the additional bus engines which would be covered by the 1993 standard.

EPA has already proposed changes to the non-compliance penalty (NCP) program for particulate emissions from 1993 model year urban buses as part of the proposal setting the 1991 and 1992 model year PM standard for urban buses. EPA issued the proposal for that rulemaking on May 29, 1991 (56 FR 24242) and is expecting to promulgate a final rule shortly. In that rulemaking, EPA proposed to revise the upper limit for NCP availability, the average and ninetieth percentile incremental costs, and the engineering and development factor. The reader is directed to that rulemaking for a more detailed discussion of the proposed changes to the NCP regulations.

Because EPA is proposing to expand the applicability of the 0.10 g/bhp-hr PM standard for the 1993 model year, EPA is also proposing changes in the NCP program for the additional buses which would be included by today's notice. EPA believes that the additional buses required to meet the 0.10 g/bhp-hr standard probably would use essentially the same types of emission controls as urban buses. Therefore today's notice proposes to apply the same NCPs and NCP parameters, as contained in the proposed rule noted above, to all buses required to meet the 0.10 g/bhp-hr PM standard for the 1993 model year. EPA believes that this approach is appropriate and will allow the establishment of NCPs sooner than if slightly different NCPs were to be promulgated separately.

With today's notice, EPA is also proposing a slightly revised definition of "urban bus". The current definition was promulgated as part of the final rule for the heavy-duty engine emissions banking and trading program (see 55 FR 30584, July 26, 1990). As discussed in that rule, the definition was adjusted to more clearly indicate that the urban bus provisions are intended for full-size transit buses, not other buses such as school buses. This was achieved in the definition by including the provision that an urban bus was a bus powered by a heavy heavy-duty diesel engine. Since that time, it has come to EPA's attention that this approach could have the unintended effect of encouraging the use of medium heavy-duty diesel-powered engines in these large buses as such buses technically may not be covered by the urban bus definition. To remedy this difficulty, the definition is being modified to indicate that urban buses include buses powered by heavy heavy-duty diesel engines as well as buses of a type normally powered by heavy heavy-duty diesel engines. EPA does not intend to extend the scope of the urban bus definition through this proposed revision. EPA invites comment on any possible impacts of this proposed revision.

B. 1994 and Later Model Year Urban Bus PM Standard

With today's notice, EPA proposes a PM standard of 0.05 g/bhp-hr for 1994 and later model year HDDEs used in urban buses. This standard represents a 50 percent reduction from the existing 1994 HDDE standard of 0.10 g/bhp-hr, as specified in the Act. EPA has analyzed the technological achievability of such standard, in light of all the factors the Agency believes are relevant: Durability, costs, lead time, and safety. This analysis is presented in the RSD for today's proposal, and is summarized below.

EPA believes that essentially the same control strategy (i.e., particulate traps) will be used to meet standards in the range of 0.05 to 0.07 g/bhp-hr. Alternative strategies (e.g., use of an oxidation catalyst) will not, in EPA's view, be effective in reaching these stringent emission levels.

In light of this position, if there were alternative technologies available that

[4] Diesel fuel with 0.05 weight percent sulfur is available today; although development of production capacity to fuel the entire heavy-duty diesel fleet may take additional time, EPA believes that a sufficient supply of 0.05 percent sulfur fuel would be available to fuel additional buses included under the 1993 standard.

could achieve emission levels in this range, EPA would have to weigh this in considering the level of the particulate standard promulgated in the final rule. However, after considering all of the relevant statutory factors noted above, EPA believes that a 0.05 g/bhp-hr PM standard is technologically achievable for engines used in urban buses. This view is based on recognition of the significant improvements urban bus engine manufacturers have recently made in both engine-out emission controls and exhaust aftertreatment technology. Engine manufacturers have reduced engine-out PM levels through improved engine design, combustion chamber design and fuel injection controls, as well as the addition of turbocharging and charge air cooling to the air intake system. In some cases, engines appear to be approaching a 0.10 g/bhp-hr PM standard without the use of exhaust aftertreatment. In addition, in recent EPA testing of a trap-equipped pre-1991 engine, particulate levels approaching 0.05 g/bhp-hr level were achieved at low mileage.[5]

Engine manufacturers report that any standard between 0.05 and 0.07 g/bhp-hr will require low engine-out emissions and particulate traps. They therefore expect little if any difference in their compliance strategies between a 0.05 versus a 0.07 g/bhp-hr standard. EPA believes that the lower standard may require a slightly larger or more efficient trap and/or more frequent regeneration; such differences would have at most a minor impact on cost and feasibility. Therefore, EPA believes that urban bus engine manufacturers will be able to achieve a 0.05 g/bhp-hr PM standard over the useful life of an urban bus, given additional time for engine and aftertreatment development work. In addition, to the extent that banked credits might be available to urban bus engine manufacturers, they potentially could ease the transition to the 0.05 g/bhp-hr PM standard. Because no significant difference in control technology appears to be necessary to meet this particulate standard compared to the 1994 model year HDE particulate standard, EPA does not believe that any safety concerns would be introduced.

The in-use durability of aftertreatment devices has not been established. Most in-use demonstration trap systems continue to accumulate mileage without extensive failure, but extensive data does not yet exist on high mileage vehicles. At this time, EPA foresees no reason why satisfactory long-term durability of such aftertreatment devices could not be achieved, given the time for development for the 1994 model year.

EPA expects that any issues surrounding urban bus applications will be similar to those faced by the heavy-duty industry in general. Since it is likely that aftertreatment will be used in many instances on heavy-duty vehicles other than urban buses to meet the 1994 standard, significant development work is underway to improve aftertreatment durability. If there are durability issues specific to the use of aftertreatment on urban buses, EPA requests comments and data on those issues. EPA also requests comments on how other heavy-duty engine applications may differ from those for urban buses.

EPA recognizes that flow-through oxidation catalysts may also be an option for achieving low particulate levels. With an oxidation catalyst, exhaust is passed through a catalyst of platinum or palladium which aids in the further combustion of the exhaust components, including particulate emissions. In recent testing, oxidation catalysts have been shown to be up to 90 percent effective, under certain operating conditions, at reducing the soluble organic fraction (SOF) component of particulate emissions, while reducing overall particulate emissions by 40 to 50 percent. However, because catalysts do not affect the carbonaceous and sulfate fractions of particulate emissions, EPA does not expect that catalysts will be used to reach levels lower than about 0.10 g/bhp-hr. Neither of the two major urban bus engine manufacturer, Detroit Diesel Corporation (DDC) or Cummins Engine Company, expects to use catalysts to meet the 1994 urban bus requirements. EPA requests comment on any potential role for catalysts in complying with this program.

Regarding leadtime, EPA believes that essentially the same control strategies (i.e., particulate traps) will be used to meet a 0.05 g/bhp-hr standard as would have been used to meet the existing 0.10 g/bhp-hr standard. Engine manufacturers already have been developing engines to meet the current 0.10 g/bhp-hr PM standard for both urban bus engines and other HDDEs. As described above, that standard will now apply for the 1993 model year and EPA expects that traps will be used to meet that standard. To comply with a 0.05 g/bhp-hr standard in the 1994 model year, the only changes anticipated are the installation of higher-efficiency traps and/or more frequent regeneration. Because the 0.10 g/bhp-hr urban bus PM standard was originally scheduled to apply beginning with the 1991 model year, the Agency believes that engine development for buses is ahead of other heavy-duty engines. Finally, Congress specifically set a 1994 model year for compliance with the statutory standard. For these reasons, EPA believes that there is adequate leadtime for urban bus engine manufacturers to meet such a standard on 1994 model year engines.

In proposing a standard of 0.05 g/bhp-hr for 1994, the Agency believes that a higher standard of up to 0.07 g/bhp-hr, as provided in the CAA, is not necessary. EPA requests comments on its assessments of technological achievability, including any information which demonstrates that different control technology would be used to meet a 0.07 g/bhp-hr standard than would be used for a 0.05 g/bhp-hr standard.

Bus engine manufacturers have expressed concerns about the feasibility of complying with a 0.05 g/bhp-hr PM standard in use. For this reason, EPA is considering, but not proposing, two alternative approaches for the 1994 and later model year PM standard which have been suggested by industry. The first approach would set a PM certification standard of 0.05 g/bhp-hr and an in-use PM standard of 0.07 g/bhp-hr. The second approach would set a PM standard of 0.05 g/bhp-hr for the first half of the useful life of an urban bus (145,000 miles or 4 years), and a PM standard of 0.07 g/bhp-hr for the second half of the useful life. EPA requests comments on the two approaches noted above for the 1994 and later model year urban bus PM standard and the legal basis for both approaches.

EPA is not proposing any changes to the current emissions trading, banking and averaging program for 1994 and later model year engines. As with the current program, manufacturers would only be allowed to trade and bank emission credits within the urban bus class. The Agency requests comments, however, on whether any changes in the trading, banking and averaging program are appropriate in light of the recent Clean Air Act Amendments, including any specific changes that are suggested and the legal or technical rationale for such suggested changes. Regarding NCPs, EPA is planning to propose changes to the NCP program for particulate emissions from 1994 model year urban buses as part of a separate rulemaking later in 1991.

Finally, in a separate rulemaking action, EPA expects to set emission

[5] In recent EPA testing, a DDC 6V92–TA DDEC engine equipped with a Donaldson particulate trap system demonstrated PM levels of 0.052 and 0.054 g/bhp-hr. Newer engines designed for lower engine-out emissions to meet the 1991–92 and 1993 standards should be capable of emissions lower than 0.05 g/bhp-hr when equipped with a trap.

standards for natural gas- and liquified petroleum gas-fueled vehicles. EPA expects that the 1994 particulate standard ultimately adopted here will also be incorporated into the final rule for those gaseous-fueled vehicles, and will apply to urban bus engines operating on those fuels.

C. Urban Bus Retrofit/Rebuild Program

The retrofit/rebuild program proposed today would apply to operators of all 1993 and earlier model year urban buses whose engines are rebuilt or replaced after January 1, 1995. The intent of the retrofit/rebuild program is to realize in-use emission reduction from 1993 and earlier model year urban buses by improving their emissions performance at the time a bus engine is rebuilt by the bus operator. The program as proposed would apply to operators of urban buses (e.g., transit authorities) only in MSAs and CMSAs with 750,000 or more people based on 1980 population; these areas account for approximately 80 percent of urban buses in operation nationwide.[6] The retrofit/rebuild program will phase itself out as the 1993 and earlier model year buses are removed from service.

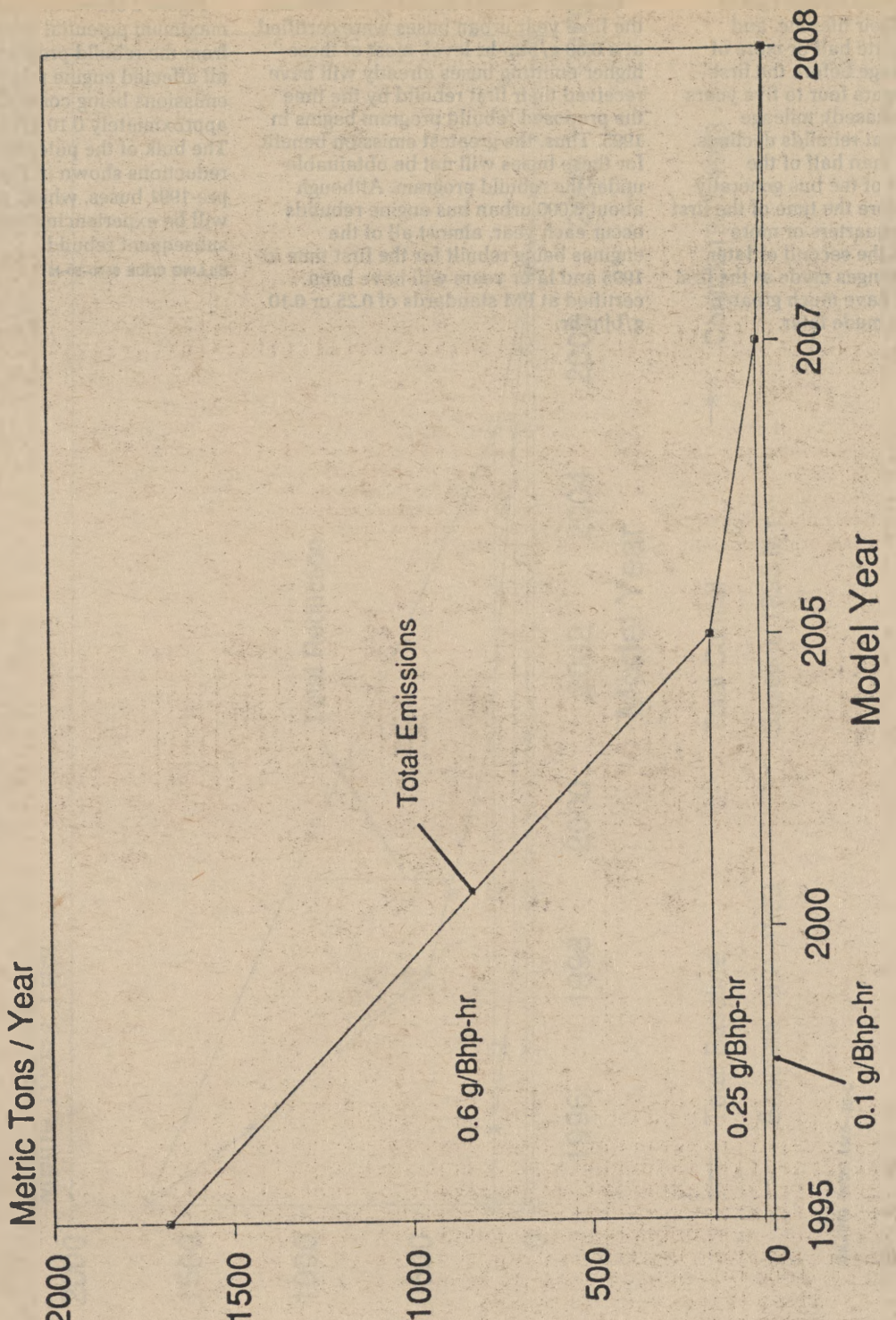
There are currently about 44,000 urban buses in operation nationwide. By 1995, when the rebuild requirements are to take effect, the fleet subject to rebuild requirements will fall primarily into three groupings. One group will consist of pre-1991 buses, either certified to a 0.60 g/bhp-hr PM level or expected to emit at a similar level; [7] 1991 and 1992 engines certified at a 0.25 g/bhp-hr PM level; and 1993 engines certified at a 0.10 g/bhp-hr PM level. In 1995, pre-1991 buses still in operation will comprise about 70 percent of the 1995 urban bus fleet; most of these engines would have had particulate emissions when new of about 0.6 g/bhp-hr. (Because diesel engines which are not equipped with aftertreatment show little in-use deterioration of PM emissions, EPA assumes in-use emission levels are essentially the same as the certified levels.) These buses will be responsible for about 90 percent of the particulate emissions from urban buses in 1995, and their contribution will decline steadily as they are retired (see Figure 1).

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[6] Although not proposed today, the rebuild/retrofit requirement would be extended to include metropolitan areas with a 1980 population of less that 750,000 if the Administrator made the necessary determination under section 219(c)(2)(C), regarding the low-polluting fuel requirement.

[7] Most 1988 model year bus engines incorporated essentially the same technology as engines sold for the previous several years.

Figure 1



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Buses are generally rebuilt two or three times over their lifetime, and generally accumulate half or more of their lifetime mileage before the first rebuild (which occurs four to five years after a bus is purchased); mileage between subsequent rebuilds declines. As a result, more than half of the lifetime emissions of the bus generally have occurred before the time of the first rebuild and three-quarters or more before the time of the second or later rebuilds. Thus, changes made at the first rebuild point will have much greater impact than those made later.

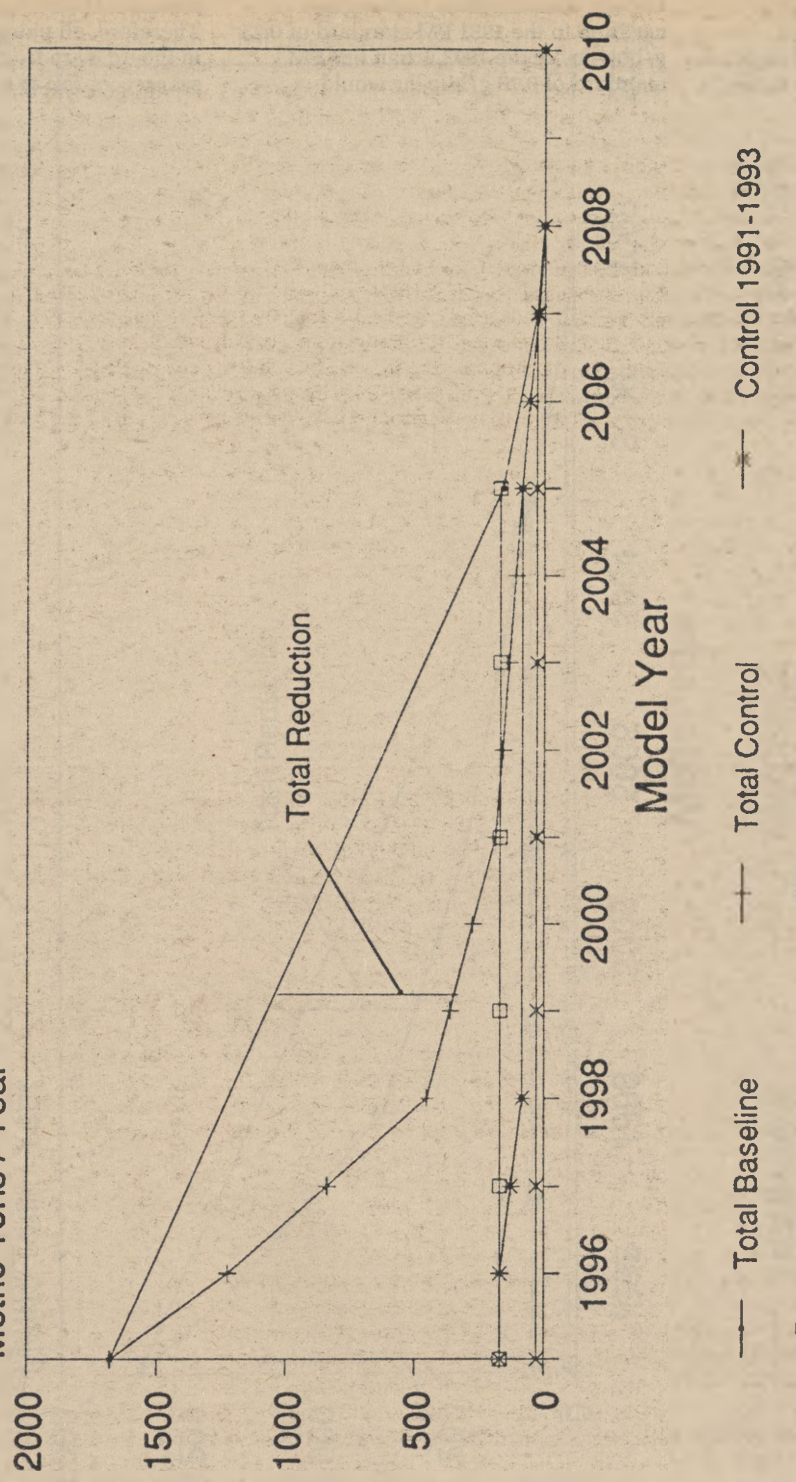
Overall, because model year 1990 was the final year urban buses were certified at a 0.60 g/bhp-hr level, most of these higher-emitting buses already will have received their first rebuild by the time the proposed rebuild program begins in 1995. Thus, the greatest emission benefit for these buses will not be obtainable under the rebuild program. Although about 8,000 urban bus engine rebuilds occur each year, almost all of the engines being rebuilt for the first time in 1995 and later years will have been certified at PM standards of 0.25 or 0.10 g/bhp-hr.

Figure 2 shows an estimate of the maximum potential emission reduction from the rebuild program assuming that all affected engine rebuilds result in emissions being controlled to approximately 0.10 g/bhp-hr or below. The bulk of the potential emission-reductions shown in Figure 2 represents pre-1991 buses, which, as noted above, will be experiencing their second or subsequent rebuild.

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Figure 2

PM Emissions from Pre-1994 Buses with a 0.1 g/bhp-hr Rebuild Standard



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Figure 3 shows an estimate of the potential benefit from the rebuild program assuming that affected engines are controlled to approximately 0.25 g/bhp–hr. This assumes that engines certified to the 1991 PM standard of 0.25 g/bhp–hr, or the 1993 urban bus PM standard of 0.10 g/bhp–hr would maintain their original PM level. Therefore, all potential benefits shown in Figure 3 are from pre-1991 engines.

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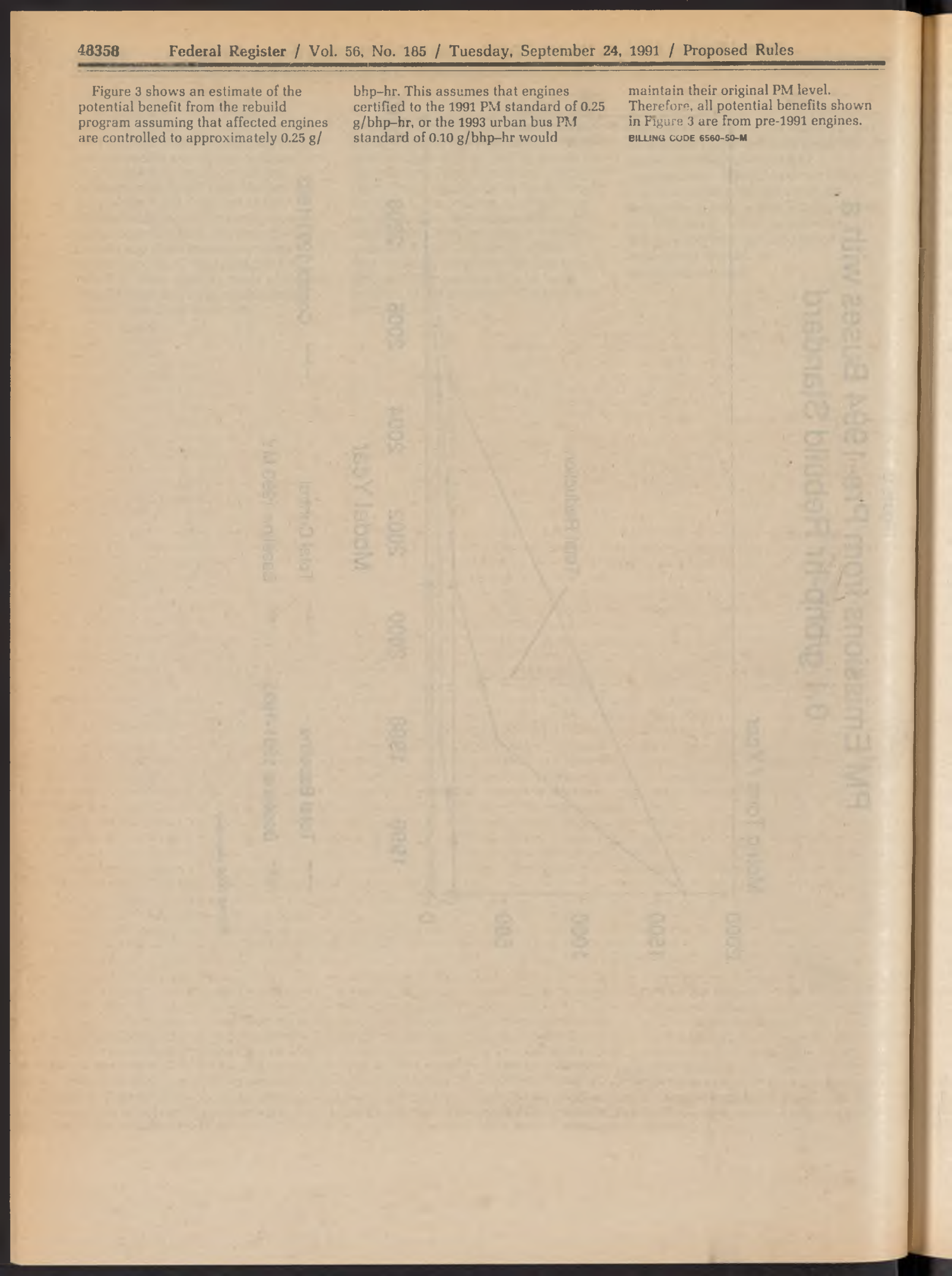
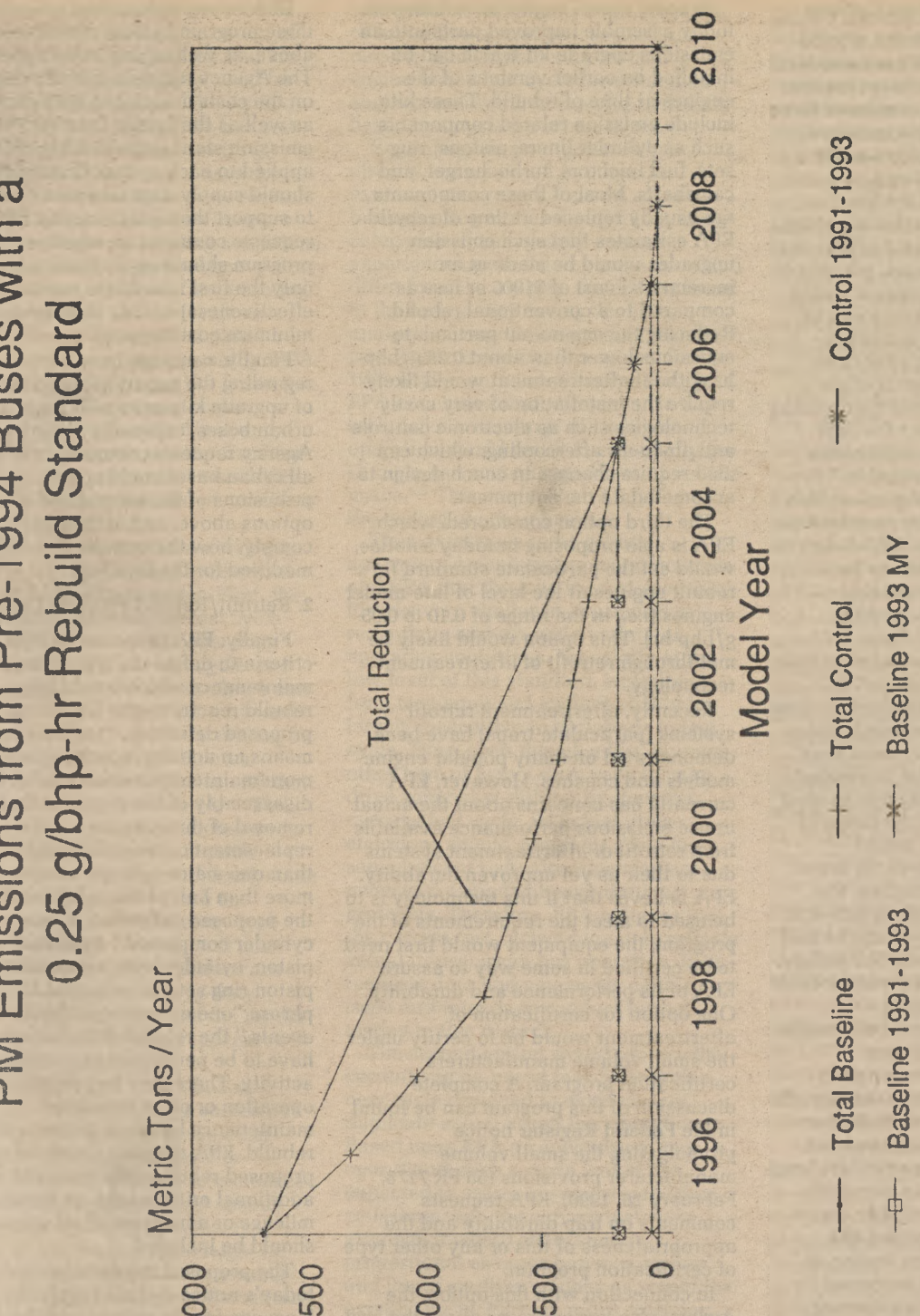


Figure 3



BILLING CODE 6560-50-C

1. Retrofit/Rebuild Program Options

EPA proposes to define the rebuild program in terms of a PM emission level which a rebuilt or replacement engine would meet.[8] We have considered three options for the level of this standard, each of which would likely result in a different compliance strategy.

The first option would set the particulate standard for rebuilds at the 1988 certification level of 0.6 g/bhp-hr or the actual certification level, whichever is less. The effect of this option would be that engines would be restored to their original "like new" condition.

This option does not appear to be consistent with requirements of the Clean Air Act, which states that rebuild requirements "shall reflect the best retrofit technology and maintenance practices reasonably achievable." For this reason, EPA does not propose this option; however, we invite comment on this and any other option. EPA believes that the following two options for a rebuild program would meet the requirements of the CAA, and the Agency proposes both of them.

The second option considered, which EPA is proposing in today's notice, would set an emission standard leading to the retrofitting of urban bus engines with upgrade kits of later model year engine components. Under this option, EPA proposes that rebuilt engines meet a particulate standard in the range of 0.25–0.30 g/bhp-hr or the actual certification level, whichever is lower. For pre-1991 urban bus engines, the Agency expects that levels in 0.25–0.30 g/bhp-hr range generally would be met by using emissions upgrade technology. As a matter of enforcement policy, EPA intends to accept as being in compliance, any properly rebuilt engine which uses original equipment manufacturer (OEM) parts, or parts meeting OEM specifications, to upgrade the engine configuration to that of an engine configuration which has been demonstrated to have a particulate level at or below the particulate standard. EPA believes it can reasonably assure compliance with the proposed PM standard without emission testing. It should be noted that this proposed option would not require equipment upgrades for 1991–93 model year urban buses. EPA believes the emission benefit from upgrading these engines would be limited because of their relatively low level of contribution to the overall urban bus particulate inventory (see Figure 1).

[8] Although the CAA would permit a requirement based directly on emission control technology, EPA believes an emission standard is likely to result in a less complex program for compliance and enforcement.

In some cases, engine manufacturers today assemble improved parts into an emissions upgrade kit which can be installed on earlier versions of the engines at time of rebuild. These kits include emission related components such as cylinder liners, pistons, ring sets, fuel injectors, turbocharger, and camshafts. Most of these components are usually replaced at time of rebuild. EPA estimates that such emission upgrades would be made at an incremental cost of $1000 or less as compared to a conventional rebuild. Reducing the engine-out particulate emissions lower than about 0.25 g/bhp-hr without aftertreatment would likely require the installation of very costly technologies such as electronic controls and air-to-air aftercooling, which can also require changes in coach design to accommodate the equipment.

The third option considered, which EPA is also proposing in today's notice, would set the particulate standard for rebuilt engines at the level of late-model engines (i.e., in the range of 0.10 to 0.05 g/bhp-hr). This option would likely be met through retrofit of aftertreatment technology.

