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June 4, 1997

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The President

Proclamation 7008 of May 30, 1997

Small Business Week, 1997

By the President of the United States of America

A Proclamation

America was built on the enterprise of our people—on their ideas, their energy, their willingness to take risks, and their willingness to pursue their dreams. Throughout the decades, men and women of independence, optimism, and determination have come to our shores, confident in the knowledge that in America they could build a life for themselves and their families through their own initiative, creating and developing businesses in every field of endeavor.

The success of the small business community has been a hallmark of our free enterprise system, helping to drive the engine of America's economy as we compete in the global marketplace. The invaluable contributions of small business owners to the strength of our economy are reflected in some extraordinary statistics. The recent record growth of the small business community has resulted in 840,000 new employer firms over the past year—the highest number ever, and a 2-percent increase over the last record set in 1995. Small businesses employ 53 percent of America's private work force, account for 47 percent of all sales in the country, and generate more than half of our private gross domestic product; and industries dominated by small business produced almost 1.5 million new jobs in the last year alone.

Our challenge now is to help America's small business community build on this phenomenal record of success. My Administration is committed to giving small business men and women the opportunity to realize their dreams. The Small Business Administration has a portfolio guaranteeing over $27 billion in loans to 185,000 small businesses that otherwise would not have access to such capital. We are encouraging microenterprise through the Department of Treasury's Community Development Financial Institution Fund, an initiative that makes it easier for prospective entrepreneurs to obtain the training and financing they need to start their own businesses. Working in partnership with State governments, we are striving to help modernize our Nation's small and medium-sized manufacturers and removing regulatory barriers to the adoption of new technologies in such fields as telemedicine, building and construction, and environmental technologies. We have also developed a National Export Strategy to help America's small and medium-sized businesses realize their export potential and compete effectively in the global marketplace.

As we observe Small Business Week, I join all Americans in saluting the men and women who have embraced the opportunities our country offers, whose hard work is transforming their communities, and whose energy and initiative are building our country into the kind of Nation we want to be in the 21st century.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim June 1 through June 7, 1997, as Small Business Week. I call upon Government officials and all the people of the United States to observe this week with appropriate

ceremonies, activities, and programs that celebrate the achievements of small business owners and encourage the development of new enterprises.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of May, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-first.

William J. Clinton

[FR Doc. 97–7008
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Rules and Regulations

Federal Register
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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.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 911 and 944

[Docket No. FV–97–911–1A IFR]

Limes Grown in Florida and Imported Limes; Change in Regulatory Period

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule changes the regulatory period currently prescribed under the lime marketing order and the lime import regulations. The marketing order regulates the handling of limes grown in Florida and is administered locally by the Florida Lime Administrative Committee (committee). This rule revokes the temporary suspension of grade and size requirements and maintains continuous, year round, implementation of regulations. This rule will maintain quality standards ensuring continued customer satisfaction with fresh limes. The change in import requirements is necessary under section 8e of the Agricultural Marketing Agreement Act of 1937.

EFFECTIVE DATE: This interim final rule becomes effective June 9, 1997; comments received by July 7, 1997, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456; Fax: (202) 720–5698. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Aleck Jonas, Southeast Marketing Field Office, Marketing Order Administration Branch, F&V, AMS, USDA, P.O. Box 2276, Winter Haven, Florida 33883; telephone: (941) 299–4770, Fax: (941) 299–5169; or Anne Dec, Marketing Order Administration Branch, F&V, AMS, USDA, room 2522–S, P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–2491, Fax: (202) 720–5698. Small businesses may request information on compliance with this regulation by contacting: Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525–S, Washington, DC 20090–6456; telephone: (202) 720–2491, Fax: (202) 720–5698.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 126 and Marketing Order No. 911 (7 CFR part 911), both as amended, regulating the handling of limes grown in Florida, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

This interim final rule is also issued under section 8e of the Act, which provides that whenever certain specified commodities, including limes, are regulated under a Federal marketing order, imports of these commodities into the United States are prohibited unless they meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically produced commodities.

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after date of the entry of the ruling.

There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of import regulations issued under section 8e of the Act.

This interim final rule revokes the temporary suspension of regulations currently prescribed under the lime marketing order and the lime import regulations. The temporary suspension was published in the **Federal Register** on August 21, 1996 (61 FR 43141) and suspended both the domestic and import regulations for the period June 1, 1997, through December 31, 1997. This rule keeps the regulations in effect beginning with its effective date and through the remainder of 1997.

Section 911.48 of the lime marketing order provides authority to issue regulations establishing specific pack, container, grade and size requirements. These requirements are specified under Sections 911.311, 911.329 and 911.344. Prior to this rule, the requirements specified under Sections 911.311, 911.329 and 911.344 were temporarily suspended from June 1, 1997, through December 31, 1997.

Beginning with its effective date, this rule revokes the suspension of regulations. The committee met on February 5, 1997, and, on a unanimous vote, recommended terminating the scheduled suspension.

The suspension of regulations was first published, as a proposed rule, in the May 8, 1996, **Federal Register** (60 FR 20754). A notice, published in the June 26, 1996, **Federal Register** (61 FR 33047), extended the comment period of the proposed rule from June 7, 1996, to July 8, 1996. The final rule was

published in the August 21, 1996, **Federal Register** (61 FR 43141).

In its deliberations, the committee noted that this issue has been argued and debated by the committee since its original proposal to suspend regulations. The committee was divided, passing the measure on a split vote of six in favor and four opposed, January 10, 1996. Comments from growers and grower/handlers concerning the changes in the proposed rule expressed concern that the loss of regulation and the associated quality standards would result in poor quality limes on the market and consumer dissatisfaction.

The committee, upon further discussion, shared these concerns. In fact, the committee revisited the issue on April 17, 1996. After deliberations on the possibilities of what could occur without regulations, the committee recommended, on a vote of seven in support, none against and one abstention, that the original proposal be modified from a permanent change to a one year experiment. This action was taken to provide the committee with an opportunity to study the effects the suspension of the handling regulations would have on the industry and market versus the cost savings derived from it.

The change was originally to have begun on June 1, 1996. However, an extended comment period, and the requested modifications to the proposal itself, resulted in the start date being delayed to June 1, 1997. This one year delay in implementation has allowed the committee time to reevaluate the need to suspend regulations.

The original rule suspending regulations was issued in response to changes in the market, rising costs of production and the cost of replanting in the aftermath of Hurricane Andrew. The committee commented that when the change was originally recommended on January 10, 1996, the industry's position and future prospects appeared quite different from today. At that time, many of the lime trees were less than 3 years old and too young to bear fruit. These lime trees had been replanted after Hurricane Andrew. Money was being expended on replanting and no revenue was coming in from these young non-bearing trees. Further, last year citrus leaf minor was a new threat to the lime trees and at that time predictions called for expensive control methods that may or may not have worked. Throughout the industry, the concern to save money was great, and the suspension of regulations was thought to be a money saving avenue. By reducing the regulatory period and its associated costs, the committee hoped to provide a decrease in industry expenses. The committee hoped the reduced costs of no regulations, no inspection fees and reduced committee expenses, resulting from fewer meetings and less compliance monitoring, would benefit the industry and foster growth.

The industry's present situation is much improved over what it was when the changes to the regulation were proposed and made final. The young lime trees are now 3 and 4 years old and bearing fruit, resulting in a larger crop and more revenue. Citrus leaf minor is far less a threat than originally presumed, due, in part, to native insect predation against it. This has resulted in less funds being required to combat this pest.

Also, the lime committee operated off reserves last season with a zero assessment, and it has budgeted to work off reserves with a zero assessment for the current season. This will result in industry savings of approximately $75,000 each season. The committee believes that all of these factors have eliminated the critical need for the further cost savings which prompted the original request for the change.

Reviewing the past year, committee members stated that fresh limes sold were generally plentiful and of good quality. However, they also noted that even with quality regulations in effect, some poor quality limes do reach the retail market. The committee is now concerned that removing quality regulations, even for an experimental period, may result in even larger quantities of poor quality fruit reaching the retail market, resulting in consumer dissatisfaction and product substitution. Committee members commented that past experience has indicated the difficulty of enticing customers to return to a product once substitution has taken place.

Committee members maintain that although some poor quality limes still appear on the market, the regulations have done much to reduce the number and help provide uniform quality. This, in turn, has ensured customer satisfaction with fresh limes which is a primary concern to the industry. Thus, the committee believes the benefits of the quality regulations outweigh the now diminished need to take action that would result in cost savings.

Section 8e of the Act provides that when certain domestically produced commodities, including limes, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. Since this rule will change the regulatory period under the domestic handling regulations, a corresponding change to the import regulations must also be made.

Minimum grade and size requirements for limes imported into the United States are currently in effect under Section 944.209 [7 CFR 944.209]. This interim final rule revokes the temporary suspension period for both the domestic and import regulations. Beginning with its effective date, this rule leaves the lime import regulations in effect throughout the remainder of 1997. This reflects the same changes being made under the order for Florida limes. The minimum size and grade requirements for Florida limes are specified in section 911.344 under marketing order 911. The minimum size and grade requirements are not specifically stated in the lime import regulation. Therefore, no change is needed in the text of Section 944.209.

Mexico is the largest exporter of limes to the United States. During the 1995–96 season, Mexico exported 5,591,451 bushels to the United States, while all other import sources shipped a combined total of 167,832 bushels during the same time period. From June 1, 1996, through December 31, 1996, Mexico exported 4,151,867 bushels of limes to the United States, approximately 67 percent of the total, 6,190,321 bushels, shipped during the 1996–97 season that ended in March. Mexico exported 559,525 bushels of limes to the United States for the month of June 1996, approximately 9 percent of the total, 6,190,321 bushels, shipped in the 1996–97 season.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility. Import regulations issued under the Act are based on those established under Federal marketing orders.

There are approximately 10 handlers subject to regulation under the order and about 50 producers of Florida limes. There are approximately 35 importers of limes. Small agricultural service firms, which include lime handlers and

importers, have been defined by the Small Business Administration (13 CFR 121.601) as those whose annual receipts are less than $5,000,000, and small agricultural producers are defined as those whose annual receipts are less than $500,000.

Based on the Florida Agricultural Statistic Service and committee data for the 1995–96 season, the average annual f.o.b. price for fresh Florida limes during the 1995-96 season was $16.50 per 55 pound bushel box equivalent for all domestic shipments, and the total shipments for the 1995–96 season were 371,413. Approximately 20 percent of all handlers handled 86 percent of Florida lime shipments. In addition, many of these handlers ship other tropical fruit and vegetable products which are not included in committee data but would contribute further to handler receipts. Using the average f.o.b. price, about 80 percent of lime handlers could be considered small businesses under SBA's definition and about 20 percent of the handlers could be considered large businesses. The majority of lime handlers, producers, and importers may be classified as small entities.

Section 911.48 of the lime marketing order provides authority to issue regulations establishing specific grade and size requirements, and section 8e of the Act requires that when such regulations are in effect for limes, the same or comparable requirements be applied to imports.

This interim final rule changes the regulatory period currently prescribed under the lime marketing order and the lime import regulations. Beginning on its effective date, this interim final rule revises both the domestic and import regulations by removing a temporary suspension of regulations and thereby maintaining handling regulations for the remainder of 1997. The regulations are specified in sections 911.311, 911.329 and 911.344 and establish pack, container, grade and size requirements. The committee recommended this change to maintain the quality of limes in the marketplace. Additionally, the need to suspend regulations to reduce handling costs has diminished.

This interim final rule will have a positive impact on growers, handlers and importers, as fruit and vegetable prices are quite responsive to quality differentials. This action is intended to maintain quality. At the meeting, the committee discussed the impact of this change on handlers and producers in terms of cost. Any costs to handlers and importers caused by this action will be the loss of projected savings from the suspension. The majority of possible cost savings would have resulted from eliminating inspection fees during the suspension.

The scheduled suspension period would have only been effective for one year, resulting in limited cost savings. The industry is already used to budgeting for inspection and associated regulation costs. The Federal/State Inspection Service assesses fees to provide their service. The cost for inspection is equitable. Small and large handlers are charged the same base rate, with the overall cost determined by a handler's volume.

During this season, and the season prior, the committee voted to operate on reserves rather than assessing the industry. This will result in an industry cost savings of approximately $75,000, the approximate cost of operating the committee for a year, during each of these two years. This will do much to offset any costs that result from the revocation of the suspension period. Assessments, when they are applied, are based on the amount of fruit handled, therefore, the costs are borne proportionally by small and large operations. Consequently, the benefits of no assessments are received equally. Importers do not have to pay assessments to maintain the marketing order.

Since the recommendation to establish the suspension period was made, industry needs for cost savings have diminished. The focus has shifted to the need for stable markets and returns. Customers are willing to pay for quality, and complementary studies show that customers return purchase rate declines considerably if they are disappointed by the quality of the original purchase. The current cost of inspection is $.14 per 55 pound equivalent. However, a drop in quality could result in a price reduction measured in dollars rather than cents on the same equivalent. Thus, the benefits of a quality standard outweigh the minimal cost savings that may have resulted from the suspension. Maintaining quality to the consumer will result in a strong and stable market, benefiting growers, handlers and importers.

Shipments of Florida limes for the 1994–95 season were 289,213 bushels, for the 1995–96 season they were 371,413 bushels, and for the current 1996–97 season shipments were 398,279 bushels. A steady increase in production is indicated. Mexican exports have also increased from 2,626,707 bushels in the 1990–91 season to 6,190,321 bushels in the 1996–97 season.

Committee members have considered alternatives to rescinding the suspension period. The committee considered a continuous period of no regulations for the months of June through December. They reconsidered the merits of such an action, determining that removing regulations to save money may have costs, such as lost market share, which would overshadow any potential savings. The committee determined that in the time that had passed since the original consideration of a suspension period, the need for cost savings measures had passed, and that the benefits of the quality standards outweighed the cost savings that may have been realized. The committee was unanimous in its belief that the need for the suspension has passed. Accordingly, the committee unanimously recommended this change as outlined.

This action will not impose any additional reporting or recordkeeping requirements on either small or large lime handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. However, limes must meet the requirements as specified in the U.S. Standards for Grades of Persian Limes (7 CFR 51.1000 through 51.1016) issued under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 through 1627).

The committee's meeting was widely publicized throughout the lime industry and all interested persons were invited to attend the meeting and participate in committee deliberations on all issues. Like all committee meetings, the February 5, 1997, meeting was a public meeting and all entities, both large and small, were able to express views on these issues. The committee itself is composed of ten members, of which four are handlers, five are producers and one is a public member. The majority of committee members represent small entities.

A proposed rule concerning this action was issued by the Department on April 25, 1997, and published in the **Federal Register** on Tuesday, April 29, 1997 (62 FR 23185). That rule also proposed an increase in the minimum size for the month of June. Copies of the rule were mailed or sent via facsimile to all Committee members and lime handlers and producers. The rule was also made available through the Internet by the Office of the Federal Register.

A 30-day comment period, ending May 29, 1997, was provided to allow interested persons to respond to the proposal. Two comments were received. The commenters, one representing a Mexican exporter and the other a Mexican exporters' and packers' union, requested that the comment period for the rule be extended to allow for additional time, 30 days and 90 days, respectively, to analyze the proposal. One commenter concluded the proposal would have a negative effect on its business and the other noted that the proposal would have a direct effect on its business.

The Department has reviewed the requests, and has determined that an extended period with no minimum quality or size standards in place would be detrimental to the industry. As previously discussed, the suspension was originally recommended at a time when cost savings were of utmost concern to the Florida lime industry. Now, however, the benefits of maintaining quality and ensuring customer satisfaction and repeat purchases outweigh the diminished need to take action that would result in cost savings.

Therefore, the Department is instituting the revocation of the suspension through this interim final rule which will allow 30 additional days to comment.

However, with regard to increasing the minimum size requirement, the Department is issuing in a separate **Federal Register** publication an extension of the proposed comment period concerning implementing the increase in minimum size from 1 ⅞ to 2 inches in diameter for the month of June. Any additional comments received during the extended comment period would be considered before the rule is finalized.

This rule also modifies language in the regulations to return the minimum size requirement of 1 ⅞ inches from June 1 through December 31. The 1 ⅞ inch minimum size requirement was inadvertently removed when the temporary suspension was issued on August 14, 1996 (61 FR 43141).

After consideration of all relevant matter presented, including the information and recommendation submitted by the committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

In accordance with section 8e of the Act, the United States Trade Representative has concurred with the issuance of this rule, as it pertains to limes imported into the United States.

Pursuant to 5 U.S.C. 553, it is also found and determined that it is impracticable, unnecessary and contrary to the public interest to give further notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because handlers are already shipping limes from the 1997–98 crop. The industry also needs the regulation in effect as close to June 1 as possible, to minimize any negative effects caused by a period of deregulation. Further, handlers are aware of this rule, which was recommended at a public meeting. A 30-day comment period is provided for in this interim final rule. A proposed rule was published previously with opportunity for comments.

List of Subjects

7 CFR Part 911

Limes, Marketing agreements, Reporting and recordkeeping requirements.

7 CFR Part 944

Avocados, Food grades and standards, Grapefruit, Grapes, Imports, Kiwifruit, Limes, Olives, Oranges.

For the reasons set forth in the preamble, 7 CFR parts 911 and 944 are amended as follows:

1. The authority citation for 7 CFR parts 911 and 944 continues to read as follows:

Authority: 7 U.S.C. 601–674.

PART 911—LIMES GROWN IN FLORIDA

§§ 911.311, 911.329 [Amended]

2. Temporary suspension of §§ 911.311 and 911.329 is revoked effective June 9, 1997.

§ 911.344 [Amended]

3. Temporary suspension of § 911.344 is revoked effective June 9, 1997, and paragraph (a)(3) is amended by removing the words ''at least 2 inches diameter'' and adding, in their place, the words ''at least 2 inches in diameter from January 1 through May 31, and at least 1 ⅞ inches in diameter from June 1 through December 31''.

PART 944—FRUITS, IMPORT REGULATIONS

§ 944.209 [Amended]

4. Temporary suspension of § 944.209 is revoked effective June 9, 1997.

Dated: May 29, 1997.

Robert C. Keeney,

Director, Fruit and Vegetable Division.

[FR Doc. 97–14650 Filed 6–2–97; 10:02 am]

BILLING CODE 3410–02–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

10 CFR Part 1703

FOIA Fee Schedule

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Update of FOIA fee schedule.

SUMMARY: The Defense Nuclear Facilities Safety Board is publishing its annual update to the Freedom of Information Act (FOIA) Fee Schedule pursuant to 10 CFR § 1703.107(b)(6) of the Board's regulations.

EFFECTIVE DATE: June 1, 1997.

FOR FURTHER INFORMATION CONTACT: Kenneth M. Pusateri, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW., Suite 700, Washington, DC 20004–2901, (202) 208–6447.

SUPPLEMENTARY INFORMATION: The FOIA requires each Federal agency covered by the Act to specify a schedule of fees applicable to processing of requests for agency records. 5 U.S.C. 552(a)(4)(i). On March 15, 1991 the Board published for comment in the **Federal Register** its proposed FOIA Fee Schedule. 56 FR 11114. No comments were received in response to that notice and the Board issued a final Fee Schedule on May 6, 1991.

Pursuant to 10 CFR § 1703.107(b)(6) of the Board's regulations, the Board's General Manager will update the FOIA Fee Schedule once every 12 months. Previous Fee Schedule updates were published in the **Federal Register** and went into effect, most recently, on June 1, 1996. 61 FR 28725.

Board Action

Accordingly, the Board issues the following schedule of updated fees for services performed in response to FOIA requests:

Defense Nuclear Facilities Safety Board Schedule of Fees for FOIA Services (Implementing 10 CFR § 1703.107(b)(6))

Search or Review Charge—$48 per hour.

Copy Charge (paper)—$.06 per page, if done in-house, or generally available commercial rate (approximately $.10 per page).

Copy Charge (3.5″ diskette)—$5.00 per diskette.

Copy Charge (audio cassette)—$3.00 per cassette.

Duplication of Video—$25.00 for each individual videotape; $16.50 for each additional individual videotape.

Copy Charge for large documents (e.g., maps, diagrams)—Actual commercial rates.

Dated: May 31, 1997.

Kenneth M. Pusateri,

General Manager.

[FR Doc. 97–14569 Filed 6–3–97; 8:45 am]

BILLING CODE 3670–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–101–AD; Amendment 39–10044; AD 97–12–01]

RIN 2120–AA64

Airworthiness Directives; Cessna Model 650 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Cessna Model 650 airplanes. This action requires inspections to detect discrepancies of a certain wire bundle assembly and to detect discrepancies of the hydraulic pump suction line in the area above the baggage compartment; and corrective actions, if necessary. This AD also requires modification of the supports for the wire bundle cable assembly and the supports for the hydraulic pump suction line. This amendment is prompted by a report that, due to inadequate clearance, an alternating current (AC) wire chafed against the hydraulic pump suction line and caused electrical arcing. The actions specified in this AD are intended to prevent such electrical arcing and consequent fire hazard.

DATES: Effective June 19, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 19, 1997.

Comments for inclusion in the Rules Docket must be received on or before August 4, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97-NM–101-AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Cessna Aircraft Co., P.O. Box 7706, Wichita, Kansas 67277. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Wichita Aircraft Certification Office, Small Airplane Directorate, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jose Flores, Aerospace Engineer, Systems and Propulsion Branch, ACE–116W, FAA, Small Airplane Directorate, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4133; fax (316) 946–4407.

SUPPLEMENTARY INFORMATION: The FAA has received a report of an in-flight fire on a Cessna Model 650 airplane. The fire burned a hole (approximately 8 x 9 inches) in the right side of the fuselage and into the right engine pylon forward of the forward engine mount beam. The fire also burned another hole (approximately 2 feet in diameter) through the fuselage to the right side of the top centerline in the area above the aft baggage compartment. In addition, the fire burned into the empty fuel tank of the fuselage and consequently burned the upper portion of the fuel cell liner. All avionics equipment and wiring above the engine mount beams also were severely burned, which caused a number of systems to be inoperative for the remainder of the flight. Furthermore, the fire is also suspected of breaching the fuel line to the auxiliary power unit and consequently providing additional fuel to the fire.

Investigation revealed that, due to inadequate clearance, the alternating current (AC) wire chafed against the hydraulic pump suction line in the area above the baggage compartment. Such chafing resulted in the electrical arcing of an AC wire and consequently led to the in-flight fire. Subsequent ground testing, which simulated these conditions, confirmed that the subject electrical arcing could result in a fire.

Inadequate clearance between the AC wire and the hydraulic pump suction line in the area above the baggage compartment, if not corrected, could result in electrical arcing and may lead to a potential fire hazard.

Explanation of Relevant Service Information

The FAA has reviewed and approved Cessna Citation Service Bulletin 650–24–57, dated May 15, 1997. The service bulletin describes procedures for performing visual inspections to detect discrepancies of the wire bundle assembly from point 1 to point 2, and to detect discrepancies of the hydraulic pump suction line in the area above the baggage compartment; and corrective actions, if necessary. The service bulletin also describes procedures for modification of the supports for the wire bundle cable assembly and the supports for the hydraulic pump suction line. The modification involves installation of a clip and five clamps with associated hardware. Accomplishment of these actions will provide a positive separation between the AC wires and the hydraulic pump suction line above the baggage compartment.

Explanation of the Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on certain other Cessna Model 650 airplanes of the same type design, this AD is being issued to prevent electrical arcing of the AC wire and consequent fire hazard. This AD requires visual inspections to detect discrepancies of the wire bundle assembly from point 1 to point 2, and to detect discrepancies of the hydraulic pump suction line in the area above the baggage compartment; and corrective actions, if necessary. This AD also requires modification of the supports for the wire bundle cable assembly and the supports for the hydraulic pump suction line. The actions are required to be accomplished in accordance with the service bulletin described previously.

Differences Between the AD and the Relevant Service Information

Operators should note that, unlike the recommended compliance time (i.e., during the next scheduled maintenance period or phase inspection) specified in the service bulletin for accomplishing the inspections and modification, this AD requires that affected airplanes be inspected and modified within 25 hours time-in-service after the effective date of the AD. In developing an appropriate compliance time for this action, the FAA considered not only the degree of urgency associated with addressing the subject unsafe condition, but the susceptibility of electrical arcing of the AC wire, which could lead to a potential fire hazard. In addition, the FAA has reviewed the results of a survey

(conducted by Cessna) of 43 Cessna Model 650 airplanes. The results indicate that the AC wire rubbed or chafed against the hydraulic pump suction line on eight of these airplanes (18 percent). In light of these factors, the FAA finds the compliance time specified in the AD for accomplishing the required inspections and modification to be warranted, in that it represents the maximum amount of time allowable for the affected airplanes to continue to operate without compromising safety.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire.

Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–101–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted 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. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

97–12–01 Cessna Aircraft Company: Amendment 39–10044. Docket 97-NM–101-AD.

Applicability: Model 650 airplanes, having serial numbers 650–0174 through 650–0241 inclusive, 650–7001 through 650–7006 inclusive, and 650–7008 through 650–7076 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been otherwise modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent electrical arcing of the alternating current wire and consequent fire hazard, accomplish the following:

(a) Within 25 hours time-in-service after the effective date of this AD, accomplish paragraphs (a)(1), (a)(2), and (a)(3) of this AD, in accordance with the Accomplishment Instructions of Cessna Service Bulletin SB650–24–57, dated May 15, 1997.

(1) Perform a visual inspection to detect discrepancies (i.e., improper clearance, wear, and damage) of the wire bundle assembly from point 1 to point 2, in accordance with the service bulletin. If any discrepancy is detected, prior to further flight, replace the wire bundle assembly with a new wire bundle assembly or install a spiral wrap, as applicable, in accordance with the service bulletin.

(2) Perform a visual inspection to detect discrepancies (i.e., chafing, rubbing, nicks, scratches, and burn marks) of the hydraulic pump suction line in the area above the baggage compartment, in accordance with the service bulletin. If any discrepancy is detected, prior to further flight, repair it in accordance with the service bulletin.

(3) Modify the supports for the wire bundle cable assembly and the supports for the hydraulic pump suction line in accordance with the service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The inspections and modification shall be done in accordance with Cessna Service Bulletin SB650–24–57, dated May 15, 1997. This incorporation by reference was approved 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 Cessna Aircraft Co., P.O. Box 7706, Wichita, Kansas 67277. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Wichita Aircraft Certification Office, Small Airplane Directorate, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on June 19, 1997.

Issued in Renton, Washington, on May 27, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–14285 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 153

[Docket No. RM97–1–000; Order No. 595]

Applications for Authorization To Construct, Operate, or Modify Facilities Used for the Export or Import of Natural Gas

Issued May 28, 1997.

AGENCY: Federal Energy Regulatory Commission. DOE.

ACTION: Final rule.

SUMMARY: The Commission is reorganizing, rewriting, and updating its regulations governing the filing of applications under section 3 of the Natural Gas Act governing the filing of applications for the siting, construction, and operation of facilities for the import or export of natural gas and the issuance and amendment of Presidential Permits for the construction and operation of border facilities. The rule is part of the Commission's ongoing program to review its filing and reporting requirements and reduce unnecessary burdens by eliminating the collection of data that is not necessary to the performance of the Commission's regulatory responsibilities. The rule is necessary to conform the Commission's regulations to the Commission's current responsibilities, as delegated by the Secretary of Energy.

EFFECTIVE DATE: This Final Rule is effective August 4, 1997.

FOR FURTHER INFORMATION CONTACT:

Albert J. Francese, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 208–0736.

Richard W. Foley, Office of Pipeline Regulation, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 208–2245.

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I. Introduction

The Federal Energy Regulatory Commission (Commission) is amending part 153 of its regulations governing the siting, construction, and operation of facilities for the import and export of natural gas between the United States and a foreign country. Part 153 has not been significantly revised since the Commission's predecessor, the Federal Power Commission (FPC), recodified its regulations in 1947.[1]

The rule conforms the Commission's filing requirements in part 153 to the Commission's current responsibilities as changed by intervening legislation and Department of Energy (DOE) delegation orders. The DOE delegation orders divide jurisdiction and authority over natural gas import and export issues arising under section 3 of the Natural Gas Act (NGA)[2] between the Commission and DOE.[3] The revisions to part 153 implement the Commission's currently delegated responsibilities under NGA section 3 and Executive Order 10485, as amended, regarding the construction and operation of facilities

[1] Order No. 141, 12 FR 8596 (December 19, 1947). The part 153 regulations originally became effective on July 11, 1938, in FPC Order Nos. 52 (section 3 authorizations) and 66 (Presidential Permits).

[2] 15 U.S.C. 717b.

[3] DOE previously issued regulations implementing its delegated authorities under NGA section 3 for the import/export of natural gas. *See* 10 CFR 590.100, *et seq.*

for the import and export of natural gas.[4]

The Final Rule redefines and clarifies the Commission's role with respect to granting the authorizations necessary to construct and operate facilities for the import and export of natural gas between a foreign country and the United States. The regulations codify existing practice which requires the applicant proposing to construct or modify LNG facilities to file exhibits concerning the environmental and safety features of those facilities.

Over the last 11 years (1986–1996), there has been a dramatic increase in the volume of natural gas import and export activity involving the United States.[5] In 1996 alone, United States firms imported 2,883.3 Bcf of natural gas from Canada, while exporting 61.4 Bcf to Canada. In the same year, United States firms imported 13.9 Bcf from Mexico and exported 33.8 Bcf of natural gas to Mexico. The issuance of the Final Rule coincides with proposals recently filed by pipelines for substantial new construction to bring even more Canadian natural gas into the United States.[6] The Final Rule will improve Commission monitoring of all facilities authorized under part 153.

The changes to the Commission's regulations are effective August 4, 1997.