Recently, aftertreatment retrofit systems (particulate traps) have been demonstrated on many popular engine models and coaches. However, EPA currently has concerns about the actual in-use emissions performance available from retrofit of aftertreatment systems due to their as yet unproven durability. EPA believes that if this technology is to be used to meet the requirements of the program, the equipment would first need to be certified in some way to assure EPA of its performance and durability. One option for certification of aftertreatment would be to certify under the small volume manufacturers certification program. A complete discussion of this program can be found in the **Federal Register** notice promulgating the small volume manufacturer provisions (55 FR 7178, February 28, 1990). EPA requests comments on trap durability and the appropriateness of this or any other type of certification program.

In connection with this option, the Agency also has concerns about the cost of retrofit particulate trap systems relative to the benefits available. Current estimates of the cost of a retrofit bypass (single element) trap system are broad, ranging from around $1500 to $9000 per bus. EPA specifically requests comments on the cost of retrofit trap systems. As with all comments received, EPA plans to take such comments into consideration in promulgating a retrofit/rebuild program for urban buses.

EPA requests comment on each of the three program options considered above, as well as any other approach. The Agency requests specific comment on the costs associated with each option as well as the lowest feasible PM emission standard which should be applied to each option. Commenters should supply data whenever possible to support their assessments. EPA also requests comment on whether the program should apply to all rebuilds or only the first rebuild (to maximize cost effectiveness) or only later rebuilds (to minimize cost impacts).

Finally, concerns have been raised regarding the potential nonavailability of upgrade kits or retrofit traps for some urban buses, especially older buses. The Agency requests comment as to whether all urban buses could comply with the provisions of the second and third options above, and, if they could not comply, how the options should be modified for the final rule.

2. Retrofit/Rebuild Program Criteria

Finally, EPA proposes today a set of criteria to define the type of engine maintenance which would trigger the rebuild requirements. Under the proposed definition, "engine rebuild" means an activity, occurring over one or more maintenance events, involving disassembly of the engine including the removal of the cylinder head(s) and the replacement or reconditioning of more than one major cylinder component in more than half of the cylinders. Under the proposed definition, a "major cylinder component" would mean piston, cylinder liner, connecting rod, or piston ring set. As indicated by the phrase "one or more maintenance events," the rebuild does not necessarily have to be performed as a continuous activity. There may be periods of bus operation or other unrelated maintenance between portions of the rebuild. EPA requests comment on the proposed rebuild definition and whether additional criteria such as maximum mileage or a measure of oil consumption should be included.

The proposed regulations contained in today's notice include regulatory language for the second and third options (0.25 g/bhp-hr and 0.10 g/bhp-hr PM standard). Should public comment and data support another regulatory option, the regulations would be constructed in a similar fashion.

D. Urban Bus Test Procedure

Section 219(e) of the CAA requires that test procedures for urban buses reflect actual operating conditions. Because urban bus standards were

originally adopted in 1985, procedures for administration and enforcement of those standards already exist, and are essentially the same as those used for other heavy-duty engines. The section 219(e) requirement that urban bus test procedures reflect actual operating conditions for those buses raises the question of the possible need to revise the test procedures for urban buses to include specific bus operating conditions rather than using the general heavy-duty engine test now in effect. The operating conditions include the test cycle on which the engine is operated plus ambient temperature and humidity. EPA is not considering revising the latter two items because they are not major determinants of emissions for diesel engines but rather are standardized (or corrected for) to reduce test variability. Thus, the following discussion considers test cycles only.

In evaluating the need for a separate urban bus test cycle, there are several important factors to consider. First, the existing heavy-duty engine test cycle already reflects actual bus operating conditions. The current test cycle uses four segments; one which simulates non-freeway driving in New York City, one which simulates non-freeway driving in Los Angeles, one which simulates freeway driving in Los Angeles and then a repeat of the non-freeway New York segment. Based on data collected on in-use buses,[9] urban buses ordinarily operate in non-freeway conditions; some less frequent operations (such as express routes) involve freeway type driving. Thus, both freeway and non-freeway bus operating conditions are included in the current heavy-duty cycle, and emissions from all the modes of bus engine operation are measured in the current test procedure.

On the other hand, urban buses experience these operations somewhat differently from those of many other types of heavy-duty vehicles. For example, they will often have increased idling time and lower average speeds than other heavy-duty vehicles. A specialized bus testing cycle might be able to duplicate actual bus operating conditions more closely than the current heavy-duty test cycle; however, as discussed below, EPA believes the most important issue is whether such a specialized test would result in different emission control strategies and thus different in-use emissions.

EPA has identified three options regarding urban bus testing. These are: First, to retain the existing heavy-duty test cycle as sufficiently representative of urban bus operations; second, to develop and implement a revised engine-based test cycle for urban bus engines; and third, to develop a chassis-based test cycle for urban buses.

Regarding the first option, it has already been pointed out that the existing test cycle represents all urban bus operating modes. In addition, many categories of heavy-duty engines experience in-use driving patterns which differ from the average conditions found in the heavy-duty test cycle. In its analysis of various heavy-duty transient test cycles, including bus cycles, for the 1985 implementation of a new test cycle, EPA concluded that a single cycle that included a wide range of transient operation would result in essentially the same in-use control regardless of vehicle usage.[10] This analysis also applies to the testing of urban buses.

There continues to be general agreement among engine manufacturers and EPA that the existing test procedure insures very similar in-use emission reductions under a wide variety of operating conditions. Especially at the low level of this standard, emissions from trap-equipped engines should be largely insensitive to variations in test cycle. Thus, even though a bus, or some other type of heavy-duty vehicle, may drive somewhat differently than the average test cycle, its actual in-use emissions should generally show the same percent reduction as emissions measured using the heavy-duty test protocols. Therefore, EPA believes that the current test cycle adequately reflects actual in-use urban bus operation. EPA requests data and comments on this issue and intends to conduct further testing in this regard.

The second option would replace the current engine-based test cycle with a new cycle designed to more closely duplicate actual urban bus operation. Based upon EPA's knowledge of bus operations, such a cycle would be expected to measure somewhat higher emissions than the current test cycle, although it would show similar proportional changes between higher and lower emitting engines as would the existing cycle. Further, a bus emission standard could arguably require adjustment to reflect the change in test procedures, as the need and justification for any standard, as well as the feasibility assessment of the standard, typically are based directly upon data collected using the associated test procedure. As described above, EPA believes that there would be no significant net benefit from changing the current engine-based test cycle for urban buses. Further, there would be a substantial effort required to develop an adequate information base from which to derive a new test cycle, assess bus engine emissions on that cycle and if necessary establish appropriate emission standards corresponding to those on the current cycle.

The third option which the Agency has identified would be to switch from using an engine-based approach for emissions testing and develop a chassis-based test procedure for urban buses. Such an approach is attractive primarily from an in-use enforcement point of view, but would involve the same kind of development effort as developing a new engine-based test. The Agency would generally find it easier to procure and test buses on a chassis test, since it does not require removal of the engine from the bus and installation on an engine dynamometer. EPA's past experience has been that owners of heavy-duty vehicles are reluctant to allow removal of engines for testing. However, based upon preliminary input from transit companies, it appears that bus operators would find it less burdensome to remove and supply an engine to EPA than to lose the entire use of a bus. Transit operators are generally well equipped to remove the engine from a bus, since this is a frequent part of the engine rebuilding process. They also maintain spare engines which could be used to replace a test engine so that the affected bus would experience minimal down time.

Another issue relevant to chassis testing is that unlike light-duty vehicle manufacturers, engine manufacturers do not make the vehicles in which their engines will be used. Therefore, a chassis test requirement would impose an increase in testing and compliance burden on engine manufacturers.

Overall, EPA favors the first option of retaining the existing heavy-duty engine test for urban bus engines. Today's action therefore proposes no change in test procedures.[11] However, the Agency

[9] Truck Driving Pattern and Use Survey (CAPE-21), performed by EPA 1977-78.

[10] The document "Summary and Analysis of Comments to the NPRM: 1983 and Later Model Year Heavy-Duty Engines; Proposed Gaseous Emission Regulations," found in the docket for this proposal, discusses the development of the heavy-duty transient test; it also includes a listing of reports by EPA and others on issues including the collection of in-use urban bus operational data and the selection of a single transient cycle.

[11] In a separate requirement in section 206(h) of the amended CAA, EPA is required to "review and revise" test procedures. If changes to the current heavy-duty test procedure or an urban bus test procedure are recommended in that study, EPA may propose such changes at a later date.

remains open to comments on all three options, or others that commenters might suggest.

E. 1998 and Later Model Year Heavy-Duty Engine NOx Standard

The amended CAA requires EPA to adopt a 4.0 g/bhp-hr NOx standard for 1998 and later model year gasoline-fueled and diesel-fueled HDEs. Today's notice proposes the regulations necessary to implement that requirement. Consistent with EPA's past practice, the proposed standard would be applicable to Otto-cycle and diesel engines, fueled by gasoline, diesel fuel, or methanol. EPA is presently in the process of developing regulations for natural gas-fueled and liquified petroleum gas-fueled heavy-duty engines and intends to extend the NOx standard of today's proposal to gaseous fueled engines as that category is established.

HDE standards are also affected by provisions relating to the banking and trading of emissions credit and to nonconformance penalties. In the case of banking and trading, regulations published on July 26, 1990 (55 FR 30584) established an ongoing three year rolling program wherein credits generated in any model year can be withdrawn for three successive model years. EPA is not in this action proposing changes to the current emissions trading, banking and averaging program for 1998 and later model year engines. The Agency requests comments, however, on whether any changes in the trading, banking and averaging program are appropriate in light of the recent Clean Air Act Amendments, including any specific changes that are suggested and the legal or technical rationale for such suggested changes.

In the case of nonconformance penalties (NCPs), the CAA provides that, under certain conditions, the certification and sale of HDEs that exceed emission standards may be permitted upon payment of appropriate nonconformance penalties. The magnitude of the financial penalties are derived from, among other things, the cost of compliance with the applicable standard. EPA does not, in this action, propose to address the establishment of penalties for nonconformance with the proposed 4.0 g/bhp-hr NOx standard. The regulatory actions necessary for the continued provisions of nonconformance penalties will be undertaken by EPA at a later date.

EPA believes that the proposed 4.0 g/bhp-hr NOx standard is feasible for gasoline-, diesel-, and methanol-fueled HDE's by the 1998 model year. Significant attention has been paid to NOx control techniques for HDE's in recent years as a result of EPA's adoption of a 5.0 g/bhp-hr NOx standard for the 1991 model year, along with stringent particulate standards which take effect in the 1991 and 1994 model years. As a result, engine manufacturers have been successful in developing various means to lower NOx emissions significantly while at the same time avoiding the adverse impacts on fuel economy and particulate emissions which were characteristic of older engines. For example, in an August 1989 presentation to EPA on what it called its "smokeless diesel engine," Navistar indicated its belief that NOx could be reduced another 20-25 percent below the 5.0 g/bhp-hr 1991 standard by the late 1990s with no significant cost or fuel economy impacts.

Navistar has also publicly supported the feasibility of the 3.5 g/bhp-hr combined nonmethane hydrocarbon plus NOx low emitting vehicle standard proposed by the California Air Resources Board as part of its clean fueled vehicle program. It should be noted that Navistar's statement regarding the feasibility of California's combined standard was made in the context of the California requirement that reductions in the aromatic content of diesel fuel would also occur. However, because the low emitting vehicle standard is a combined nonmethane hydrocarbon plus NOx standard, it requires NOx levels substantially lower than the 4.0 g/bhp-hr standard in today's proposal. Thus, even without changes in the aromatic content of diesel fuel, EPA believes the 4.0 g/bhp-hr NOx standard will be feasible.

III. Environmental Impact

The following section summarizes the environmental impacts expected to result from the items proposed today. As detailed further below, continuing reductions in urban ambient levels of diesel particulate are expected to result from the 1993 model year bus PM standard, the 1994 and later model year urban bus PM standard, and the urban bus retrofit/rebuild program. Such particulate reductions will help many of the approximately 85 areas of the country presently designated nonattainment or expected to be designated nonattainment with the National Ambient Air Quality Standard for PM10 and have other potential health benefits. Diesel particulate is a possible human carcinogen, and at high levels of exposure, can cause non-cancer effects, including lung disease and neurotoxic effects. Therefore, the diesel particulate reductions expected from the programs proposed today potentially could reduce the number of expected cancer incidences associated with exposures to overall diesel particulate emissions and lower the potential for exposures that could result in other adverse effects.

A. 1993 Model Year Bus PM Standard

As discussed earlier, the only change which would occur as a result of this proposal would be to require a number of additional buses that use heavy heavy-duty engines and are capable of being centrally fueled, to meet the 0.10 g/bhp-hr PM standard in the 1993 model year. As previously mentioned, those additional buses are currently required to meet a 0.25 g/bhp-hr PM standard in the 1993 model year. Therefore, EPA might expect to achieve additional emissions benefits from moving the implementation of the standard forward by one model year for these buses. However, this benefit may not be realized if, as some parties have suggested, purchasers pre-buy additional buses in the 1992 model year to avoid additional costs. Further, if engine manufacturers are not able to offer the 1993 model year engines because of difficulty in meeting the 0.10 g/bhp-hr PM standard one model year earlier than previously expected, there would be no environmental benefit from the proposed change in the applicability of the bus standard.

B. 1994 and Later Model Year Urban Bus PM Standard

EPA's environmental impact analysis of the proposed 1994 and later model year urban bus PM standard is presented in more detail in the Regulatory Support Document (RSD) associated with today's proposal. Based on an assumed PM reduction equivalent to a change in standards from 0.10 to 0.05 g/bhp-hr, EPA estimates a discounted lifetime per-vehicle PM emission reduction of 49 kilograms (assuming a 10 percent discount rate). Once the entire fleet is made up of buses meeting the 0.05 g/bhp-hr standard, the annual emission reduction resulting from this regulation will be about 270 tons.

C. Retrofit/Rebuild Program

As described above, the potential environmental benefits from the proposed rebuild options would be realized primarily from improvements in the emissions of pre-1991 buses. EPA estimates that the discounted emission

from 0.60 to 0.10 g/bhp-hr at the time of its first rebuild.
reduction could range from near zero for conventional rebuilds to about 370 kg per vehicle over its remaining lifetime for a vehicle seeing an improvement

D. Heavy-Duty Engine Emissions-NOx Standard

As described in the Regulatory Support Document, EPA's MOBILE4 emission factors model was utilized to develop anticipated benefits attributable to the proposed 4.0 g/bhp-hr NOx standard. The projected effects on the national emissions inventory for oxides of nitrogen and on the contributions to the national inventory by all heavy-duty vehicles are summarized in Table 1.

TABLE 1.—PROJECTED EFFECTS ON NOX EMISSIONS INVENTORY RESULTING FROM 4.0 G/BHP-HR NOX STANDARD FOR HDES

[NOx emissions inventories (×1000 tons per year]

	National Total			HDV Contributions		
Year	Without Std [1]	With Std [2]	Percent reduction	Without Std [1]	With Std [2]	Percent reduction
2000	9,581	9,482	1	1,306	1,207	8
2005	10,273	10,056	2	1,350	1,133	16
2010	11,114	10,849	2	1,434	1,169	19

[1] 5.0 g/bhp-hr NOx standard remains in effect.
[2] 4.0 g/bhp-hr NOx standard is implemented in 1998.

As can be seen from Table 1, the 4.0 g/bhp-hr NOx standard is expected to lower NOx emissions from heavy-duty vehicles on the order of 16 to 19 percent in the 2005 to 2010 time frame. This reduction, when translated to the national NOx inventory, is expected to yield an approximate 2 percent reduction. Readers may consult the regulatory support document in the docket for further information on the impacts of this proposal.

IV. Economic Impact

A. 1993 Model Year Bus PM Standard

The inclusion of additional buses under the 1993 PM standard is expected to result in increased costs for these buses. As previously mentioned, these buses, which would be included in the 1993 model year PM standard of 0.10 g/bhp-hr, are currently required to meet a 0.25 g/bhp-hr PM standard in the 1993 model year. To meet the lower PM standard, engine manufacturers may need to redesign the engine to achieve lower engine-out emissions or they may utilize exhaust aftertreatment devices; EPA believes the cost of a bypass (single-element) trap could range from about $1500 to $9000 per bus.

B. 1994 and Later Model Year Urban Bus PM Standard

EPA believes that very little change in control technology and thus little incremental cost will be necessary to meet the 0.05 g/bhp-hr PM standard over a 0.10 g/bhp-hr PM standard. EPA has not calculated specific estimates for such costs and requests comment as to their magnitude.

C. Retrofit/Rebuild Program

The cost of a retrofit/rebuild program depends on the option selected. The first option (conventional rebuild) should have essentially no incremental cost over current practice. The second option (emissions upgrade) would cost, we believe, $1000 or less per vehicle incremental to a conventional rebuild.

For the third option (retrofit aftertreatment), EPA believes that incremental costs could range from about $1500 to about $9000, depending on the cost of a retrofit bypass (single-element) trap system in the 1995 time frame. For the entire fleet being rebuilt, the aggregate cost would thus range from about $13–80 million per year in the first year of the program, declining rapidly thereafter as engines subject to the program are retired.

D. Heavy-Duty Engine NOx Standards

From an economic perspective, the strategies for lowering emissions in response to a 4.0 g/bhp-hr NOx standard are similar to those used in meeting the 1991 model year 5.0 g/bhp-hr NOx standard. For Otto-cycle engines, technologies available for the control of NOx emissions include such things as reducing catalysts, exhaust gas recirculation, ignition timing retard, combustion chamber and intake system configuration changes, valve timing and duration changes and fuel metering enhancements. For diesel engines, NOx reduction techniques include changes in injection pressure and injection rate by way of modifications to the injector and/or the injection pump, injection timing retard, combustion chamber configuration changes and some additional control of intake air temperature. The Agency therefore expects the cost impacts of the 4.0 g/bhp-hr standard to be similar to those of the 5.0 g/bhp-hr standard, after accounting for inflation. The EPA analysis is described further in the regulatory support document found in the public docket. The results are summarized below.

In the final rule implementing the 5.0 g/bhp-hr (50 FR 10606, March 15, 1985), EPA presented the results of analyses of the costs of compliance for average new Otto-cycle and diesel heavy-duty engines for the first three model years of the 5.0 g/bhp-hr NOx standard. The total first year costs were developed from estimates of the costs of research and development, and certification (discounted to the year of the standard) and redesigned hardware (see "Regulatory Impact Analysis, Oxides of Nitrogen Pollutant Specific Study and Summary and Analysis of Comments", March 1985 contained in the docket for this rulemaking). On a per engine basis, estimated increases in purchase price were $14 for Otto-cycle engines and $68 for diesel engines. Between 1985 and 1990, the consumer price index for new vehicle prices increased by 14.4 percent. When adjusted for the consumer price index for new vehicle first year price, the projected first costs for compliance with the 4.0 g/bhp-hr NOx standard per new Otto-cycle and diesel engines are estimated to be $16 and $78 per engine respectively.

Total costs to the nation of the 4.0 g/bhp-hr standard are anticipated to result only from first cost increases in new engines. EPA anticipates that manufacturers will comply with the 4.0 g/bhp-hr NOx standard without significant effect on the fuel efficiency of the engines and as a consequence, EPA expects there will not be any significant effect on costs attributable to increased fuel consumption. Based upon projected HDE sales, the anticipated annual costs to the nation resulting from the first year price increase of HDEs in each of the three years following implementation of the 4.0 g/bhp-hr NOx standard for

HDEs, are shown in Table 2.

TABLE 2.—COST OF COMPLIANCE WITH THE 4.0 G/BHP-HR NOx STANDARD

[Millions of 1991 dollars]

Year	Otto-cycle HDEs	Diesel HDEs	All HDEs
1998	$9	$38	$47
1999	9	39	48
2000	9	40	49

The projected cost-effectiveness of the 4.0 g/bhp-hr standard, over the useful life of an average heavy-duty Otto-cycle engine and an average heavy-duty diesel engine is estimated to be $260 per ton for Otto-cycle engines and $210 per ton for diesel engines.

V. Public Participation

A. Comments and the Public Docket

EPA solicits comments on all aspects of this proposal from all interested parties since it is our desire to ensure full public participation in arriving at final decisions. Wherever applicable, complete supporting data and detailed analyses should be submitted to allow EPA to make the maximum use of comments. Commenters are especially encouraged to provide specific suggestions for changes to any aspect of the proposal. All comments should be directed to the EPA Air Docket, Docket No. A–91–28 (See **"ADDRESSES"**)

Commenters wishing to submit proprietary information for consideration should clearly distinguish such information from other comments to the greatest extent possible, and clearly label it "Confidential Business Information." Submissions containing such proprietary information should be sent directly to the contact person listed above (See **"FOR FURTHER INFORMATION CONTACT"**), and not to the public docket, to ensure that proprietary information is not inadvertently placed in the docket.

Information covered by such a claim of confidentiality will be disclosed by EPA only to the extent allowed and by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies the submission when it is received by EPA, it will be made available to the public without further notice to the commenter.

The Agency will base its decision on the disclosable record. If a commenter wants EPA to base the final rule in part on a submission labeled as confidential business information, then a nonconfidential version of the document which summarizes the key data or information should be placed in the public docket.

B. Public Hearing

Any person desiring to testify at the public hearing (See **"DATES"**) should notify the contact person listed above (See **"FOR FURTHER INFORMATION CONTACT"**) prior to the day of the hearing. Persons wishing to testify at the hearing should also provide an estimate of the time required for the presentation of the testimony and notification of any need for audio/visual equipment. It is suggested that sufficient copies of the statement or material to be presented be brought to the hearing for distribution to the audience. A sign-up sheet also will be available at the registration table the morning of the hearing for scheduling of the order of testimony.

The hearing will be conducted informally, and technical rules of evidence will not apply. Written transcripts of the hearing will be made. Anyone desiring a copy of the transcript should make individual arrangements with the court reporter recording the proceedings.

The official record of the hearing will be kept open for 30 days following the hearing to allow submission of rebuttal and supplementary testimony. All such submittals should be directed to the EPA Air Docket, Docket No. A–91–28 (See **"ADDRESSES"**).

VI. Administrative Designation and Regulatory Analysis

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement that a Regulatory Impact Analysis be prepared. Major regulations have an annual effect on the economy in excess of $100 million, have a significant adverse impact on competition, investment, employment or innovation, or result in a major price increase. The elements of this proposal, individually and together, do not constitute major rules according to the established criteria. Therefore, I have determined that this proposal does not constitute a "major" regulation.

This proposal was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA responses to those comments have been placed in the public docket for this rulemaking.

VII. Impact on Small Entities

Under section 605 of the Regulatory Flexibility Act, the Administrator is required to certify that a regulation will not have a significant adverse economic impact on a substantial number of small business entities. There will not be a significant impact on a substantial number of small business entities due to the new PM or NOx standards since none of the vehicle manufacturers which will be affected by these regulations are small business entities. The retrofit/rebuild requirements for urban buses should not have a significant impact on a substantial number of small businesses entities either; urban bus engines are rebuilt by the transit agencies which operate buses, and these are not small businesses. For these reasons, I certify that the proposed rules contained in today's notice will not have a significant adverse economic impact on a substantial number of small entities.

VIII. Reporting and Recordkeeping Requirements

Under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et. seq.*, EPA must obtain OMB clearance for any activity that will involve collecting substantially the same information from 10 or more non-Federal respondents. EPA believes the records which are required to be maintained and submitted for the urban bus retrofit/rebuild program consist of information currently maintained by bus operators. Therefore this proposed rule does not contain any new information collection activities which are not common business practice. EPA requests comments on the reporting and recordkeeping requirements of today's proposal, including the applicability of the Paperwork Reduction Act.

IX. Statutory Authority

Authority for actions proposed in this notice are granted to EPA by sections 202, 219, and 301 of the Clean Air Act as amended.

List of Subjects

40 CFR Part 85

Imports, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements, Research, Warranties.

40 CFR Part 86

Administrative practice and procedure, Air pollution control, Environmental protection, Motor vehicles, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: September 6, 1991.

William K. Reilly,

Administrator.

APPENDIX TO PREAMBLE—TABLE OF CHANGES MADE TO VARIOUS SUBPARTS

Section	Change	Reason
1. Part 85 Table of contents.	Addition of new Subpart O.	Incorporation of urban bus rebuild requirements.
2. Part 85, subpart O.	Do	Do.
3. § 86.093–2	Add § 86.093–2	Incorporation of definition for separate class of buses.
4. § 86.093–11 Revise paragraph (a)(1)(iv)(A).	Addition of new bus particulate standard.	Incorporation of separate bus particulate standard.
5. § 86.094–11 Revise paragraph (a)(1)(iv).	Addition of new urban bus particulate standard.	Incorporation of separate urban bus particulate standard.
6. § 86.098–10	Add § 86.098–10.	Implementation of 1998 NOx standard.
7. § 86.098–11	Add § 86.098–11.	Do.

For the reasons set out in the preamble, title 40, chapter I, parts 85 and 86 of the Code of Federal Regulations are proposed to be amended as follows.

PART 85—CONTROL OF AIR POLLUTION FROM MOTOR VEHICLES AND MOTOR VEHICLE ENGINES

1. The authority citation for part 85 continues to read as follows:

Authority: Secs. 202, 203, 205, 206, 207, 208, 212, and 301(a), Clean Air Act as amended, 42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7546, and 7601(a), unless otherwise noted.

2. A new subpart O is proposed to be added to part 85 to read as follows:

Subpart O—Urban Bus Rebuild Requirements

Sec.

85.1401 General applicability.
85.1402 Definitions.
85.1403 Particulate standard for pre-1994 model year urban buses effective at time of engine rebuild or engine replacement.
85.1404 Maintenance of records; submittal of information; right of entry.

Subpart O—Urban Bus Rebuild Requirements

§ 85.1401 General applicability.

The requirements of this subpart shall be applicable to 1993 and earlier model year petroleum fueled urban buses that have their engines rebuilt or replaced after January 1, 1995; operating in consolidated metropolitan statistical areas and metropolitan statistical areas with a 1980 population of 750,000 or more.

§ 85.1402 Definitions.

(a) *Major Cylinder Component* means piston, cylinder liner, connecting rod, or piston ring set.

(b) *Engine Rebuild* means an activity, occurring over one or more maintenance events, involving disassembly of the engine including the removal of the cylinder head(s) and the replacement or reconditioning of more than one major cylinder component in more than half of the cylinders.

(c) *Engine Replacement* means the removal of an engine from the coach followed by the installation of another engine.

(d) *Engine configuration* means the set of components, tolerances, and calibrations specific to a subclassification of an engine family.

(e) *operator* means transit authority, state, city department, or private or public entity controlling the use of one or more urban buses.

(f) *urban bus* has the meaning set forth in § 86.091–2 of this chapter.

§ 85.1403 Particulate standard for pre-1994 model year urban buses effective at time of engine rebuild or engine replacement.

OPTION 1 FOR PARAGRAPH (a)(1)

(a)(1) Particulate emissions from an urban bus for which the regulations are applicable as described in § 85.1401 of this subpart shall not exceed 0.25 grams per brake horsepower-hour.

OPTION 2 FOR PARAGRAPH (a)(1)

(a)(1) Particulate emissions from an urban bus for which the regulations are applicable as described in § 85.1401 of this subpart shall not exceed 0.10 grams per brake horsepower-hour.

(2) The standard set forth in paragraph (a)(1) of this section refers to exhaust emitted over the operating schedule set forth in paragraph (f)(2) of appendix I to Part 86 of this chapter and measured and calculated in accordance with the procedures set forth in subpart N of part 86 of this chapter.

(b) Every operator of one or more urban buses subject to the standard prescribed in this section shall keep records of all engine rebuilds and replacements done to the urban bus and maintain evidence that the urban bus is in compliance with the standard.

§ 85.1404 Maintenance of records; submittal of information; right of entry.

(a) The operator of any urban bus for which this regulation is applicable shall maintain and retain the following adequately organized and indexed records beginning January 1, 1995.

(1) *General records.* The records required to be maintained under this paragraph shall consist of all purchase records, receipts, and part numbers for parts and components used in the rebuilding of urban bus engines.

(2) *Individual records.* A brief history of each urban bus subject to the standard prescribed under this section including the records and documentation required to be maintained under § 85.1403(b) of this subpart.

(b)(1) Any operator subject to the requirements under this section shall provide any EPA Enforcement Officer, upon presentation of credentials during operating hours, access to the following:

(A) Any facility where records required to be maintained under this section are generated or stored;

(B) Any facility where engine rebuilding or replacement takes place.

(2) Upon admission to any facility referred to in paragraph (b)(1) of this section any EPA Enforcement Officer shall be allowed:

(A) To inspect and make copies of records required to be maintained under this section;

(B) To inspect and photograph any urban bus and engine subject to the standard set forth in § 85.1403 of this subpart;

(C) To inspect and monitor any activity related to the rebuilding or replacement of an engine in an urban bus for which this subpart is applicable as described in § 85.1401 of this subpart.

PART 86—CONTROL OF AIR POLLUTION FROM NEW AND IN-USE MOTOR VEHICLES AND NEW AND IN-USE MOTOR VEHICLE ENGINES: CERTIFICATION AND TEST PROCEDURES

2a. The authority citation for part 86 continues to read as follows:

Authority: Secs. 202, 203, 205, 206, 207, 208, 215, 216, 301(a) Clean Air Act as amended (42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7549, 7550, and 7601(a)).

3. A new § 86.093–2 is proposed to be added to subpart A to read as follows:

§ 86.093–2 Definitions.

The definitions of § 86.092–2 remain effective. The definitions listed in this section apply beginning with the 1993 model year.

Bus means a heavy-duty diesel-powered passenger-carrying vehicle with a load capacity of fifteen or more passengers and the capability of being

centrally fueled as well as all urban buses.

Urban bus means a passenger-carrying vehicle powered by a heavy heavy-duty diesel engine, or of a type normally powered by a heavy heavy-duty diesel engine, with a load capacity of fifteen or more passengers and intended primarily for intra-city operation, *i.e.*, within the confines of a city or greater metropolitan area. Urban bus operation is characterized by short rides and frequent stops. To facilitate this type of operation, more than one set of quick-operating entrance and exit doors would normally be installed. Since fares are usually paid in cash or tokens, rather than purchased in advance in the form of tickets, urban buses would normally have equipment installed for collection of fares. Urban buses are also typically characterized by the absence of equipment and facilities for long distance travel, *e.g.*, rest rooms, large luggage compartments, and facilities for stowing carry-on luggage. The useful life for urban buses is the same as the useful life for other heavy heavy-duty diesel engines.

4. Section 86.093–11 of subpart A (which was proposed to be added on May 29, 1991 at 56 FR 24249) is proposed to be amended by revising paragraphs (a)(1)(iv)(A) and (a)(1)(iv)(C) to read as follows:

§ 86.093–11 Emission standards for 1993 and later model year diesel heavy-duty engines.

(a)(1) * * *

* * * * * *

(iv) *Particulate.* (A) For diesel engines to be used in buses, 0.10 grams per brake horsepower-hour (0.037 gram per megajoule), as measured under transient operating conditions.

(B) * * *

(C) A manufacturer may elect to include any or all of its diesel heavy-duty engine families in any or all or all of the particulate averaging, trading, or banking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in any of these programs, the particulate FEL may not exceed:

(*1*) 0.25 gram per brake horsepower-hour (0.093 gram per megajoule) for diesel engines intended for use in urban buses;

(*2*) 0.60 gram per brake horsepower-hour (0.22 gram per megajoule) for diesel engines not intended for use in urban buses.

This ceiling value applies whether credits for the family are derived from averaging, trading or banking programs.

* * * * * *

5. Section 86.094–11 of subpart A is proposed to be amended by revising paragraph (a)(1)(iv), to read as follows:

§ 86.094–11 Emission standards for 1994 and later model year diesel heavy-duty engines.

(a)(1) * * *

(iv) *Particulate.* (A) For diesel engines to be used in urban buses, 0.05 gram per brake horsepower-hour (0.019 gram per megajoule), as measured under transient operating conditions.

(B) For all other diesel engines only, 0.10 gram per brake horsepower-hour (0.037 gram per megajoule), as measured under transient operating conditions.

(C) A manufacturer may elect to include any or all of its diesel heavy-duty engine families in any or all of the particulate averaging, trading, or banking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in all of these programs, the particulate FEL may not exceed:

(*1*) For engine families intended for use in urban buses, 0.25 gram per brake horsepower-hour (0.093 gram per megajoule);

(*2*) For engine families not intended for use in urban buses, 0.60 gram per brake horsepower-hour (0.22 gram per megajoule).

These ceiling values apply whether credits for the family are derived from averaging, trading, or banking programs.

* * * * * *

6. A new § 86.098–10 is proposed to be added to subpart A to read as follows:

§ 86.098–10 Emission standards for 1998 and later model year Otto-cycle heavy-duty engines and vehicles.

(a)(1) Exhaust emissions from new 1998 and later model year Otto-cycle heavy-duty engines shall not exceed:

(i) For gasoline-fueled Otto-cycle engines intended for use in all vehicles except as provided in paragraph (a)(3) of this section.

(A) *Hydrocarbons.* 1.1 grams per brake horsepower-hour (0.41 gram per megajoule), as measured under transient operating conditions.

(B) *Carbon monoxide.* (*1*) 14.4 grams per brake horsepower-hour (5.36 grams per megajoule), as measured under transient operating conditions.

(*2*) *For gasoline-fueled Otto-cycle heavy-duty engines utilizing after-treatment technology.* 0.50 percent of exhaust gas flow at curb idle.

(C) *Oxides of nitrogen.* (*1*) 4.0 grams per brake horsepower-hour (1.49 grams per megajoule), as measured under transient operating conditions.

(*2*) A manufacturer may elect to include any or all of its gasoline-fueled Otto-cycle heavy-duty engine families in any or all of the NOx averaging, trading, or baking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in any of these programs, the NOx FELs may not exceed 5.0 grams per brake horsepower-hour (1.9 grams per megajoule). This ceiling value applies whether credits for the family are derived from averaging, trading or banking programs.

(ii) For gasoline-fueled Otto-cycle engines intended for use only in vehicles with a Gross Vehicle Weight Rating of greater than 14,000 lbs.

(A) *Hydrocarbons.* 1.9 grams per brake horsepower-hour (0.71 gram per megajoule), as measured under transient operating conditions.

(B) *Carbon monoxide.* (*1*) 37.1 grams per brake horsepower-hour (13.8 grams per megajoule), as measured under transient operating conditions.

(*2*) *For gasoline-fueled Otto-cycle heavy-duty engine utilizing after-treatment technology.* 0.50 percent of exhaust gas flow at curb idle.

(C) *Oxides of nitrogen* (*1*) 4.0 grams per brake horsepower-hour (1.49 grams per megajoule), as measured under transient operating conditions.

(*2*) A manufacturer may elect to include any or all of its gasoline-fueled Otto-cycle heavy-duty engine families in any or all of the NOx averaging, trading, or banking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in any of these programs, the Nox FELs may not exceed 5.0 grams per brake horsepower-hour (1.9 grams per megajoule). This ceiling value applies whether credits for the family are derived from averaging, trading or banking programs.

(iii) For methanol-fueled Otto cycle heavy-duty engines intended for use in all vehicles, except as provided in paragraph (a)(3) of this section.

(A) *Organic material hydrocarbon equivalent.* 1.1 gram per brake horsepower-hour (0.41 gram per megajoule), as measured under transient operating conditions.

(B) *Carbon monoxide.* (*1*) 14.4 grams per brake horsepower-hour (5.36 grams per megajoule), as measured under transient operating conditions.

(2) 0.50 percent of exhaust gas flow at curb idle.

(C) *Oxides of nitrogen.* (1) 4.0 grams per brake horsepower-hour (1.49 grams per megajoule), as measured under transient operating conditions.

(2) A manufacturer may elect to include any or all of its methanol-fueled Otto-cycle heavy-duty engine families in any or all of the NOx averaging, trading, or banking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in any of these programs, the NOx FELs may not exceed 5.0 grams per brake horsepower-hour (1.9 grams per megajoule). This ceiling value applies whether credits for the family are derived from averaging, trading or banking programs.

(iv) For methanol-fueled Otto-cycle heavy-duty engines intended for use only in vehicles with a Gross Vehicle Weight Rating of greater than 14,000 lbs.

(A) *Organic material hydrocarbon Equivalent.* 1.9 grams per brake horsepower-hour (0.71 gram per megajoule), as measured under transient operating conditions.

(B) *Carbon monoxide.* (1) 37.1 grams per brake horsepower-hour (13.8 grams per megajoule), as measured under transient operating conditions.

(2) 0.50 percent of exhaust gas flow at curb idle.

(C) *Oxides of nitrogen.* (1) 4.0 grams per brake horsepower-hour (1.49 grams per megajoule), as measured under transient operating conditions.

(2) A manufacturer may elect to include any or all of is methanol-fueled Otto-cycle heavy-duty engine families in any or all of the NOx averaging, trading, or banking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in any of these programs, the NOx FELs may not exceed 5.0 grams per brake horsepower-hour (1.9 grams per megajoule). This ceiling value applies whether credits for the family are derived from averaging, trading or banking programs.

(2) The standards set forth in paragraph (a)(1) of this section refer to the exhaust emitted over the operating schedule set forth in paragraph (f)(1) of appendix I to this part, and measured and calculated in accordance with the procedures set forth in subpart N or P of this part.

(3)(i) A manufacturer may certify one or more gasoline-fueled Otto-cycle heavy-duty engine configurations intended for use in all vehicles to the emission standards set forth in paragraph (a)(1)(ii) of this section: *Provided,* That the total model year sales of such configuration(s) being certified to the emission standards in paragraph (a)(1)(ii) of this section represent no more than 5 percent of total model year sales of all gasoline-fueled Otto-cycle heavy-duty engines intended for use in vehicles with a Gross Vehicle Weight Rating of up to 14,000 pounds by the manufacturer.

(ii) A manufacturer may certify one or more methanol-fueled Otto-cycle heavy-duty engine configurations intended for use in all vehicles to the emissions standards set forth in paragraph (a)(1)(iv) of this section: *Provided,* That the total model year sales of such configuration(s) being certified to the emission standards in paragraph (a)(1)(iv) of this section represent no more than 5 percent of total model year sales of all methanol-fueled Otto-cycle heavy-duty engines intended for use in vehicles with a Gross Vehicle Weight Rating of up to 14,000 pounds by the manufacturer.

(iii) The configurations certified to the emission standards of paragraphs (a)(1)(ii) and (iv) of this section under the provisions of paragraphs (a)(3)(i) and (ii) of this section shall still be required to meet the evaporative emission standards set forth in paragraphs (b)(1)(i), (b)(2)(i) and (b)(3)(i) of this section.

(b) *Evaporative emissions* from 1998 and later model year heavy-duty vehicles shall not exceed:

(1) *Hydrocarbons (for vehicles equipped with gasoline-fueled engines).* (i) For vehicles with a Gross Vehicle Weight Rating of up to 14,000 lbs., 3.0 grams per test.

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 14,000 lbs., 4.0 grams per test.

(2) *Organic material hydrocarbon equivalent (for vehicles equipped with methanol-fueled engines).* (i) For vehicles with a Gross Vehicle Weight Rating of up to 14,000 lbs., 3.0 grams per test.

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 14,000 lbs., 4.0 grams per test.

(3)(i) For vehicles with a Gross Vehicle Weight Rating of up to 26,000 lbs., the standards set forth in paragraphs (b)(1) and (b)(2) of this section refer to a composite sample of evaporative emissions collected under the conditions set forth in subpart M of this part and measured in accordance with those procedures.

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 26,000 lbs., the standards set forth in paragraphs (b)(1)(ii) and (b)(2)(ii) of this section refer to the manufacturers engineering design evaluation using good engineering practice (a statement of which is required in § 86.091–23(b)(4)(ii)).

(c) No crankcase emissions shall be discharged into the ambient atmosphere from any new 1998 or later model year Otto-cycle heavy-duty engine.

(d) Every manufacturer of new motor vehicle engines subject to the standards prescribed in this section shall, prior to taking any of the actions specified in section 203(a)(1) of the Act, test or cause to be tested motor vehicle engines in accordance with applicable procedures in subpart N or P of this part to ascertain that such test engines meet the requirements of paragraphs (a) and (c) of this section.

7. A new § 86.098–11 is proposed to be added to subpart A to read as follows:

§ 86.098–11 Emission standards for 1998 and later model year diesel heavy-duty engines.

(a) Exhaust emissions from new 1998 and later model year diesel heavy-duty engines shall not exceed the following:

(1)(i) *Hydrocarbons (for petroleum-fueled diesel engines).* 1.3 grams per brake horsepower-hour (0.48 gram per megajoule), as measured under transient operating conditions.

(ii) *Organic Material Hydrocarbon Equivalent (for methanol-fueled diesel engines).* 1.3 grams per brake horsepower-hour (0.48 gram per megajoule), as measured under transient operating conditions.

(2) *Carbon monoxide.* (i) 15.5 grams per brake horsepower-hour (5.77 grams per megajoule), as measured under transient operating conditions.

(ii) 0.50 percent of exhaust gas flow at curb idle (methanol-fueled diesel only).

(3) *Oxides of Nitrogen.* (i) 4.0 grams per brake horsepower-hour (1.49 grams per megajoule), as measured under transient operating conditions.

(ii) A manufacturer may elect to include any or all of its diesel heavy-duty engine families in any or all of the NOx averaging, trading, or banking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in any of these programs, the NOx FELs may not exceed 5.0 grams per brake horsepower-hour (1.9 grams per megajoule). This ceiling value applies whether credits for the family are derived from averaging, trading or banking programs.

(4) *Particulate.* (i) For diesel engines to be used in urban buses, 0.05 gram per brake horsepower-hour (0.019 gram per megajoule), as measured under transient operating conditions.

(ii) For all other diesel engines only, 0.10 gram per brake horsepower-hour (0.037 gram per megajoule), as measured under transient operating conditions.

(iii) A manufacturer may elect to include any or all of its diesel heavy-duty engine families in any or all or the particulate averaging, trading, or banking programs for heavy-duty engines, within the restrictions described in § 86.094–15. If the manufacturer elects to include engine families in any of these programs, the particulate FEL may not exceed:

(A) For engine families intended for use in urban buses, 0.25 gram per brake horsepower-hour (0.093 gram per megajoule);

(B) For engine families not intended for use in urban buses, 0.60 gram per brake horsepower-hour (0.22 gram per megajoule).

This ceiling value applies whether credits for the family are derived from averaging, trading or banking programs.

(b)(1) The opacity of smoke emission from new 1998 and later model year diesel heavy-duty engine shall not exceed:

(i) 20 percent during the engine acceleration mode;

(ii) 15 percent during the engine lugging mode;

(iii) 50 percent during the peaks in either mode.

(2) The standards set forth in paragraph (b)(1) of this section refer to exhaust smoke emissions generated under the conditions set forth in subpart I of this part and measured and calculated in accordance with those procedures.

(3) *Evaporative emissions* (total of non-oxygenated hydrocarbons plus methanol) from 1998 and later model year heavy-duty vehicles equipped with methanol-fueled diesel engines shall not exceed:

(i) For vehicles with a Gross Vehicle Weight Rating of up to 14,000 lbs, 3.0 grams per test;

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 14,000 lbs, 4.0 grams per test.

(4)(i) For vehicles with a Gross Vehicle Weight Rating of up to 26,000 lbs, the standards set forth in paragraph (b)(3) of this section refer to a composite sample of evaporative emissions collected under the conditions set forth in Subpart M of this part and measured in accordance with those procedures.

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 26,000 lbs, the standard set forth in paragraph (b)(3)(ii) of this section refers to the manufacturers engineering design evaluation using good engineering practice (a statement of which is required in § 86.091–23(b)(4)(ii)).

(c) No crankcase emissions shall be discharged into the ambient atmosphere from any new 1998 or later model year methanol-fueled diesel, or any naturally-aspirated diesel heavy-duty engine. For petroleum-fueled engines only, this provision does not apply to engines using turbochargers, pumps, blowers, or supercharges for air induction.

(d) Every manufacturer of new motor vehicle engines subject to the standards prescribed in this section shall, prior to taking any of the actions specified in section 203(a)(1) of the Act, test or cause to be tested motor vehicle engines in accordance with applicable procedures in subpart I or N of this part to ascertain that such test engines meet the requirements of paragraphs (a), (b), (c) and (d) of this section.

[FR Doc. 91–22191 Filed 9–23–91; 8:45 am]

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Federal Register

Tuesday
September 24, 1991

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Parts 108 and 129
Use of X-ray Systems; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 108 and 129

[Docket No. 26268; Amendments 108–11, 129–23]

RIN 2120–AD13

Use of X-ray Systems

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is amending the airplane operator security regulations by removing the exception to meeting the current X-ray imaging standard for X-ray screening systems in use prior to July 22, 1985. Each United States air carrier conducting screening under a mandatory security program will be required to use only X-ray systems that meet the current X-ray imaging standard required under its approved security program to screen carry-on and checked articles. Likewise, each foreign air carrier that lands or takes off in the United States will be required to use only X-ray screening systems that meet the current X-ray imaging standard under its accepted security program to screen carry-on and checked articles in the United States. This action is needed due to the increased sophistication of terrorist acts. The intended effect is to increase the safety of passengers and crewmembers aboard aircraft by providing an upgraded aid at airport screening points to prevent the carriage of explosives, incendiaries, or deadly or dangerous weapons.

EFFECTIVE DATE: October 24, 1991.

FOR FURTHER INFORMATION CONTACT: Max D. Payne, Civil Aviation Security Policy and Standards Division (ACP–110), Office of Civil Aviation Security, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7839.

SUPPLEMENTARY INFORMATION:

Background

Statement of the Problem

Attacks against civil aviation have increased in sophistication over the past decade. As a result, security has become an even greater concern of the aviation community. In recent years, sophisticated explosive devices have been used to damage or destroy civilian airliners resulting in the loss of many lives. The bombing of Pan American World Airways (Pan Am) Flight 103 demonstrates the continuing need to protect the safety and security of passengers and crewmembers aboard air carriers. Eliminating any exceptions to meeting the most current X-ray imaging standard is one way to address this need, and is consistent with recommendations made by the President's Commission on Aviation Security and Terrorism. The commission's report, issued on May 15, 1990, repeatedly recommended "use of the most modern X-ray equipment." (See, for example, pages 58, 61, and 122 of the report.)

History

The FAA's present Civil Aviation Security Program, initiated in 1973, requires certain U.S. air carriers to conduct security screening to prevent or deter the carriage aboard aircraft of any explosive, incendiary, or deadly or dangerous weapon on or about any individual's person or accessible property. Part 108 of the Federal Aviation Regulations (FAR) (14 CFR part 108), which pertains to U.S. air carrier security, was promulgated in 1981 (46 FR 3782, January 15, 1981). The pertinent provisions in part 129, which govern the operations of foreign air carriers that hold a permit issued by the Civil Aeronautics Board or the Department of Transportation under section 402 of the Federal Aviation Act or that hold another appropriate economic or exemption authority issued by those entities, were promulgated in 1976 (41 FR 30106, July 22, 1976).

On November 29, 1976, the FAA promulgated new 14 CFR part 191 (41 FR 53777, December 9, 1976) establishing the requirements for withholding security information from disclosure under the Air Transportation Security Act of 1974. Air carrier security programs are documents detailing how U.S. and foreign air carriers will comply with the security requirements contained in the FAR. They contain sensitive security requirements, including specific performance criteria and operational information for X-ray systems, and are not available to the public.

On May 28, 1985, the FAA issued Amendments Nos. 108–1 and 129–13 (50 FR 25654, June 20, 1985), which established a new standard for testing the effectiveness of X-ray systems (14 CFR 108.17 and 129.26). This new standard was effective on July 22, 1985; however, it did not apply to X-ray systems in use prior to that date. In a parallel action, the FAA amended each air carrier's approved security program to include a "grandfather" provision for X-ray systems in use prior to July 22, 1985.

Related Activities

For many years, the passenger screening system has been effective in countering the threat to domestic and international civil aviation, which primarily came from hijackers. In recent years, this threat has expanded to include aircraft bombings. The bombing of Pan Am Flight 103 is a reminder that civil aviation is still vulnerable to criminal and terrorist acts.

A comprehensive review of security procedures has been conducted to determine where existing procedures may be improved and where new procedures may be warranted. On April 3, 1989, Secretary of Transportation Samuel K. Skinner announced a number of aviation security initiatives to enhance protection of travelers at airports in the United States and other countries. Significant among these initiatives was the commitment to propose the removal of grandfather provisions for older X-ray systems. To accomplish this, a Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** (55 FR 25806) on June 22, 1990. This final rule makes the changes proposed in the NPRM.

Other recent FAA security initiatives include requiring the use of explosives detection systems (EDS) and the establishment of a mandatory security directives system, both the subject of separate rulemakings that resulted in the issuance of final rules. The final rule requiring EDS was issued on August 30, 1989 (54 FR 36938, September 5, 1989). See 14 CFR 108.20. The final rule establishing the Security Directives and Information Circulars system was issued on July 6, 1989 (54 FR 28982, July 10, 1989). See 14 CFR 108.18.

Current Requirements

Currently, part 108 requires each holder of an FAA air carrier operating certificate required to conduct screening to use the procedures, facilities, and equipment described in its approved security program to prevent or deter the carriage aboard airplanes of any explosives, incendiaries, or deadly or dangerous weapons on or about each individual's person or accessible property. Part 129 requires each foreign air carrier landing or taking off in the United States to adopt and use a security program acceptable to the Administrator and designed to prevent or deter the carriage aboard airplanes of any explosive, incendiary device, or deadly or dangerous weapon on or about each individual's person or accessible property, through screening by weapon-detecting procedures or

facilities. Both parts 108 and 129 require X-ray systems used to inspect carry-on and checked articles in the United States to meet the imaging standard set by the Administrator, except that an X-ray system in use prior to July 22, 1985 may meet the requirements in effect on July 21, 1985. See 14 CFR 108.17(a)(5) and 129.26(a)(5).

Future Actions

The U.S. Government has actively supported research and development efforts in X-ray systems and the FAA has been evaluating X-ray systems on a continuing basis. The FAA recognizes that there have been significant technological advancements made in X-ray systems. Consequently, the FAA is considering a separate action proposing to amend approved air carrier security programs and accepted foreign air carrier security programs to establish a more stringent imaging standard than the current standard established in 1985.

The NPRM for this action anticipated a final determination regarding a new imaging standard prior to publication of this rule. However, the FAA is still gathering data to evaluate the technical aspects and impact of a new standard. The FAA is proceeding with this rule to address the need to protect the safety and security of passengers and crewmembers, and to implement the recommendations of the President's Commission on Aviation Security and Terrorism. Given the benefits expected to result from this rule, and the minimal costs involved, the FAA has determined that it is cost-beneficial to proceed with this rule to bring all X-ray systems up to current standards. Air carriers and foreign air carriers will be given the opportunity to comment on any proposed amendment to their security programs that would establish a new imaging standard.

As previously stated, security programs are exempt from disclosure under 14 CFR part 191. In accordance with 14 CFR 191.5, the FAA will not provide the current or any future performance criteria or detailed operational information in any document generally available to the public. The FAA has determined that disclosure of this information would be detrimental to the safety of persons traveling in air transportation or intrastate air transportation.

General Discussion

The FAA is amending part 108 to ensure that all certificate holders use only X-ray systems that meet the current imaging requirements of their approved security programs to screen carry-on and checked articles. The FAA is also amending part 129 to require foreign air carriers who land or take off in the United States and who conduct screening under an accepted security program to use only X-ray systems that meet the current imaging requirements in their accepted security programs to screen carry-on and checked articles in the United States.

Section 108.17

Paragraph (a)(5) of this section is revised to eliminate a grandfather clause allowing for the exception of certain X-ray systems from the requirement to meet the imaging requirements set forth in an approved air carrier security program using the step wedge specified in American Society for Testing and Materials Standard F792–82.

Section 129.26

Paragraph (a)(5) of this section is revised to eliminate a grandfather clause allowing for the exception of certain X-ray systems from the requirement to meet the imaging requirements set forth in an accepted air carrier security program using the step wedge specified in American Society for Testing and Materials Standard F792–82.

Discussion of Comments

The FAA received comments from three air carriers, one foreign air carrier, five crewmember organizations, and the National Transportation Safety Board. Eight commenters supported the proposed rule and two opposed it.

One commenter expressed support with the understanding that X-ray systems installed prior to July 22, 1985 could continue to be used for screening if they meet the current imaging standard. This understanding is correct. The FAA did not propose to require air carriers to replace all X-ray systems installed prior to July 22, 1985. Any X-ray system, regardless of age, may continue to be used for screening when it meets the imaging standard specified in the air carrier's approved security program.

Another supporting commenter noted that many of the older X-ray systems that do not meet the current imaging standard are located at smaller airports. A requirement to replace all of these X-ray systems at once was said to be an economic burden at stations with marginal passenger volume. A two year implementation period was suggested to gradually phase in replacement X-ray systems at larger airports before proceeding to smaller airports.

The actual schedule for replacement of X-ray systems that do not meet the current imaging standard will be contained in amendments to each air carrier's approved security program. The FAA has notified air carriers of a proposed amendment that would require them to implement this rule. The FAA believes a six-month implementation period will provide sufficient time to order, deliver, and install replacement X-ray units at any airport in the United States. To permit a longer implementation period would significantly detract from the FAA's goal of achieving a uniform imaging standard as soon as possible. The amendment to the carriers' approved security programs will provide an implementation period that ends six months after the effective date of this final rule.

The regulatory evaluation included in this rule has identified the net cost of this rule as only $1,380 per replacement X-ray system. Therefore, the FAA does not believe that this rule will impose undue economic hardship on carriers operating out of smaller airports. Further, this rule does not require the use of an X-ray system to inspect carry-on and checked articles. Air carriers may physically inspect all such articles to comply with their approved security programs.

The application of the rule to X-ray systems used by foreign air carriers for flights to the United States was opposed by one commenter. The comment expressed the view that if a State wishes to implement enhancements to security measures for flights to that State from another State the appropriate procedure is to request the foreign State to establish the desired standard. Sections 108.17(a) and 129.26(a) both apply only to "an X-ray system within the United States". This rule does not change that application to include X-ray systems at foreign airports.

One commenter opposed the proposed rule as unnecessary and unjustified at smaller airports, arguing that X-ray systems that do not meet the current imaging standard should continue to be used with more physical searches to clear items that cannot be identified by the X-ray operator. The commenter said it might be appropriate to require a higher imaging standard at larger airports.

The FAA does not agree that a clearly outdated imaging standard is acceptable even at smaller airports. If physical searches are not used exclusively, the decision to conduct a physical search is made by the X-ray system operator viewing the X-ray image. The ability of the operator to recognize a potential explosive, incendiary, or deadly or dangerous weapon is dependent upon the imaging capability of the X-ray

system. The intent of this rule is to increase the safety of passengers and crewmembers by providing a better image to the operator and increasing the probability that weapons, explosives, and incendiaries will be detected.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96–511), there are no collection of information requirements associated with this rule.

Regulatory Evaluation Summary

Introduction

This section summarizes a full regulatory evaluation prepared by the FAA that provides detailed estimates of the economic consequences of this regulatory action. The full evaluation quantifies, to the extent practicable, estimated costs to the private sector, consumers, Federal, State and local governments, as well as anticipated benefits and impacts.

Executive Order 12291 dated February 17, 1981, directs Federal agencies to promulgate new regulations or modify existing regulations only if potential benefits to society for each regulatory change outweigh potential costs. The order also requires the preparation of a Regulatory Impact Analysis of all "major" rules except those responding to emergency situations or other narrowly defined exigencies. A "major" rule is one that is likely to result in an annual effect on the economy of $100 million or more, a major increase in consumer costs, or a significant adverse effect on competition.

The FAA has determined that this rule is not "major" as defined in the Executive Order; therefore a regulatory analysis, which includes the identification and evaluation of cost-reducing alternatives to the rule, has not been performed. Instead, the FAA has prepared a regulatory evaluation of just this rule without identifying alternatives. In addition to a summary of the regulatory evaluation, this section also contains a regulatory flexibility determination required by the 1980 Regulatory Flexibility Act (Pub.L. 96–354) and an international trade impact assessment. If more detailed economic information is desired than is contained in this summary, the reader is referred to the full regulatory evaluation contained in the docket.

Costs

The FAA estimates there are 114 U.S. air carrier and two foreign air carrier X-ray systems currently in service in the United States that are incapable of meeting current imaging requirements using the step wedge as specified in American Society for Testing and Materials Standard F792–82. These requirements have been in effect since July 1985. (In the NPRM published in 1990, the FAA estimated there were approximately 170 U.S. carrier and 2 foreign carrier X-ray systems in use in 1989 that did not meet this standard. Because some time has elapsed since this survey was completed, the FAA estimates that 56 of the U.S. systems have been retired since then.) Such systems will no longer be acceptable for airport security purposes under this amended regulation and the parallel amendment of the carriers' approved security programs. Thus, air carriers must phase in acquisition of new systems within six months after the regulation's effective date, as will be provided in the security program amendment.

Even in the absence of this rule, the 116 systems will have to be replaced once they reach the end of their useful lives. According to one manufacturer of X-ray systems, these units have a life expectancy of approximately eight to ten years. Because carriers have been prohibited since July 1985 from purchasing additional X-ray systems that do not meet the current imaging standard, all existing systems that fail to meet the standard must be at least 5 years old now. Therefore, by assuming a 9-year average life for X-ray systems, the cost of this rule is the difference between purchasing 116 new standard X-ray systems immediately (net of salvage value for replaced systems) versus purchasing new systems over a 4-year period as the existing systems wear out.

For the purposes of this analysis, replacement system costs reflect the price of a standard black and white X-ray system used for hand-carried articles because this system is a basic model that meets the current standard. Industry sources state such systems retail for about $32,000 each, including installation. Prices will vary, however, based on location and number of systems ordered. At $32,000 each, 116 new systems would cost about $3.71 million. The replaced system, which has somewhere between zero and 4 years of useful life remaining, will have some resale value for non-aviation purposes such as industrial security. The FAA estimates the current average resale value per system at $4,000, or about $0.46 million for the estimated 116 systems still in use. Therefore, the total immediate outlay for new X-ray systems will be $3.71 million less $0.46 million = $3.25 million.

The net cost of this rule will be $3.25 million less the discounted cost of replacing systems when they wear out. Thus, the net cost of the rule is the difference between the current replacement cost of the systems and the discounted cost of the systems if purchased at a later date. No information is readily available concerning the exact age of each existing system that will need to be replaced, or the current replacement rate of such systems. It has been assumed for this analysis that one-fourth (29) of these systems will be replaced in each of the next 4 years. The discounted cost (a 10 percent discount rate is used) of replacing these 116 systems over a 4-year period is $3.09 million. Therefore, the net cost of this rule is $3.25 million less $3.09 million = $0.16 million, or about $1,380 per replacement X-ray system.

These costs ($0.16 million) were calculated as of year-end 1990. The costs of this rule will decrease over time, as more X-ray systems that do not meet the current imaging standard reach the end of their useful lives and are replaced with new systems. Taking into account the time that has elapsed since these costs were calculated, plus a six-month implementation period following the rule's effective date, the actual costs of this rule will be substantially lower than stated here by the time carriers actually implement the changes mandated by the rule.

Another cost factor concerns anticipated differences in maintenance costs between the replaced systems and the replacement systems. The FAA expects their maintenance costs to be very similar, and will, therefore, not alter the above cost calculations. However, one industry representative indicated that many of the systems that will be replaced are equipped with image intensifiers that are relatively expensive, and might need replacing once a year. In comparison, technological improvements in the replacement systems have eliminated the need for image intensifiers. Therefore, it is possible that the overall costs of this rule are somewhat overstated.

Benefits

The amended regulation will make it more difficult to carry an explosive device onto domestic and international flights. Therefore, it is expected to provide an additional margin of safety and security for passengers and crew members aboard air carriers. The FAA cannot predict the number or severity of future incidents nor the number of

incidents that would be perpetrated if this rule did not go into effect. The frequency of terrorist incidents would depend on several factors such as the world-wide political climate, the skill and technical sophistication of terrorist organizations, and the success of efforts to avert these incidents.

The historical record reveals that 19 separate criminal acts and incidents of terrorism using explosives were perpetrated against U.S. air carriers between 1979 and 1988. Because the FAA expects the threat of sabotage to increase in the future, and because the X-ray systems in question have been identified as a weak link in the overall U.S. civil aviation security system, the FAA expects that substantial benefits will result from the rule.

One way to assess the benefits of this rule is to put expected costs into perspective. The total estimated cost of this rule, discounted over 4 years (the estimated remaining life of the systems to be replaced), is $160,000. Therefore, if one life is saved sometime in the 4-year period after the rule is in effect, the cost of saving that life would be approximately $160,000. Similarly, if one aircraft with 200 passengers is saved from destruction as a result of this rule, the cost per life saved would be only $800.

In order to provide the public and government officials with a benchmark comparison of the expected safety benefits of rulemaking actions over an extended period of time with estimated costs in dollars, the FAA currently uses a value of $1.5 million to represent statistically a human fatality avoided (in accordance with guidelines issued by the Office of the Secretary of Transportation dated June 22, 1990). Using a statistical value of a human life of $1.5 million, or about $1.25 million when discounted over 4 years, the benefits associated with saving a single life during the next 4 years would be about 7.8 times the estimated $160,000 cost to accomplish it. Given the large difference between potential benefits and known costs, the FAA believes this rule to be cost-beneficial.

International Trade Impact

The rule will have little or no impact on trade for U.S. firms doing business overseas or for foreign firms doing business in the United States. The rule affects all carriers of U.S. registry and foreign air carriers operating scheduled passenger service or public charter passenger operations in the United States that are required to screen passengers under a security program. The expected additional annual costs should not create an economic disadvantage to either domestic operators or foreign carriers operating in the United States.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily burdened by government regulations. The RFA requires agencies to review rules to determine whether they may have a "significant economic impact on a substantial number of small entities." The FAA's criterion for a "substantial number" is a number that is not less than 11 and that is more than one third of the small entities subject to the rule. For air carrier operators, a small entity has been defined as one who owns, but does not necessarily operate, nine aircraft or less. The FAA's criteria for "a significant impact" are at least $4,200 per year for an unscheduled carrier, $60,300 per year for a scheduled carrier having an airplane or airplanes with only 60 or fewer seats, and $107,900 per year for a scheduled carrier having an airplane or airplanes with 61 or more seats.

The FAA believes that it is very unlikely that the rule will have a significant economic impact on a substantial number of small entities. This amendment has relatively low costs because the estimated cost per replacement X-ray system is only $1,380. At least 11 of the small unscheduled carriers would have to own three or more of the X-ray systems in need of replacement for this rule to have a significant economic impact on a substantial number of small entities. The FAA believes that less than 33 of these X-ray systems are currently owned and operated by small entities. Therefore, the FAA finds that this final rule will not have a significant impact on a substantial number of small entities.