II. Background

On February 3, 1997, the Commission issued a Notice of Proposed Rulemaking (NOPR) proposing a major overhaul of its regulations governing applications for the construction of facilities for the import/export of natural gas.[7] The Commission is determined to issue sensible regulations that impose the least burden without sacrificing rational and necessary protections.[8] The Commission is bringing its filing requirements and procedures up to date to match its current substantive policies and authority and is not significantly changing its procedures for processing applications filed under part 153. The revised regulations are designed to provide the Commission and interested parties with the information generally required to process an application under part 153. Where more information is needed, it may be collected on a case-by-case basis.

The Commission received six comments on the NOPR.[9] The commenters suggested various clarifications and modifications some of which are incorporated into the Final Rule with appropriate revisions. The Final Rule:

- Clarifies that § 153.5 does not require the holder of a Commission section 3 authorization to file an amendment with the Commission upon DOE/FE's extension of import/export authority;
- Clarifies that § 153.5 requires the holder of an existing section 3 authorization for LNG facilities to file for additional section 3 authorization to modify existing LNG facilities with facilities to be used for the import/export of natural gas, but no amendment would be required if the holder seeks to modify facilities at the LNG plant site that are not used to import/export LNG;
- Requires in § 153.6 an applicant to state for the first time whether an application for DOE/FE authorization is required or has been obtained at the time of filing a section 3 application with the Commission;
- Clarifies that the list in § 153.7(c)(1) of public interest criteria is illustrative and adds as a factor for consideration the enhancement of competition within the United States for natural gas transportation or supply;
- Clarifies that § 153.9 permits the transfer or assignment of section 3 authorizations and related facilities upon prior Commission approval, and;
- Exempts applicants that do not possess pipeline transportation capacity (such as LNG terminals) from the new requirement in § 153.23 to report annually estimated peak day capacity and actual peak day usage of the import/export facility.

III. Discussion

A. Background and Statutory Authority

Section 3 of the NGA requires prior authorization before exporting or importing natural gas from or to the United States.[10] Section 3 authorizes the Commission to grant an application, in whole or in part, with modifications and upon terms and conditions as the Commission may find necessary or appropriate. Section 3 also authorizes the Commission to make ''such supplemental order in the premises as it may find necessary or appropriate.''

Currently, responsibilities under section 3 are divided between DOE/FE and the Commission. The Commission's responsibilities under section 3, as under the other provisions of the Natural Gas Act, are to be administered ''to protect consumers against exploitation at the hands of natural gas companies.''[11]

Initially, the FPC was vested with exclusive jurisdiction under section 3 to decide all natural gas import and export issues, including the authorization to import and export natural gas and to construct and operate necessary facilities. The FPC also had the authority, pursuant to Executive Order 10485, as amended, to issue or modify a Presidential Permit for the construction and operation of border facilities at the international boundary between the United States and Canada or Mexico.

The Department of Energy Organization Act (DOE Act), enacted in 1977, transferred all the FPC's authority over natural gas imports and exports to the Secretary of Energy ''unless the Secretary assigns such a function to the (Federal Energy Regulatory) Commission.''[12] Between October 1, 1977, and February, 1984, DOE and the Commission shared responsibility over natural gas import and export issues pursuant to DOE delegation orders (which have since been rescinded). The Secretary of Energy administered his authority over natural gas import and export issues pursuant to FPC rules in place on September 30, 1977, until DOE issued its own final regulations.[13]

The Secretary issued new delegation orders 0204–111 and 0204–112, discussed below, in February 1984, to minimize problems of coordination on certain import/export issues.[14] These delegation orders allocated regulatory functions concerning the import and

[4] Executive Order 10485, 3 CFR, 2949–1953 Comp., p. 970, as amended by Executive Order 12038, 3 CFR 1978 Comp., p. 136.

[5] DOE/FE, Natural Gas Imports and Exports, Fourth Quarter Report (1996) at p. ii.

[6] The Final Rule will apply to all part 153 applications filed after the effective date of the Final Rule.

[7] Applications for Authorization to Construct, Operate, or Modify Facilities Used for the Export or Import of Natural Gas, 62 FR 5940 (February 10, 1997), IV FERC Stats. & Regs. ¶ 32,523 (1997).

[8] The President's memorandum, dated March 4, 1995, concerning the National Performance Review, requires agencies, among other things, to eliminate or revise outdated regulations and to move from a process that creates large numbers of regulations to issuing ''sensible regulations that impose the least burden without sacrificing rational and necessary protections.''

[9] The commenters were the Canadian Association of Petroleum Producers, Coastal Companies, Great Lakes Gas Transmission Limited Partnership, PanEnergy Pipelines, Phillips Petroleum Company, and Yukon Pacific Company L.P. While PanEnergy Pipelines' comments were filed three days late, the Commission will consider them in order to address all issues raised in this proceeding.

[10] 15 U.S.C. 717b.

[11] FPC v. Hope Natural Gas Co., 320 U.S. 591, 610 (1944).

[12] *See* sections 301(b), 402(a) and 402(f) of the Department of Energy Organization Act, 42 U.S.C. 7151(b), 7172(a) and 7172(f).

[13] DOE's final rules establishing procedures for processing applications for the import and export of natural gas and revised *ex parte* rules became effective on September 6, 1984. 49 FR 35302 (September 6, 1984).

[14] Both delegation orders were published at 49 FR 6684 (February 22, 1984).

export of natural gas to the Commission and DOE/Economic Regulatory Administration (ERA).[15] DOE and the Commission continue to share responsibility for determining natural gas import/export issues under these currently applicable delegation orders.

Under DOE Delegation Order 0204–111, effective February 22, 1984, the Secretary of Energy delegated to the Administrator of ERA authority under section 3 of the NGA to regulate the import (including the place of entry) and the export (including the place of exit) of natural gas. On the same date, the Secretary of Energy issued Delegation Order 0204–112 which delegated to the Commission exclusive authority over specific import/export matters.

The responsibilities delegated to the Commission include the authority to approve or disapprove proposals for the construction, operation, and siting of facilities, and when the construction of new domestic facilities is involved, the place of entry for imports or place of exit for exports. The Commission's delegated authority is subject to DOE's right of disapproval if the Administrator finds disapproval to be appropriate ''in the circumstances of a particular case.'' Thus, under the most recent and presently applicable delegation orders, the facility and siting aspects of natural gas import and export are delegated and assigned to the Commission for determination of the public interest.

Section 3 of the NGA provides that the Commission ''shall issue an order upon application, unless * * * it finds that the proposed exportation or importation will not be consistent with the public interest.'' The Commission determines the public interest in particular proceedings upon consideration of all relevant factors. For example, the Commission has authorized the construction and operation of import/export facilities under NGA section 3 based upon substantial evidence that the proposal is necessary to access gas supplies, deliver imported gas to an industrial user,[16] provide a more economic source of natural gas,[17] or enhance competition, system reliability, flexibility, or the dependability of international energy trade, and will not adversely affect the service or rates of existing customers.[18] The Commission's current practice in implementing NGA section 3 does not require that an applicant include in its application evidence of specific market support for its project (such as precedent agreements between the applicant and shippers), although construction authorized under section 3 must be associated with the import/export of natural gas.[19]

A person applying to the Commission for authority under section 3 must also apply to the Commission, pursuant to DOE Delegation Order No. 0204–112, for the issuance of a Presidential Permit or an amendment to an existing Presidential Permit if the proposed facilities are to be located at the borders of the United States and either Canada or Mexico.[20] A Presidential Permit authorizes the applicant to construct, operate, maintain, or connect natural gas pipeline facilities at the international borders.

The Commission has the jurisdiction, pursuant to Executive Order 10485, as amended, to condition a Presidential Permit ''as the public interest may in its judgment require.'' [21] In addition, Executive Order 10485, as amended, requires the Commission to obtain the concurrence of the Secretary of State and the Secretary of Defense who will consider foreign policy and national security aspects of the application.

An applicant proposing to alter a term of an existing Presidential Permit that does not also necessitate new construction, *e.g.*, a revision to the authorized operating or design capacity of an existing import/export facility, must file to amend its Presidential Permit.[22] That applicant, however, does not also require section 3 authorization when existing facilities are unchanged. On the other hand, the applicant granted authorization under NGA section 3 does not require a Presidential Permit for the construction of natural gas import/export facilities located at tidewater or on the border of the United States and international waters because, as the Commission interprets and applies Executive Order 10485, as amended, there would be no physical connection of border facilities at the boundary between the United States and a foreign country.[23]

The holder of a Presidential Permit may file to terminate, revoke, or surrender its Presidential Permit which had been activated by the construction of authorized facilities. Pursuant to uniform article 9 of a Presidential Permit, the holder of a surrendered Presidential Permit must remove the authorized import/export facilities as prescribed by Commission order. The holder of a surrendered Presidential Permit may not transfer the related section 3 authorization and facilities to another owner/operator without prior Commission authorization. [24]

The holder of a Presidential Permit also may file a request to surrender its Presidential Permit if the Presidential Permit was never activated and no facilities were constructed. [25] Upon receipt of an application to surrender a Presidential Permit, the Commission's practice is to provide public notice of the application to determine whether its surrender would be disputed. [26]

B. Objectives of the Final Rule

Part 153 currently imposes specific filing requirements on applicants for authorization under section 3 and Executive Order 10485, as amended, to site, construct, and operate facilities for

[15] Effective on February 7, 1989, the Assistant Secretary for Fossil Energy (DOE/FE) assumed the delegated responsibilities of the Administrator of ERA. *See* DOE Delegation Order No. 0204–127. 54 11436 (March 20, 1989).

[16] *See* National Steel Corp., 45 FERC ¶ 61,100 (1988).

[17] *See* Atlantic Richfield Co. and Intalco Aluminum Corp., 49 FERC ¶ 61,294 (1989), *reh'g denied in part,* 50 FERC ¶ 61,210 (1990).

[18] Great Lakes Transmission Limited Partnership, 76 FERC ¶ 61,148 (1996).

[19] Unlike precedent under section 3, Commission precedent under NGA section 7 requires an applicant to file executed precedent or service agreements to demonstrate sufficient demand for proposed capacity. *See,* e.g., El Paso Natural Gas Co., 65 FERC ¶ 61,276 (1993).

[20] Pursuant to an opinion rendered by the Office of the Legal Counsel of the Department of Justice, the FPC determined that Executive Order No. 10485 does not apply to gas facilities on the border of the United States and international waters because there would be no border facilities involving any physical connection between the facilities involving any physical connection between the United States and a foreign country. *See* Phillips Petroleum Co., *et al.*, 37 FPC 777 (1967).

[21] These conditions are stated as ''articles'' in the body of a Presidential Permit. The articles describe the facilities, design capacity, nature of the service and include various uniform provisions concerning transferability of the Presidential Permit or facilities, inspection and access to the facilities, liability for damages, filing of information, removal of facilities upon surrender/revocation of the Presidential Permit, possession by the United States, and control by a foreign government.

[22] *See* Panhandle Eastern Pipe Line Co., 62 FERC ¶ 61,190 (1993).

[23] *See* EcoElectrica, L.P., 75 FERC ¶ 61,157 (1996), Yukon Pacific Corp., 39 FERC ¶ 61,216 (1987), and Phillips Petroleum Co., 37 FPC 777 (1967).

[24] *See* Western Gas Interstate Co., 74 FERC ¶ 61,347 (1996) and Northern Natural Gas Co., et al., 71 FERC ¶ 61,292 (1995).

[25] Application pending Commission review in Western Gas Interstate Co.'s Docket No. CP69–169–000 to discontinue a Presidential Permit authorized by prior FPC order (41 FPC 385 (1969)) because certain border facilities were never constructed.

[26] The Commission's review of the annual report for non-natural gas company applicants required by § 153.23 of the Final Rule and Form No. 2 and other reports for natural gas companies will enable the Commission to determine the current status of import/export facilities authorized under section 3 and a Presidential Permit.

the import or export of natural gas. [27] The Final Rule incorporates basic housekeeping changes to eliminate obsolete and redundant language and sections concerning filing fees, bundled sales service, and the filing of import/export contracts and rate schedules. The Final Rule also makes conforming changes to the current regulations to reflect the Commission's diminished responsibilities in the regulation of natural gas imports and exports under DOE's currently effective delegation orders.

The Final Rule also updates the type of information and exhibits that an applicant must include in its application. The Commission is revising its filing requirements to match its current responsibilities and does not propose to change its substantive policies.

Other changes to part 153 reflect the separate but related nature of the Commission's and DOE's responsibilities concerning natural gas import and export issues. The Commission's revisions will make clear that the part 153 regulations apply only to the siting, construction, operation, or modification of facilities for the import or export of natural gas. On the other hand, DOE's responsibility is the authorization of requests to import/export natural gas.[28]

Section 153.6 of the Final Rule requires the FERC applicant, for the first time, to include in its application a statement indicating whether a related application with DOE/FE (or an amendment to an existing blanket authorization) is required, and if so, whether that application or amendment has been granted by DOE/FE.[29] Section 153.6 of the Final Rule also requires the FERC applicant to file a statement before it commences construction that DOE/FE has granted any required, related import/export authority. Based on comments received, the Final Rule deletes § 153.6 of the NOPR which provided for the simultaneous or prior filing of a related application with DOE/FE.

Section 153.7 of the Final Rule codifies Commission practice concerning evidentiary support for an application for authorization for the construction of facilities under section 3 or an amendment to an existing authorization. Section 153.7(c)(1) permits an applicant to support its statement that its application is not inconsistent with the public interest by including evidence that its proposal or proposed construction is beneficial (with examples stated in the Final Rule), that there will be no impairment of service at reasonable rates, and that no anti-competitive agreements are involved. In addition, the applicant must submit, pursuant to § 153.7(c)(2), a statement describing the nature of the transportation service that the applicant will provide using the import/export facilities. This statement will assist the Commission in determining the extent to which a pipeline applicant will use its import/export capacity for all shippers.

Subpart D of the Final Rule provides for the rejection of incomplete applications and for amendments and withdrawals of pending applications consistent with the Commission's practice in part 157. Certain section 3 applicants are not natural gas companies, and, thus, are not currently required to notify the Commission of basic operational data (such as the completion of construction or start-up of service through authorized facilities). The Final Rule requires those applicants to report such information to the Commission.

C. Electronic Filing

The Commission is not modifying part 153 at this time to require an applicant to file its applications on electronic media. The Commission will review in a future proceeding the electronic filing requirements for the entire certificate application process, including existing electronic filing requirements for part 157 applications and appropriate electronic filing procedures to adopt for part 153 applications. The Commission will determine where changes are necessary to reflect current policies and will modify existing electronic filing requirements as necessary to streamline and update the filing process.

As was done in proceedings in Docket Nos. RM95–3–000 [30] and RM95–4–000, [31] the Commission will solicit participation of the industry and other users of filed information in formulating final electronic filing instructions.

D. The Revised Regulations

The revised part 153 has a new organization, different from that in the current regulations, and virtually every section has been changed in some way. The text has been revised to remove outdated references to the import/export of natural gas and fees and rewritten to be more concise with separate subparts A through D. Part 153 starts with a new heading and updated legal authorities. The final regulations are discussed below.