Federalism Implications

The regulations herein will 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. Thus, in accordance with Executive Order 12612, it is determined that such a regulation does not have federalism implications warranting the preparation of a Federalism Assessment.

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this final rule is not major under Executive Order 12291. In addition, the FAA certifies that this rule will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This rule is considered significant under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). A regulatory evaluation of this rule, including a Regulatory Flexibility Determination and International Trade Impact Analysis, has been placed in the docket. A copy may be obtained by contacting the person identified under **"FOR FURTHER INFORMATION CONTACT."**

List of Subjects

14 CFR Part 108

Air carriers, Airports, Air safety, Air transportation, Aviation safety, Baggage, Safety, Security measures, Transportation.

14 CFR Part 129

Air carriers, Airports, Weapons.

The Amendments

In consideration of the foregoing, the Federal Aviation Administration is amending parts 108 and 129 of the Federal Aviation Regulations (14 CFR parts 108 and 129) as follows:

PART 108—AIRPLANE OPERATOR SECURITY

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

Authority: 49 U.S.C. App. 1354, 1356, 1357, 1421, 1424, and 1511; 49 U.S.C. 106(g); Sec. 101 *et seq.*, Pub. L. 101–604, 104 Stat. 3066.

2. Section 108.17(a)(5) is revised to read as follows:

§ 108.17 Use of X-ray systems.

(a) * * *

(5) The system meets the imaging requirements set forth in an approved Air Carrier Security Program using the step wedge specified in American Society for Testing and Materials Standard F792–82.

* * * * *

PART 129—OPERATIONS: FOREIGN AIR CARRIERS AND FOREIGN OPERATORS OF U.S.-REGISTERED AIRCRAFT ENGAGED IN COMMON CARRIAGE

3. The authority citation for part 129 is revised to read as follows:

Authority: 49 U.S.C. App. 1346, 1354(a), 1356, 1357, 1421, 1502, and 1511; 49 U.S.C. 106(g); Sec. 101 *et seq.*, Pub. L. 101–604, 104 Stat. 3066.

4. Section 129.26(a)(5) is revised to read as follows:

§ 129.26 Use of X-ray systems.

(a) * * *

(5) The system meets the imaging requirements set forth in an accepted Foreign Air Carrier Security Program using the step-wedge specified in American Society for Testing and Materials Standard F792–82.

* * * * *

Issued in Washington, DC, on September 16, 1991.

James B. Busey,

Administrator.

[FR Doc. 91–22795 Filed 9–23–91; 8:45 am]

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federal register

Tuesday
September 24, 1991

Part VI

Department of Labor

Mine Safety and Health Administration

30 CFR Parts 48, 75, and 77
Training and Retraining of Miners;
Proposed Rule

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 48, 75, and 77

RIN 1219-AA55

Training and Retraining of Miners

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Proposed rule.

SUMMARY: The Mine Safety and Health Administration (MSHA) is proposing to amend its training requirements for miners in 30 CFR part 48. The proposal would revise the definition of "miner" to include all supervisory personnel. It would revise the definition of "experienced miner" to mean a miner who has had one year of mining experience and, for miners hired after October 13, 1978, "experienced miner" would mean those who have completed new miner training. In addition, the proposal would strengthen the training for experienced miners, including supervisory personnel, by adding course requirements. MSHA also proposes to remove or revise certain coal mine training requirements in parts 75 and 77 of 30 CFR which are covered under part 48.

DATES: Written comments must be received by November 25, 1991.

ADDRESSES: Send written comments to the Mine Safety and Health Administration; Office of Standards, Regulations and Variances; Ballston Tower No. 3, room 631; 4015 Wilson Boulevard; Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director; Office of Standards, Regulations and Variances; MSHA; (703) 235-1910.

SUPPLEMENTARY INFORMATION:

I. Paperwork Reduction Act

MSHA has determined that the proposed changes to this rule would impose no additional paperwork hours on mine operators.

II. Rulemaking Background

Section 115 of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 825, directs the Secretary of Labor to promulgate regulations concerning health and safety training programs for miners. Section 115 states that each mine operator must have a training program approved by the Secretary and specifies the minimum training that these programs must include.

On October 13, 1978, MSHA published regulations for the training of miners in 30 CFR part 48 (43 FR 47453). The regulations define "miner" (§§ 48.2(a)(1) and 48.22(a)(1)) and "experienced miner" (§§ 48.2(b) and 48.22(b)); they require training for new miners (§§ 48.5 and 48.25), newly employed experienced miners (§§ 48.6 and 48.26), and miners assigned to new tasks (§§ 48.7 and 48.27); and they require annual refresher training for miners (§§ 48.8 and 48.28).

This proposed rule would revise portions of the existing part 48 regulations to ensure that when an experienced miner goes to work in a mine, the miner has received adequate training to prevent accidents and injuries.

The present training requirements for newly employed experienced miners are not as comprehensive as are those for other miners. Currently, an experienced miner is one who has had at least 12 months of mining experience during the previous 3 years; or has received MSHA approved new miner training within the preceding 12 months; or has received training acceptable to MSHA from an appropriate state agency within the preceding 12 months. For a miner employed on or before October, 13, 1978, it means a miner who has had 12 months of mining experience. While comprising seven percent of the mining work force excluding supervisors and office workers, newly employed experienced miners accounted for an average of 22 percent of miner fatalities from 1984 through 1989. Clearly, the fatality rate among newly employed experienced miners is substantially higher than the rate that exists for all other miners. The proposed rule would strengthen the training for these miners by adding new course requirements.

The proposal would revise all references to "training of newly employed experienced miners" to read "experienced miner training," and all references to "training newly employed experienced miners" to read "training experienced miners."

The proposed rule also focuses on supervisory personnel who work in the mine and are exposed to general mining hazards. As a consequence of their responsibilities to direct the work force, supervisory personnel may encounter a broader array of hazards than miners who work in one particular place or with one particular piece of equipment. Supervisory personnel often respond by personally intervening when interruptions of normal work operations occur or when hazardous situations arise. Often, they must perform nonsupervisory tasks for which MSHA requires them to receive some part 48 training. That training has been limited to task training, however, which is not sufficient to cover all of the training nonsupervisory miners receive. MSHA data substantiate that accidents happen under those circumstances.

The disproportionate fatality rate for supervisory personnel indicates their high exposure to hazards. From 1984 to 1989, there were 67 underground coal mine supervisor fatalities. Had the fatality rate been the same for underground coal supervisors as it was for underground coal production miners, there would have been 39 underground coal supervisor fatalities (rather than 67) during this time period. The average of these higher than expected fatalities is between four and five per year.

With respect to surface coal mines and metal and nonmetal mines, no significant difference is observed between the actual number of supervisor fatalities in comparison to the expected number of supervisor fatalities. Most surface coal supervisors have received part 48 training because there are relatively few state certification programs for surface coal. Metal and nonmetal supervisors are required to receive the same training that miners receive. Consequently, the fact that the surface coal supervisor fatality rate is nearly the same as the surface coal miner fatality rate and that the metal and nonmetal miner supervisor fatality rate is the same as the metal and nonmetal miner fatality rate indicates that miner training for supervisors likely has had a positive effect on reducing the number of supervisor fatalities in surface coal and in metal and nonmetal mining. Although not all of this difference can be solely explained by differences in training, this evidence supports the contention that the lack of part 48 miner safety training for underground coal supervisors is at least a partial explanation for the greater than expected number of underground coal supervisor fatalities. As a result, the proposed rule would provide comparable safety and health training for all supervisory personnel to address the high fatality rate for such workers.

III. Discussion of the Proposed Rule

Sections 48.2 and 48.22 Definitions

The proposal would revise the definitions of "miner" and "experienced miner."

Under existing §§ 48.2(a)(1)(ii) (underground miners) and 48.22(a)(1)(ii) (surface miners), supervisory personnel subject to MSHA approved State certification requirements are excluded from the definition of "miner" for the purpose of training. It is only when these

persons perform nonsupervisory tasks and are no longer supervising that MSHA currently requires them to receive part 48 training. However, that training is limited to task training and does not include the comprehensive training that MSHA believes miners and supervisors need.

In 1989, MSHA conducted a study of State certification and qualification requirements with the 46 States participating in MSHA's State grants program. This study concentrated on current State supervisory training requirements. Twenty-two of the States have some kind of supervisory training or certification programs. Most, however, do not provide the 8 minimum hours of instruction or courses now required as annual refresher training for miners under part 48. Only nine States require any annual supervisory training and that training does not fulfill the part 48 course requirements or hours of instruction. Under this proposal, supervisors would have the 8 hours of annual refresher training required of all miners.

The training that these supervisory personnel currently receive as federally certified persons under 30 CFR parts 75 and 77 does not match the part 48 training. Part 48 subjects that are not specifically required elsewhere include introduction to the work environment, hazard recognition, health, transportation, clean-up and rock dusting, health and safety aspects of tasks, accident prevention, and explosives. Furthermore, unlike part 48, the current training requirements for certified persons do not include training when a supervisor starts work at a new mine.

Given the observed excessive fatality rate and the existing training program for supervisors, MSHA believes that this exclusion needs to be rescinded so that all miners, including supervisory personnel, would receive the training mandated by the Mine Act. This change is consistent with section 3(g) of the Mine Act, which defines "miner" to include "any individual working in a coal or other mine." The legislative history explains that this training should be commensurate with a person's exposure to mine hazards, not the miner's employment status. Supervisory personnel are commonly exposed to the same or similar hazards as are other employees but are exposed to a greater variety of hazards as they are involved in several different workplaces during their workday and they often help out miners in critical or hazardous situations. Therefore, the proposed rule would remove the exclusion in paragraph (a)(1)(ii) of §§ 48.2 and 48.22 and require certified supervisory personnel to receive the complete part 48 training.

Sections 48.2(b) (underground miners) and 48.22(b) (surface miners) define who is an "experienced miner" for purposes of training. MSHA believes that the current definition of an "experienced miner" needs to be simplified. Presently, varying combinations of experience and training are used to determine who is an experienced miner. The complexity has caused some confusion in the mining community.

The present system has resulted in some coal miners losing "experienced" status. Experienced coal miners have found themselves termed and treated as being "inexperienced" or "new" because they had failed to have worked in a mine for 12 months out of the previous 36 months. Consequently, in order to be employed at a mine, these miners must complete an introductory training course that is more suitable for persons without prior mining experience. The reverting of experienced miners to new miner status because they have not worked or maintained their status as an experienced miner has acted to limit their employment opportunities in mining.

The proposed rule would address the problem of miners losing their status as "experienced miners." Under the proposed rule, a miner would become an experienced surface or underground miner by having one year of surface or underground mining experience and, for those miners hired after October 13, 1978, by completing MSHA approved new miner training. Thus, a miner once defined as an experienced miner would remain an experienced miner for training purposes. As appropriate, such miners would receive experienced miner training that recognizes their familiarity with mining fundamentals while focusing on mine-specific training needs.

MSHA believes that a year of mining experience, together with 40 hours (for underground miners) or 24 hours (for surface miners) of new miner training, adequately prepares the miner to deal with mining and its associated safety and health problems. Until the miner attains one year of experience, he or she would be a new miner.

In both the existing and the proposed rule, MSHA approved new miner training would not be required for miners employed on or before October 13, 1978. In addition, all supervisory personnel employed on the date of promulgation of the proposed rule would be considered to be experienced miners.

Sections 48.6 and 48.26 Experienced Miner Training

Sections 48.6 (underground miners) and 48.26 (surface miners) cover the training requirements for experienced miners when they begin work at a mine. The proposed rule would change the present title of these sections from "Training of newly employed experienced miners; minimum courses of instruction" to "Experienced miner training." The proposed rule also would add some new standards to this section and renumber some existing provisions (for example, existing § 48.6(b)(8) would be renumbered § 48.6(b)(12)).

Proposed §§ 48.6(a) and 48.26(a) would incorporate existing policy and clarify MSHA's intention that experienced miner training would apply to transfers, newly hired miners with sufficient experience and training, and miners returning to the mine after an absence of more than 12 months.

Proposed §§ 48.6(b) and 48.26(b) would require the training to be thorough and effective, and the time spent on training to be sufficient to cover the required course material. MSHA has not specified a required number of minimum hours of training because MSHA needs the flexibility to allow operators to tailor their training programs to fulfill their specific needs.

Except for some generic subject matter, such as elements of first aid, this training would be mine-specific. MSHA believes that such training is critically important to acquaint an entering miner with the operations, environment, and hazards at the mine.

The proposal would retain paragraphs 1 through 6 of existing §§ 48.6(b) and 48.26(b), with the exception of paragraph 5 of existing § 48.26(b) which would be modified for clarification. These paragraphs address the following topics: paragraph (b)(1)—introduction to the work environment; paragraph (b)(2)—mandatory health and safety standards; paragraph (b)(3)—authority and responsibility of supervisors and miners' representatives; paragraph (b)(4)—entering and leaving the mine, transportation and communication systems; paragraph (b)(5)—mine map, escapeways, emergency evacuation, and barricading; and paragraph (b)(6)—roof or ground control and ventilation plans (underground miners only), or ground controls; working in areas of highwalls, water hazards, pits, and spoil banks; and illumination and night work (surface miners only).

Proposed paragraph 7 of §§ 48.6(b) and 48.26(b) would be modified so that hazard recognition focuses on the

recognition and avoidance of hazards present at that specific mine.

Proposed paragraph 8 of §§ 48.6(b) and 48.26(b) would be added to require the training to include a comprehensive review of accidents, focusing upon their general causes and prevention but with particular emphasis upon the causes and means of prevention for accidents that have occurred at that mine.

Proposed paragraph 9 of §§ 48.6(b) and 48.26(b) would be added to require the training to include a review of first aid methods.

Proposed paragraph 10 of §§ 48.6(b) and 48.26(b) would be added to require the training to include instruction on the purpose of taking dust, noise, and other health measurements, an explanation of any health control plan in effect at the mine, a review of the health provisions of the Mine Act, and a review of warning labels.

Proposed paragraph 11 of §§ 48.6(b) and 48.26(b) would be added to require the training to include instruction in the health and safety aspects of the tasks to which the miner is assigned.

Proposed paragraph 12 of § 48.6(b) would be the same as existing § 48.6(b)(8) which addresses self-rescue and respiratory devices.

Proposed paragraph 12 of § 48.26(b) would be the same as existing § 48.26(b)(8) which states that other courses may be required by the District Manager based on circumstances and conditions at the mine.

Proposed paragraph 13 of § 48.6(b) would be the same as existing § 48.6(b)(9) which states that other courses may be required by the District Manager based on circumstances and conditions at the mine.

Proposed §§ 48.6(c) and 48.26(c) would be added to permit the operator to include instruction in additional safety and health subjects based on circumstances and conditions at the mine.

New proposed §§ 48.6(d) and 48.26(d) would be added to permit the experienced miner training to be flexible. It would allow the course lengths to vary as needed to provide the most effective learning situation.

New proposed §§ 48.6(e) and 48.26(e) would require experienced miners to complete the new task training required in §§ 48.7 and 48.27, as appropriate.

Proposed §§ 48.6(f) and 48.26(f) would require training to meet the safety and health needs of the miners. Miners with different training and experience backgrounds may require different amounts of training in each subject. Training needs may also vary depending upon circumstances and conditions at the mine. When a miner returns to work after an absence, however, the miner would be required, at a minimum, to receive instruction covering any changes in mine conditions or procedures.

The proposed change in the experienced miner requirements would require the operators to revise their existing training plans to include the additional courses. MSHA would allow operators 90 days after the effective date of these regulations to submit the revised portion of their training plans for approval.

Section 48.8 and 48.28 Annual Refresher Training of Miners; Minimum Courses of Instruction; Hours of Instruction

Paragraph (c) of §§ 48.8 (underground miners) and 48.28 (surface miners) would be revised to require annual refresher training for all supervisory personnel who are certified under an MSHA approved State certification program and who are employed at the mine on the effective date of this rule. To ensure that supervisory personnel become part of the part 48 training cycle, the proposal would require that they receive annual refresher training within 12 months of the last training they received as certified persons under § 75.161 or § 77.107–1.

MSHA believes that requiring supervisory personnel to receive annual refresher training would not impose a significant additional burden on the industry for the following reasons:

(1) As there are no MSHA approved State certification programs for metal and nonmetal supervisory personnel, all metal and nonmetal supervisory personnel are currently required to receive part 48 training;

(2) Many coal mine operators now voluntarily give their "excluded" supervisory personnel the part 48 training—this training is generally comprehensive and satisfies many of the training requirements under parts 75 and 77; and

(3) MSHA proposes to rescind those training provisions in parts 75 and 77 that would be covered by the proposed part 48 training.

Sections 75.161 and 77.107–1 Plans for Training Programs

MSHA is proposing to remove or revise various training provisions in 30 CFR parts 75 and 77 to avoid duplicating the training requirements under part 48. These provisions apply to underground and surface coal mines respectively.

Accordingly, the proposal would amend § 75.161(a) by removing the training requirement for methane measurement and oxygen deficiency testing which is covered under § 48.8(b)(10) (mine gases). It would remove the training requirement for roof and rib control and ventilation which is covered under § 48.8(b)(4) (roof or ground control and ventilation plans). The proposal also would remove § 75.161(c) which requires training in self-contained self-rescue devices because it is covered in § 48.8(b)(8) (self-rescue devices and respiratory devices).

The proposal would revise § 77.107–1(a) by deleting the reference to principles of mine rescue, as this training is covered under existing § 48.28(b)(3) (escape and emergency evacuation plans; firewarning and firefighting).

Section 77.1709 Safety Training; Inexperienced Employees

The proposal would remove § 77.1709 which requires new employees and inexperienced employees to be trained in safety rules and safe work procedures before they begin work at the mine. These requirements are covered under §§ 48.23 (training plans), 48.25 (training of new miners), 48.26 (experienced miner training), and 48.27 (new task training).

MSHA welcomes public comments on all facets of the proposed rule, and encourages commenters to include examples or alternative language where appropriate. The Agency particularly seeks comments on whether time requirements for experienced miner training should be specified in the regulations. MSHA is aware that many operators already specify training times in their training plans. While time requirements do not guarantee quality training, they may be an effective mechanism for setting the times necessary to cover course material.

IV. Executive Order 12291 and Regulatory Flexibility Act

In accordance with Executive Order 12291, MSHA prepared a preliminary regulatory impact analysis (PRIA) to estimate the potential costs and benefits associated with the proposed changes to part 48. In this PRIA, MSHA determined that this rule neither results in major cost increases nor has an effect of $100 million or more on the economy. A copy of the PRIA analysis is available upon request.

MSHA estimated that the annual costs of compliance of the proposed rule would be about $1.8 million. Mine operators would incur first-year costs of about $320,000 to set up new and strengthened training programs.

The number of supervisor and newly employed experienced miner fatalities is higher than their proportion in the mining workforce. MSHA estimates that

compliance with the changes in the proposed rule regarding supervisors and experienced miners would prevent about 6 fatalities annually, 2 to supervisors and 4 to experienced miners.

The Agency has not exempted small mines from any provision of the proposal. Of the approximately 15,000 mine operations affected by the proposed rule, MSHA estimates that about 12,000 are small businesses employing fewer than 20 miners. The average annual costs to a small mine is estimated to be about $115 per mine or about $15 per miner. These costs would not have a significant economic impact on small mines.

The Agency solicits comments and data on how the proposed rule would affect all mines. MSHA requests specific comments on the cost of developing and conducting the training programs required in the proposed rule and on the estimates of the potential effectiveness of these training programs in reducing in number of supervisor and newly employed experienced miner fatalities. In particular, the Agency solicits comments on whether there are additional reasons other than those identified in this proposal that would contribute to the observed excess fatalities occurring to underground coal supervisors and to newly employed experienced miners.

List of Subjects in 30 CFR Parts 48, 75, and 77

Education, Miner training, Mine safety and health.

Dated: September 16, 1991.

William J. Tattersall,

Assistant Secretary for Mine Safety and Health.

A. It is proposed to amend chapter I, title 30 of the Code of Federal Regulations as follows:

PART 48—TRAINING AND RETRAINING OF MINERS

1. The authority citation for part 48 continues to read as follows:

Authority: 30 U.S.C. 811 and 825.

2. Section 48.2 is amended by removing paragraph (a)(1)(ii), and redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(ii).

3. Section 48.2 is amended by revising paragraph (b) as follows:

§ 48.2 Definitions.

* * * * *

(b) *Experienced miner* means, except as otherwise provided in this paragraph, a miner who has had at least 12 months of underground mining experience and has completed MSHA approved new miner training for underground miners given by an operator or State. For a miner employed as an underground miner on or before October 13, 1978, "experienced miner" means a miner who has had at least 12 months of underground mining experience. Supervisory personnel who are certified under an MSHA approved State certification program and who are employed as underground supervisory personnel on the date of the promulgation of this revision are *experienced miners.*

* * * * *

4. Section 48.6 is amended by revising paragraphs (a), (b) introductory text, (b)(7)–(9) and adding paragraphs (b)(11)–(13), (c), (d), (e) and (f) to read as follows:

§ 48.6 Experienced miner training.

(a) Except as provided in paragraph (f), this section applies to experienced miners who are—

(1) Newly employed by the operator;

(2) Transferred to the mine;

(3) Transferred from surface to underground; or

(4) Returning to the mine after lay-off, work stoppage, illness, or injury resulting in an absence of more than 12 months.

(b) Experienced miners shall complete the training prescribed in this section before beginning work duties. The training shall be thorough and effective and shall include the following instruction:

* * * * *

(7) *Hazard recognition.* The course shall include the recognition and avoidance of hazards present in the mine.

(8) *Prevention of accidents.* The course shall include a review of accidents; general causes of accidents; causes of specific accidents at the mine; and instruction in accident prevention in the work environment.

(9) *First aid.* The course shall include a review of first aid methods acceptable to MSHA.

(10) *Health.* The course shall include instruction on the purpose of taking dust, noise, and other health measurements. Any health control plan in effect at the mine shall be explained. The course shall review the health provisions of the Act. Warning labels shall be addressed.

(11) *Health and safety aspects of the tasks to which the experienced miner is assigned.* This course is required for experienced miners who are not immediately required to receive task training as required by § 48.7 of this subpart. The course shall include instruction in the health and safety aspects of the tasks assigned, the safe work procedures of such tasks, and the mandatory health and safety standards pertinent to such tasks.

(12) *Self-rescue and respiratory devices.* The course shall include instruction and demonstration in the use, care, and maintenance of self-rescue and respiratory devices used at the mine. Training in the use of self-contained self-rescue devices shall include complete donning procedures in which each person assumes a donning position, opens the device, activates the device, inserts the mouthpiece or simulates this task while explaining proper insertion of the mouthpiece, and puts on the nose clip.

(13) Such other courses as may be required by the District Manager based on circumstances and conditions at the mine.

(c) The operator may include instruction in additional safety and health subjects based on circumstances and conditions at the mine.

(d) The time spent on instruction of individual subjects shall vary depending upon the training needs of the miners.

(e) Experienced miners shall also complete new task training as required in § 48.7, as appropriate.

(f) When an experienced miner returns to the mine after having not worked at the mine for 12 months or less, the operator shall provide the miner with the training specified in this paragraph before that miner begins work duties. This training shall cover, at a minimum, any changes in mine conditions or procedures that occurred during the time the miner was not working at the mine. This training shall include the annual refresher training required under § 48.8 if the miner missed taking such scheduled training during the time the miner did not work at the mine.

5. Section 48.8 is amended by revising paragraph (c) to read as follows:

§ 48.8 Annual refresher training of miners; minimum courses of instruction; hours of instruction.

* * * * *

(c) All supervisory personnel who are certified under an MSHA approved State certification program and who are employed at the mine on the effective date of this part 48 revision shall receive refresher training required by this section not more than 12 months after the date of the last training received as required by § 75.161(a) of this title. If this training is due within 30 days of the effective date of this revision, refresher

training shall begin not more than 31 days after the effective date.

* * * * *

§ 48.22 [Amended]

6. Section 48.22 is amended by removing (a)(1)(ii) and redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(ii).

7. Section 48.22 is amended by revising paragraph (b) as follows:

§ 48.22 Definitions.

* * * * *

(b) *Experienced miner* means, except as otherwise provided in this paragraph, a miner who has had at least 12 months of surface mining experience and has completed MSHA approved new miner training for surface miners given by an operator or a State. For a miner employed as a surface miner on or before October 13, 1978, *experienced miner* means a miner who has had at least 12 months of surface mining experience. Supervisory personnel who are certified under an MSHA approved State certification program and who are employed as surface supervisory personnel on the date of the promulgation of this revision are *experienced miners.*

* * * * *

8. Section 48.26 is amended by revising paragraphs (a), (b) introductory text, (b)(5), (b)(7), and (b)(8), and adding paragraphs (b)(9)–(12), (c), (d), (e) and (f) to read as follows:

§ 48.26 Experienced miner training.

(a) Except as provided in paragraph (f), this section applies to experienced miners who are—

(1) Newly employed by the operator;

(2) Transferred to the mine;

(3) Transferred from underground to surface; or

(4) Returning to the mine after lay-off, work stoppage, illness, or injury resulting in an absence of more than 12 months.

(b) Experienced miners shall complete the training prescribed in this section before beginning work duties. The training shall be thorough and effective and shall include the following instruction:

* * * * *

(5) Escape and emergency evacuation plans; firewarning and firefighting. The course shall include a review of the mine escape system; escape and emergency evacuation plans in effect at the mine; and instruction in the firewarning signals and firefighting procedures in effect at the mine.

* * * * *

(7) Hazard recognition. The course shall include the recognition and avoidance of hazards present in the mine.

(8) Prevention of accidents. The course shall include a review of accidents; general causes of accidents; causes of specific accidents at the mine; and instruction in accident prevention in the work environment.

(9) First aid. The course shall include a review of first aid methods acceptable to MSHA.

(10) Health. The course shall include instruction on the purpose of taking dust, noise, and other health measurements. Any health control plan in effect at the mine shall be explained. The course shall review the health provisions of the Act. Warning labels shall be addressed.

(11) Health and safety aspects of the tasks to which the experienced miner is assigned. This course is required for experienced miners who are not immediately required to receive task training as required by § 48.27. The course shall include instruction in the health and safety aspects of the tasks assigned, the safe work procedures of such tasks, and the mandatory health and safety standards pertinent to such tasks.

(12) Such other courses as may be required by the District Manager based on circumstances and conditions at the mine.

(c) The operator may include instruction in additional safety and health subjects based on circumstances and conditions at the mine.

(d) The time spent on instruction of individual subjects shall vary depending upon the training needs of the miners.

(e) Experienced miners shall also complete new task training as required by § 48.27, as appropriate.

(f) When an experienced miner returns to the mine after having not worked at the mine for 12 months or less, the operator shall provide the miner with the training specified in this paragraph before that miner begins work duties. This training shall cover, at a minimum, any changes in mine conditions or procedures that occurred during the time the miner was not working at the mine. This training shall include the annual refresher training required under § 48.28 if the miner missed taking such scheduled training during the time the miner did not work at the mine.

9. Section 48.28 is amended by revising paragraph (c) to read as follows:

§ 48.28 Annual refresher training of miners; minimum courses of instruction; hours of instruction.

* * * * *

(c) All supervisory personnel who are certified under an MSHA approved State certification program and who are employed at the mine on the effective date of this part 48 revision shall receive refresher training required by this section not more than 12 months after the date of the last training received as required previously by § 77.107–1 of this title. If this training is due within 30 days of the effective date of this revision, refresher training shall begin not more than 31 days after the effective date.

* * * * *

§§ 48.6, 48.22, 48.25, 48.26 [Amended]

All references to "training of newly employed experienced miners" are revised to read "experienced miner training," in the following sections: Section 48.6 (section heading) § 48.22 (a)(1), § 48.25(d) and § 48.26 (section heading).

B. It is proposed to amend part 75 of chapter I, title 30 of the Code of Federal Regulations as follows:

PART 75—MANDATORY SAFETY STANDARDS—UNDERGROUND COAL MINES

1. The authority citation for part 75 continues to read as follows:

Authority: 30 U.S.C. 811, 957, and 961.

2. Paragraph (a) of § 75.161 is revised to read as follows:

§ 75.161 Plans for training programs.

* * * * *

(a) For certified persons, annual training courses in first aid, principles of mine rescue, and the provisions of this part 75;

* * * * *

§ 75.161 [Amended]

3. Section 75.161 is amended by removing paragraph (c).

C. It is proposed to amend part 77 of chapter I, title 30 of the Code of Federal Regulations as follows:

PART 77—MANDATORY SAFETY STANDARDS, SURFACE COAL MINES AND SURFACE WORK AREAS OF UNDERGROUND COAL MINES

1. The authority citation for part 77 continues to read as follows:

Authority: 30 U.S.C. 811, 957, and 961.

2. Section 77.107–1 is revised to read as follows:

§ 77.107–1 Plans for training programs.

On or before September 30, 1971, each operator shall submit to the District Manager of the Coal Mine Safety and

Health District in which the mine is located a program or plan setting forth what, when, how, and where the operator will train and retrain persons whose work assignments require that they be certified or qualified. The program shall provide—

(a) For certified persons, annual training courses in the tasks and duties which they perform as certified persons, first aid, and the provisions of this part 77; and

(b) For qualified persons, annual courses in performance of the tasks which they perform as qualified persons.

§ 77.1709 [Removed]

3. Section 77.1709 is removed and reserved.

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federal register

Tuesday
September 24, 1991

Part VII

Department of Transportation

Urban Mass Transportation Administration

49 CFR Part 663

Pre-Award and Post-Delivery Audits of Rolling Stock Purchases; Final Rule

DEPARTMENT OF TRANSPORTATION

Urban Mass Transportation Administration

49 CFR Part 663

[Docket No. 88-H]

RIN 2132-AA29

Pre-Award and Post-Delivery Audits of Rolling Stock Purchases

AGENCY: Urban Mass Transportation Administration (UMTA), DOT.

ACTION: Final rule.

SUMMARY: This final rule requires pre-award and post-delivery audits of rolling stock purchased with Federal financial assistance under the Urban Mass Transportation Act of 1964, as amended. Section 319 of the Surface Transportation and Uniform Relocation Assistance Act of 1987 (the STURAA) requires UMTA to issue regulations to ensure that federally funded vehicles meet Federal motor vehicle safety requirements, Federal "Buy America" requirements, and a grantee's bid specifications.

DATES: This rule is effective October 24, 1991. It applies to funds obligated by UMTA on and after October 24, 1991.

FOR FURTHER INFORMATION CONTACT: Albert L. Neumann, Senior Mechanical Engineer, Office of Grants Management, (202) 366–1638; or Theodore A. Munter, Deputy Chief Counsel, Office of Chief Counsel (202) 366–1936.

SUPPLEMENTARY INFORMATION:

Outline

This preamble is divided into a number of different sections, briefly outlined below.

I. Background
II. Summary of the NPRM
III. Summary of the Final Rule
IV. Public Comments
V. Issues Raised in Comments
  A. Buy America Audits
  B. Specification Audits
  C. Federal Motor Vehicle Safety Standards
  D. Financial Impacts
  E. Definitions
  F. Effect on Other Federal Regulations
VI. Section-by-Section Analyses
VII. Availability of Final Rule
VIII. Regulatory Impacts
  A. Executive Order 12291
  B. Regulatory Evaluation
  C. Regulatory Flexibility Act
  D. Paperwork Reduction Act
  E. Executive Order 12612; New 49 CFR Part 663

I. Background

The quality of mass transportation service depends in large part on the quality of the equipment used. Inspection of equipment at the time of its purchase for compliance with the buyer's requirements is essential to ensuring the proper use of Federal financial assistance. UMTA requires a recipient of Federal financial assistance to provide adequate technical inspection of all work in progress when it purchases equipment. UMTA permits this inspection to be done directly by the recipient or through technical consultants. The cost of the technical inspection has always been eligible for UMTA funding. Additionally, UMTA requires that recipients comply with all the terms of their grant agreements, applicable statutes, codes, ordinances and safety standards.

Because Congress was concerned about the quality of mass transportation equipment purchased with Federal financial assistance, and the inspection and verification procedures used in the procurement process, the Surface Transportation and Uniform Relocation Assistance Act of 1987 (the STURAA), Public Law 100–17, mandated pre-award and post-delivery audits with respect to any UMTA grant for the purchase of buses or other rolling stock. Specifically, section 319 of STURAA directs UMTA (as delegated from the Secretary) to require pre-award and post-delivery audits to ensure compliance with Federal motor vehicle safety requirements, the Buy America requirements of section 165 of the Surface Transportation Assistance Act of 1982, as amended, and the recipient's own specified solicitation specifications. Additionally, section 319 provides that UMTA must require independent inspection and audits, noting that a manufacturer's certification of compliance with certain requirements is not sufficient. This final rule implements section 319.

II. Summary of the Notice of Proposed Rulemaking (NPRM)

On October 18, 1988, UMTA published an NPRM in the **Federal Register** in connection with the requirements of section 319 of the STURAA. To make the regulation comprehensive, the NPRM proposed to extend the applicability of the requirements to two other programs funded by the agency: The interstate transfer provision (23 U.S.C. 103(e)(4)), and funding for the Washington, DC, Metrorail system (section 14 of the National Capital Transportation Act of 1969, as amended).

The NPRM applied to rolling stock in revenue service, affecting procurement of buses, vans, cars, railcars, locomotives, trolley cars and buses, ferry boats, and vehicles for fixed guideways and incline planes. The NPRM did not affect the procurement of vehicles used for maintenance purposes, or other rolling stock not used to carry fare-paying passengers. While Congress made it clear that a certification of an audit from a manufacturer would not meet the requirements of section 319, language in the bill's Conference Report also provided that "(i)t is the intent of the Conferees that any paperwork requirements imposed by this provision will not create a significant cost burden." (House Report 100–27, p. 231.) In an effort to limit the cost burden on grantees, the NPRM proposed allowing the use of certifications by the grantee with independent support documentation wherever possible, similar to other self-certifications UMTA currently uses under the Section 9 program. The NPRM essentially proposed that a recipient conduct the Buy America and bid specification audits, and seek independent verification of motor vehicle safety compliance.

III. Summary of Final Rule

The final rule requires a recipient who will purchase revenue rolling stock with funds obligated by UMTA on or after October 24, 1991, to certify to UMTA that it has or will conduct a pre-award and post-delivery audit to assure compliance with its bid specifications, Buy America, and Federal Motor Vehicle Safety requirements.

Beyond this certification to UMTA, a recipient is required to keep on file separate certifications it makes regarding compliance with Buy America and bid specifications. In addition, such a recipient also is required to keep on file a certification that it received from the manufacturer of the vehicle certification information required to meet Federal Motor Vehicle Safety Standards or a certification from the manufacturer that such standards are inapplicable (except for rolling stock other than motor vehicles, in which case no such certification is necessary). These certifications that are kept on file will be reviewed by UMTA during the triennial review process, or in response to specific complaints.

With regard to the Buy America audit, if a manufacturer is unwilling to share its cost data with a recipient, some other alternative would be necessary to perform the audit. In such cases, UMTA expects that some third party separate from the manufacturer would perform the audit, which would then form the basis for the recipient's certification. Regarding the bid specifications audit, the final rule requires, for UMTA-funded

procurements of 10 or more buses or any number of railcars or other rolling stock, that a resident inspector be at the site of the manufacture of the vehicles throughout their construction. At the conclusion of the construction the inspector would prepare a report describing how the vehicles meet the bid specifications. This report, along with a visual inspection and road test of the buses when delivered to the recipient, would form the basis for the recipient's post-delivery bid specification certification. For procurement of 10 or fewer buses, or for procurements of any number of unmodified vans sold by the major automobile companies, no resident inspector is required. Rather, a recipient would make its certification after visually inspecting and road testing the vehicles after their delivery.

The final rule applies to purchases of revenue rolling stock under sections 3, 9, 16(b)(2), and 18 of the UMT Act, grants under the interstate transfer-transit program, and funding of the Washington, DC Metrorail system.

V. Public Comments

General Overview

UMTA received 50 comments in response to the NPRM, as follows:

Transit systems	25
State DOTs	11
Cities and counties	2
Trade associations	4
Suppliers and manufacturers	5
Consultants	2
Members of Congress	1

In general, the commenters supported the goals of section 319 of STURAA and UMTA's efforts to achieve safety, Buy America and bid specification compliance in the NPRM. However, most commenters objected to the actual implementation scheme proposed. The commenters found the requirements to be overly burdensome, redundant, and costly.

The discussion below separately addresses these concerns with respect to the Buy America, bid specification, and motor vehicle safety standard requirements. Each of these three areas raises somewhat unique issues, and each is discussed separately. The discussion also addresses other issues raised, including exempting cars and vans from the NPRM's safety certification requirement, the availability of sanctions against noncomplying contractors, shifting legal liability from manufacturers to recipients, and protection of proprietary information.

V. Issues Raised in the Comments

A. Buy America Audits

In the NPRM, UMTA proposed that the Buy America audits be made by a person who is not an agent or employee of the manufacturer, and that such an audit would be the basis for a recipient to certify to UMTA that the equipment meets the applicable Buy America requirements. The NPRM noted that before a person could make this certification he or she must have reviewed documentation provided by the manufacturer as to the cost of the components and any subcomponents of the rolling stock, their country of origin and the location of final assembly and the activities that will take place at the location. UMTA anticipated that these audits were likely to be done by independent contractors, since the information that must be reviewed is generally considered proprietary.

Overview. Twenty-four commenters addressed a variety of concerns about the NPRM Buy America certification provisions. The commenters greatest concerns were the disclosure of proprietary information and the financial impact of the requirements on recipients and manufacturers. The commenters also questioned the practicability of the NPRM's provisions, that is, requiring a pre-award and a post-delivery Buy America certification; the lack of guidelines for conducting the certifications; the potential for disputes when different transit agencies issue conflicting certification reports for the same vehicle; and whether the penalty provisions were strong enough to ensure compliance. These concerns are discussed in greater detail below.

Disclosure of Proprietary Information. Seven commenters discussed this issue. Both the pre-award and post-delivery requirements would prohibit manufacturers' employees and agents from performing the certifications. Recipients thus could do the certifications in-house or hire independent consultants to perform the audits. According to the commenters, both alternatives had drawbacks.

A few recipients indicated they would perform the Buy America certifications in-house. The majority of commenters, however, stated that they would have to contract out this requirement to consultants because they either lacked the expertise or did not have sufficient personnel to do the certifications.

Several manufacturers and suppliers, on the other hand, stated that they would file legal protests against any requirements to disclose cost breakdown information to recipients before finalizing a contract between them. Their opposition had three bases. First, they argued that recipients should not have the right to access such information when procurements were handled through sealed bids. Second, they contended that disclosure could cause disputes between prime contractors and sub-contractors as well as between prime contractors and recipients if problems or delays occurred before contract finalization. Third, they argued that disclosure could jeopardize contractors' ability to compete effectively on future contracts because recipients and competitors might have access to information from which they could determine how these contractors operate and develop their bids.

Commenters generally preferred either having independent contractors perform the certifications or having UMTA certify manufacturers compliance with Buy America on a nationwide basis. Because they believed using independent consultants would be expensive, particularly for smaller transit agencies, recipients and manufacturers both favored UMTA certification. They contend that UMTA certification provided other advantages as well, including the assurance of independent certifications, reduced paperwork and other administrative burdens on recipients, provision of a centralized source of information on manufacturers whose products meet Buy America standards, elimination of potential disputes regarding compliance, and minimal duplication of effort.

Practicability. Many of the criticisms of the Buy America audit requirements involved their alleged impracticability. For example, one commenter, a consultant with forty years experience at a major motor vehicle manufacturer's truck and coach division, said that Buy America compliance could only be ensured by checking the origin of every part and visually inspecting final assembly operations of all manufacturers.

This commenter believed Buy America certifications would be extremely complex because of the number of parts and suppliers involved, estimating that buses may contain as many as 18,000–20,000 parts. The effort necessary for a meaningful certification, he concluded, would be extremely burdensome in terms of administrative and economic costs. The commenter also said that limiting the inspection requirement to "first tier"components, such as basic engine, compressor and muffler, would still leave approximately 5,000 parts numbers to be checked.

The same commenter estimated that between 200 and 500 suppliers are involved in any given procurement, each of whom would have to supply information about the parts sold to the prime contractor. If so, he concluded that the process of certifying compliance for more complex vehicles would take approximately 50 workdays, or 400 hours, to complete.

Vans, having many fewer parts to inspect, would probably only require 5 workdays, or 40 hours, to certify.

Pre-Award Certification. Other commenters also contended that the magnitude of the NPRM's Buy America certification process made the pre-award requirements impossible to fulfill. They used the time frame established by § 663.21 to make their point. Section 663.21 would require recipients to complete their pre-award Buy America certification before entering into a formal contract with the vendor. In contrast, the commenters said, normal industry practice permits the parties to delay negotiation on final design specifications until after the contract has been granted. Within this context, they argued that any pre-award Buy America certification would be meaningless.

These commenters were concerned that the procurement process could be delayed for months if Buy America compliance were required to be made at the subcomponent level. Some contended that such a requirement would be extremely harmful to recipients required to complete the bid process within a mandatory time frame. The commenters contended that when mandatory deadlines are exceeded, recipients can be required to repeat the entire bid process. Suppliers and manufacturers, on the other hand, argued that sub-component certification would be harmful to them because they would have to hold bids open longer. They said this would adversely affect their liquidity and their ability to bid on other procurements, ultimately driving up costs for everyone.

Second, manufacturers noted that the NPRM's Buy America requirements restricted their ability to make needed design changes or to substitute parts because of the potential effect of any such change on the final product's overall Buy America compliance.

Third, commenters objected to the absence of guidelines in applying the NPRM's Buy America provisions. Specifically, the commenters wanted UMTA to specify whether certification was limited to "first tier" components or extended to the subcomponent level and whether Buy America auditors were required to have particular qualifications.

Fourth, commenters wanted guidance on sharing certification/waiver information and on compliance disputes resolution. Recipients therefore requested the agency to develop a system to disseminate information on earlier certifications and existing manufacturers' Buy America waivers and a methodology for resolving compliance disputes.

Fifth, commenters criticized the NPRM's provisions for requiring both a pre-award and a post-delivery Buy America certification. The commenters characterized this as "costly and duplicative overkill," noting that the statute requires a double check on compliance not primary compliance verification. The commenters contended that section 319 of STURAA could be equally well-served by permitting self-certification at the pre-award stage and using independent reviews and visual inspections at the post-delivery audit stage.

Commenters' Suggestions. Several commenters suggested that UMTA undertake a nationwide manufacturer certification program. A Congressman, for example, called for UMTA to take a larger part in the pre-award audits for both Buy America and FMVSS compliance.

Other commenters suggested that recipients should be allowed to rely on other recipients' certifications as long as no significant changes were made to the vehicle design and final assembly process. Alternatively, other commenters believed that if such a practice were adopted it would lead to disputes when transit agencies differed about whether or not the "same" vehicle complied with Buy America requirements or not.

In the latter group's opinion, the NPRM did not address the question of how to resolve such disputes adequately. One commenter asked if disputants would have recourse to UMTA. Two others suggested establishing a dispute resolution committee within the transit industry which would have the authority to make binding determinations in such disputes. A fourth commenter, on the other hand, stated that the potential for such disputes was another reason why UMTA should provide nationwide Buy America certifications.

Finally, two commenters suggested that a "public necessity" waiver be instituted. They argued that such waivers could permit rolling stock with minor Buy America deviations to be used in revenue service while preserving the manufacturer's duty to correct deviations, which would permit recipients to put needed rolling stock into revenue service without passing title before the required changes were made.

Post-delivery Certifications. Post-delivery certification requirements had their own drawbacks according to the commenters. For example, one large transit agency pointed out that the NPRM's prohibition on accepting uncertified vehicles punished recipients rather than manufacturers, at least when rail rolling stock procurements were involved, because railcar procurement contracts generally provide for periodic payments of up to 80 percent of the contract price during manufacture. The transit agency argued that this practice diminishes manufacturers' incentive to correct deviations and that its negative effects on recipients would be increased by the NPRM's prohibitions against recipients accepting delivery of needed revenue rolling stock. The transit agency therefore encouraged UMTA to strengthen the penalties available to recipients and to permit "post-delivery" certifications to begin earlier.

Another large transit agency also contended that the NPRM's post-delivery certification requirement came too late in the procurement process. This transit agency argued that quarterly reviews during manufacture would ensure compliance and minimize delays in accepting final delivery and getting rolling stock into service.

The criticisms raised by these two transit agencies were echoed by a third, which also called for earlier post-delivery reviews because of the non-acceptance requirement imposed on recipients in § 663.39(a).

Sanctions. Four transit agencies commented on the issue of appropriate penalties against non-complying manufacturers. All were concerned that the NPRM's provisions, contained in § 663.39(a), harmed transit agencies as much as the manufacturers by increasing delays and costs, especially for large orders. According to one commenter, the NPRM appeared to require completed certification for all items before final delivery could be made for any item.

Commenters' Suggestions. Commenters made several suggestions for improving the proposals in the NPRM. One was to provide for UMTA-wide debarment. Another was to require manufacturers to post surety bonds whenever compliance disputes arose, which would cover the cost of the non-complying material, the cost to replace it with complying material, and a penalty of up to 100% of these costs to be

imposed at the grantees's discretion. The commenters' third suggestion was to allow recipients to put non-complying vehicles into revenue service but withhold payment until deviations were corrected. Lastly, they asked that § 663.39 be clarified to indicate that recipients could seek any remedies available under the contract or by law.

UMTA Response. While recognizing the many comments on the issue of cost and practicability involved in requiring a recipient to perform Buy America audits, UMTA has decided that the final rule should continue to require, as the NPRM proposed, that the recipient be responsible for performing the Buy America audits of rolling stock purchased with UMTA funds. UMTA believes this approach is consistent with the statute, the requirement that the recipient also perform bid specification audits (discussed below), and best assures compliance with Buy America by requiring the actual purchasers of the rolling stock to be responsible for making certain that the vehicles meet the statutory Buy America requirements.

Regarding consistency with the statute, neither the law nor its legislative history indicate who is to be responsible for the audits. Rather, the statute provides that manufacturer certification is not sufficient, "* * * and independent inspections and auditing shall be required."

We believe it is clear, however, that the bid specification audit (discussed below) should be done by the grantee. Indeed, even in the absence of this statutory provision it is sound business practice—if not a contract requirement—that a recipient carefully review a vehicle it is purchasing to make certain the vehicle complies with the specifications set forth in the bid. If Congress did not mean for UMTA or a national contractor to perform these bid specification audits, it is not unreasonable to apply this same standard to the other audits required by the statute: Those for Buy America and compliance with Federal motor vehicle safety standards (discussed below). UMTA believes that there would be considerable administrative difficulties to require a recipient to perform only two of the audits, with UMTA responsible for the other. Moreover, had Congress meant for UMTA to perform the audits it could have explicitly so required. Accordingly, the agency is requiring a recipient to be responsible for each of the audits.

We recognize that this could involve costs that in some instances could be considerable. As the docket notes, a manufacturer can be expected to be reluctant to share proprietary cost data with a recipient involving the very vehicle that the manufacturer is bidding on. Thus the recipient may have to use an independent third party contractor to perform the audit—and assure the manufacturer that the cost data will be kept confidential. It is important to note, however, that the final rule does not require a recipient to hire a third party to perform the Buy America audit. Rather, the rule recognizes that this is an option that is likely to be often used. On the other hand, a recipient itself could perform the audit if a manufacturer was willing to provide cost information to the recipient.

In this connection, a recipient might be able to keep its Buy America audit function independent by using a "Chinese wall" and assuring the manufacturer that those workers of the recipient performing the Buy America audit are prohibited from disclosing any of the manufacturer's propriety data to anyone working for the recipient. In fact, UMTA particularly encourages manufacturers and grantees involved in a small number of vehicle purchases to use this method to avoid the additional cost of hiring an outside auditor.

UMTA also encourages recipients to share their Buy America audits with each other, or to join together on related vehicle buys and share the cost of the audit function. UMTA would respond on a case-by-case basis to requests to determine whether a previously-audited vehicle that is being purchased by another recipient with some minor modification, would require a new audit.

In response to those comments about the difficulty of performing the Buy America audits, it is important to note that this is a congressional requirement designed to assure compliance with the Buy America statute. Thus, a recipient must be able to certify to UMTA that its rolling stock purchases comply with the Buy America regulation (49 CFR part 661). This congressional mandate was in response to a belief that recipients and manufacturers in some cases were not able to assure total compliance with Buy America requirements, and that an audit in each case would be necessary to assure such compliance. Nor does UMTA believe that such audits necessarily will be unduly burdensome and complicated. In response to complaints UMTA or its contractors have carried out such audits by reviewing manufacturer documentation to determine whether the regulation was being complied with. These audits can be performed in a timely fashion and do not have to cover an unduly large number of components and subcomponents.

The Joint Explanatory Statement of the Conference Committee accompanying the STURAA (Conference Report) (H.R. Rep. No. 27, 100th Cong., 1st Session (1987)), points out that the relevant provisions of the STURAA are intended to cover only the "major components" and "primary subcomponents" listed therein. Therefore, a manufacturer's compliance with the Buy America requirements and the recipient's audit of such compliance, may be limited to these major components and subcomponents, following, inasmuch as possible, the listing provided in the Conference Report and reflected in the Buy America regulation (49 CFR part 661). The audit should list the name and address of each component and subcomponent supplier and the cost of each item, and should provide the overall percentage, by cost, of domestic and foreign parts. Of course, the list presented to the recipient may, in order to protect proprietary information, not reflect the actual cost of items but rather their percentage of the total vehicle cost. After reviewing the audit report, the recipient would certify on the basis of it that the requirements of 49 CFR part 661 have been met, and would keep that certification on file. The audit should also address where final assembly of the vehicles occurred. A recipient of course should make its certification only after it is fully satisfied that the Buy America requirements have been met, and should seek further information or documentation from the manufacturer or auditor if it has reason to question the sufficiency of the documentation it has.

In response to concerns about sanctions, we have revised § 663.39 to make it clear that if the recipient or its agent cannot certify Buy America or bid specification compliance, the recipient is not required to finally accept the rolling stock and may exercise any legal rights it has under the contract or at law. This provision, however, specifically states that it does not prevent a recipient and manufacturer from agreeing to a conditional acceptance of rolling stock pending manufacturer's correction of deviations within a reasonable period of time.

B. Purchaser's Requirements Certification

Overview. Sixteen commenters addressed a variety of concerns related to part 663's purchaser requirements certification provisions. In the NPRM, UMTA had proposed that a recipient be responsible for assuring compliance with its own specifications. Several commenters stated that the pre-award

provisions were unworkable and several believed post-delivery operational testing requirements should be limited. On the other hand, many endorsed the idea of doing post-delivery visual inspections on all rolling stock. Costs were not emphasized, in contrast to the concern they caused with respect to the FMVSS and Buy America certifications. Commenters were very concerned, however, that the NPRM lacked flexibility with respect to the acceptability of post-award changes and minor deviations, and about the extent of operational testing and visual inspection required. Some were also concerned about compliance disputes resolution, penalties, and the conflict between the NPRM's post-delivery requirements and rail rolling stock procurement practices.

Deviations. Four commenters criticized the NPRM's pre-award provisions, stating that they were in irreconcilable conflict with actual procurement practices. The NPRM's § 663.21 required pre-award certification to be complete before contract finalization while § 663.29 required the auditor to certify that the recipient was agreeing to purchase the same item set out in the bid specifications. The commenters explained that, in contrast to these requirements, current practice set out relatively general specifications in the IFB or RFP, that the recipient and vendor determined final design specifications during negotiations after the initial contract award, and that the vendor did not select its subcontractors until the final design specifications were agreed upon. The commenters argued that the time frames for the pre-award certification and these industry practices were in direct conflict, and in their opinion the NPRM's requirements could not be satisfied.

Two commenters were concerned about the authority to be given independent auditors. They feared that auditors could become overly concerned about minor deviations and might halt or delay production until deviations were corrected. They worried that such actions would increase costs and delay introduction of new vehicles into revenue service. Commenters did not argue that the post-delivery certifications were impossible. They did, however, make a number of suggestions for improving the provisions to minimize delays and cut costs, which are discussed below.

Six commenters raised the issue of the NPRM's rigidity with respect to later post-award modifications and deviations from bid specifications due to unavailability of parts or changes in technology. They asked that § 663.37's language be changed to reflect the acceptability of substituted parts or the incorporation of new technology. They also asked UMTA to set guidelines for accepting rolling stock with minor deviations.

One commenter suggested revising § 663.37's language to require certification that "rolling stock is in all material respects the same item set out in the contract document." The commenter contended that revising the language in this manner would allow transit agencies to certify rolling stock even when minor deviations were present and clarified that transit agencies could rely on all contract documents for the post-delivery certification, including bid specifications, final design requirements, and change orders.

Commenters also asked that § 663.37 be modified to permit them to perform post-delivery related inspections while the rolling stock was still at the manufacturing plant. They argued that this would eliminate transportation costs to and from the recipient and shorten any delay before the vehicles were placed in revenue service.

Testing and Inspections. Six commenters were concerned about the operational testing and visual inspection requirements imposed by § 663.37. One believed the operational testing requirement was unnecessary and would substantially increase costs. That commenter preferred limiting certification requirements to visual inspection of one prototype vehicle. Two others believed that post-delivery operational testing was acceptable if limited to one vehicle, unless major changes were made to subsequent vehicles on the same procurement. A fourth commenter argued that the NPRM's post-delivery certification came too late to be effective. That commenter proposed requiring periodic checks on compliance from the time the vendor was given notice to proceed throughout the entire manufacturing process until final delivery. The commenter also argued that deviations would be caught when they could most easily be corrected and that this would cut down on post-delivery delays and associated costs. The last two commenters favored post-delivery visual inspection of all vehicles to ensure compliance.

Rail Rolling Stock. Another commenter was concerned that post-delivery certification came too late to serve any useful purpose for rail rolling stock purchases. The primary sources of the commenter's concern apparently centered on manufacturers' accountability for correcting deviations in light of the complexity involved in building railcars together with the practice in rail rolling stock procurements of making periodic payments of up to 80 percent of the contract price prior to delivery. This commenter also preferred periodic inspections during the manufacturing process.

Sanctions. One commenter was concerned that § 663.39(b)'s language was not broad enough. The commenter suggested modifying this subsection to clarify that all other applicable legal and contract remedies were available. The commenter also suggested modifying the section to permit recipients to recover both the cost of deviating materials and the cost of correcting the deviations.

UMTA's Response. After careful evaluation of the commenters' concerns regarding the NPRM's bid specification provisions, and its own re-assessment of section 319, UMTA has concluded the following.

First, commenters were unduly concerned about the NPRM's pre-award bid specification provisions. The NPRM's §§ 663.21 and 663.29 were relatively general in their requirements. The NPRM did not require detailed design specifications or prototype vehicles at this stage. The NPRM's only requirement was sufficient congruency between the recipient's bid specifications and the vendor's proposal to support certification that the recipient was purchasing what it asked for in its bid specifications. For example, if bid specifications called for ten diesel-powered, air conditioned buses with seating capacity for forty people, and the contractor's proposal documentation met these requirements at the pre-award stage, the auditor could certify compliance. Furthermore, subsequent agreement to use a particular type of seat or seat covering, or a change order to increase seating capacity to forty-two, would not negate the validity of the original pre-award certification. In light of what we perceive as a misconception of the NPRM's requirements, we have therefore concluded that it is unnecessary to revise the provisions to accommodate a nonexistent time frame conflict. In our opinion, the pre-award certification should flow directly from the recipient's pre-award determination of which vendors are responsive and responsible bidders. We have, however, added a requirement that the pre-award certification include a statement that the manufacturer is capable of constructing the vehicles.

Second, we believe that commenters' concern regarding the acceptability of

minor deviations and the threat of delays due to auditors' stop orders was also misplaced for two reasons. First, § 663.39(b) gave recipients the discretion to accept or reject rolling stock which could not be certified due to deviations from the contract's terms. Second, auditors, whether in-house or independent, act as agents of the recipient and the recipient therefore can develop its own criteria for accepting minor deviations or requiring auditors to consult with it before taking any action to halt or delay production. UMTA believes that decisions on how deviations from specification terms should be dealt with are better left to the recipient and auditor. We therefore do not deem it necessary to set guidelines for accepting minor deviations or to modify § 663.37's provisions as suggested.

Third, the NPRM's § 663.37 specified that compliance would be determined in accordance with the terms of the contract, not the terms of the pre-award bid specifications. We have revised this in the final rule, however. Because change orders or modifications normally are reflected in the specifications, compliance certification should be based upon the contract specifications, including any changes reflected in those specifications.

Fourth, we have changed our position with respect to the issue of operational testing and visual inspection requirements. While the NPRM left to the recipient the issue of whether in-plant inspection was necessary, we have decided in the final rule to require the recipient to have an in-plant inspector at the manufacturer site for any procurements of ten or more buses or any number of rail cars or other rolling stock. This is consistent with the statute, which provides that "* * * independent *inspections* and auditing shall be required." (Emphasis supplied.)

This is also a good business practice that has long been encouraged by UMTA in its grant management circulars. In fact, most recipients already use some form of in-plant inspection in their rolling stock procurements. A recipient could join with other recipients purchasing the same rolling stock in paying for the in-plant inspection. The only requirement regarding this inspection in the final rule is that the inspector not be an agent or employee of the manufacturer.

The inspector would prepare a report providing accurate records of all vehicle construction activities and summarizing how the construction of the vehicles and their operational characteristics met (or did not meet) the terms of the contract specifications.

Upon delivery of the vehicles to the recipient, and after reviewing the report, the recipient would make a visual inspection and road test of the vehicles to make certain that they met the contract specifications. The recipient would then certify to this effect, and keep that certification on file.

For a bus procurement of 10 or fewer buses or for procurement of any number of vans manufactured by the automobile companies (and unmodified), in-plant inspection would not be required. Only a visual inspection and a road test after delivery to the recipient would be required for such purchases. On the basis of this review, a recipient would certify compliance with the specification and would keep that certification on file.

Fifth, regarding the difficulties some commenters perceived in relation to railcar procurement practices and the feasibility of post-delivery compliance certification, we recognize the complexity involved in designing and building rail rolling stock. We also recognize that the level of effort involved in producing railcars probably requires recipients to make substantial periodic payments against the contract price. Nevertheless, we are not convinced that these "facts of railcar procurements" affect the in-plant inspection requirement. At the same time, however, UMTA intends these in-plant inspections to be consistent with current industry practices. This is particularly true in the railcar industry where the construction of a vehicle may stretch out over a period of time. In short, because of the length of the construction period, in-plant inspection in the railcar industry may be more periodic than that for the bus industry, although the resulting report should be equally comprehensive in both cases.

Lastly, we considered the commenters' request for a clarification of the remedies available to recipients under (663.39(b) of the NPRM. We believe the language of that section was sufficient to cover situations which amount to breach of contract, i.e., delivering a vehicle which does not meet the contract's specifications. We nonetheless recognize recipients' concern that this NPRM provision was open to a contrary interpretation limiting recipients to contract remedies when other statutory or common law remedies might also be available. We do not wish to deprive recipients of such alternative remedies and have therefore revised § 663.39 in the final rule to include any other remedies available under the law.

C. Compliance with Federal Motor Vehicle Safety Standards

The commenters addressed a number of concerns regarding the FMVSS certification requirements of part 663. Their concerns included (1) the inapplicability of FMVSS to rail rolling stock, (2) general support for an exemption for cars and vans, (3) the redundancy of the independent testing requirement, (4) the practicability of the safety audit at the pre-award stage, (5) the likelihood that the NPRM's safety audit requirements would lead to recipient liability for negligent certification, and (6) the safety audit's cost to recipients and vendors. Each of these issues is discussed at length below.

Inapplicability of FMVSS to Rail Rolling Stock. Five commenters called attention to the fact that the NPRM's safety certification was tied to the FMVSS and therefore did not apply to rail rolling stock. The comments reflected some confusion as to whether such testing nevertheless would be required for railcars. One commenter stated that testing railcars for FMVSS compliance would be an inappropriate use of scarce transit resources. This commenter made two additional observations: First, that railcars normally are not designed at the time of contract award and, second, that the Federal Railroad Administration, the Association of American Railroads, and local public utility commissions have their own safety standards specifically applicable to railcars. Other commenters realized that the provision for certifying non-applicability of FMVSS, contained in § 663.25(a)(2) of the NPRM, applied to rail rolling stock but they nonetheless requested clarification of this point in the final rule.

Exemptions for Cars and Vans. Fifteen commenters responded to the question in the NPRM about whether cars and vans ought to be exempted from FMVSS certification requirements. All but one commenter favored exempting cars and vans from these requirements. The principal points advocated include the following:

First, the National Highway Traffic Safety Administration (NHTSA) currently requires all motor vehicles to meet certain Federal motor vehicle safety requirements before these vehicles are offered for sale. The commenters pointed out the NHTSA requires manufacturer self-certification of compliance for this purpose, undertaking enforcement actions against noncomplying manufacturers when

necessary. The majority of commenters argued that UMTA and recipients should be able to rely on the same certifications, at least for standard, unmodified cars and vans. Several also contended that other governmental agencies accept these self-certifications.

Second, pro-exemption commenters contended that suppliers of vehicles modified to transport the elderly and handicapped would either increase prices or withdraw from the marketplace if forced to absorb the cost of additional, independent safety testing. They argued, third, that Congress was concerned about vehicles in "regular" revenue service, i.e., buses, rather than cars and vans when it adopted section 319 of STURAA.

Other more general comments made by pro-exemption commenters were that: (1) Manufacturer self-certification augmented with State safety inspections ought to meet the safety requirements of section 319 of STURAA and part 663; and (2) legal costs resulting from NHTSA enforcement or judicial proceedings constitute a substantial incentive for manufacturer compliance with Federal motor vehicle safety requirements. These commenters also contended that the effect of negative publicity arising from apparent noncompliance would have a similar effect.

Only one commenter opposed exempting cars and vans from FMVSS certification requirements. That commenter argued that an exemption for cars and vans was inappropriate because of the modifications made to these vehicles for carrying the elderly and handicapped.