1. Subpart A—General Provisions

a. Section 153.1 Purpose

The Commission has included in § 153.1 a statement of the purpose of its part 153 regulations—to implement the Commission's authorities delegated under section 3 of the Natural Gas Act and Executive Order 10485, as amended. Part 153 revamps the Commission's procedures and evidentiary requirements for applying for section 3 authorization and for a Presidential Permit.

b. Section 153.2 Definitions

The Final Rule includes a section defining key terms used in part 153—''DOE/FE'' (Department of Energy/Office of Fossil Energy), ''NBSIR'' (National Bureau of Standards Information Report), and ''person'' for purposes of part 153 (''person'' is currently undefined in part 153). The Commission's definition of person is identical with and cross-references DOE's definition of ''person'' stated at 10 CFR 590.102(m), which DOE uses for purposes of considering applications for import/export authorization.[32] The Commission's definition will by its own terms automatically incorporate any future changes in DOE's definition of ''person.'' The Commission's definition would not change current Commission practice in processing applications under section 3 or Executive Order 10485, as amended.

[27] Thus, neither the current regulations nor the Final Rule address filing requirements applicable to the construction of any connecting facilities transporting natural gas in interstate commerce. Such facilities would be within the scope of section 7 and the Commission's part 157 regulations. *See* Williston Basin Interstate Pipeline Co., 63 FERC ¶ 61,179 (1993) and Panhandle Eastern Pipe Line Co., 5 FPC 476 (1946).

[28] Under DOE regulations, applications must be filed at least 90 days prior to the proposed import or export, unless a later date is permitted for good cause shown. *See* 10 CFR 590.201. DOE processes applications for import/export authority where a free trade agreement applies on an expedited basis. NGA section 3(c), added by the Energy Policy Act of 1992, provides that ''applications for such importation or exportation shall be granted without modification or delay.'' 15 U.S.C. 717b(c).

[29] The person filing with DOE/FE for import/export authorization may be a shipper on the facilities of the FERC applicant and need not be the FERC applicant.

[30] Filing and Reporting Requirements for Interstate Natural Gas Company Rate Schedules and Tariffs, 60 FR 3111 (January 13, 1995).

[31] Revisions to Uniform System of Accounts, Forms, Statements, and Reporting Requirements for Natural Gas Companies, 60 FR 3141 (January 13, 1995).

[32] 10 CFR 590.102(m).

2. Subpart B—Application Under Section 3

a. Section 153.5 Who Shall Apply

Section 153.5(a) of the Final Rule retains the requirement in current § 153.1 that a person file an application to seek authorization under section 3 and adds a new provision, codifying current practice, requiring the filing of an application in order to amend an existing authorization under section 3, including the modification of existing import/export facilities.

Phillips Petroleum Company (Phillips) asks the Commission to clarify that the proposed § 153.5(a) does not require it to file an application with the Commission under section 3 to amend its existing Commission authorization, if DOE/FE authorizes an extension of its existing LNG export agreement.[33]

If an entity seeks to modify its facilities authorized under section 3, that entity must file an application with the Commission under section 3 in order to amend its existing authorization. A grant by DOE/FE of an extension of an existing contract to export LNG would not by itself require a Commission-authorized entity to file an application to modify its facilities, and no amendment to its section 3 authorization would be required. Accordingly, the requested clarification is granted. Proposed § 153.5(a) is revised to eliminate duplicative language concerning the necessity to file an amendment to an existing Commission authorization in order to modify facilities authorized under section 3.

Phillips also asks the Commission to clarify that proposed § 153.5(a) would not require it to file an application with the Commission under section 3 in order to modify facilities at its LNG plant site which are not used for the export of natural gas.

The holder of a section 3 authorization is required to obtain prior Commission authorization under section 3 to amend that current section 3 authorization if the applicant proposes to implement changes in its import/export facilities or operations.[34] Thus, if Phillips seeks to modify facilities which serve its LNG function at the Cook Inlet area in order to provide incidental activities, such as intrastate sales of LNG or regassified natural gas to industrials, Phillips must file an amendment to its existing section 3 authorization to undertake that construction.[35] This is so because Phillips would be modifying existing export facilities that would continue to serve its LNG export function while providing non-export service. The additional service could not occur without the underlying LNG facilities for storage, gasification, or transportation.

If Phillips seeks to modify facilities at its LNG plant site which are not currently used to export LNG in order to sell natural gas or natural gas products within the state of Alaska, Phillips would not need to make a Commission filing to implement that construction which would facilitate intrastate transactions. If Phillips is unclear about whether proposed modifications involve dual-purpose facilities providing LNG-export and non-LNG export service, it may also file a request for a declaratory order with the Commission to resolve the uncertainty.

PanEnergy asks the Commission to clarify § 153.5(a) to provide that a pipeline does not have to file an amendment to its existing section 3 authorization if it proposes to change the valves, meters, piping, or other minor construction associated with import/export facilities. [36] PanEnergy's request for an exemption for minor facilities, if granted, would be inconsistent with the public interest. That construction could affect the reliability of service through the import/export facility, and may require the modification of facilities in Canada or Mexico. The Commission might not become aware of self-implemented construction until years after the facilities are altered as in the case of *Panhandle Eastern Pipeline Co.*(*Panhandle*).[37] While *Panhandle* involved a certificated export delivery point and not the modification of border-crossing facilities, the same result should apply in the case of modifications of border-crossing facilities authorized under section 3 or a Presidential Permit. The request for rule clarification is rejected.

Section 153.5(b) of the Final Rule cross-references subpart C (applications for a Presidential Permit). Section 153.5(b) establishes a requirement that an applicant must also simultaneously apply under subpart C for a Presidential Permit for the construction of border facilities at the international boundary between the United States and Canada or Mexico.

b. Section 153.6 Time of Filing

Filing requirements prescribing the number of copies and form of applications for section 3 authorizations (and for Presidential Permits) are moved from current § 153.2 to § 153.20(a) of subpart D of the Final Rule. This change avoids duplication of regulatory text.

The current part 153 regulations do not require a pipeline to file an FERC application under section 3 under any particular timetable in relation to its shippers' filing of a related, required application for import/export authorization with DOE/FE. That is so because the current regulations became effective when the FPC had exclusive jurisdiction over all natural gas import/export issues. The NOPR recognized that under current delegation orders separate applications would be filed with the Commission and DOE/FE. Proposed § 153.6 recognized the related nature of those applications before the Commission and DOE/FE on import/export issues by requiring the pipeline's shipper to make prior or simultaneous filings with DOE/FE for import/export authority.[38]

The Coastal Companies and Great Lakes Gas Transmission Limited Partnership (Great Lakes) assert that proposed § 153.6 would establish a new

[33] *See* Phillips Petroleum Co., *et al.*, 37 FPC 777 (1967). The Commission authorized, pursuant to NGA section 3, the export of LNG and the construction of facilities currently known as the Kenai LNG plant in the Cook Inlet area of Alaska for the liquefaction and storage of natural gas and the loading of LNG onto ships for export and delivery to Japan. From time to time, Phillips has filed with DOE/FE requests to extend the term of its export authorization.

[34] A pipeline may not construct or modify an existing LNG facility, whether an import facility authorized under section 3 or not, under its part 157 blanket (subpart F) certificate pursuant to 18 CFR 157.202(b)(2)(ii)(D), which excludes such construction from the scope of a part 157 blanket (subpart F) certificate. *See* Algonquin LNG, Inc., 79 FERC ¶ 61,139 (1997).

[35] Ordering Paragraph (d) of the FPC's 1967 order provides that Phillips and Marathon Oil Co., joint applicants, ''shall not * * * materially change or alter their export operations without first obtaining the permission and approval of the Commission.'' 37 FPC at 778.

[36] PanEnergy's motion questions the need to file an amendment to its ''import/export license'' for such minor construction. We construe PanEnergy's request as referring to the need to file to amend the Commission's section 3/Presidential Permit authorization. There would not necessarily be a need to amend a DOE/FE import/export authorization because of Commission-authorized section 3 construction.

[37] 65 FERC ¶ 61,169 (1993). In Panhandle, the Commission found that the pipeline had abandoned an existing certificated delivery point and constructed a new delivery point at the United States-Canada border without prior Commission authorization under section 7(b) and without following the prior notice procedures of its part 157 (subpart) F) certificate. The Commission granted retroactive abandonment authorization as well as the authority to operate the new delivery point under the pipeline's part 157 (subpart F) certificate.

[38] *See* Atlantic Richfield Co., *et al.*, 49 FERC ¶ 61.294 (1989), *reh'g denied*, 50 FERC ¶ 61,210 (1990) and National Steel Corp., 45 FERC ¶ 61,100 (1988). In both cases, DOE issued import authorizations before the Commission issued an order approving the place of import under section 3.

requirement which is not workable. Both assert that DOE/FE filings are likely to be made after the filing of border-crossing applications with the Commission. According to Great Lakes, a potential FERC applicant should not be required to coordinate its filing with third parties and to wait to file with the Commission until its shippers have filed their applications before DOE/FE. Great Lakes argues that an applicant should file with the Commission under section 3 before filing an application with DOE because Commission proceedings, with environmental reviews, may continue longer than the minimum 90-day period of review under DOE's regulations for applications to import/export natural gas.[39] Great Lakes asks the Commission to revise its proposed regulations to require an applicant to state whether an application for DOE/FE authorization will be required and, if so, to agree to a condition that ''all necessary DOE authorizations have been or will be obtained prior to the operation of import/export facilities.''

The Commission's purpose in the NOPR was two-fold. First, the Commission was proposing to amend its filing requirements to reflect the division of authority between the Commission and DOE on import/export issues. Second, the proposed regulation was based on the assumption that an application for new or changed import/export authority is a step which would precede an application before the Commission for necessary, related import/export facilities.

Great Lakes proposes substitute language in proposed § 153.6 that would require a pipeline to state whether an application for DOE/FE authorization is also required, and, if so, to represent that DOE/FE will grant that application prior to the *operation* of the border facilities.

The Commission recognizes that not all applications filed with the Commission under NGA section 3 require modification to an existing import/export authorization. For example, some construction may be undertaken to enhance system reliability and flexibility, which does not necessitate a change in an existing import/export authorization. Other construction may be used to transport volumes previously authorized under an existing DOE/FE blanket certificate. Moreover, it may be difficult for a pipeline to control the timing of its shippers' filing of required, related applications for import/export authorization.

Accordingly, we will delete proposed § 153.6 and, in its place, add a new paragraph (a) to § 153.6 requiring an applicant to state whether DOE/FE authorization is required[40] and, if so, whether all required DOE/FE authorizations have been granted prior to *filing* a section 3 application with the Commission.

Great Lakes also suggests that the Commission could require the FERC applicant, as a condition of its authorization, to file a statement that DOE/FE authorizations ''will be obtained prior to the *operation* of the border facilities.'' This recommendation is not workable because if the applicant's representation of DOE/FE approval does not materialize, the Commission would be in the undesirable position of having authorized the construction of facilities which may never become operational. The pipelines' customers would derive no benefits from unused construction, and the environment would have been needlessly disturbed.

Accordingly, the Commission will also revise proposed § 153.6 to condition its grant of section 3 authorization on the applicant's filing a subsequent statement, before the applicant may commence construction, that its shippers have applied for and obtained all required DOE/FE authorizations for the import/export of natural gas. We will adopt Great Lakes' proposed condition, as revised, in § 153.6(b) of the Final Rule. The Commission intends to apply the Final Rule to all future section 3 applications that also require an application for DOE/FE authorization or an amendment to an existing authorization for the import/export of natural gas.

c. Section 153.7 Contents of Application

i. Information Regarding Applicant

The requirements in §§ 153.7 and 153.8 (exhibits) of the Final Rule apply to applications under subpart B for authorization under NGA section 3 and under subpart C for Presidential Permits for the construction of import/export facilities at the border. Informational requirements in current §§ 153.3(a) through 153.3(c), identifying the applicant, its authorized agent, legal status, and address, are revised and retained in proposed § 153.7(a)(1) through (a)(3) of the Final Rule with a paragraph heading added. The informational requirements in current §§ 153.3(d) through 153.3(f) are deleted because they require information no longer essential to the Commission's delegated responsibilities—the name and location of gas production fields and reserves as well as the name of the seller and producer of gas to be imported and the proposed rates to the paid by the applicant. For the same reason, current § 153.8, requiring the filing of import/export contracts and rate schedules, is deleted.

Section 153.7(a)(3) of the Final Rule reflects a merging of application requirements for section 3 authorizations and Presidential Permits which are separately stated in current regulations. The Final Rule relocates in § 153.7(a)(3) the current requirement in § 153.11(a)(4) that applications for Presidential Permits identify foreign ownership or subsidy of the applicant.

The Canadian Producers ask the Commission to clarify why it is necessary for an applicant to indicate whether the applicant is owned or subsidized by a foreign government. As noted, the current regulations applicable to Presidential Permits require a section 3 applicant to supply information about foreign government ownership/subsidy. This information assists the Commission's implementation of its delegated authorities under Executive Order No. 10485, as amended, which derives from the constitutional authority vested in the President of the United States over foreign relations and as Commander-in-Chief.[41] This informational requirement enables the Commission and the Secretaries of State and Defense, upon their review of a Commission request for concurrence, to consider all relevant factors in determining whether an application for a Presidential Permit for the construction of border facilities is in the public interest. Foreign ownership or subsidy of an applicant is one such material factor.

ii. Summary

The requirement in current § 153.3(g) to describe proposed facilities is retained, expanded, and redesignated as § 153.7(b) of the Final Rule with a ''summary'' paragraph heading added. The Final Rule requires the applicant to summarize its proposal and to file a description of the proposed facilities and a description of state, foreign, or other Federal licenses or permits for the construction or operation of facilities (revising a similar requirement in

[39] Under DOE's regulations, applications to import/export natural gas must be filed at least 90 days prior to the proposed import/export date, unless a later date is permitted for good cause shown. 10 CFR 590.201.

[40] A shipper's blanket import/export authorization from DOE/FE satisfies the Final Rule, and no further DOE/FE authorization would be ''required.''

[41] *See* Yukon Pacific Corp., 39 FERC ¶ 61,216 at pp. 61,759–60 (1987).

current § 153.11(d) applicable to Presidential Permits). In addition, § 153.7(b) of the Final Rule adds a new requirement that the applicant must also state the status of any non-FERC regulatory proceedings (United States or foreign) related to the proposal.

iii. Statements

Section 153.7(c) of the Final Rule requires the applicant to file two statements with its application. The first statement demonstrates the public interest. It consists of three elements (§ 153.7(c)(1) (i) through (iii))—demonstrating, respectively, benefits from the proposal, whether existing service at reasonable rates would be impaired, and whether there are any applicable anti-competitive agreements. Section 153.7(c)(1)(i) of the Final Rule is new, while the requirements in §§ 153.7(c)(1)(ii) and (iii) are in the current regulations and have been continued with revisions. The second statement (§ 153.7(c)(2)) requires, for the first time, a description of the nature of the transportation service offered through the authorized border-crossing facilities.

With respect to the first element of the public interest statement, § 153.7(c)(1)(i) of the NOPR identified illustrative elements of the public interest, including a demonstration that the proposal will access new foreign supplies of natural gas and new markets, or enhance system reliability and/or flexibility. Section 153.7(c)1)(ii) and (iii) required representations that the proposal would not impair service to existing customers at reasonable rates or involve anti-competitive agreements that may prevent other United States companies from competing in the same general area.