Another commenter, while not opposing the idea of exempting cars and vans from the NPRM's FMVSS certification requirements, questioned whether such an exemption could be justified. That commenter pointed out that the language of section 319 made no distinction between cars and vans and other rolling stock. That commenter urged UMTA to find ways to reduce the cost of FMVSS certification and suggested modifying the rule to allow bidders to include evidence of independent compliance testing in their bid documentation. That commenter also proposed making such information acceptable as evidence for certification purposes. Doing so, it argued, would help to eliminate further delays in the procurement process.

Redundancy of the NPRM's Independent Testing Requirement. Seventeen commenters addressed this issue, generally advocating elimination of the NPRM's safety provisions. Also citing NHTSA's requirement that motor vehicle manufacturers certify FMVSS compliance, these commenters argued that vehicle manufacturers have established sophisticated testing programs to comply with this NHTSA mandate. The commenters therefore contended that the NPRM's independent certification requirements would be a waste of both time and money.

The commenters also disfavored independent safety testing because adequate means of sharing certification information were not provided for in the NPRM. The commenters pointed out that § 663.25(b) of the NPRM permitted NHTSA or an independent laboratory to re-issue certification reports in certain circumstances. They noted language in the NPRM's preamble discussing § 663.25 which said, "In order to avoid duplication of effort, this section also provides that a laboratory or NHTSA may reissue a safety certification it issued for one recipient if another recipient is purchasing the same rolling stock," 53 FR 40851. The commenters concluded that § 663.25's attempt to avoid duplication of effort was undermined by the lack of a clearinghouse or some other means of sharing certification information, and that this deficiency would lead to "regulatory overkill" with recipients retesting essentially identical vehicles over and over again simply because they were unaware of previous certifications

Third, the commenters argued that the NPRM's safety provisions exposed recipients to liability for negligent certifications, shifting that burden away from the manufacturers who were in the best position to ensure compliance with Federal motor vehicle safety requirements.

Practicability. Thirty-one commenters questioned the adequacy of various aspects of part 663's safety requirements and their effects on rolling stock procurement practices. The concerns ranged from the NPRM's time frame for completing safety certifications, to the availability of independent testing laboratories (alluded to above), to the adequacy of the NPRM's guidelines for determining when re-testing becomes necessary. The commenters' concerns are addressed more fully below.

The NPRM's § 663.21 required recipients, as part of the preaward audit, to complete safety compliance certifications before entering into a final contact with the vendor. The commenters found this time frame not only unrealistic but also inherently incompatible with existing rolling stock procurement processes. The commenters stated that if the NPRM's provisions were adopted, they anticipated significant delays to result. Where mandatory time limits apply to bid procedures, the commenters warned that many transit agencies would be forced to reprocess whole procurements as a result of the NPRM's requirements. The commenters contended that this would increase administrative costs substantially, nearly doubling paperwork requirements and increasing costs for both recipients and bidders.

The commenters also expressed concern that § 663.21's time frame would reduce the parties' flexibility in negotiating detailed specifications after contract finalization. The commenters pointed out that current procedures permit recipients and vendors to negotiate specific details on components, customized features, and so forth after contract formation.

According to the commenters, vendors decide which subcontractors and suppliers they will use and where final assembly will take place after these post-contract negotiations are complete. The commenters argued that this practice increases vendors' liquidity by permitting them to keep inventories to a minimum, that it allows vendors to keep labor and facilities costs down and take advantage of competitive pricing among suppliers and subcontractors until contract finalization. The commenters argued further that vendors are able to pass their savings along to recipients in the form of lower bids, in turn allowing recipients to increase the productivity of scarce transit dollars. Implementation of § 663.21 with regard to the safety certification would, the commenters contended, either drastically reduce this flexibility or lead to certifications bearing little relation to final procurement products.

With regard to their concern about the availability of independent laboratories capable of performing complete FMVSS certifications, the commenters pointed out that because the Motor Vehicle Safety Act, 15 U.S.C. 1403, requires manufacturer self-certification, most testing facilities are affiliated directly with manufacturers. According to recipients comments, their ability to obtain the necessary independent certifications is undermined seriously by this manufacturer-laboratory affiliation. The situation was further exacerbated by the lack of in-house expertise in all but the largest transit agencies.

Finally, eight commenters were concerned that the NPRM's FMVSS audit requirements did not give adequate guidance on the question of retesting. They asked for clarifications on such questions as (1) how much change, if any, would be permitted

before retesting becomes necessary, (2) would all components have to be retested or could retesting be limited to the components directly affected, (3) who would decide if retesting were necessary, (4) who would initiate the retesting process, (5) who would pay for retesting, and (6) who would resolve disputes when one recipient introduced changes to a basic design and decided retesting was unnecessary while another recipient introduced the same changes but decided retesting was necessary.

Liability. As alluded to in earlier parts of this discussion, several recipient-commenters were worried that, because they would have to certify FMVSS compliance before accepting rolling stock, they would also be made liable for any losses resulting from a negligent certification. One commenter, a State transportation department, pointed out that even though it was protected from liability, because the State had not waived its sovereign immunity, the law was uncertain as to whether that protection would extend to its inspectors.

Other commenters on this issue, primarily transit agencies and State transportation departments, believed that shifting the burden of making FMVSS compliance certifications would be inappropriate because vehicle manufacturers are in a better position to detect and correct any flaws in design or construction. They felt that the NPRM did not address this issue adequately.

Costs. Because of the importance of the various cost issues, they are dealt with in a separate section covering financial burdens resulting from the NPRM as a whole.

Commenters' Suggestions. The commenters believed that only two alternatives were capable of satisfying the NPRM's safety requirements. They contended that either manufacturers would have to provide prototypes for FMVSS testing as part of the procurement process or recipients would have to buy vehicles that were already certified. The commenters argued that the first alternative could double procurement costs, especially for smaller transit agencies that only buy one or two vehicles at a time. On the other hand, they concluded that the second alternative could stultify innovations in transit vehicle technology. In their opinion, the NPRM's lack of guidelines for determining what constitutes the "same" vehicle design would magnify the latter effect. The commenters concluded that both these alternatives therefore were undesirable.

Because of perceived inadequacies in the NPRM's safety provisions, commenters made many suggestions to rectify the situation. Many commenters suggested, for example, that UMTA or NHTSA undertake the task of certifying FMVSS compliance. They contended that such a change would ensure independence in the certification process, minimize duplication of effort by transit agencies, and provide a centralized source for information on certified vehicles. A few commenters also suggested that UMTA could require grantees to buy only those vehicles so certified whenever Federal funds are involved.

A second frequent suggestion made by commenters was to permit bidders to include evidence of independent testing in their bid documents. The commenters also recommended that such information should be acceptable evidence for FMVSS certification purposes.

The commenters also proposed exempting small transit agencies or small purchases from the FMVSS requirement. Proponents justified such an exemption based on the disproportionate administrative burdens and costs the NPRM would create in such situations.

Finally, two commenters suggested establishing a committee from the transit industry with the power to hear disputes and make binding decisions resolving them.

UMTA's Response. After careful consideration of the comments, UMTA has decided to substantively revise its proposal in the NPRM. UMTA bases this decision on its assessment of the statutory requirements of section 319 and on its own evaluation of the NPRM's impact on recipients and vendors. In making this decision, UMTA determined that the following factors, drawn from the comments, were important considerations.

First, insufficient numbers of non-manufacturer affiliated testing laboratories and expert consultants are available to ensure that independent certifications can be made. Second, testing costs would be overly burdensome on the majority of transit agencies because of the extensiveness of the testing required and because some of the tests could involve destruction of all or part of the test vehicle. Third, the NPRM's requirement for certification before contract finalization is in direct conflict with customary procurement practices and its imposition would either undermine the parties' flexibility in negotiating customized requirements or result in safety certifications that bear little relationship to the final product supplied. Fourth, the threat of NHTSA enforcement action, tort liability based on negligent certification, and loss of business due to negative publicity arising from noncompliance with FMVSS provides a substantial incentive to manufacturers to comply with FMVSS requirements.

UMTA also considered the option suggested by several commenters that either UMTA or NHTSA take responsibility for FMVSS certification. UMTA concluded that such a significant change in either agency's mandate or responsibility was not what Congress intended in adopting this requirement. Accordingly, we have decided that, since manufacturer certification of compliance is required by NHTSA under the FMVSS, and since Congress did not appear to intend to significantly change the method of compliance of this requirement, a grantee can satisfy the safety audit requirements of section 319 by certifying that it will require the manufacturer to provide, both at the pre-award and post-delivery stage, self certification information necessary to meet the FMVSS. Essentially, this means that a manufacturer would describe in writing the content of the certification label contained on the vehicle pursuant to 49 CFR part 567. (If a new model vehicle is to be built in response to the specification, in which case no FMVSS certification would be available at the pre-award stage, the manufacturer should so state in its statement to the purchaser.) The manufacturer's responsibilities with respect to NHTSA would remain unchanged. We believe the existing sanctions applicable to manufacturers for false or inaccurate certifications under the FMVSS are sufficiently effective that a separate and independent review by an UMTA recipient would be redundant and costly. Nor do we believe such an independent and costly review was meant to be imposed by Congress.

If a vehicle was not subject to the Federal Motor Vehicle Safety Standards, a recipient would so certify based upon a manufacturer's certification to that effect. Finally, in response to comments, this section would clearly specify that it was not applicable to rolling stock that is not a motor vehicle—such things as rail cars, ferryboats and the like.

D. Financial Impact

Overview. Thirty-seven commenters contended that the NPRM's provisions would significantly increase rolling stock procurement costs. Eleven provided more detailed estimates in terms of dollars and delays, almost all of which related to the FMVSS or Buy America requirements.

Specific Cost Estimates. Regarding FMVSS costs, one commenter estimated that it would take 2–8 weeks and cost $25,000–$150,000 per vehicle, depending on size and complexity, to certify compliance. According to another commenter, 35 Federal Motor Vehicle Safety Standards apply to buses and the average cost of testing would be $5000 per test. The lowest cost estimate for FMVSS certification was $2,500–$10,000 per procurement.

In regard to Buy America costs, one commenter estimated it would take 5 days to certify vans and 50 days to certify buses. A second stated that bus certification would cost $32,000 and railcars between $110,000 and $225,000.

Estimates of the overall cost impact of the NPRM ranged from $40,000–$60,000 per year for in-house certification to $11,680–$66,000 and $81,800–$151,800 per year for third-party certification.

Effect on Small Transit Agencies. Several commenters were concerned that the NPRM would have a disproportionately severe impact on smaller transit agencies. Small transit agencies were defined generally as agencies serving a population of fewer than 200,000 people or which buy fewer than 10 vehicles per year. Because such recipients would be unable to spread costs over a sufficiently large procurement base, the commenters feared that the increased cost per vehicle would seriously impair their purchasing power, forcing them to cut the number of vehicles purchased even though NPRM-related costs were eligible for UMTA funding.

Other Concerns. Commenters believed NPRM costs were unjustified because Congress had intended the certifications to serve as a secondary means of compliance verification. Second, the commenters contended that, although the NPRM called for the recipients to share information, a mechanism for data sharing did not exist and the NPRM did not provide guidance for developing the infrastructure needed to implement that goal. Third, the commenters criticized the NPRM for promoting the establishment of a new group of consultants to perform the work. Fourth, they pointed out that few transit agencies have in-house experts and that few laboratories or consultants were available, apart from those affiliated with rolling stock manufacturers. The commenters contended that all these factors correlated into high implementation costs, assuming some of the NPRM's provisions were even possible.

Commenter Recommendations. As a result of the drawbacks they saw in the NPRM, commenters made a number of suggestions for alleviating its financial impact, some of which have been addressed in other sections of this preamble. Their suggestions included exempting smaller transit agencies from the NPRM's provisions; having UMTA, NHTSA or an independent consultant perform the FMVSS and Buy America certifications for entire classes of vehicles; permitting manufacturers to include certifications done by independent consultants in their bid documentation packages which would suffice for pre-award certifications while visual inspections of final products served for post-delivery certification; requiring manufacturers to post surety bonds to cover the cost of noncomplying materials and the cost of replacing them; and having UMTA certify pre-existing transit agency procedures which meet the requirements of section 319 of STURAA, rather than requiring those agencies to adopt the NPRM's requirements.

The commenters also asked that the final rule be prospective only, exempting procurements in progress from the provisions, and that testing for FMVSS and Buy America compliance be limited to one vehicle per procurement. Lastly, commenters asked UMTA to specify what documents were necessary for certification and set deadlines for vendors to supply such documents to recipients or their independent auditors.

UMTA Response. Because UMTA has decided to withdraw the NPRM's FMVSS certification requirements, one of the more potentially costly elements of part 663 has been eliminated. By requiring a recipient to perform a Buy America audit and by requiring in-plant inspectors for purposes of the bid specification audit, however, there is no question that increased costs will result. These cost issues are discussed in more detail in the final regulatory evaluation, available for review as part of the rule's docket.

It is important to note, moreover, that UMTA has made efforts to lessen the impacts of these costs. For example, the in-plant inspector requirement for the bid specification audits does not apply to procurement of 10 or fewer vehicles or to procurement of standard vans produced by the major automobile manufacturers that are not modified. These exceptions should significantly lessen the impact of the rule on smaller operators. Regarding the Buy America audits, UMTA encourages its grantees to share costs where possible, thereby lessening the cost impact of the requirement.

E. Definitions

Several commenters requested changes or additions to NPRM definitions in order to clarify the proposed regulations' meaning and scope. A number of their suggestions relating to the NPRM's FMVSS provisions were not adopted because those requirements were withdrawn from the final rule.

Pre-award. One commenter asked that the phrase "after a supplier is selected but" be deleted from the definition of "pre-award," set forth in § 663.5(a). The commenter argued that this change would permit certification activities to begin as early as possible in the procurement process, thereby minimizing delays between vendor selection and contract finalization. The suggested definition would be, " 'Pre-award' means that period in the procurement process before the recipient enters into a formal contract with the supplier."

UMTA Response. After careful consideration of the statutory requirements of section 319, UMTA believes that the proposed change would further Congress' purposes in adopting section 319 and alleviate potential delays encountered as a result of part 663's implementation, and it accordingly is reflected in the final rule.

Revenue service. Several commenters suggested that § 663.5(d) be changed to read " 'Revenue service' means operation of rolling stock for the transportation of fare-paying passengers as anticipated by the recipient." The commenters argued that insertion of the word "fare-paying" before the word "passengers" eliminated any suggestion that part 663 applied to non-revenue rolling stock used to carry non-revenue passengers and brought the definition into alignment with the scope of part 663 set forth in § 663.3.

UMTA Response. UMTA considered the proposed change and agrees that it would eliminate any ambiguity regarding part 663's applicability to revenue rolling stock only. We have therefore adopted this language in the final regulation.

Audit. NPRM § 663.9(b) provided that "an audit conducted under [part 663] is separate from the single annual audit requirement established by Office of Management and Budget Circular A–128, "Audits of State and Local Governments," dated May 16, 1985." The term "audit" was not otherwise specifically defined in part 663. One commenter therefore suggested that this term be defined to mean a report containing the necessary certifications

of compliance, and that the definition be included in § 663.5.

UMTA Response. UMTA recognizes that the term "audit" is used somewhat differently in the context of part 663 than in general usage. In order to clarify its use, UMTA has therefore adopted the suggested definition and incorporated it in § 663.5.

Independent and *Agent.* Several commenters asked for clarification of these terms in reference to the person making the compliance certifications. They asked whether the person performing the certifications was intended to be independent of the manufacturer only, or of both the manufacturer and the recipient.

UMTA Response. First, UMTA notes that the term "independent" only appeared in the NPRM in § 663.25(b), in relation to laboratories issuing certifications of FMVSS compliance. With regard to the term "agent", however, UMTA believes that the NPRM's language clearly indicated that UMTA intended the person performing compliance certifications to be independent of the manufacturer, and that no such intention extended to agents or employees of the recipients. UMTA intended that recipients should have the option of performing certifications in-house, using their own personnel, or of hiring third-party consultants.

Same rolling stock. Commenters asked for a definition of this term in relation to the FMVSS provisions set forth in § 663.25(b).

UMTA Response. Inasmuch as the FMVSS requirements are revised in the final regulation, we do not find it necessary to consider this issue.

Significant changes. Commenters asked UMTA to define what constitutes the "same" vehicle or a "significant change" in order to clarify bid specification and Buy America certifications could be applied to more than one vehicle in a contract order or used by other grant recipients purchasing the same rolling stock.

UMTA Response. UMTA encourages recipients to share bid specification and Buy America audit data where vehicles to be purchased are essentially the same, i.e., where minor deviations would not affect the bid specification or Buy America requirement audits. It is impossible, however, to specifically state when a new audit would not be required, and UMTA will review such requests on a case-by-case basis taking into consideration the nature of the changes in the specification.

F. Effect of Part 663 on Other Federal Regulations

A commenter brought to UMTA's attention an issue we had not addressed in the NPRM, i.e., the effect of part 663 on Office of Management and Budget Circular A–102. That Circular directs the States to use their own procurement practices and procedures when procuring property or services under a Federal grant.

UMTA's Response. UMTA does not view part 663 as having any effect on OMB Circular A–102's directive. Part 663 does impose the additional requirement of providing the pre-award and post-delivery certifications it describes. Otherwise, State and local government agencies will continue to follow their own procurement practices. UMTA anticipates that where State agencies already have procedures in place to provide independent verification of manufacturer compliance with Buy America and purchaser requirements provisions that the certifications they issue pursuant to part 663 will probably be little more than formal confirmations of the findings made in accordance with their own procedures. Where satisfactory procedures are not in place, State and local agencies will have to develop them in conformity with the final rule. Furthermore, the fact that part 663 was promulgated pursuant to a statutory mandate means that, in any case of conflict between part 663 and OMB Circular A–102, part 663's provisions will govern.

VI. Section-by-Section Analysis

This final rule includes three parts: Subpart A covering general matters; subpart B covering pre-award audit requirements; subpart C addressing post-delivery audit requirements; and subpart D addressing compliance with Federal Motor Vehicle Safety requirements.

Subpart A contains general information about audit requirements. Sections 663.1 and 663.3 set out the purpose and scope of the regulation. Section 663.5 defines terms used in the regulation, including "audit," "revenue service," and "rolling stock."

Section 663.7 sets out the pre-award and post-delivery requirements. This general certification is the only certification in the rule that must be made to UMTA. The remaining certifications required under subparts B, C, and D must be kept on file by the recipient. UMTA will review these certifications during the triennial review process or in response to specific complaints.

Section 663.9 reflects the language of section 319 of the Act and lists the three components of the required audits, including the subpart D requirement that a manufacturer provide the recipient with its self certification of compliance with the FMVSS. The remaining audits are intended to verify compliance with applicable Buy America and purchaser requirements provisions, and as such are separate from the single annual audit required by the Office of Management and Budget. UMTA does not intend that the standards used for financial audits be used on audits under this final rule. The term "audit" is used only for purposes of consistency with section 319.

Section 663.11 reflects UMTA's position that the costs of testing and auditing rolling stock purchases are eligible costs of an UMTA grant. Section 663.13 provides that this regulation does not change the compliance or verification of compliance provisions of the Buy America regulation in 49 CFR part 661 but is in addition to them. That is, UMTA's authority under 49 CFR part 661 to investigate a manufacturer's certification is unchanged. Moreover, UMTA in this regulation may now investigate a recipient's certification under this part.

Section 663.15 reflects the compliance requirements applicable to all of UMTA's certification requirements, namely, that failure to certify, or failure to certify correctly, could result in the suspension or withholding of Federal funds until appropriate corrective actions have been taken. Failure to take such corrective action could result in the repayment of Federal funds to UMTA.

Subpart B sets out the specifics of the pre-award audits. Section 663.21 specifies that a pre-award audit must be complete before a recipient enters into a formal contract to purchase the rolling stock.

Section 663.23 explains that a pre-award audit consists of two separate certifications regarding Buy America certification and purchase requirements certification, as required by section 319.

As previously noted, the third required audit, for FMVSS compliance, was withdrawn from the final rule and replaced with the subpart D requirement. UMTA will not undertake this certification process because our sister agency, NHTSA, has authority for promulgating and enforcing Federal Motor Vehicle Safety Standards, and therefore has unique qualifications for requiring FMVSS certifications and waivers. Instead, a manufacturer is required in subpart D to provide its certification of compliance with or

inapplicability of the FMVSS, and this then forms the basis for the recipient's certification which it keeps on file.

Section 663.25 describes the pre-award Buy America certification. This section is essentially the same as the NPRM. The pre-award Buy America certification must be made by a person who is not an agent or employee of the manufacturer and it must state that there is a letter from UMTA which determines that the rolling stock to be purchased has received a waiver under the Buy America requirements or that the person making the certification is satisfied that the rolling stock to be purchased meets the Buy America requirements of 49 CFR part 661. Before a person can make this certification, the person must have reviewed documentation provided by the manufacturer as to the cost of the components and subcomponents of the rolling stock, their country of origin and the location of final assembly and the activities that will take place at the location. UMTA anticipates that the review required by this section will be performed by an independent contractor in most instances since the information that must be reviewed is generally considered proprietary. However, a recipient may perform the review required by this section if the manufacturer will provide the recipient with the information necessary.

Section 663.27 describes the pre-award purchaser requirements certification. The pre-award certification must be made by a person who is not an agent or employee of the manufacturer, and must state that the rolling stock being purchased meets the requirements set out in the purchaser's bid specifications, which of course must meet all pertinent Federal requirements, including those under the Americans with Disabilities Act. UMTA recognizes that this certification will probably be based on general design specifications contained in the recipient's bid specifications and the vendor's bid documentation package.

Subpart C sets out the requirements of a post-delivery audit. Section 663.31 specifies the time period for the post-delivery audit.

Section 663.33 provides that the post-delivery audit shall consist of a post-delivery UMTA Buy-America certification and a post-delivery purchase requirements certification. The FMVSS requirement is the same as that for the pre-award stage, discussed above.

Section 663.35 describes the post-delivery Buy-America certification. The post-delivery Buy-America certification must be made by a person who is not an agent or employee of the manufacturer and, like the pre-award Buy-America certification, must state that there is a letter from UMTA which determines that the rolling stock to be purchased has received a waiver under the Buy-America requirements or that the person making the certification is satisfied that the rolling stock to be purchased meets the Buy-America requirements of 49 CFR part 661. Before a person can make this certification, the person must have reviewed documentation provided by the manufacturer as to the cost of the components and subcomponents of the rolling stock, their country of origin and the location of final assembly and the activities that took place at that location.

Section 663.37 describes the post-delivery purchaser's requirements certification. This certification must be made by a person who is not an agent or employee of the manufacturer. It must state, in the case of procurement of ten or fewer buses or procurement of any number of unmodified vans from the major automobile manufacturers, that the rolling stock has been visually inspected and road tested and determined to meet the terms of the contract specification. For all other revenue rolling stock procurements, a recipient must certify that an inspector was at the manufacturing site during construction of the vehicles (or periodically in the case of rail cars) and prepared a report regarding how the construction and operation of the vehicles meets the contract specifications. This report, and a visual inspection and road test by the recipient after delivery, forms the basis of the recipient's certification the vehicles meet specification. The recipient keeps this certification on file.

Section 663.39 has also been revised. Former paragraph (a) was withdrawn from the final rule. Former paragraph (b) has been expanded to give recipients an option to accept rolling stock which cannot be certified to meet purchase specification or Buy-America requirements. The revised provision also permits recipients to seek enforcement of any remedies available at law as well as any legal rights under the contract when rolling stock is noncompliant.

Finally, subpart D addresses the requirements relating to FMVSS compliance. A recipient is required to receive from the manufacturer of the vehicles the manufacturer's FMVSS certification of compliance information or inapplicability of such standards, and this forms the basis of the recipient's certification to UMTA. This section notes that no such certification information is necessary for non-motor vehicle rolling stock, such as rail cars, ferryboats and the like.

VII. Availability of Final Rule

Any person may obtain a copy of this final rule by submitting a request to the Urban Mass Transportation Administration, Office of Public Affairs, 400 Seventh Street SW., Washington, DC 20590 or by calling (202) 366–4043.

VIII. Regulatory Impacts

A. Executive Order 12291

This action has been reviewed under Executive Order 12291, and UMTA has determined that it is not a major rule. This rule will not result in an annual effect on the economy of $100 million or more.

B. Regulatory Evaluation

This regulation is not significant under the Department's Regulatory Policies and Procedures. UMTA has prepared a final regulatory evaluation in support of this rulemaking. This final regulatory evaluation is on file as part of the docket to this rulemaking.

C. Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b), as amended by the Regulatory Flexibility Act, Public Law 96–354, UMTA certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Act.

The wide range of agency sizes, modes of operation, and geographical locations makes it difficult to determine the actual economic impact of this rulemaking. However, UMTA has decided to withdraw the FMVSS certification requirement in the NPRM. Moreover, the bid specification in-plant inspection requirement in the final rule does not apply to procurements of 10 or fewer vehicles, or to procurement of standard vehicles—such as vans—manufactured by the major automobile companies. Thus, this requirement should not have a significant impact on small entities, which typically do not purchase large quantities of vehicles. These decisions eliminate many of the major areas of concern regarding economic impact raised in the comments.

D. Paperwork Reduction Act

The collection of information requirements of this rule are subject to the Paperwork Reduction Act, Public Law 96–511, 44 U.S.C. chapter 35. Section 319 of the Surface Transportation and Uniform Relocation Assistance Act specifically requires a grantee to perform pre-award and post-

delivery audits. The required audits are reflected in this rule which has been submitted to the Office of Management and Budget for review. Information will not be collected under this rule until OMB clearance is received and the OMB clearance number is published in the **Federal Register.**

E. Executive Order 12612

UMTA has reviewed this final rule in light of the Federalism considerations set forth in Executive Order 12612. Although this rule would have definite Federalism implications because it would impose additional requirements on States, local governments and public transit operators receiving Federal financial assistance from UMTA, this rulemaking is required by statute. UMTA considered the Federalism implications of this rulemaking when it formulated the NPRM. UMTA therefore designed the NPRM to provide recipients with as much flexibility as possible under the law. It has done the same thing in adopting this final rule. UMTA does not expect that this final rule will have a substantial direct effect on the relationship between the Federal Government and the States or the distribution of power and responsibilities among the various levels of government. In addition, UMTA has considered the Federalism implications of this rulemaking on public transit operators which are quasi-governmental or instrumentalities of States and local governments, and UMTA does not expect that this final rule will have a substantial direct effect on the relationship between those public operators and the governmental entities with which they are associated. Accordingly, UMTA has determined that the preparation of a Federalism Assessment under Executive Order 12612 is not warranted.

List of Subjects in 49 CFR Part 663

Government contracts, Grant programs—transportation, mass transportation.

VI. New 49 CFR Part 663

Accordingly, for the reasons described in the preamble, 49 CFR chapter VI is amended by adding new part 663 to read as follows:

PART 663—PRE-AWARD AND POST-DELIVERY AUDITS OF ROLLING STOCK PURCHASES

Subpart A—General

Sec.
663.1 Purpose.
663.3 Scope.
663.5 Definitions.
663.7 Certification of Compliance to UMTA.
663.9 Audit limitations.
663.11 Audit financing.
663.13 Buy America Requirements.
663.15 Compliance.

Subpart B—Pre-Award Audits

663.21 Pre-Award Audit Requirement.
663.23 Description of Pre-Award Audit.
663.25 Pre-Award Buy America Certification.
663.27 Pre-Award Purchaser's Requirements Certification.

Subpart C—Post-Delivery Audits

663.31 Post-Delivery Audit Requirement.
663.33 Description of Post-Delivery Audit.
663.35 Post-Delivery Buy America Certification.
663.37 Post-Delivery Purchaser's Requirements Certification.
663.39 Post-Delivery Audit Review.

Subpart D—Certification of Compliance with or Inapplicability of Federal Motor Vehicle Safety Standards

663.41 Certification of Compliance with Federal Motor Vehicle Standards.
663.43 Certification that Federal Motor Vehicle Standards do not apply.

Authority: 49 U.S.C. 1608(j); 23 U.S.C. 103(e)(4); Pub. L. 96–184, 93 Stat. 1320; Pub. L. 101–551, 104 Stat. 2733; 49 CFR 1.51.

Subpart A—General

§ 663.1 Purpose.

This part implements section 12(j) of the Urban Mass Transportation Act of 1964, as amended, which was added by section 319 of the 1987 Surface Transportation and Uniform Relocation Assistance Act (Pub. L. 100–17). Section 12(j) requires the Urban Mass Transportation Administration, by delegation from the Secretary of Transportation, to issue regulations requiring pre-award and post-delivery audits when a recipient of Federal financial assistance purchases rolling stock with funds made available under the Urban Mass Transportation Act, as amended.

§ 663.3 Scope.

This part applies to a recipient purchasing rolling stock to carry passengers in revenue service with funds made available under sections 3, 9, 18, and 16(b)(2) of the Urban Mass Transportation Act, as amended; 23 U.S.C. 103(e)(4); and section 14 of the National Capital Transportation Act of 1969, as amended.

§ 663. 5 Definitions.

As used in this part—

(a) *Pre-award* means that period in the procurement process before the recipient enters into a formal contract with the supplier.

(b) *Post-delivery* means the time period in the procurement process from when the rolling stock is delivered to the recipient until title to the rolling stock is transferred to the recipient or the rolling stock is put into revenue service, whichever is first.

(c) *Recipient* means a recipient of Federal financial assistance from UMTA.

(d) *Revenue service* means operation of rolling stock for transportation of fare-paying passengers as anticipated by the recipient.

(e) *Rolling stock* means buses, vans, cars, railcars, locomotives, trolley cars and buses, ferry boats, and vehicles used for guideways and incline planes.

(f) *Audit* means a review resulting in a report containing the necessary certifications of compliance with Buy America standards, purchaser's requirements specifications, and, where appropriate, a manufacturer's certification of compliance with or inapplicability of the Federal Motor Vehicle Safety Standards, required by section 319 of STURAA and this part.

(g) *UMTA* means the Urban Mass Transportation Administration.

§ 663.7 Certification of compliance to UMTA.

A recipient purchasing revenue service rolling stock with funds obligated by UMTA on or after October 24, 1991, must certify to UMTA that it will conduct or cause to be conducted pre-award and post-delivery audits as prescribed in this part. In addition, such a recipient must maintain on file the certifications required under subparts B, C, and D of this part.

§ 663.9 Audit limitations.

(a) An audit under this part is limited to verifying compliance with

(1) Applicable Buy America requirements [section 165 of the Surface Transportation Assistance Act of 1982, as amended,]; and

(2) Solicitation specification requirements of the recipient.

(b) An audit under this part includes, where appropriate, a copy of a manufacturer's self certification information that the vehicle complies with Federal Motor Vehicle Safety Standards or a certification that such standards are inapplicable.

(c) An audit conducted under this part is separate from the single annual audit requirement established by Office of Management and Budget Circular A–128, "Audits of State and Local Governments," dated May 16, 1985.

§ 663.11 Audit financing.

A recipient purchasing revenue rolling stock with UMTA funds may charge the cost of activities required by this part to the grant which UMTA made for such purchase.

§ 663.13 Buy America requirements.

A Buy America certification under this part shall be issued in addition to any certification which may be required by part 661 of this title. Nothing in this part precludes UMTA from conducting a Buy America investigation under part 661 of this title.

§ 663.15 Compliance.

A recipient subject to this part shall comply with all applicable requirements of this part. Such compliance is a condition of receiving Federal financial assistance from UMTA. A recipient determined not to be in compliance with this part will be subject to the immediate suspension, withholding, or repayment of Federal financial assistance from UMTA or other appropriate actions unless and until it comes into compliance with this part.

Subpart B—Pre-Award Audits.

§ 663.21 Pre-award audit requirements.

A recipient purchasing revenue service rolling stock with UMTA funds must ensure that a pre-award audit under this part is complete before the recipient enters into a formal contract for the purchase of such rolling stock.

§ 663.23 Description of pre-award audit.

A pre-award audit under this part includes—

(a) A Buy America certification as described in § 663.25 of this part;

(b) A purchaser's requirements certification as described in § 663.27 of this part; and

(c) where appropriate, a manufacturer's Federal Motor Vehicle Safety certification information as described in § 663.41 or § 663.43 of this part.

§ 663.25 Pre-award Buy America certification.

For purposes of this part, a pre-award Buy America certification is a certification that the recipient keeps on file that—

(a) There is a letter from UMTA which grants a waiver to the rolling stock to be purchased from the Buy America requirements under section 165(b)(1), (b)(2), or (b)(4) of the Surface Transportation Assistance Act of 1982, as amended; or

(b) The recipient is satisfied that the rolling stock to be purchased meets the requirements of section 165(a) or (b)(3) of the Surface Transportation Assistance Act of 1982, as amended, after having reviewed itself or through an audit prepared by someone other than the manufacturer or its agent documentation provided by the manufacturer which lists—

(1) Component and subcomponent parts of the rolling stock to be purchased identified by manufacturer of the parts, their country of origin and costs; and

(2) The location of the final assembly point for the rolling stock, including a description of the activities that will take place at the final assembly point and the cost of final assembly.

§ 663.27 Pre-award purchaser's requirements certification.

For purposes of this part, a pre-award purchaser's requirements certification is a certification a recipient keeps on file that—

(a) The rolling stock the recipient is contracting for is the same product described in the purchaser's solicitation specification; and

(b) The proposed manufacturer is a responsible manufacturer with the capability to produce a vehicle that meets the recipient's specification set forth in the recipient's solicitation.

Subpart C—Post-Delivery Audits

§ 663.31 Post-delivery audit requirements.

A recipient purchasing revenue service rolling stock with UMTA funds must ensure that a post-delivery audit under this part is complete before title to the rolling stock is transferred to the recipient.

§ 663.33 Description of post-delivery audit.

A post-delivery audit under this part includes—

(a) A post-delivery Buy America certification as described in § 663.35 of this part;

(b) A post-delivery purchaser's requirements certification as described in § 663.37 of this part; and

(c) When appropriate, a manufacturer's Federal Motor Vehicle Safety Standard self-certification information as described in § 663.41 or § 663.43 of this part.

§ 663.35 Post-delivery Buy America certification.

For purposes of this part, a post-delivery Buy America certification is a certification that the recipient keeps on file that—

(a) There is a letter from UMTA which grants a waiver to the rolling stock received from the Buy America requirements under sections 165 (b)(1), or (b)(4) of the Surface Transportation Assistance Act of 1982, as amended; or

(b) The recipient is satisfied that the rolling stock received meets the requirements of section 165 (a) or (b)(3) of the Surface Transportation Assistance Act of 1982, as amended, after having reviewed itself or by means of an audit prepared by someone other than the manufacturer or its agent documentation provided by the manufacturer which lists—

(1) Components and subcomponent parts of the rolling stock identified by manufacturer of the parts, their country of origin and costs; and

(2) The actual location of the final assembly point for the rolling stock including a description of the activities which took place at the final assembly point and the cost of the final assembly.

§ 663.37 Post-delivery purchaser's requirements certification.

For purposes of this part, a post-delivery purchaser's requirements certification is a certification that the recipient keeps on file that—

(a) except for procurements covered under paragraph (c) in this section, a resident inspector (other than an agent or employee of the manufacturer) was at the manufacturing site throughout the period of manufacture of the rolling stock to be purchased and monitored and completed a report on the manufacture of such rolling stock. Such a report, at a minimum, shall—

(1) Provide accurate records of all vehicle construction activities; and

(2) Address how the construction and operation of the vehicles fulfills the contract specifications.

(b) After reviewing the report required under paragraph (a) of this section, and visually inspecting and road testing the delivered vehicles, the vehicles meet the contract specifications.

(c) for procurements of ten or fewer buses, or any number of primary manufacturer standard production and unmodified vans, after visually inspecting and road testing the vehicles, the vehicles meet the contract specifications.

§ 663.39 Post-delivery audit review.

(a) If a recipient cannot complete a post-delivery audit because the recipient or its agent cannot certify Buy America compliance or that the rolling stock meets the purchaser's requirements specified in the contract, the rolling stock may be rejected and final acceptance by the recipient will not be required. The recipient may exercise any legal rights it has under the contract or at law.

(b) This provision does not preclude the recipient and manufacturer from agreeing to a conditional acceptance of rolling stock pending manufacturer's correction of deviations within a reasonable period of time.

Subpart D—Certification of Compliance With or Inapplicability of Federal Motor Vehicle Safety Standards

§ 663.41 Certification of compliance with Federal motor vehicle safety standards.

If a vehicle purchased under this part is subject to the Federal Motor Vehicle Safety Standards issued by the National Highway Traffic Safety Administration in part 571 of this title, a recipient shall keep on file its certification that it received, both at the pre-award and post-delivery stage, a copy of the manufacturer's self-certification information that the vehicle complies with relevant Federal Motor Vehicle Safety Standards.

§ 663.43. Certification that Federal motor vehicle standards do not apply.

(a) Except for rolling stock subject to paragraph (b) of this section, if a vehicle purchased under this part is not subject to the Federal Motor Vehicle Safety Standards issued by the National Highway Traffic Safety Administration in part 571 of this title, the recipient shall keep on file its certification that it received a statement to that effect from the manufacturer.

(b) This subpart shall not apply to rolling stock that is not a motor vehicle.

Issued on: September 17, 1991.

Brian W. Clymer,

Administrator.

[FR Doc. 91–22786 Filed 9–23–91; 8:45 am]

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federal register

Tuesday
September 24, 1991

Part VIII

Department of Education

National Science Foundation

34 CFR Part 652

National Science Scholars Program; Proposed Rule

DEPARTMENT OF EDUCATION

National Science Foundation

34 CFR Part 652

National Science Scholars Program

AGENCY: Department of Education and National Science Foundation.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary of Education (Secretary) proposes regulations for the newly enacted National Science Scholars Program (NSSP) in accordance with the provisions of the NSSP authorizing legislation in title VI, part A, of the Excellence in Mathematics, Science and Engineering Education Act of 1990, Public Law 101–589 (the Act). These proposed regulations specify the role of the Secretary and the responsibilities of chief State school officers, State nominating committees, and institutions of higher education in the administration of the program. The proposed regulations also specify the applicant eligibility requirements and the selection criteria by which National Science Scholars (Scholars) are nominated and receive scholarships and describe the responsibilities of the Scholars. The Secretary and the Director of the National Science Foundation (Director) jointly propose § 652.32 of the regulations, containing the selection criteria to which applicants must respond and which State nominating committees must apply in selecting scholarship nominees for submission to the President.

DATES: Comments must be received on or before October 24, 1991.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Fred H. Sellers, Chief, State Student Incentive Grant Section (room 4018, ROB #3), Office of Student Financial Assistance, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202–5447. Telephone (202) 708–4607.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: Stephen Wingard, Charles Brazil, or Denise Boulanger (room 4018, ROB #3), Office of Student Financial Assistance, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202–5447, Telephone (202) 708–4607. Deaf and hearing impaired individuals may call: the Federal Dual Party Relay Service at 1–800–877–8339 (in Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION: Under the National Science Scholars Program, the Secretary is authorized to award scholarships to students for the undergraduate study of the life, physical, or computer sciences, mathematics, or engineering. The program's purpose is to recognize student excellence and academic achievement in the life, physical, and computer sciences, mathematics, and engineering by providing scholarships to meritorious graduating high school students to encourage and enable them to continue their studies at the postsecondary level. Once implemented, the program will strengthen the leadership of the United States in the sciences, mathematics, and engineering by attracting both men and women into these fields and by encouraging them to pursue teaching careers in these areas.

The Secretary is authorized to award initial scholarships of up to $5,000 for the first year of undergraduate study at institutions of higher education to students who: (1) Are graduating from high school or receiving GEDs, (2) are nominated by State nominating committees, and (3) are selected by the President. A Scholar who maintains eligibility may receive additional awards in subsequent years in order to complete his or her undergraduate course of study. Actual award amounts depend on the availability of appropriated funds, the number of States that elect to participate, and the statutory prohibition against an award exceeding a Scholar's cost of attendance. In the Excellence in Mathematics, Science and Engineering Education Act of 1990 (Pub. L. 101–589), Congress authorized $4.5 million for the NSSP in 1991 and in the Department of Education Appropriations Act, 1991 (Pub. L. 101–517), Congress appropriated $976,000 for fiscal year 1991.

The eligibility criterion in section 604(a)(3) of the Act requires a demonstration by each applicant of outstanding achievement in one or more of the scholarship disciplines at the secondary level. A State nominating committee must use the selection criteria in these proposed regulations, which have been developed by the Director in conjunction with the Secretary, to select and prioritize nominees from among those eligible students who submit applications to the committee for NSSP scholarships. Moreover, under the selection criteria in these proposed regulations, a successful applicant must have clearly demonstrated in his or her application that he or she has the potential and motivation to complete a postsecondary education at an outstanding level of academic achievement in one of the scholarship disciplines. Section 603(b)(2) of the Act provides that at least one half of the nominees from each congressional district must be female. The President selects two Scholars per Congressional district from a prioritized list of nominees submitted by nominating committees in each State.

Section 603(b)(4) of the Act requires that the President announce the selection of NSSP Scholars prior to January 1 of each fiscal year. The Secretary disburses scholarship funds on behalf of a Scholar to the institution of higher education at which each Scholar enrolls. No scholarship proceeds can be disbursed by the Secretary on behalf of a Scholar until the Scholar is enrolled at the institution of higher education that he or she plans to attend.

Some of the areas in which the proposed regulations clarify or amplify the statutory requirements are explained below.

Definitions of Scholarship Disciplines

In § 652.6 of the proposed regulations, the Secretary, in consultation with the Director, decided to use only broad dictionary definitions of the five scholarship disciplines that include examples of the academic areas covered by the definitions. The Secretary particularly requests comments on whether these proposed definitions adequately define each discipline.

State Nominating Committees

Section 603(b)(1) of the Act requires each State desiring to participate in the NSSP to establish a broad-based nominating committee that shall serve on a voluntary basis and without compensation. Under section 603(b)(1), the nominating committee must be composed of educators, scientists, mathematicians, and engineers, and must be approved by the Secretary. In order to ensure the highest quality membership of each State nominating committee, § 652.20 of the proposed regulations specifies the number of individuals that must be appointed from each career field and requires the appointment of at least two postsecondary faculty members, a secondary school teacher, a member from a private-sector business, who is a scientist, mathematician, or engineer, and another member who is an admissions officer from an institution of higher education. The Secretary and

Director believe that the establishment of State nominating committees with memberships of the highest quality and of varying perspectives is of critical importance to ensure that the best possible applicants are nominated for National Science Scholarships.

The Secretary and Director also believe that it is necessary that the State nominating committees establish written procedures to resolve potential conflicts of interest of members of the nominating committee in order to ensure that individual student applicants do not receive an unfair advantage from their relationship with a member of the nominating committee who is reviewing their NSSP application. Therefore, the Secretary has included a requirement for written procedures to address potential conflicts of interest in § 652.21(c)(2).

Section 652.30(e) of the proposed regulations requires each State nominating committee to provide specific information to the Secretary with regard to each student nominated for a NSSP scholarship. The Secretary requires this information so that: (1) He may verify the congressional district of the nominated students; (2) Scholars can be contacted by the Secretary; and (3) scholarship funds provided to institutions on behalf of a Scholar can be awarded to that Scholar upon his or her enrollment at an institution of higher education.

Selection Criteria

Section 603(a) of the Act requires the Director and the Secretary to develop and publish jointly in the **Federal Register** the selection criteria to be used by State nominating committees to select Scholar nominees. For fiscal year 1991, a notice of final selection criteria was jointly published in the **Federal Register** on May 1, 1991, at 56 FR 20092. Public comment was waived in order to enable States to establish committees, solicit student applications, and select NSSP nominees for submission to the President, in time for scholarship awards to be made before the end of fiscal year 1991. The Secretary and Director have included the same selection criteria in § 652.32, of the proposed regulations as were published in the notice.

Through the selection criteria in § 652.32, the Secretary and the Director seek to encourage and attract to a career in the sciences, mathematics, or engineering, not only those individuals who have excelled specifically in the scholarship disciplines during their secondary education and are already committed to a career in the scholarship disciplines, but also those academically superior individuals who have not yet decided on the direction of their postsecondary educations and professional careers. The Secretary and the Director believe that selection criteria that place primary or exclusive emphasis on evidence of outstanding academic achievement in the scholarship disciplines would not only be redundant, in light of both the program authority in section 602(a)(2) of the Act, and the fact that all Scholars must meet the eligibility requirement in section 604(a)(3)) of the Act as implemented in § 652.2(c) of the proposed regulations, but might also discourage a student who excelled in other academic areas as well as the scholarship disciplines from considering a career in the sciences, mathematics, or engineering and applying for a NSSP scholarship. Under the proposed equally-weighted application-scoring methodology, the Secretary and the Director direct the State nominating committees to review, and score accordingly, those applications in which a student provides clear and specific evidence that demonstrates his or her potential and motivation to succeed at an outstanding level of academic achievement at the postsecondary level in the sciences, mathematics, and engineering.

Scholar Nomination and Selection

Section 603(b)(2) of the Act requires the State nominating committees for the NSSP to submit to the President the names of four candidates from each congressional district, at least half of whom must be female. The Secretary proposes to implement this statutory requirement in § 652.30(d) of the proposed regulations. Section 603(b)(3) of the Act requires the President to select two Scholars from each congressional district, at least half of whom must be female. In his proposal to the Congress for the reauthorization of the Higher Education Act of 1965, as amended (HEA), the Secretary has proposed that the State nominating committee provision as well as the provision governing the President's selection of NSSP Scholars be amended so as to delete the requirements that at least half of the students from each congressional district the States nominate and the President selects be female.

Student Eligibility Requirements

Based on section 604 of the statute, "Eligibility of Scholars," the Secretary has developed one set of eligibility requirements in § 652.2 of the proposed regulations that pertain to a student who wants to apply for a NSSP scholarship, and another set of eligibility requirements in § 652.40 of the proposed regulations that must be met by a Scholar in order to receive his or her scholarship. The separate eligibility criteria are necessary to ensure that high school students are eligible to apply for the NSSP, even if they are not yet eligible to receive a NSSP scholarship, because in most cases, seniors in high school will not be able to comply with several of the eligibility criteria for receiving a NSSP scholarship. For example, section 604(a)(4) of the program statute requires that a student be accepted for enrollment as a full-time undergraduate student at an institution of higher education in order to receive a NSSP scholarship. Students who will apply for NSSP scholarship consideration for the fiscal year 1992 NSSP awards and awards for subsequent years must apply during the fall of their senior year in high school. It is unlikely that each applicant will be accepted for enrollment as a full-time undergraduate student at an institution of higher education prior to January 1, the date by which the President is to announce the selection of NSSP Scholars. Therefore, under § 652.2(d) of the proposed regulations, a student must demonstrate to the nominating committee that he or she intends to apply for enrollment at an institution of higher education. If a student is selected to be a Scholar by the President, then under § 652.40(b) of the proposed regulations, he or she must have been accepted for enrollment at an institution of higher education to be eligible to receive the scholarship.

Other Scholarship Considerations

Section 603(a)(1) of the Act permits the Director and the Secretary to give consideration to the financial need of an individual seeking a scholarship and to promote participation by minorities and individuals with disabilities.

The Secretary and the Director have addressed the promotion of participation by minorities, individuals with disabilities and individuals who may have financial need. Section 652.21(b) requires State nominating committees to make special efforts to inform students from groups underrepresented in the scholarship disciplines, such as minorities, individuals with disabilities, and individuals that may have financial need, of the availability of NSSP scholarships.

The Secretary and the Director could not develop regulations that give consideration to the financial need of an individual during the application evaluation process due to the timing of

the process which is a result of the statutory requirement in section 603(b)(4) that requires the President to announce the selection of Scholars prior to January 1 of each fiscal year. The effect of this provision is to compel State nominating committees, for fiscal year 1992 and beyond, to solicit applications from students early in the fall term of their final year in high school, well before the date that financial aid applications become available. Since students must complete these financial aid applications before a determination of financial need can be made under the current statutory schedule it is impracticable for financial need, determined by a federally approved need analysis methodology, to be considered as a factor in the nomination process.

However, although it may be impracticable to consider financial need in the nomination process, a Scholar's cost of attendance, a major element in determining financial need, must be considered in determining the scholarship amount. Pursuant to section 605(b) of the Act, the amount of a Scholar's NSSP scholarship may not exceed the Scholar's cost of attendance. Moreover, since other means of considering the financial need of NSSP applicants may exist that potentially could be applied by the States in a uniform manner during the nomination process, the Secretary and the Director are specifically requesting comments concerning methods by which the financial need of an applicant may be considered by the States and their nominating committees.

Under section 605(b) of the Act, a Scholar receiving an NSSP award cannot have his or her award reduced on the basis of his or her receipt of other forms of Federal student financial assistance. However, the NSSP award must be taken into consideration for those other forms of assistance, including a Pell Grant. In addition, under § 652.4(b) of the proposed regulations, the Secretary reduces the scholarship amount awarded by the amount that the scholarship would otherwise exceed the Scholar's cost of attendance.

Requirements for Continuation Awards

Section 604(b)(1) of the Act requires a Scholar to maintain a high level of academic achievement as determined in the program regulations in order to receive continuation awards after the first year. Under § 652.42(c) of the proposed regulations, a Scholar must maintain a high level of overall academic achievement as well as a high level of academic achievement in the scholarship disciplines. Under § 652.42(c), the Secretary proposes to require each Scholar's institution to make this determination rather than to attempt to set a national standard. The institution has the Scholar's records and the Secretary believes that, in each case, the institution is in the best position to determine whether the Scholar is maintaining a high level of achievement at that particular institution. Under § 652.50 of the proposed regulations, each institution of higher education at which a Scholar is enrolled must provide annual assurances to the Secretary that each Scholar has maintained eligibility for the NSSP.

Section 604(b)(2) of the Act requires a Scholar who has not yet declared a major in one of the scholarship disciplines to provide a statement to the State of his or her continuing intent to major in one of the scholarship disciplines in order to receive a continuation award. In § 652.42(b) of the proposed regulations, the Secretary is proposing to modify this requirement to require the Scholar to provide his or her statement of intent to major in one of the scholarship disciplines to the institution of higher education at which he or she is enrolled as well as providing it to the State. The Secretary finds that, while the statute requires a Scholar who has not yet declared a major to provide such a statement to the State, it is appropriate for all documentation, including such a statement, pertaining to a Scholar's eligibility for a continuation award to be provided to, and maintained by, the institution at which the Scholar is enrolled. One of the assurances described above must be that the Scholar has provided the institution with a statement of intent to major in one of the scholarship fields, if the scholar has not already declared such a major.

Waiver of Full-time Attendance

Under section 604(c) of the Act, the Secretary may waive the statute's full-time attendance requirements in unusual circumstances. Under § 652.43(b) of the proposed regulations, the Secretary may waive the full-time attendance requirement for a Scholar if the Scholar's institution determines that unusual circumstances have caused the Scholar's noncompliance with the statute's full-time attendance requirement and that suspension of scholarship eligibility would cause the Scholar undue hardship. The Secretary elects to require each Scholar's institution to make this determination, rather than attempt to set national criteria, because the Secretary believes that the Scholar's institution is in the best position to know the Scholar's individual circumstances and needs that might justify such a waiver. If an institution makes a determination that unusual circumstances exist in the case of a particular Scholar and the Secretary waives the full-time attendance requirement for that Scholar, the Scholar continues to receive a scholarship payment to which he or she is otherwise entitled. Under such circumstances, the scholarship payment will be prorated by the institution according to the Scholar's enrollment status for the academic period during which he or she continues to be enrolled on a part-time basis and is otherwise eligible for the scholarship award. For example, a student who is enrolled for 9 semester hours at an institution where full-time status is 12 semester hours would receive ¾ of a scholarship payment for the academic period.

Reinstatement of a Scholarship

Under section 604(e) of the Act, the Secretary determines circumstances under which a Scholar may have his or her eligibility for a NSSP scholarship reinstated after a period of interruption or suspension. Under § 652.44 of the proposed regulations, the Secretary permits the institution of higher education to reinstate a Scholar's eligibility for the scholarship if the period of interruption or suspension was for a period of no more than 12 months and if, prior to reinstatement, the Scholar can demonstrate to the institution that he or she is in compliance with the relevant eligibility requirements. The Secretary permits the institution of higher education to waive the 12-month limitation if the institution determines that the Scholar's period of interruption was due to exceptional circumstances that necessitated such an interruption.

Administrative Responsibilities of Institutions of Higher Education

Section 603(d) of the Act requires the Secretary to disburse scholarship proceeds on behalf of Scholars to the institutions of higher education at which the Scholars are enrolled. Under "Subpart F—What Are the Administrative Responsibilities of the Institutions of Higher Education at Which NSSP Scholars Are Enrolled?" of the proposed regulations, the Secretary establishes the requirements that an institution of higher education must follow to administer the awarding of scholarships under the NSSP. These proposed procedures are consistent with other current procedures used by institutions of higher education in the

administration of other Federal student financial aid programs. The Secretary considers these to be the minimum procedures necessary to ensure the proper administration of and accounting for Federal funds disbursed to the institutions under the NSSP.

Under section 603(d) of the statute, the Secretary disburses funds on behalf of a Scholar to an institution of higher education once the Scholar is enrolled at the institution. However, the Secretary must obligate the NSSP scholarship funds to the institution before September 30 of each year in order to avoid a lapsing of those funds. Accordingly, in these proposed regulations, the Secretary provides for the submission of the equivalent of a certification of enrollment by the institutions of higher education in order to avoid the lapsing of scholarship funds due to student registration occurring very late in the fiscal year. Under § 652.53(a)(1)(i)(A), for purposes of the disbursal of NSSP scholarship funds to an institution of higher education, the Secretary considers a Scholar to be enrolled when he or she has provided the institution with a written, formal commitment to attend the institution, under § 652.42, during the relevant academic year and has complied with any other institutional requirements for indicating such a commitment, *e.g.*, providing the institution with a monetary deposit. However, neither the institution nor the Scholar is entitled to receive any portion of the NSSP scholarship funds until the Scholar starts attending classes at the institution of higher education. If the Scholar does not attend classes and the institution has obtained the funds in anticipation of disbursing them to the Scholar, or crediting the Scholar's account, then the institution must return all of the scholarship funds for that Scholar to the Secretary.

While § 652.22 of the proposed regulations provides specific recordkeeping requirements for States, the recordkeeping requirements for institutions of higher education participating in the NSSP are found in 34 CFR 74.20 through 74.25 of the Education Department General Administrative Regulations (EDGAR).

Executive Order 12291

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. States and State nominating committees administer the program in part. States and State nominating committees are not defined as "small entities" in the Regulatory Flexibility Act. The small entities affected by these regulations would be small institutions of higher education with NSSP Scholars in attendance. Certain reporting, recordkeeping, and compliance requirements are imposed on participating institutions of higher education by the proposed regulations. However, these requirements are modeled on existing student financial assistance programs requirements imposed on these institutions under title IV of the Higher Education Act of 1965, as amended. Therefore, the Secretary has determined that these provisions will have minimal impact on the small institutions of higher education.

Paperwork Reduction Act of 1980

Sections 652.10, 652.20, 652.22, 652.30, 652.32, 652.40 and 652.42 contain information collection or recordkeeping requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of these sections to the Office of Management and Budget (OMB) for its review. (44 U.S.C. 3504(h))

Estimates of annual public reporting burden for the information collections required in this notice of proposed rulemaking were prepared in consultation with several State scholarship agencies. The estimates are as follows:

1. State submissions of nominating committee memberships are estimated to average 12 hours per State response for approximately 56 respondents for a total burden of 672 hours.

2. Applicant responses to selection criteria are estimated to average 16 hours per applicant response for 15,435 respondents, including the time for reviewing instructions and selection criteria, requesting the required information, writing the essay, and reviewing and transmitting the collection of information, for a total annual burden of 246,960 hours.

3. State nominating committee submission of nominations to the President are estimated to average 40 hours to review an estimated 35 applications from each congressional district per 441 congressional districts and other eligible participating entities, for a total of 17,640 hours if all 56 States participate. The estimated hours include the time for reviewing and rating student applications, prioritizing nominees, and transmitting the collection of information.

4. A Scholar providing his or her institution of higher education a Statement of Educational Purpose is estimated to average 15 minutes per Scholar. There is a potential of 882 Scholars with an additional 882 scholars per year for an overall potential of up to 3,528 Scholars. Therefore, the estimated burden for this collection will range from 220.5 hours to 882 hours per year.

Organizations and individuals desiring to submit comments on the information collection requirements contained in these proposed regulations should direct them to the Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington DC, 20503; Attention: Daniel Chenok.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in room 4018, ROB–3 7th and D Streets SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, public comment is invited on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

Assessment of Education Impact

The Secretary particularly requests comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 652

Education, Grant programs-education, State administered-education, Student aid-education, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance No. 84.242, National Science Scholars Program)

Dated: July 2, 1991.

Lamar Alexander,

Secretary of Education.

Dated: July 10, 1991.

Walter E. Massey,

Director, National Science Foundation.

The Secretary proposes to amend title 34 of the Code of Federal Regulations by adding a new part 652 to read as follows:

PART 652—NATIONAL SCIENCE SCHOLARS PROGRAM

Subpart A—General

Sec.

652.1 What is the National Science Scholars Program?
652.2 Who is eligible to apply for a scholarship under this program?
652.3 How are awards distributed?
652.4 In what amounts are scholarships awarded?
652.5 What regulations apply to this program?
652.6 What definitions apply to this program?

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Authority: 20 U.S.C. 5381 to 5386, unless otherwise noted.

Subpart A—General

§ 652.1 What is the National Science Scholars Program?

Under the National Science Scholars Program (NSSP) the Secretary awards scholarships to students who have demonstrated outstanding academic achievement, who show promise of continued outstanding academic performance, and who are selected by the President, for the following purposes:

(a) To recognize student excellence and achievement in the physical, life, and computer sciences, mathematics, and engineering.

(b) To provide financial assistance to students to continue their postsecondary education in those fields of study at sustained outstanding levels of performance.

(c) To contribute to strengthening the leadership of the United States in those fields.

(d) To strengthen the United States' mathematics, science, and engineering base by offering opportunities to pursue postsecondary education in physical, life, and computer sciences, mathematics, and engineering.

(e) To encourage role models in scientific, mathematics, and engineering fields for young people.

(f) To strengthen the United States' mathematics, scientific, and engineering potential by encouraging equal participation of women with men in mathematics, scientific, and engineering fields.

(g) To attract talented students to teaching careers in mathematics and science in elementary and secondary schools.

(Authority: 20 U.S.C. 5381)

§ 652.2 Who is eligible to apply for a scholarship under this program?

An individual is eligible to apply for an initial scholarship under the NSSP if the individual—

(a) Is scheduled to graduate from a public or private secondary school or to obtain the recognized equivalent of a high school diploma, as defined in 34 CFR 600.2, during the award year prior to the award year in which the NSSP scholarship is to be awarded;

(b) (1) Is a citizen or national of the United States; or

(2) Provides evidence from the U.S. Immigration and Naturalization Service that he or she—

(i) Is a permanent resident of the United States; or

(ii) Is in the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident;

(c) Has demonstrated outstanding academic achievement in secondary school in the physical, life, or computer sciences, mathematics, or engineering as determined by the State nominating committee established under § 652.20;

(d) Demonstrates to the State nominating committee that he or she intends to apply for enrollment at an institution of higher education as a full-time undergraduate student for the purpose of receiving a baccalaureate degree; and

(e) Demonstrates to the State nominating committee that he or she intends to major, at an institution of higher education, in one of the physical, life, or computer sciences, mathematics, or engineering.

(Authority: 20 U.S.C. 5384)

§ 652.3 How are awards distributed?

(a) In each award year, the Secretary awards one initial scholarship to each of two eligible Scholars selected by the President under § 652.33 from each congressional district.

(b) The Secretary disburses the scholarship proceeds, on behalf of each Scholar selected by the President, to the institution of higher education at which each Scholar is enrolled.

(c) A student awarded a scholarship under this part may attend any institution of higher education, as defined in § 652.6, that enters into an agreement with the Secretary under § 652.50, for the purpose of obtaining a baccalaureate degree in the physical, life, or computer sciences, mathematics, or engineering.

(Authority: 20 U.S.C. 5382 and 5383)

§ 652.4 In what amounts are scholarships awarded?

(a) Except as provided in paragraphs (b) and (c) of this section, the amount of a scholarship awarded under this part for a full-time student for any academic year is $5,000.

(b) The Secretary reduces the scholarship amount awarded under this part by the amount that the scholarship would otherwise exceed the Scholar's cost of attendance, as defined in section 472 of the Higher Education Act of 1965, as amended.

(c) In the event that funds available in a fiscal year are insufficient to fund fully each award under this part, the Secretary reduces proportionately each scholarship and the amount paid to each Scholar.

(Authority: 20 U.S.C. 5385)

§ 652.5 What regulations apply to this program?

The following regulations apply to the National Science Scholars Program:

(a) The Education Department General Administrative Regulations (EDGAR), as follows, except as provided in paragraph (b) of this section:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations).

(2) 34 CFR part 75 (Direct Grant Programs) except for the following:

(i) Subpart C (How To Apply for a Grant).

(ii) Subpart D (How Grants Are Made).

(iii) Sections 75.580 through 75.592 of Subpart E (What Conditions Must Be Met By a Grantee?).

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 81 (General Education Provisions Act—Enforcement).

(6) 34 CFR part 82 (New Restrictions on Lobbying).

(7) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(8) 34 CFR part 86 (Drug-Free Schools and Campuses).

(b) For the purposes of the regulations in this part, the terms "grantee" and "recipient," as used in EDGAR, mean an institution of higher education that administers a scholarship award on behalf of a National Science Scholar.

(c) The regulations in this part 652.

(Authority: 20 U.S.C. 5381 to 5386)

§ 652.6 What definitions apply to this program?

The following definitions apply to terms used in this part:

(a) *Definitions in the Act.* The following terms are defined in section 603(b)(5) and 602(d) of the Act

Congressional district

National Science Scholar (Scholar)

(b) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1: Applicant, Application, Award, Department, Fiscal Year, Private, Secondary school, Secretary, State.

(c) *Other definitions that apply to this part.* The following additional definitions apply to this part:

Academic year means—

(1) A period of time in which a full-time student is expected to complete the equivalent of at least two semesters, two trimesters, or three quarters, at an institution that measures academic progress in credit hours and uses a semester, trimester, or quarter system; or

(2) A period of time in which a full-time student is expected to complete at least 24 semester hours or 36 quarter hours at an institution that measures academic progress in credit hours but does not use a semester, trimester, or quarter system.

Act means the Excellence in Mathematics, Science and Engineering Education Act of 1990.

Award year means the period of time from July 1 of one year through June 30 of the following year.