Great Lakes and PanEnergy Pipelines (PanEnergy) ask the Commission to clarify that the criteria relating to the public interest in § 153.7(c)(1)(i) are illustrative only and, because the listing is not all-inclusive, that an applicant should not be required to make a showing of ''any of those specific criteria * * * since there are other criteria that can also demonstrate that the proposed siting and construction are not inconsistent with the public interest.''[42] These parties assert that an applicant should be allowed to raise any factor showing that its project is not inconsistent with the public interest. In particular, Great Lakes points out certain situations, not enumerated in the NOPR, which it believes would not be inconsistent with the public interest. These situations include border facilities required by an existing market to provide an alternative less costly transportation path to import gas from existing foreign supply sources, or border facilities to reach new markets in the United States or to allow existing markets to access new foreign supply sources.

Great Lakes offers substitute regulatory text which would revise proposed § 153.7(c)(1), assign separate paragraphs to the items listed in proposed § 153.7(c)(1)(i) with the addition of an item for the enhancement of competition, and renumber proposed §§ 153.7(c)(1) (ii) and (iii) as §§ 153.7(c)(1) (vi) and (vii), respectively.

Section 153.7(c)(1)(i) of the Final Rule does not change the statutory standard under NGA section 3 that the Commission ''shall issue such order upon application, unless * * * it finds that the proposed exportation or importation will not be consistent with the public interest.'' In Commission orders issued under section 3, the Commission determines the public interest on the basis of all relevant factors of record.

As Great Lakes and PanEnergy state, the list in § 153.7(c)(1)(i) illustrates particular factors which may be relevant in a specific proceeding as evidence that the proposal or proposed construction is not inconsistent with the public interest. An applicant does not have to make a showing with respect to each of the factors listed in paragraph (i) unless each applies to the applicant's project. Accordingly, Great Lake's and PanEnergy's requested clarification is granted.

It is unnecessary to revise proposed § 153.7(c)(1) or to designate separate paragraphs in § 153.7(c)(1)(i), as Great Lakes proposes. The last item listed in proposed § 153.7(c)(1)(i) (that an application ''will not impair transportation service to existing customers'') is deleted as duplicative of the same item separately stated in proposed § 153.7(c)(1)(ii). Proposed § 153.7(c)(1)(i) is revised to add as a factor evidencing the public interest the enhancement of competition within the United States for natural gas transportation or supply, as Great Lakes proposes.

Proposed § 153.7(c)(1)(i) permitted the applicant to indicate in its application whether its proposal will access ''new foreign supplies of natural gas and service new market demand.'' PanEnergy asks the Commission to clarify that the proposed regulation covers both ''new and additional'' supplies without reference to foreign or domestic sources. Great Lakes states that import/export facilities may be warranted to provide a cheaper transportation path between existing supplies and existing markets.

Since the Final Rule is intended to apply to export facilities which transport domestic gas supplies (as well as to import facilities), the reference to ''foreign'' gas supplies is deleted from § 153.7(c)(1)(i). Moreover, the reference in § 153.7(c)(1)(i) to ''new'' gas supplies is deleted because it excludes the construction of facilities used to transport existing supplies to existing or new markets.

Proposed § 153.7(c)(1)(ii) required the pipeline applicant to show that the proposal ''will not impair the ability of the applicant to render transportation service at reasonable rates to customers in the United States.'' Thus, proposed paragraph (ii) would require the pipeline applicant to make a showing both that its proposal will not interfere with its ability to continue to provide transportation service and that its proposal would not cause the pipeline's systemwide rates to become unreasonable.

The Canadian Association of Petroleum Producers (Canadian Producers) contends that temporary operational restrictions could constitute a service impairment to the applicant's existing United States customers that could require rejection of a section 3 application. The NOPR, however, continued the same service continuation obligation in current § 153.3(h)—to avoid the impairment of service (at reasonable rates) to existing customers. The construction of a new import point would make more gas available for delivery to the pipeline's customers and could result in capacity constraints downstream. Likewise, a new export point could cause constraints on the capacity of non-export customers. The required statement puts the burden on the pipeline applicant to review the service consequences of its application before proposing an import or export project.[43] The Canadian Producers' concern appears unwarranted.

The Canadian Producers ask the Commission to clarify that the Commission intends to apply the 1995 pricing policy statement to new import/export facilities (without an additional reasonableness analysis).[44] PanEnergy asks the Commission to clarify that the Commission does not intend in

[42] Comments at p. 5 (filed April 11, 1997).

[43] Pipelines may avoid possible constraints by simultaneously proposing the construction of necessary facilities under NGA section 7. *See, e.g.*, Williston Basin Interstate Pipeline Co., 63 FERC ¶ 61,179 (1993).

[44] Pricing Policy for New and Existing Facilities Constructed by Interstate Natural Gas Pipelines, 71 FERC ¶ 61,241 (1995).

proposed § 153.7(c)(1)(ii) to require the pipeline applicant to make any additional showing about the justness and reasonableness of its rates beyond that established under NGA sections 4, 5, and 7.

The Commission's practice is to apply its 1995 facilities pricing policy statement to determine the reasonableness of a pipeline's rates resulting from the construction of import/export facilities by interstate pipelines in the same fashion as the Commission applies that policy statement to interstate facilities under section 7 in certificate proceedings.[45] We do not regard the application of the policy statement to a section 3 proceeding as requiring an additional showing by the pipeline. There is no basis for exempting facilities authorized under section 3 from the pricing policy statement which applies to all other construction by interstate pipelines.

PanEnergy also asks the Commission to clarify that the reasonable rate standard of proposed § 153.7(c)(1)(ii) is satisfied if the pipeline represents that it can continue to ''render transportation service at the rates approved by the Commission and contained in applicant's tariff.'' [46] In light of our application of the pricing policy statement to an interstate pipeline's facilities authorized under section 3, PanEnergy's proposed clarification is granted.

The Canadian Producers ask the Commission to revise proposed § 157.7(c)(1)(ii) to state that there should be no impairment of service at reasonable rates to *applicant's* existing customers in the North American market (instead of the NOPR's impairment of service ''to customers in the United States.'') The Canadian Producers read the NOPR as applying to service rendered to all United States customers of all pipelines. We clarify the Final Rule to track the current regulation, which requires the pipeline's demonstration to relate to the pipeline-applicant's customers. The Final Rule also relocates the reference ''in the United States'' in the current regulation and the NOPR to modify ''transportation service'' instead of ''customers.'' This revision makes it clear that the facilities and transportation service that the Commission authorizes are located in the United States (or its possessions) and that a pipeline's Canadian or Mexican customers may receive transportation service through the pipeline's import/export facilities.

Section 153.7(c)(1)(iii) of the NOPR revised the requirement in current § 153.11(c) to file a statement describing certain contracts applicable to Presidential Permits. Proposed § 153.7(c)(1)(iii) required the applicant for section 3 authorization to file a statement describing any existing contracts involving the control of operations at import/export facilities or transportation rates that could prevent competing United States companies from extending their activities in the same general area.

The Canadian Producers ask the Commission to clarify why the Commission established the new requirement in § 153.7(c)(1)(iii) to file certain agreements and whether such agreements could impact free trade. First, § 153.7(c)(1)(iii) does not establish a new requirement. A similar provision in § 153.11(c) currently applies to the filing of applications for Presidential Permits. Second, there could be exclusivity or market allocation agreements between the applicant-transporter and its shipper or the applicant and a foreign government that could prevent other transporters from competing for the same customers in the same general area. If they existed, such agreements could be anti-competitive and could interfere with free trade. The parties to a section 3 proceeding should have the opportunity to comment on the acceptability of those contracts. Thus, it is appropriate to require their disclosure at the time of filing.

With respect to the second statement an applicant for section 3 authorization must file, the NOPR established a new requirement in § 153.7(c)(2) requiring the applicant's demonstration that the proposed import/export facilities will be used: (1) To render transportation services under part 284, (2) to provide private transportation, or (3) to provide service that is exempt from the provisions of the NGA pursuant to sections 1(b) or 1(c) thereof.[47] This requirement was intended to enable the Commission to determine whether the applicant's operations are consistent with the Commission's open access transportation policies.

PanEnergy asserts that the NOPR failed to refer to the continued existence of individually certificated part 157 transportation service, which section 3 facilities could enhance. Under Commission policy after Order No. 436, transportation service through available capacity on a pipeline's facilities, including import/export facilities, must be offered on an open access and non-discriminatory basis. The Commission almost always rejects applications for service under new part 157 certificates, extensions to existing part 157 certificates, or amendments to part 157 certificates that seek to provide some of the benefits of part 284 status without the affected customer's converting to service under part 284.[48]

We will amend proposed § 153.7(c)(2) to recognize that some pipelines, operating as open access transporters, currently provide individually certificated transportation services under part 157. The Commission will revise proposed § 153.7(c)(2) to require the pipeline-applicant to represent that: (1) The pipeline's proposed increases in capacity at existing import/export points is not exclusively reserved for part 157 users and (2) all services made available as a result of new or modified import/export facilities will be under part 284.

The Canadian Producers ask the Commission to clarify what ''private transportation'' means in proposed § 153.7(c)(2). We intend private transportation to mean transportation service provided through facilities owned by the same person that uses the natural gas transported. Private transportation typically arises in the case of transportation through a pipeline constructed and owned by an industrial user to transport natural gas only to its industrial facility.[49]

d. Section 153.8 Required Exhibits.

The Commission in the Final Rule is redesignating current § 153.4 as § 153.8, which retains the requirement to file current Exhibits A through C in new paragraphs (a)(1), (a)(2), and (a)(3), respectively, with editorial revisions. Current Exhibit A is revised to incorporate the requirement of current § 153.11(a)(3) that an applicant for a Presidential Permit describe the amount and classes of capital stock issued by a corporate applicant and the nationality

[45] *See, e.g.,* Great Lakes Transmission Limited Partnership, 76 FERC ¶ 61,148 (1996), in which the Commission applied the pricing policy statement to the construction of import/export facilities.

[46] Comments of PanEnergy at 5 (filed April 14, 1997).

[47] Section 1(b) states that the provisions of the NGA apply, *inter alia,* to the transportation of natural gas in interstate commerce but not to ''any other transporation,'' the local distribution of natural gas, or the production or gathering of natural gas. Section 1(c) exempts a Hinshaw pipeline from the provisions of the NGA. The Commission, however, regulates the activities of these exempt entities in foreign commerce under section 3. *See, e.g.,* Interenergy Sheffield Processing, 78 FERC ¶ 61,085 (1997) (gathering); Havre Pipeline Co., *et al.,* 71 FERC ¶ 61,292 (1995) (intrastate pipeline/gatherer engaging in foreign commerce); and Vermont Gas System, Inc., 24 FERC ¶ 61,366 (1983) (local gas distribution company).

[48] *See* Algonquin LNG, Inc. 79 FERC ¶ 61,139 (1997) and Tennessee Gas Pipeline Co., 78 FERC ¶ 61,340 (1997).

[49] *See, e.g.,* Sumas Energy Inc., 55 FERC ¶ 61,163 (1991) and National Steel Corp., 45 FERC ¶ 61,100 (1988).

of officers, directors, and stockholders, and the amount and class of stock held by each. The Commission is eliminating obsolete exhibits D and E (contracts for the export or import of natural gas) because DOE/FE oversees those activities.

Section 153.8(a) of the Final Rule requires an applicant to file new exhibits D (copy of any construction and operation agreements), E (LNG-related engineering data), E–1 (LNG-related seismic information for certain facilities), and F (an environmental report required by part 380 for LNG and non-LNG related facilities). Applicants may refer to the ''Guidance Manual for Environmental Report Preparation'' to assist in the preparation of these exhibits.

In the NOPR, the Commission proposed to require the applicant to file a new Exhibit D consisting of copies of construction and operation agreements between the applicant and the operator of border facilities in the United States and Canada or Mexico. The NOPR stated that Exhibit D would enable the Commission to verify the business feasibility of the import/export project and would show how the applicant and its Canadian or Mexican counterpart intend to jointly construct and operate the border-crossing facilities.

Coastal asks the Commission to eliminate proposed Exhibit D as a filing requirement because construction/operation agreements may not be available at the time application is filed. As a general observation, the Commission can not process an incomplete application because it would not contain the material elements of information required by our regulations. We regard a construction and operation agreement as a material element of an application because it would show the business feasibility of the import/export project. If the executed agreement is not available when the potential applicant wishes to file its application, the Commission expects the applicant to wait to file its application until after the agreement is available. At a minimum, the applicant must seek to obtain waiver of § 153.8 (Exhibit D) of the Final Rule which may be granted upon the pipeline's filing of an agreement in principle that shows the roles and responsibilities of the parties. The Final Rule is clarified accordingly.

Great Lakes would exempt from filing construction and operation agreements involving facilities constructed or operated by a single entity on the United States or Canadian border. Great Lakes, however, takes an unduly narrow view of the variety of possible operational agreements for border-crossing facilities in the United States or Canada and Mexico that could affect the public interest. Most of the United States facilities may be operated only by United States entities, and operating agreements with respect to these facilities are no less relevant to the public interest than United States facilities which may be jointly operated by United States and Canadian entities. The Commission intends the Final Rule to require the applicant to file as part of its application copies of all agreements between the applicant and the facility operator(s) for the construction and operation of border facilities.

New Exhibits E, E–1, and F in the NOPR codified existing practice which requires an applicant for the construction of LNG facilities to provide sufficient information that will enable the Commission to determine whether the new facilities will be constructed and operated safely, reliably, and with minimal adverse environmental impact. These exhibits are retained in the Final Rule and are justified by the significant safety and environmental implications of LNG terminal facilities. The requirement to file a map is revised as Exhibit G to require a map of suitable scale.

Phillips asks the Commission to clarify that its safety and environmental review of Exhibits E, E–1, and F relating to any proposed modification of LNG facilities will be limited to the proposed new facilities and will exclude existing facilities. The primary focus of Exhibits E, E–1, and F of the Final Rule is to demonstrate that the safety and environmental consequences of the proposed facilities (*i.e.*, a new LNG facility or modification of an existing LNG facility) are within acceptable limits and that the plant design provides a reliable natural gas service. Thus, the Commission will not impose revised environmental/safety conditions or scrutinize again the operation of a previously authorized LNG import/export facility unless there has been a material change in circumstances.

The Commission's staff conducts cryogenic design and facility reviews of LNG facilities on a two-year basis. While the Commission will not reopen its previous environmental/safety review of Phillips' LNG facility, which has been operational since November 1969, a modification of existing LNG facilities is related to the function, operation, and environmental/safety integrity of the existing facilities. Accordingly, the applicant proposing to modify an existing LNG facility with new LNG facilities must describe the environmental/safety aspects of the proposed facilities and how the proposed facilities integrate with the existing facilities. The Commission must determine that the proposed modification will not materially alter the safe and environmentally sound operation of the integrated facility. Section 153.8 (Exhibits E, E–1, and F) of the Final Rule are clarified accordingly.

e. Section 153.9 Transferability.

The NOPR continued in § 153.9(a) the provision in the current regulations (§ 153.6(a) (transferability)) that authorizations under subpart B are not transferable or assignable except temporarily in the case of involuntary transfer of facilities to receivers, trustees, or purchasers under foreclosure or judicial sale. Section 153.9(b) in the NOPR continued current § 153.6(b) to permit the Commission to make supplemental orders as it may find necessary or appropriate.

Yukon Pacific Company L.P. (Yukon Pacific) states that it is unclear whether the proposed (or current) regulations would allow Yukon Pacific to transfer or assign its existing section 3 authorization except in the limited case of involuntary transfer.[50] Yukon Pacific asks the Commission to amend proposed § 153.9 to clarify that the holder of a section 3 authorization can transfer or assign that authorization for ''good commercial or other reasons'' subject to prior Commission approval. In the alternative, Yukon Pacific asks the Commission to state in the preamble of the Final Rule that proposed § 153.9(b), permitting supplemental orders, authorizes the Commission to permit the transfer of section 3 authorizations in the same fashion that DOE/FE currently permits the transfer of its authorizations upon prior DOE approval.[51]

Under the Commission's current practice, the holder of a section 3 authorization (and a Presidential Permit) may not transfer those authorizations or related facilities without prior Commission authorization.[52] For example, the

[50] On May 22, 1995, the Commission issued an order granting Yukon Pacific auhtorization under section 3 for the siting, construction, and operation of an LNG export facility at Port Valdez, Alaska. 71 FERC ¶ 61,197 (1995), *reh'g denied*, 72 FERC ¶ 61,226 (1995), *affirming* 39 FERC ¶ 61,216 (1987). Yukon Pacific's proposed LNG export facility is not yet constructed.

[51] Under DOE regulations, import/export authorizations are not transferable or assignable ''unless specifically authorized by the Assistant Secretary.'' 10 CFR 590.405.

[52] The Commission similarly reviews and approves under section 7 of the NGA the proposed abandonment of interstate facilities and services

Continued

Commission implements a transfer of section 3 authorization and/or facilities by approving the amendment of an existing authorization [53] or granting a new authorization to the acquiring entity.[54] The Final Rule continues this practice and revises proposed § 153.9(a) to deny transfer or assignment of a section 3 authorization (absent an involuntary transfer) without prior Commission authorization.[55] Thus, Yukon Pacific's request for clarification is granted. The Final Rule relocates as substitute text in § 153.9(b) the NOPR's provision (based on current § 153.6) permitting the temporary transfer of facilities in the event of an involuntary transfer.

Section 3(a) of the NGA gives the Commission the authority, after hearing, for good cause shown, to make ''such supplemental order in the premises as it may find necessary or appropriate.'' Section 153.9(b) of the NOPR, following NGA section 3(a) and current regulations, gave the Commission the discretion to issue supplemental orders in the case of a transfer of a section 3 authorization or facilities depending on the public interest considerations in particular proceedings. Since the Commission's authority under section 3 to issue supplemental orders applies to all aspects of the Commission's implementation of section 3, the Commission is relocating § 153.9(b) of the NOPR to § 153.11 (supplemental orders) in subpart B of part 153.

PanEnergy asserts that proposed § 153.9(b)(supplemental orders) is ambiguous and, in the alternative, asks the Commission to clarify that proposed § 153.9(b) may not be applied to impose retroactive requirements that would change the economics of border construction.

PanEnergy's dispute is with NGA section 3 itself, which authorizes the Commission for good cause after hearing to issue necessary or appropriate supplemental orders. In *Distrigas Corporation* v. *FPC,* the Court observed that section 3 (now section 3(a)) authorizes the Commission to reexamine its decisions authorizing imports/exports based on its view of the public interest.[56] The Commission, however, would be limited by ''principles of fairness implicit in all standards governing exercise of regulatory power.'' [57] There is no justification to eliminate the provision permitting supplemental orders (relocated to § 153.11) from the Final Rule, as PanEnergy implies, or to clarify the Final Rule as requested.

f. Section 153.10 Authorization Not Exclusive

The Commission is redesignating current § 153.7 as § 153.10 and is revising the current regulation to eliminate references to authorizations for the import/export of natural gas, replacing them with references to authorizations for construction and operation under section 3 of the NGA. Under § 153.10, which codifies current Commission practice, if the Commission authorizes the construction of facilities pursuant to section 3, the Commission is not prevented from granting authorization to another applicant under section 3 at the same general location.[58]

g. Supplemental Orders

The Final Rule removes proposed § 153.9(b)(supplemental orders) and relocates it as new § 153.11. The provision concerning supplemental orders would apply to each section in subpart B of the Final Rule instead of only to § 153.9 concerning transferability of section 3 authorizations.

3. Subpart C—Application for a Presidential Permit

a. Section 153.15 Who Shall Apply

The existing heading prefacing current §§ 153.10 through 153.12 is deleted and replaced with a more concise heading (Application for a Presidential Permit) substituted under a new subpart C of part 153. The Final Rule redesignates current § 153.10 as § 153.15 and divides proposed § 153.15 into paragraphs (a) and (b) with individual headings.

The Commission is using the same definition of person in subpart C of the Final Rule as is used in subpart B. It is appropriate in the Final Rule to use the same definition because the same entity that applies under subpart C to construct and operate border facilities would need to apply for authorization under subpart B. Section 153.15(b) of the Final Rule cross-references the requirement to file simultaneously an application under subpart B for the siting or construction of facilities, deleting the current cross-reference to applications for authorization to import or export natural gas. Since the NOPR required the filing of an application to amend an existing Presidential Permit, it is appropriate to delete from proposed § 153.15(a) the duplicative requirement to file an application ''to change the operation or maintenance of facilities.''

b. Section 153.16 Contents of Application

The Final Rule redesignates current § 153.11 as § 153.16, with a revised heading. Filing requirements prescribing the number of copies for Presidential Permit applications stated in the first sentence of current § 153.11 are deleted and relocated to new subpart D of part 153.

The Final Rule merges the informational requirements for filing an application for a Presidential Permit and for an application under NGA section 3. Thus, § 153.16(a) states that an applicant for a Presidential Permit that complies with the informational filing requirements under subpart B is not required to satisfy separate filing requirements under subpart C.

Accordingly, current §§ 153.11 (a)(1) and (a)(2) and the first part of paragraph (a)(3) are deleted as they duplicate the same provisions in § 153.7(a) of the Final Rule. The remainder of current § 153.11(a)(3) is redesignated in § 153.8 (Exhibit A). Current § 153.11(a)(4) is revised to update references to applicants ''subventioned'' (subsidized) by a foreign government and is relocated to § 153.7(a)(3). Current § 153.11(b), requiring an applicant to file a map, is deleted because it duplicates the same requirement in § 153.8(a)(8) (Exhibit G) of the Final Rule.

Current § 153.11(c), concerning anti-competitive agreements, and current § 153.11(d), concerning permits granted by a foreign government, are revised to eliminate out-dated references to bundled gas service, ''landing licenses,'' and import/export permits. These sections are redesignated as §§ 153.7(c)(1)(iii) and 153.7(b), respectively, of the Final Rule.

For amendments to an existing Presidential Permit that do not involve related section 3 applications or amendments, § 153.16(b) of the Final Rule requires that applicant to provide information identifying itself pursuant to § 153.7(a) and to fully explain and

and the acquisition of those facilities by natural gas companies.

[53] The Commission may approve an amendment to an existing Presidential Permit in order to change the legal status of the Permittee from corporation to limited partnership pursuant to a reorganization or to change its name. *See, e.g.,* PNM Gas Services, Secretary's notice in Docket No. CP93–98–002 of redesignation of name, January 17, 1997 (unreported) and Great Lakes Gas Transmission Limited Partnership, 53 FERC ¶ 61,264 (1990).

[54] Western Gas Interstate Co., *et al.,* 74 FERC ¶61,347 (1996) (issuance of a new section 3 authorization and Presidential Permit to entity acquiring facilities incident to reorganization).

[55] Similarly, uniform article 8 of a Presidential Permit prohibits the voluntary transfer of a Presidential Permit or related facilities.

[56] 495 F.2d 1057, 1065–66 (D.C. Cir. 1974).

[57] 495 F.2d 1065.

[58] *See, e.g.,* Tenneco Baja California Corp., 75 FERC ¶ 61,192 (1996) and Pacific Interstate Offshore Co., 74 FERC ¶ 61,350 (1996).

justify its proposed amendment. This applicant would not be required to provide the remainder of information required by §§ 153.7 and 153.8 of the Final Rule, applicable to the construction of facilities.

Current § 153.12, authorizing the Commission to request such other information in connection with an application as it may deem pertinent, is deleted. In its place, § 153.21(b), in subpart D of the Final Rule, authorizes the Commission to direct the applicant to file such information as may be necessary to cure a deficient application.

c. Section 153.17 Effectiveness of Presidential Permit

Section 153.17 of the Final Rule codifies the Commission's existing practice of requiring a Permittee to accept an issued Presidential Permit by executing, with proof of proper authorization, the Testimony of Acceptance of the Presidential Permit. The Permittee is required to file a copy of the executed Testimony of Acceptance with the Secretary prior to the start of construction.[59]

4. Subpart D—Paper Media and Other Requirements

a. Section 153.20 General Rule

The Commission is relocating its current filing requirements for paper media in subpart D.

b. Section 153.21 Conformity with Requirements

Section 153.21 of the Final Rule states the requirement that an application must conform to the requirements of part 153 or be rejected. The Commission will reject and wishes to discourage undocumented applications for section 3 authorization.[60]

c. Section 153.22 Amendments and Withdrawals

Section 153.22 of the Final Rule applies the Commission's Rules of Practice and Procedure applicable to amending or withdrawing pleadings to amending or withdrawing an application under subpart B or subpart C of part 153.

d. Section 153.23 Reporting Requirement

Interstate pipelines are currently required to file operational information about facilities authorized under section 3 in their FERC Form No. 2 (annual report), FERC Format No. 567 (annual system flow diagram), and annual report of estimated peak capacity pursuant to 18 CFR 284.12. Commission regulations do not require applicants which are not natural gas companies to file operational information with the Commission concerning facilities authorized under section 3.[61] Uniform article 7 of a Presidential Permit requires the Permittee to file with the Commission requested statements or reports concerning the natural gas exported/imported and the facilities described in the Presidential Permit.

Proposed § 153.23 required applicants which are not otherwise required to file operating information concerning facilities authorized under section 3 with the Commission to report the completion of construction or modification, and the date service commenced through the authorized facilities.[62] The NOPR also required each applicant to report annually by March 1 the estimated peak day capacity and actual peak day usage of its import/export facilities.

Phillips asks the Commission to exempt the owners/operators of LNG facilities that are not used as peak shaving facilities or pipelines from the requirement to file peak day capacity and actual peak day usage information. The Commission is aware that the capacity and usage of non-pipeline facilities are subject to many variables not applicable to pipeline operations. Thus, we agree with Phillips that peak day capacity and actual peak day usage information is irrelevant in the case of entities that do not own or operate pipeline capacity. The proposed regulation is revised to exempt applicants that do not own or operate pipeline capacity, including the owners/operators of LNG facilities, from the requirement to file annually peak day capacity/usage information. The Commission, however, retains the right to seek capacity/usage information from non-pipeline operators should such information be needed for the performance of its duties on a case-by-case basis. Phillips' requested clarification is granted.

IV. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (RFA) requires agencies to prepare certain statements, descriptions, and analyses of proposed rules that will have a significant economic impact on a substantial number of small entities.[63] The Commission is not required to make such analyses if a rule would not have such an effect.

The Commission does not believe that this rule would have such an impact on small entities. Most filing companies regulated by the Commission do not fall within the RFA's definition of small entity.[64] Further, the filing requirements of small entities are reduced by the rule. Therefore, the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, no regulatory flexibility analysis is required.

V. Information Collection Statement

The OMB regulations require OMB to approve certain reporting and recordkeeping (collections of information) imposed by agency rule.[65] OMB has approved the NOPR without comment. The Final Rule will affect one existing data collection, FERC–539. Respondents subject to the filing requirements of this Final Rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

Title: FERC–539, Gas Pipeline Certificate: Import/Export.

Action: Proposed Data Collection.

OMB Control No.: 1902–0062.

Respondents: Interstate natural gas pipelines (Business or other for-profit, including small businesses).

Frequency of Responses: On occasion.

Necessity of the Information: The Final Rule revises the filing requirements contained in 18 CFR part 153 for the siting, construction, and operation of facilities for the import or export of natural gas under NGA section

[59] *See* MidCon Texas Pipeline Corp., 77 FERC ¶ 61,205 (1996).

[60] In the past, the Commission has rejected applications for import/export facilities that were not properly supported by required documentation. *See* SouthCoast Transmission Corp., 49 FERC ¶ 61,161 (1989) and Flormax Energy Corp., 21 FERC ¶ 61,319 (1982).

[61] The Commission has imposed such reporting as a condition in individual section 3 proceedings. *See, e.g.,* Yukon Pacific Co., L.P., 71 FERC ¶ 61,197 (1995) and EcoElectrica, L.P., 75 FERC ¶ 61,157 (1996).

[62] Effective November 13, 1995, the Commission eliminated its annual report of import/export volumes in FPC Form 14. *See* Final rule, Revisions to Uniform System of Accounts, Forms, Statements and Reporting Requirements for Natural Gas Companies, 60 FE 53019 (October 11, 1995). The Commission eliminated FPC Form 14 because importers/exporters currently file quarterly reports with DOE/FE including the same volume and price information.

[63] 5 U.S.C. 601–612.

[64] 5 U.S.C. 601(3), citing to section 3 of the Small Business Act, 15 U.S.C. 632. Section 3 of the Small Business Act defines a ''small-business concern'' as a business which is independently owned and operated and which is not dominant in its field of operation.

[65] 5 CFR 1320.11.

3 and for Presidential Permits that have been issued and modified for the construction and operation of border facilities. These filing requirements are being updated to conform to the Commission's current responsibilities as changed by intervening legislation and DOE delegation orders.

The Commission received six comments on its NOPR but none on its reporting burden or cost estimates. The Commission's responses to the comments are addressed in the Discussion portion (Part III) of this Final Rule. The Commission is submitting a copy of this Final Rule to OMB for information purposes because the Final Rule is not significantly different from the NOPR and OMB has not provided any comments on the NOPR.

Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 (Attention: Michael Miller, Information Services Division, (202) 208–1415) or send comments to the Office of Management and Budget (Attention: Desk Officer for the Federal Energy Regulatory Commission (202) 395–3087, fax: 395–728). You shall not be penalized for failure to respond to this collection of information unless the collection of information displays a valid OMB control number.

VI. Environmental Statement

The Commission excludes certain actions not having a significant effect on the human environment from the requirement to prepare an environmental assessment or an environmental impact statement.[66] No environmental consideration is raised by the promulgation of a rule that is procedural or that does not substantially change the effect of legislation or regulations being amended.[67] The instant rule updates the part 153 regulations and does not substantially change the effect of the underlying legislation or the regulations being revised or eliminated. Accordingly, no environmental consideration is necessary.