Computer sciences means the branch of knowledge or study of computers. The term encompasses, but is not limited to, such fields of knowledge or study as computer hardware, computer software, computer engineering, information systems, and robotics.

Director means the Director of the National Science Foundation.

Engineering means the science by which the properties of matter and the sources of energy in nature are made useful to humanity in structures, machines and products as in the construction of engines, bridges, buildings, mines, and chemical plants. The term encompasses, but is not limited to, such fields of knowledge or study as aeronautical engineering, chemical engineering, civil engineering, electrical engineering, industrial engineering, materials engineering, and mechanical engineering.

Full-time student means a student enrolled in an institution of higher education, other than a correspondence school, who is carrying a full-time academic workload as determined by the institution under standards applicable to all students enrolled in that student's educational program.

Institution of higher education (institution) means an institution of higher education as defined in 34 CFR 600.4 (institutional eligibility regulations).

Life sciences means the branch of knowledge or study of living things. The term encompasses, but is not limited to, such fields of knowledge or study as biology, biochemistry, biophysics, microbiology, genetics, physiology, botany, zoology, ecology, and behavioral biology. This term does not encompass social psychology or the health professions.

Mathematics means the branch of knowledge or study of numbers and the systematic treatment of magnitude, relationships between figures and forms, and relations between quantities expressed symbolically. The term encompasses, but is not limited to, such fields of knowledge or study as statistics, applied mathematics, and operations research.

Physical sciences means the branch of knowledge or study of the material universe. The term encompasses, but is not limited to, such fields of knowledge or study as astronomy, atmospheric sciences, chemistry, earth sciences, ocean sciences, and physics.

Scholarship means an award made to an individual in an award year under this part for one academic year.

Scholarship disciplines means the physical, life, and computer sciences, mathematics, and engineering.

(Authority: 20 U.S.C. 5381 to 5386)

Subpart B—How Does A Student Apply for a Scholarship?

§ 652.10 How does a student apply for a scholarship?

(a) To apply for a scholarship under this part, an individual, who meets the eligibility requirements of § 652.2, must submit an application as required by the State nominating committee administering the NSSP in the State of his or her legal residence.

(b) In his or her application, the applicant shall address the selection criteria contained in § 652.32.

(c) The applicant shall submit the application to the State nominating committee within the deadline established by the committee.

(Authority: 20 U.S.C. 5383)

Subpart C—What Are the Administrative Responsibilities of a State?

§ 652.20 How does a State establish a nominating committee?

(a) To participate in the NSSP, a State shall establish a nominating committee for the purpose of nominating students for NSSP scholarships.

(b) The State nominating committee may be appointed either by the Chief State School Officer (CSSO) or by an existing grant agency or panel that was previously designated by the CSSO.

(c) Before the nominating committee may begin to fulfill its functions under § 652.21, the CSSO, grant agency, or panel that appoints the nominating committee shall submit for the Secretary's approval the names and qualifications of the individuals to be appointed.

(d) The nominating committee must include the following:

(1) At least one individual from each of the following fields:

(i) Education.

(ii) Science.

(iii) Mathematics.

(iv) Engineering.

(2) At least two faculty members teaching in two or more of the scholarship disciplines at the postsecondary level.

(3) At least one teacher teaching in one or more of the scholarship disciplines at the secondary level.

(4) At least one person who is a scientist, mathematician, or engineer from a private-sector business that is oriented to the sciences, mathematics, or engineering.

(5) At least one admissions officer from an institution of higher education.

(e) An individual representing one of the nominating committee membership categories under paragraphs (d) (2) through (5) of this section, may, if qualified, also represent a category in paragraph (d)(1) of this section.

(f) Each State shall require that its State nominating committee members serve as volunteers without compensation.

(Authority: 20 U.S.C. 5383)

§ 652.21 What are the responsibilities of a State and its nominating committee?

Each State shall require its nominating committee to establish operating procedures governing the scholarship nomination process that include—

(a) The dissemination of program information and application materials to the State's public and private secondary schools and GED test centers;

(b) The promotion of participation in the NSSP by students from groups underrepresented in the scholarship disciplines, such as students from minority groups, students with disabilities, or students who are economically disadvantaged; and

(c) The establishment of internal administrative procedures for—

(1) The timely submission, processing, and review of applications submitted by eligible students; and

(2) The resolution of conflicts of interest of members of the nominating committee.

(Authority: 20 U.S.C. 5383)

§ 652.22 What records must a State maintain?

The CSSO, State agency, or panel that appoints the nominating committee under § 652.20(b) shall maintain all student applications and the records and written procedures related to the selection of nominees for a scholarship competition for a period of five award years following the award year of the scholarship competition.

(Authority: 20 U.S.C. 5383 and 5384)

Subpart D—How Are Scholars Nominated and Selected?

§ 652.30 How are Scholars nominated?

(a) Scholars are nominated by State nominating committees that are established in accordance with § 652.20.

(b) Each State nominating committee shall review and evaluate the applications received each year under this program.

(c) Each State nominating committee shall select nominees in accordance with the program eligibility requirements for an initial award. Each State nominating committee may adopt one or more minimum standards to demonstrate outstanding academic achievement at the secondary school level that may include such standards as an overall minimum grade point average or a minimum class rank combined with a minimum grade point average in the sciences, mathematics, and engineering.

(d) Each State nominating committee shall submit to the President the nominations of at least four applicants legally residing in each congressional district in the State, at least half of whom must be female. The nominations must be—

(1) Ranked in order of evaluated score; and

(2) Submitted to the Secretary, who receives the nominations on behalf of the President, in the manner and by the date established by the Secretary in a notice published in the **Federal Register**.

(e) Each nominating committee shall provide the following information for each nominee to the Secretary:

(1) Name.

(2) Sex.

(3) Address.

(4) Telephone number.

(5) Social security number (if provided by the nominee).

(6) Congressional district and name of Representative or Delegate.

(7) Other information that the Secretary considers necessary for the proper administration of the program.

(Authority: 20 U.S.C. 5383)

§ 652.31 How shall a State nominating committee evaluate an application?

(a) Each State nominating committee shall evaluate an application on the basis of the selection criteria in § 652.32.

(b) The committee shall give each of the selection criteria equal weight.

(c) The State nominating committee shall score each applicant's responses to the selection criteria in § 652.32 using the following scale: 5 (truly exceptional), 4 (outstanding), 3 (excellent), 2 (good), 1 (fair), 0 (poor).

(d) Each applicant may receive a maximum of 25 points.

(Authority: 20 U.S.C. 5383)

§ 652.32 What selection criteria shall the State nominating committee use?

The State nominating committee shall use the following selection criteria to evaluate and rate applications:

(a) *Evidence of exceptional academic achievement at the secondary level.* The nominating committee shall rate the applicant's overall academic achievement at the secondary level by considering one or more of the following:

(1) High school class rank and grades.

(2) For an applicant who is earning the recognized equivalent of a high school diploma in lieu of graduating from high school, the applicant's score on the high school equivalency examination and high school record before leaving school.

(3) (i) The applicant's composite score on the ACT Assessment;

(ii) The sum of the applicant's verbal and quantitative scores on the Scholastic Aptitude Test (SAT); or

(iii) Both the composite score on the ACT Assessment and the sum of the applicant's SAT scores.

(b) *Evidence of exceptional nonacademic accomplishment in extracurricular areas and in the physical, life, or computer sciences, mathematics, or engineering.* The nominating committee shall rate the applicant's achievement in activities in areas such as community service,

leadership, and artistic and athletic performance along with achievement outside the classroom in the sciences, mathematics, and engineering.

(c) *Letters of reference.* The nominating committee shall rate letters of reference written by three individuals chosen by the applicant and determine the degree to which these letters reflect the applicant's qualifications for a National Science Scholarship, based upon relevant factors such as—

(1) The author's qualifications to provide a recommendation for the particular applicant;

(2) The extent to which each letter of reference describes the applicant's motivation and potential to pursue a career in the physical, life, or computer sciences, mathematics, or engineering; or

(3) The extent to which each letter of reference describes the applicant's overall potential and abilities.

(d) *Applicant essay.* The applicant must write an essay that the nominating committee shall analyze and rate. The essay of 500 words or less must be on a topic that the applicant chooses and considers to be of interest to the nominating committee. The essay must reflect the applicant's motivation to pursue a career in the physical, life, or computer sciences, mathematics, or engineering, and otherwise be of relevance to the committee's determination of the applicant's qualification for a National Science Scholarship.

(e) *Meeting the purposes of the authorizing statute.* The nominating committee shall rate each application to determine how well it meets the purposes of the National Science Scholars Program as set forth in § 652.1.

(Authority: 20 U.S.C. 5381–5383)

§ 652.33 How are Scholars selected?

(a) For each award year, after consultation with the Secretary and the Director of the National Science Foundation, the President selects and announces from among the nominees submitted by State nominating committees under § 652.30, two National Science Scholars legally residing in each congressional district.

(b) The selection of National Science Scholars is announced prior to January 1 of each fiscal year for which funds are appropriated.

(Authority: 20 U.S.C. 5383)

Subpart E—What Conditions Must Be Met By Scholars?

§ 652.40 What requirements must a Scholar meet in order to receive a scholarship?

To be eligible to receive a scholarship, a Scholar who has been selected by the President under § 652.33, must—

(a) Meet the eligibility requirements in § 652.2;

(b) Have been accepted for enrollment at an institution of higher education as a full-time undergraduate student (as determined by the institution) for the purpose of obtaining a baccalaureate degree;

(c) Have declared a major in one of the physical, life, or computer sciences, mathematics, or engineering, or have provided a written statement to the institution of higher education of his or her intent to major in one of these fields of study if it is the policy of the institution at which the Scholar has been accepted for enrollment that students not declare a major until a later point in their course of study; and

(d) Have filed with the institution he or she plans to attend or is attending, a Statement of Educational Purpose in accordance with § 668.32 of the Student Assistance General Provisions regulations.

(Authority: 20 U.S.C. 5381 and 5383)

§ 652.41 What is the duration of a scholarship?

(a) In the first award year after a Scholar is selected by the President, the Scholar receives his or her initial scholarship, for a period of one academic year, for his or her first year of undergraduate study in one of the scholarship disciplines at an institution of higher education.

(b) Except for a Scholar covered in paragraph (c) of this section, a Scholar who satisfies the requirements of § 652.42 may receive up to three additional scholarships in subsequent award years, each awarded for a period of one academic year, in order to complete his or her undergraduate course of study.

(c) A Scholar who satisfies the requirements of § 652.42 and who is enrolled in an undergraduate course of study that requires attendance for five academic years may receive additional scholarships for not more than four additional academic years of undergraduate study.

(Authority: 20 U.S.C. 5382)

§ 652.42 What are the requirements for a Scholar to continue to receive scholarship payments under the NSSP?

A Scholar who has received a scholarship under this part for at least one year of undergraduate study is eligible to receive a scholarship for a subsequent year of undergraduate study under § 652.41 (b) or (c), if, at the beginning of that subsequent academic year, the Scholar—

(a) Is enrolled as a full-time student at an institution of higher education for the purpose of receiving a baccalaureate degree, unless the institution has determined that unusual circumstances justify waiver of the full-time attendance requirement and the Secretary has waived the full-time attendance required as provided for in § 652.43(b);

(b) Continues to major in one of the scholarship disciplines, or provides a written assurance to both the State and the institution of higher education at which the Scholar is enrolled of his or her intent to major in one of the scholarship disciplines, if it is the policy of that institution that a student not declare a major until later in his or her course of study;

(c) Maintains a high level of academic achievement, as defined by the institution, in—

(1) His or her overall course of study;

(2) Those science, mathematics, or engineering courses in which the Scholar has enrolled; and

(3) The Scholar's major, if declared.

(Authority: 20 U.S.C. 5382 and 5384)

§ 652.43 What are the consequences of a Scholar's noncompliance with the scholarship eligibility requirements in § 652.40 or § 652.42?

(a) (1) Except as provided in paragraph (b) of this section, if an institution of higher education finds that a Scholar fails to meet the requirements of § 652.40 or § 652.42 within an award year, the institution shall suspend the Scholar's eligibility to receive further scholarships, or scholarship proceeds.

(2) A suspension of a Scholar's eligibility for failure to meet the requirements of § 652.40 or § 652.42 must remain in effect until the Scholar is able to demonstrate to the satisfaction of the institution that he or she is in compliance with all applicable scholarship eligibility requirements, including renewal requirements in § 652.42 and reinstatement requirements in § 652.44.

(3) If the total period of suspension exceeds 12 months, the Scholar's eligibility for NSSP scholarships shall be terminated.

(b) The Secretary may waive the full-time attendance requirement in § 652.42 for periods during which the institution determines that unusual circumstances have caused the Scholar's noncompliance with the full-time attendance requirement of § 652.42(a) and that suspension of scholarship eligibility would cause a Scholar undue hardship.

(c) If a Scholar's full-time attendance requirement is waived under paragraph (b) of this section, he or she may continue to receive a scholarship payment. The institution shall prorate the payment according to the Scholar's enrollment status for the academic period during which he or she continues to be enrolled on a part-time basis but remains otherwise eligible for the award. For example, if a Scholar for whom the full-time enrollment requirement is waived by the Secretary is enrolled as a half-time student for one semester, he or she is eligible to receive one-half of the scholarship payment for a full-time student for that semester. Therefore, the Scholar would receive one-quarter of his or her scholarship during that semester, which would count as one-forth of a year for purposes of the four-year limit.

(Authority: 20 U.S.C. 5384)

§ 652.44 Under what conditions may scholarship eligibility be reinstated?

A Scholar whose eligibility is suspended under § 652.43(a), such as a Scholar whose attendance at an institution of higher education was interrupted for reasons including, but not limited to, pregnancy, child-rearing, or other family responsibilities, may have his or her scholarship eligibility reinstated by the institution of higher education at which he or she is enrolled if—

(a) The period of suspension or interruption was for a period of no more than 12 months unless the institution determines that the 12-month limitation should be waived due to exceptional circumstances; and

(b) The Scholar demonstrates to the institution that he or she is in compliance with the relevant eligibility and renewal requirements in §§ 652.40 and 652.42.

(Authority: 20 U.S.C. 5384)

Subpart F—What Are the Administrative Responsibilities of the Institutions of Higher Education at Which NSSP Scholars Are Enrolled?

§ 652.50 What institutional agreement is required?

Any institution at which one or more NSSP Scholars are enrolled shall enter into an agreement with the Secretary under which the institution shall agree to comply with the provisions of the Act and of this part, including providing annual assurances of the eligibility of enrolled Scholars under §§ 652.40 and 652.42 and the awarding of scholarships to those Scholars.

(Authority: 20 U.S.C. 5383 and 5384)

§ 652.51 How are scholarships to be administered by institutions of higher education?

(a) The Secretary sends a roster of Scholars and an allocation of scholarship funds for each award year to an institution of higher education that has entered into an agreement with the Secretary under § 652.50.

(b) An institution of higher education may not disburse scholarship funds to a Scholar until the Scholar is attending classes at that institution of higher education and meets the other eligibility requirements in § 652.40 and, if applicable, the renewal requirements of § 652.42.

(c) The institution shall award the Scholar a scholarship for an amount that is determined under § 652.4.

(Authority: 20 U.S.C. 5383–5385)

§ 652.52 How are scholarship awards to be made and scholarship proceeds returned?

(a) An institution shall provide scholarship proceeds to a Scholar in at least two payments per academic year.

(b) In the event that a Scholar refuses a scholarship, does not attend classes, or is ineligible for a scholarship and cannot be reinstated in that award year, the institution shall return the scholarship proceeds to the Secretary.

(c) A Scholar who ceases to be eligible for NSSP scholarship proceeds at an institution before completion of an academic period for which payment of a scholarship award has been received, is only eligible for a prorated portion of the scholarship award and is liable to the Secretary for any overpayment. The prorated portion of the scholarship to be returned to the Secretary must be in proportion to the portion of the academic period the Scholar failed to complete. The institution shall return the overpayment to the Secretary in accordance with the provisions governing the recovery of overpayments in 34 CFR 690.79 of the Pell Grant Program regulations.

(d) The institution shall pay a *pro rata* share of the scholarship for which he or she is eligible if the Scholar enrolls for less than a full academic year to complete his or her baccalaureate degree. The institution shall return the remaining share of the scholarship to the Secretary.

(Authority: 20 U.S.C. 5383 and 5384)

§ 652.53 What reports are required from an institution?

(a) Prior to the receipt of funds for disbursement to a Scholar, an institution of higher education shall provide to the Secretary the following:

(1) For a Scholar receiving his or her initial scholarship, a statement from the appropriate official at the institution indicating—

(i) (A) That the Scholar has provided the institution with a written formal commitment to attend the institution for the relevant academic year and has complied with any other institutional requirements for indicating such a commitment including a monetary deposit; or

(B) That the Scholar is currently in attendance at that institution for the relevant academic year; and

(ii) The Scholar's cost of attendance.

(2) For a Scholar who is eligible to receive an additional award in a subsequent award year, a statement from the appropriate official at the institution indicating that the Scholar is in compliance with the renewal requirements of § 652.42.

(b) An institution shall provide such reports to the Secretary as are necessary to carry out the Secretary's functions under this part, in accordance with Departmental requirements in EDGAR.

(Authority: 20 U.S.C. 5384)

[FR Doc. 91–22919 Filed 9–23–91; 8:45 am]
BILLING CODE 4000–01–M

federal register

Tuesday
September 24, 1991

Part IX

Department of the Interior

Bureau of Indian Affairs

Fiscal Year 1991 Plan for Services to Indian Infants and Toddlers With Disabilities and Their Families; Notice of Public Hearings and Public Comment Period

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Fiscal Year 1990 Plan for Services to Indian Infants and Toddlers With Disabilities and Their Families

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of public hearings and public comment period.

SUMMARY: The Office of Indian Education Programs (OIEP), Branch of Exceptional Education, has completed the required application for fourth year funds under part H (Infants and Toddlers Program) of the Individuals with Disabilities Education Act, Public Law 94–142 as Amended by Public Law 101–476 (Sec. 678). The application describes activities that will be implemented to facilitate the development of early intervention services on reservations served by elementary and secondary schools operated for Indians by the Department of the Interior.

The application is available to all interested parties and members of the general public. Each BIA Area/Agency Education will have copies of the application available for inspection. In addition, copies may be obtained from the Branch of Exceptional Education by calling 202–208–6675. Copies will also be available at each meeting site.

Public hearings will be held at several locations. Persons interested in making public comment should contact one of the BIA Area/Agency Education Offices listed below for more information. Individuals who make public comment are encouraged to submit a written statement summarizing their comments to the proctor at the actual hearing.

DATES AND TIMES: October 10, 1991 from 8–11 a.m. and 4–7 p.m. (local time) at each site listed below.

MEETING SITES:

Location	Contact person	Telephone
Billings Area	Larry Parker or Levon French.	406/675-6375
Crow Creek/ Lower Brule Agency.	William H. Schmidt or Catherine Gallagher.	605/245-2398
Pima Agency	Harvey Jacobs or Roseila Lawrence.	602/562-3557 602/379-6741
Portland Area	Van Peters or Verna Houle.	503/230-5682
Shiprock Agency.	Bobby Dean or Steve Gillenwater.	505/368-4427
South and Eastern States Agency.	Lena Sanders or Kimberley Marciano.	703/235-3233
Southern Pueblos Agency.	Val Cordova or Barbara DeLoach.	505/766-3034

WRITTEN COMMENTS: Written comments must be received at the address listed below no later than October 31, 1991: Office of Indian Education Programs, Branch of Exceptional Education, Attn: Carol L. Zilka, MS 3530 MIB Code 523, 1849 C Street NW., Washington, DC 20240–4000.

FOR FURTHER INFORMATION CONTACT: Goodwin K. Cobb, III, Chief, Branch of Exceptional Education at the above address or call (202) 208–6675.

Dated: September 18, 1991.

Eddie F. Brown,

Assistant Secretary—Indian Affairs.

[FR Doc. 91–22927 Filed 9–23–91; 8:45 am]

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federal register

Tuesday
September 24, 1991

Part X

The President

Proclamation 6337—National Hispanic Heritage Month, 1991

Legislative Calendar

Federal Register
Vol. 56, No. 185
Tuesday, September 24, 1991

Presidential Documents

Title 3—

The President

Proclamation 6337 of September 20, 1991

National Hispanic Heritage Month, 1991

By the President of the United States of America

A Proclamation

When we speak of our Hispanic heritage, we speak of more than one particular set of customs and traditions. Indeed, the Hispanic American heritage can be traced back to many different lands—to places as far-flung as Cuba, Mexico, Spain, and Peru. Nevertheless, Americans of Spanish and Latin American descent share a great sense of pride in the deep cultural and historical ties that exist between them.

Rich and varied, the Hispanic American heritage is as old as the story of America itself. Daring Spanish navigators who explored the New World nearly half a millennium ago were the first Europeans to establish settlements in what is now United States territory. In fact, by 1565—almost half a century before British colonists landed at Jamestown—the Spanish had established a permanent settlement at Saint Augustine, Florida. Traders and missionaries followed in the wake of explorers such as Coronado, Ponce de León, and Álvar Núñez Cabeza de Vaca, helping to open the American Southwest to further settlement and development.

Making use of the land's resources through farming, ranching, and mining, Spanish peoples shaped much of the Western frontier. Thriving communities took root around many Spanish missions, and today cities such as San Diego, Los Angeles, San Antonio, and Santa Fe continue to bear evidence of their celebrated past. However, over the years, Hispanic Americans have made vital contributions in communities across the country and in virtually every field of endeavor.

Today Hispanic Americans are our Nation's fastest growing minority. The number of Hispanics in this country grew by 53 percent during the past decade, up from 14.6 million to 22.4 million. This means that Hispanics now constitute about 9 percent of our population.

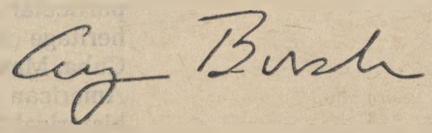
Many Hispanic Americans have come to these shores as immigrants, seeking better lives for themselves and their children. The achievements of these men and women indicate that they have not taken liberty for granted. Today Hispanic Americans are reaping the rewards of hard work: more and more are entering the political, social, and economic mainstream of American life.

Hispanic Americans are eager to enjoy the blessings of freedom and economic opportunity because many have known the bitter reality of life without them. As a Nation, we must keep faith with them and continue working to ensure equal opportunity for all of our citizens. With that in mind, last September I signed the Executive Order on Educational Excellence for Hispanic Americans. This order established a special Presidential Advisory Commission that will help to identify ways that the Federal Government can improve educational opportunities for Hispanic Americans.

The Congress, by Joint Resolution approved September 17, 1968, as amended by Public Law 100–402, has authorized and requested the President to issue annually a proclamation designating the month beginning September 15 and ending October 15 as "National Hispanic Heritage Month."

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the month beginning September 15, 1991, and ending October 15, 1991, as National Hispanic Heritage Month. I call upon the people of the United States to observe this month with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this 20 day of September, in the year of our Lord nineteen hundred and ninety-one, and of the Independence of the United States of America the two hundred and sixteenth.



[FR Doc. 91–23200
Filed 9–23–91; 11:12 am]
Billing code 3195–01–M

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Vol. 56, No. 185

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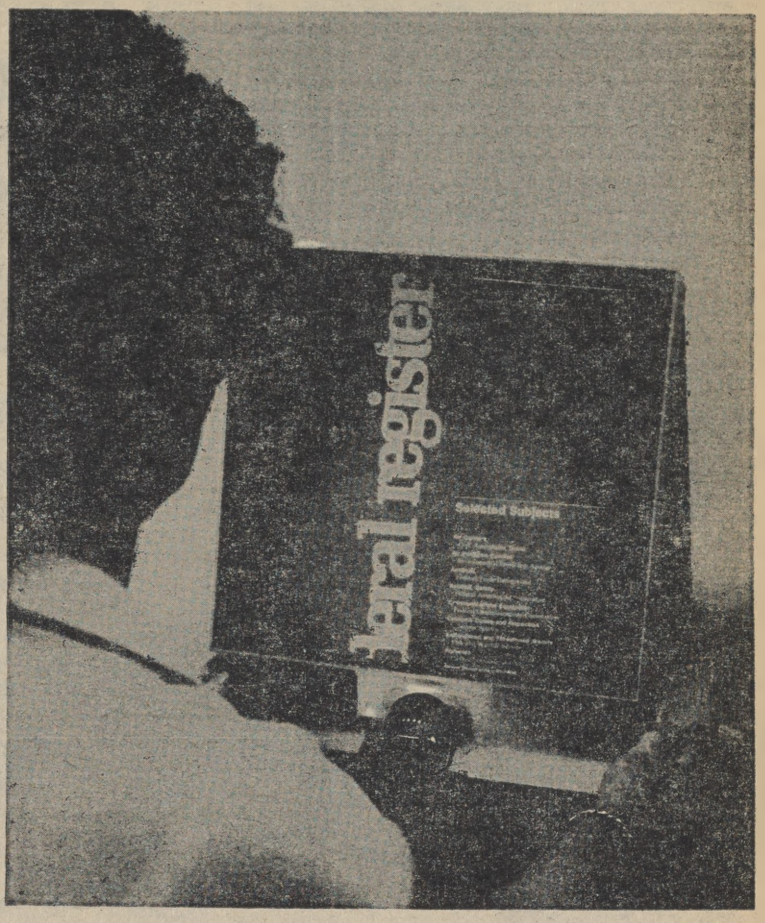
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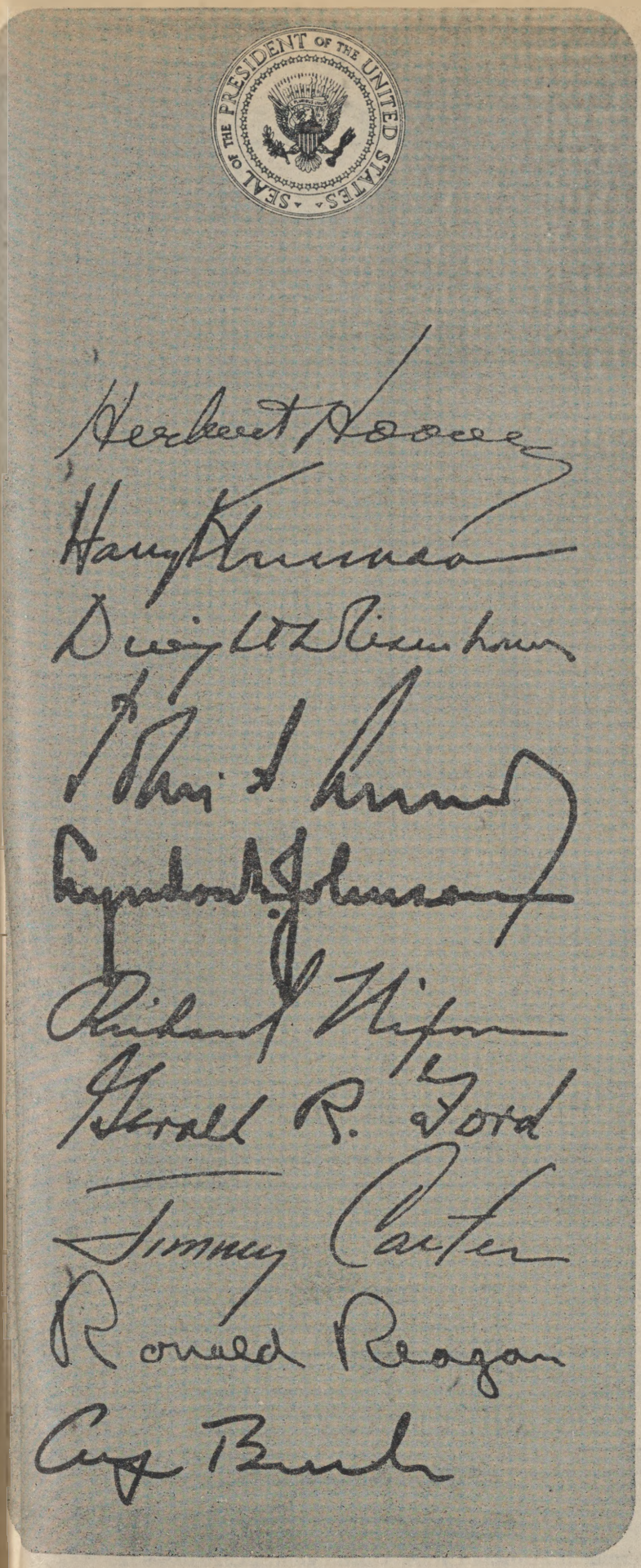
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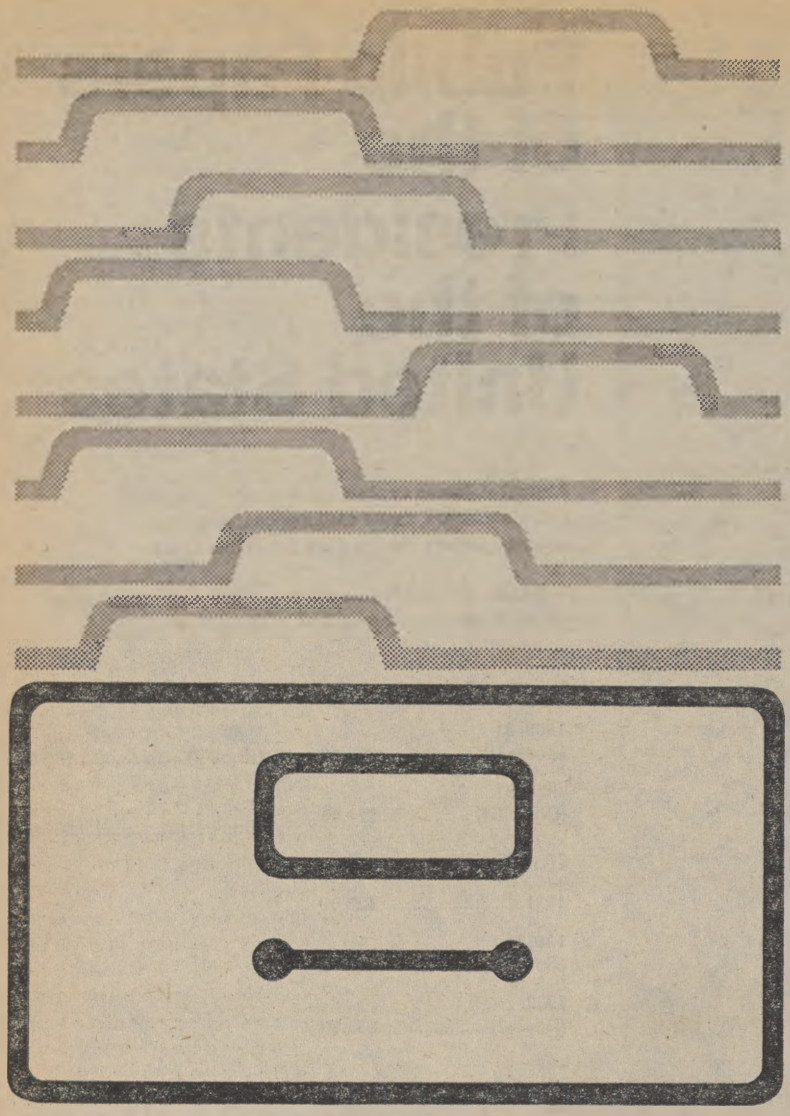
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