VII. Effective Date and Congressional Notification

The regulations are effective August 4, 1997. The Small Business Regulatory Enforcement Fairness Act of 1996 requires agencies to report to Congress on the promulgation of certain final rules prior to their effective dates.[68] That reporting requirement applies to this Final Rule. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 18 CFR Part 153

Exports, Imports, Natural gas, Reporting and recordkeeping requirements.

By the Commission.

Lois D. Cashell,

Secretary.

For the reasons set out in the preamble, the Commission is revising 18 CFR part 153 to read as follows:

PART 153—APPLICATIONS FOR AUTHORIZATION TO CONSTRUCT, OPERATE, OR MODIFY FACILITIES USED FOR THE EXPORT OR IMPORT OF NATURAL GAS

Subpart A—General Provisions

Sec.
153.1 Purpose and scope.
153.2 Definitions.

Subpart B—Application Under Section 3

Sec.
153.5 Who shall apply.
153.6 Time of filing.
153.7 Contents of application.
153.8 Required exhibits.
153.9 Transferability.
153.10 Authorization not exclusive.
153.11 Supplemental orders.

Subpart C—Application for a Presidential Permit

153.15 Who shall apply.
153.16 Contents of application.
153.17 Effectiveness of Presidential Permit.

Subpart D—Paper Media and Other Requirements

153.20 General rule.
153.21 Conformity with requirements.
153.22 Amendments and withdrawals.
153.23 Reporting Requirements.

Authority: 15 U.S.C. 717b, 717o; E.O. 10485, 3 CFR, 1949–1953 Comp., p. 970, as amended by E.O. 12038, 3 CFR, 1978 Comp., p. 136, DOE Delegation Order No. 0204–112, 49 FR 6684 (February 22, 1984).

Subpart A—General Provisions

§ 153.1 Purpose and scope.

The purpose of this part is to implement the Commission's delegated authorities under section 3 of the Natural Gas Act and Executive Order 10485, as amended by Executive Order 12038. Subpart B of this part establishes filing requirements an applicant must follow to obtain authorization under section 3 of the Natural Gas Act for the siting, construction, operation, place of entry for imports or place of exit for exports. Subpart C of this part establishes filing requirements an applicant must follow to apply for a Presidential Permit, or an amendment to an existing Presidential Permit, for border facilities at the international boundary between the United States and Canada or Mexico.

§ 153.2 Definitions.

(a) *DOE/FE* means the Department of Energy/Office of Fossil Energy or its successor office.

(b) *NBSIR* means the National Bureau of Standards Information Report.

(c) *Person* means an individual or entity as defined in 10 CFR 590.102(m).

Subpart B—Application Under Section 3

§ 153.5 Who shall apply.

(a) *Applicant.* Any person proposing to site, construct, or operate facilities which are to be used for the export of natural gas from the United States to a foreign country or for the import of natural gas from a foreign country or to amend an existing Commission authorization, including the modification of existing authorized facilities, shall file with the Commission an application for authorization therefor under subpart B of this part and section 3 of the Natural Gas Act.

(b) *Cross-reference.* Any person applying under paragraph (a) of this section to construct facilities at the borders of the United States and Canada or Mexico must also simultaneously apply for a Presidential Permit under subpart C of this part.

§ 153.6 Time of filing.

(a) An application filed pursuant to § 153.5(a) shall state whether DOE/FE authorization for the import/export of natural gas is required and whether DOE/FE has granted all required authorizations for the import/export of natural gas.

(b) If all required DOE/FE authorizations have not been obtained prior to filing an application with the Commission, the applicant agrees, as a condition of its authorization, to file a statement that all required DOE/FE authorizations have been obtained prior to applicant's construction of border facilities.

§ 153.7 Contents of application.

Every application under subpart B of this part shall include, in the order indicated, the following:

(a) *Information regarding applicant.* (1) The exact legal name of applicant;

[66] 18 CFR 380.4.

[67] 18 CFR 380.4(a)(2)(ii).

[68] Pub. L. No. 104–121, 110 Stat. 847 (1996).

(2) The name, title, and post office address, telephone and facsimile numbers of the person to whom correspondence in regard to the application shall be addressed;

(3) If a corporation, the state or territory under the laws of which the applicant was organized, and the town or city where applicant's principal office is located. If applicant is incorporated under the laws of, or authorized to operate in, more than one state, all pertinent facts should be stated. If applicant company is owned wholly or in part by any foreign government entity, or directly or indirectly subsidized by any foreign government entity; or, if applicant company has any agreement for such ownership or subsidization from any foreign government, provide full details of ownership and/or subsidies.

(b) *Summary.* A detailed summary of the proposal, including descriptions of the facilities utilized in the proposed export or import of natural gas; state, foreign, or other Federal governmental licenses or permits for the construction, operation, or modification of facilities in the United States, Canada, or Mexico; and the status of any state, foreign, or other Federal regulatory proceedings which are related to the proposal.

(c) *Statements.* (1) A statement demonstrating that the proposal or proposed construction is not inconsistent with the public interest, including, where applicable to the applicant's operations and proposal, a demonstration that the proposal:

(i) Will improve access to supplies of natural gas, serve new market demand, enhance the reliability, security, and/or flexibility of the applicant's pipeline system, improve the dependability of international energy trade, or enhance competition within the United States for natural gas transportation or supply;

(ii) Will not impair the ability of the applicant to render transportation service in the United States at reasonable rates to its existing customers; and,

(iii) Will not involve any existing contract(s) between the applicant and a foreign government or person concerning the control of operations or rates for the delivery or receipt of natural gas which may restrict or prevent other United States companies from extending their activities in the same general area, with copies of such contracts; and,

(2) A statement representing that the proposal will be used to render transportation services under Parts 157 or 284 of this chapter, private transportation, or service that is exempt from the provisions of the Natural Gas Act pursuant to sections 1(b) or 1(c) thereof. The applicant providing transportation service under part 157 of this chapter must represent that the pipeline's proposed increase in capacity at an existing import/export point is not exclusively reserved for Part 157 users and that all new service made available as a result of a new or modified import/export facility will be under part 284 of this chapter.

§ 153.8 Required exhibits.

(a) An application must include the following exhibits:

(1) *Exhibit A.* A certified copy of articles of incorporation, partnership or joint venture agreements, and by-laws of applicant; the amount and classes of capital stock; nationality of officers, directors, and stockholders, and the amount and class of stock held by each;

(2) *Exhibit B.* A detailed statement of the financial and corporate relationship existing between applicant and any other person or corporation;

(3) *Exhibit C.* A statement, including signed opinion of counsel, showing that the construction, operation, or modification of facilities for the export or the import of natural gas is within the authorized powers of applicant, that applicant has complied with laws and regulations of the state or states in which applicant operates;

(4) *Exhibit D.* If the proposal is for a pipeline interconnection to import or export natural gas, a copy of any construction and operation agreement between the applicant and the operator(s) of border facilities in the United States and Canada or Mexico;

(5) *Exhibit E.* If the proposal is to import or export LNG, evidence that an appropriate and qualified concern will properly and safely receive or deliver such LNG, including a report containing detailed engineering and design information. The Commission staff's ''Guidance Manual for Environmental Report Preparation'' may be obtained from the Commission's Office of Pipeline Regulation, 888 First Street, NE., Washington, DC 20426;

(6) *Exhibit E–1.* If the LNG import/export facility is to be located at a site in zones 2, 3, or 4 of the Uniform Building Code's Seismic Risk Map of the United States, or where there is a risk of surface faulting or ground liquefaction, a report on earthquake hazards and engineering. Guidelines are contained in ''Data Requirements for the Seismic Review of LNG Facilities,'' NBSIR 84–2833. This document may be obtained from the National Technical Information Service or the Commission's Office of Pipeline Regulation, 888 First Street, NE., Washington, DC 20426;

(7) *Exhibit F.* An environmental report as specified in § 380.3 of this chapter. Refer to Commission staff's ''Guidance Manual for Environmental Report Preparation;'' and

(8) *Exhibit G.* A geographical map of a suitable scale and detail showing the physical location of the facilities to be utilized for the applicant's proposed export or import operations The map should indicate with particularity the ownership of such facilities at or on each side of the border between the United States and Canada or Mexico, if applicable.

(b) The applicant may incorporate by reference any Exhibit required by paragraph (a) of this section already on file with the Commission.

§ 153.9 Transferability.

(a) *Non-transferable.* Authorizations under subpart B of this part and section 3 of the Natural Gas Act and related facilities shall not be transferable or assignable without prior Commission authorization.

(b) *Involuntary transfer.* A Commission order granting such authorization shall continue in effect temporarily for a reasonable time in the event of the involuntary transfer of facilities used thereunder by operation of law (including such transfers to receivers, trustees, or purchasers under foreclosure or judicial sale) pending the making of an application for permanent authorization and decision thereon, provided notice is promptly given in writing to the Commission accompanied by a statement that the physical facts relating to operations of the facilities remain substantially the same as before the transfer and as stated in the initial application for such authorization.

§ 153.10 Authorization not exclusive.

No authorization granted pursuant to subpart B of this part and section 3 of the Natural Gas Act shall be deemed to prevent the Commission from granting authorization under subpart B to any other person at the same general location, or to prevent any other person from making application for such authorization.

§ 153.11 Supplemental Orders.

The Commission also may make, at any time subsequent to the original order of authorization, after opportunity for hearing, such supplemental orders implementing its authority under section 3 of the Natural Gas Act as it may find necessary or appropriate.

Subpart C—Application for a Presidential Permit

§ 153.15 Who shall apply.

(a) *Applicant.* Any person proposing to construct, operate, maintain, or connect facilities at the borders of the United States and Canada or Mexico, for the export or import of natural gas to or from those countries, or to amend an existing Presidential Permit, shall file with the Commission an application for a Presidential Permit under subpart C of this part and Executive Order 10485, as amended by Executive Order 12038.

(b) *Cross-reference.* Any person applying under paragraph (a) of this section for a Presidential Permit for the construction and operation of border facilities must also simultaneously apply for authorization under subpart B of this part.

§ 153.16 Contents of application.

(a) *Cross-reference.* The submission of information under §§ 153.7 and 153.8 of subpart B of this part shall be deemed sufficient for purposes of applying for a Presidential Permit or an amendment to an existing Presidential Permit under subpart C of this part for the construction and operation of border facilities.

(b) *Amendment not proposing construction.* An applicant proposing to amend the article(s) of an existing Presidential Permit (other than facilities aspects) must file information pursuant to § 153.7(a) and a summary and justification of its proposal.

§ 153.17 Effectiveness of Presidential Permit.

A Presidential Permit, once issued by the Commission, shall not be effective until it has been accepted by the highest authority of the Permittee, as indicated by Permittee's execution of a Testimony of Acceptance, and a certified copy of the accepted Presidential Permit and the executed Testimony of Acceptance has been filed with the Commission.

Subpart D—Paper Media and Other Requirements

§ 153.20 General rule.

(a) *Number of copies.* Applications under subpart B of this part must be submitted to the Commission in an original and 7 conformed paper copies. Applications under subpart C of this part must be submitted to the Commission in an original and 9 conformed paper copies.

(b) *Certification.* All applications must be signed in compliance with § 385.2005 of this chapter.

(1) The signature on an application constitutes a certification that: The signer has read the filing signed and knows the contents of the paper copies; and, the signer possesses the full power and authority to sign the filing.

(2) An application must be signed by one of the following:

(i) The person on behalf of whom the application is made;

(ii) An officer, agent, or employee of the governmental authority, agency, or instrumentality on behalf of which the filing is made; or,

(iii) A representative qualified to practice before the Commission under § 385.2101 of this chapter who possesses authority to sign.

(c) *Where to file.* The paper copies and an accompanying transmittal letter must be submitted in one package to: Office of the Secretary, Federal Energy Regulatory Commission, Washington, DC 20426.

§ 153.21 Conformity with requirements.

(a) *General Rule.* Applications under subparts B and C of this part must conform with the requirements of this part.

(b) *Rejection of applications.* If an application does not conform to the requirements of this part, the Director of the Office of Pipeline Regulation will notify the applicant of all deficiencies. Deficient applications not amended within 20 days of the notice of deficiency, or such longer period as may be specified in the notice of deficiency, will be rejected by the Director of the Office of Pipeline Regulation as provided by § 385.2001(b) of this chapter. Copies of a rejected application will be returned. An application which relates to an operation, service, or construction concerning which a prior application has been filed and rejected, shall be docketed as a new application. Such new application shall state the docket number of the prior rejected application.

§ 153.22 Amendments and withdrawals.

Amendments to or withdrawals of applications must conform to the requirements of §§ 385.215 and 385.216 of this chapter.

§ 153.23 Reporting requirements.

Each person authorized under this part 153 that is not otherwise required to file information concerning the start of construction or modification of import/export facilities, the completion of construction or modification, and the commencement of service must file such information with the Commission within 10 days after such event. Each person, other than entities without pipeline capacity, must also report by March 1 of each year the estimated peak day capacity and actual peak day usage of its import/export facilities.

[FR Doc. 97–14418 Filed 6–3–97; 8:45 am]

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 24

[T.D. 97–45]

RIN 1515–AA57

Update of Ports Subject to the Harbor Maintenance Fee

AGENCY: Customs Service, Department of the Treasury.

ACTION: Interim regulation; solicitation of comments.

SUMMARY: Commercial vessels transporting cargo at certain ports are subject to a harbor maintenance fee pursuant to the Water Resources Development Act of 1986 and interim Customs Regulations regarding the harbor maintenance fee. This document amends the list of ports subject to the fee. This amendment is made to further clarify the port descriptions and to update the list as to locations which are exempt from the fee.

DATES: Effective June 4, 1997. Written comments must be received by July 7, 1997.

ADDRESSES: Written comments (preferably in triplicate) may be submitted to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, Franklin Court, 1301 Constitution Avenue, NW, Washington, DC 20229, and may be inspected at Franklin Court, 1099 14th Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Patricia Barbare, Office of Finance, U.S. Customs Service, 202–927–0034.

SUPPLEMENTARY INFORMATION:

Background

The Water Resources Development Act of 1986 (Pub. L. 99–662) established a Harbor Maintenance Trust Fund to be used for improving and maintaining ports and harbors in the U.S. Pursuant to the Act, this fund is supported by a harbor maintenance fee assessed on port use by vessels carrying waterborne commercial cargo. By assessing a charge for port use, the Act causes those shippers, exporters and importers who benefit from the maintenance of a Federal port or harbor to share in the cost of that maintenance.

The Act defines port generally as any channel or harbor or component thereof

in the U.S. which is not an inland waterway, is open to public navigation, and at which Federal funds have been used since 1977 for construction, maintenance or operation.

Customs published T.D. 87–44 in the **Federal Register** (52 FR 10198) on March 30, 1987, establishing interim regulations for the collection of the harbor maintenance fee. The regulations are set forth in § 24.24, Customs Regulations (19 CFR 24.24). When drafting T.D. 87–44, Customs, in conjunction with the U.S. Army Corps of Engineers, took the definition of port in the Act and established a list of ports in § 24.24(b)(1), Customs Regulations (19 CFR 24.24(b)(1)). The list of ports includes in the descriptions and notations column the description of movements which are considered intraport; pursuant to the Act and § 24.24(d)(1) of the regulations, the fee is not to be assessed on the mere movement of commercial cargo within a port. Commercial ports with depths of less than 14 feet were not included on the list. Customs stated in T.D. 87–44 that the list is subject to change and will be amended, if necessary, to reflect money spent by the U.S. Army Corps of Engineers for construction, maintenance or operation of any port not on the original list. The list of ports which are subject to the HMF was amended in T.D. 92–7.

Since the publication of T.D. 92–7, there has been some modification of ports on which there is relevant Corps of Engineers activity. In order to provide the shipping public with the best available information on which ports the HMF will be assessed, Customs has decided to publish this revised list of HMF ports.

Litigation is ongoing regarding the constitutionality of the HMF as it is applied to port use associated with exports. However, the fee is still being collected for all purposes pending the outcome of the litigation and will most likely continue to be collected on port use not associated with exports regardless of the outcome of the litigation.

In this document, Customs again is amending the interim regulations on the harbor maintenance fee to clarify the listing in § 24.24(b)(1) of ports subject to the HMF. A document finalizing the interim regulations on the HMF will be published once the litigation involving the constitutionality of the fee has been completed.

Comments

It is noted that the harbor maintenance fee regulations are still interim. While the comment period has expired on the main portion of the interim regulations (see 52 FR 20593, dated June 2, 1987; extension of comment period on interim regulations to August 28, 1987), Customs will give consideration any written comments (preferably in triplicate) timely submitted relating to the description of the ports set forth in this document. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m., at the Regulations Branch, 1099 14th Street, NW., Suite 4000, Washington, DC.

Inapplicability of Notice and Delayed Effective Date

The statutory effective date of the harbor maintenance fee was April 1, 1987. Because these amendments merely clarify the interim regulations that implement the statutory provision and do not impose any additional burdens on, or take away any existing rights or privileges from the public, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure is impracticable and unnecessary. Similarly, pursuant to 5 U.S.C. 553(d)(1)(3), a delayed effective date is not provided. These amendments are effective as of the date of publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This amendment does not meet the criteria for a ''significant regulatory action'' under E.O. 12866. Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

Drafting Information:

The principal author of this document was Peter T. Lynch, Regulations Branch, Office of Regulations and Rulings, U. S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 24

Accounting, Customs duties and inspection, Imports, Taxes.

Amendment to the Regulations

Part 24, Customs Regulations (19 CFR part 24) is amended as set forth below:

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

1. The general authority for part 24, Customs Regulations (19 CFR part 24) and the specific relevant authority for § 24.24 Customs Regulations (19 CFR 24.24), continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 58a–58c, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1624; 31 U.S.C. 9701.

* * * * *

Section 24.24 also issued under 26 U.S.C. 4461, 4462;

* * * * *

2. The list of ports subject to the harbor maintenance fee set forth in § 24.24(b)(1), Customs Regulations (19 CFR 24.24(b)(1)) is revised to read as follows:

§ 24.24 Harbor Maintenance Fee.

* * * * *

(b) Definitions. * * *

(1) * * *

PORT CODES, NAMES, AND DESCRIPTIONS OF PORTS SUBJECT TO HARBOR MAINTENANCE FEE

[Section 1402 of PL 99–662, as amended]

Port code, port name and state	Port descriptions and notations
Alabama	
1901—Mobile	
Alaska	
3126—Anchorage	Includes Seldovia Harbor, and Homer. Movements between these points are intraport.
3106—Dalton Cache	Includes Haines Harbor.
3101—Juneau	Includes only Hoonah Harbor. Fee does not apply to Juneau Harbor.
3102—Ketchikan	Includes Metlakatla Harbor. Fee does not apply to Wades Cove.
3127—Kodiak	

PORT CODES, NAMES, AND DESCRIPTIONS OF PORTS SUBJECT TO HARBOR MAINTENANCE FEE—Continued

[Section 1402 of PL 99–662, as amended]

Port code, port name and state	Port descriptions and notations
3112—Petersburg	Includes Wrangell Narrows.
3125—Sand Point	Includes Humboldt, King Cove and Iliuliuk Harbor. Fee does not apply to Dutch Harbor.
3115—Sitka	Includes Sergius-Whitestone Narrows.
—St. Paul	
California	
2802—Eureka	Includes Crescent City.
Los Angeles/Long Beach Ports	Includes Ventura, Port Hueneme, Channel Islands Harbor, Santa Barbara, Marina Del Ray, Los Angeles and Long Beach. Movements between these points are intraport.
2709—Long Beach Harbor	
2704—Los Angeles	
2713—Port Hueneme	
2712—Ventura	
2805—Monterrey	
2719—Moro Bay	Includes only Moro Bay.
2501—San Diego	Includes San Diego River and Mission Bay, and Oceanside Harbor.
2707—San Luis	
San Francisco Bay Area Ports *	Includes all points inshore of the Golden Gate Bridge on the bays and the straits and on the Napa, Sacramento and San Joaquin Rivers, and on the deep water channels to Sacramento and Stockton. Movements between points above Suisun Bay (Longitude 122 degrees West at Port Chicago) are intraport. Movements between points below Longitude 122 degrees West and the Golden Bridge are all intraport. All other movements are interport.
2813—Alameda	
2830—Carquinez Strait	
2815—Crockett	
2820—Martinez	
2811—Oakland	
2821—Redwood City	
2812—Richmond	
2816—Sacramento	
2809—San Francisco	
2828—San Joaquin	
2829—San Pablo Bay	
2827—Selby	
2810—Stockton	
2831—Suisun Bay	
Connecticut	
0410—Bridgeport	Includes Housatonic River, and Stamford Harbor, and Wilson Point Harbor. Movements between these points are intraport.
0411—Hartford	Includes all points on the Connecticut River between Hartford and Long Island Sound. Movements within this area are intraport.
0412—New Haven	
0413—New London	Includes all points on the Thames River from the mouth to, and including Norwich, CT. Also includes Groton, CT.
Delaware	
Delaware River Ports, DE, NJ, PA *	Includes all points on the Delaware River from Trenton to the sea at a line between Cape Henlopen and Cape May, all points on the four miles of the Christina River, Delaware, and all points on the lower six miles of Schuylkill River, Pennsylvania. Fee applies to all movements on the Chesapeake and Delaware Canal east of U.S. Highway 13. Includes Absecon Inlet (Atlantic City) and Cold Spring Inlet. Movements within this area are intraport.
1102—Chester, PA	
1107—Camden, NJ	
1113—Gloucester, NJ	
1118—Marcus Hook, PA	
1105—Paulsboro, NJ	
1101—Philadelphia, PA	
1103—Wilmington, DE	
District of Columbia	
Potomac River Ports, DC, D, VA *	Includes all points on the Potomac River (see Chesapeake Bay Ports map) from a line between Point Lookout and the Little Wicomico River at Chesapeake Bay to and including Washington and Alexandria. Movements between these points are intraport.
5402—Alexandria, VA	
5401—Washington, DC	
Florida	
1807—Boca Grande	
1805—Fernandina Beach	
5205—Fort Pierce	
1803—Jacksonville	
5202—Key West	
5201—Miami	
1818—Panama City	For HMF purposes, also includes Carrabelle and Port St. Joe.
1819—Pensacola	
1816—Port Canaveral	
5203—Port Everglades	

PORT CODES, NAMES, AND DESCRIPTIONS OF PORTS SUBJECT TO HARBOR MAINTENANCE FEE—Continued

[Section 1402 of PL 99–662, as amended]

Port code, port name and state	Port descriptions and notations
Tampa Bay Ports*	Includes Alafia River, Port Manatee, Port Sutton, Port Tampa Weedon Island, and all other points on or approached using the Tampa Harbor Channel inshore of the Sunshine Skyway Bridge. Movements between these points are intraport.
1814—St Petersburg	
1801—Tampa	
5204—West Palm Beach	
Georgia	
1701—Brunswick	Includes St. Marys River.
1703—Savannah	
Hawaii	
3202—Hilo	Includes Kawaihae.
3201—Honolulu	Includes Barbers Point Harbor.
3203—Kahului	Includes Kaunakakai Harbor.
3204—Nawiliwili-Port Allen	Includes both Nawiliwili and Port Allen.
Illinois	
Southern Lake Michigan Ports	Includes Waukegan Harbor, Il., Indiana Harbor (East Chicago, IN) Calumet Harbor, the Chicago River (up to the North Avenue Bridge) and the Chicago Harbor. Fee applies at the ports of Michigan City and Burns Waterway Harbor, IN. Fee does not apply at Buffington Harbor or Gary Harbor. Movements within an area from Waukegan, IL to Michigan City, IN are intraport.
3901—Chicago, IL	
3902—East Chicago, IN	
3905—Gary, IN	
Indiana	
Southern Lake Michigan Ports	Includes Waukegan Harbor, IL. Indiana Harbor (East Chicago, IN) Calumet Harbor, the Chicago River (up to the North Avenue Bridge) and the Chicago Harbor. Fee applies at the ports of Michigan City and Burns Waterway Harbor, IN. Fee does not apply at Buffington Harbor or Gary Harbor. Movements within an area from Waukegan, IL to Michigan City, IN are intraport.
3901—Chicago, IL	
3904—East Chicago, IN	
3905—Gary, IN	
Louisiana	
2017—Lake Charles	Includes all points on the Calcasieu River and Pass. Also includes Mermentau River from Catfish Point Control Structure to the Gulf.
Mississippi River Ports/Baton Rouge and Vicinity*	Includes all river points from River Mile 115 Above Head of Passes (AHP) at the St. Charles Parish-Jefferson Parish line, to River Mile 233.9 AHP at Baton Rouge. Includes Destrehan, Good Hope, and St. Rose. Movements between these points are intraport.
2004—Baton Rouge	
2010—Gramercy	
Mississippi River Ports/New Orleans and Vicinity*	Includes all river points from River mile 115 Above Head of Passes (AHP) to Mile 21.6 Below Head of Passes (BHP) via Southwest Pass and to Mile 14.7 BHP via South Pass. Also includes all points on the Inner Harbor Navigation Canal, Avondale, and the Mississippi River Gulf Outlet. Movements between these points are intraport.
2002—New Orleans	
2005—Port Sulphur	
2001—Morgan City*	Includes Atchafalaya River from Morgan City to the Gulf. Includes all points on the Houma Navigation Canal, and points on the Gulf Intracoastal Waterway between Mile 49.8 West and Mile 107.0 West. Movements between these points are intraport.
Maine	
0102—Bangor	
0111—Bath	
0131—Portsmouth, NH	
0132—Belfast	Includes all Penobscot River points (Bucksport and Winterport), and Georges River. Fee does not apply at Belfast, Searsport, Sandy Point, or Castine Harbor.
0101—Portland	
Maryland	
Chesapeake Bay Ports, MD*	Includes all Maryland points on the Chesapeake Bay and its tributary waters except for the Potomac River. Also includes the Waterway from the Delaware River to the Chesapeake Bay west of U.S. 13 highway bridge. Movements between these points are intraport. (Also see Chesapeake Bay Ports: VA.)
1303—Baltimore	
1302—Cambridge	
1301—Annapolis	
Massachusetts	
0401—Boston	Includes all of the Port of Boston inshore of Castle Island on the Inner Harbor and Chelsea and Mystic River and all points on the Weymouth Fore, and Town and Black Rivers, and Dorchester Bay. Also includes Plymouth Harbor. Movements between points on the Saugus River in the North and Plymouth Harbor in the South are intraport.
0404—Gloucester	

PORT CODES, NAMES, AND DESCRIPTIONS OF PORTS SUBJECT TO HARBOR MAINTENANCE FEE—Continued

[Section 1402 of PL 99–662, as amended]

Port code, port name and state	Port descriptions and notations
0407—Fall River	
Michigan	
3843—Alpena	Fee does not apply to Stoneport.
Monroe/Detroit/Harbor Beach 3801—Detroit 3802—Port Huron	Includes Monroe, Detroit, and the Detroit River, St. Clair River, Port Huron and all points on the Rouge and Black Rivers. Fee also applies at Harbor Beach, MI. All movements within this area between Monroe and Harbor Beach, MI are intraport.
3803—Escanaba	Fee applies at all points on the little Bay de Noc above Escanaba, including Gladstone and Kipling. Movements within an area from Escanaba to the Mackinac Bridge are intraport. Fee does not apply at Escanaba.
South Central Lake Superior Ports 3809—Marquette 3842—Presque Isle	Includes Ontonagon Harbor, all points on the Harbor, all points on the Keweenaw Waterway, Presque Isle Harbor and Marquette and Grand Marais. Movements between all Michigan ports on Lake Superior are intraport.
Eastern Lake Michigan Ports 3815—Muskegon 3816—Grand Haven 3844—Ferrysburg	Fee applies at Charlevoix, Frankfort, Portage Lake, Manatee, Ludington, Pentwater Harbor, Ferrysburg, White Lake Harbor, Muskegon, Grand Haven, and South Haven, Holland, and St. Joseph/Benton Harbor, MI. All movements between Eastern Lake Michigan ports are intraport.
Upper Lake Huron Ports 3803—Sault Ste. Marie 3804—Saginaw-Flint-Bay City 3843—Alpena	Includes all points on the St. Mary's River, the ports of Cheyboygan, Alpena, Bay City, and Saginaw River. Does not include Alabaster, Cacit, Port Dolomite, Port Inland, Port Gypum or Stoneport. Movements within an area from Sault Ste. Marie and the Saginaw River are intraport.
Minnesota	
Duluth/Superior Area Ports 3601—Duluth 3602—Ashland 3608—Superior 3614—Silver Bay	Fee applies at Two Harbors and Duluth, MN, and Superior, WI. Fee also applies at Ashland and Port Wing, WI and Grand Marais, MN. Fee does not apply at Taconite, or Silver Bay, MN. All movements between Silver Bay, MN and Ashland, WI are considered intraport.
Mississippi	
1902—Gulfport 1903—Pascagoula	Does not include Bienville.
New Hampshire	
0131—Portsmouth, NH	
New Jersey	
Delaware River Ports, DE, NJ, PA* 1102—Chester, PA 1107—Camden, NJ 1113—Gloucester, NJ 1118—Marcus Hook, PA 1105—Paulsboro, NJ 1101—Philadelphia, PA 1103—Wilmington, DE	Includes all points on the Delaware River from Trenton to the sea at a line between Cape Henlopen and Cape May, all points on the lower four miles of the Christina River, Delaware, and all points on the lower six miles of the Schuylkill River, PA. Fee applies to all movements on the Chesapeake and Delaware Canal east of U.S. Highway 13. Includes Absecon Inlet (Atlantic City) and Cold Spring Inlet. Movements between these points are intraport.
1003—Newark	See New York Harbor.
1004—Perth Amboy	See New York Harbor.
New York	
New York Harbor, NY, NJ* 1001—New York 1003-Newark 1004—Perth Amboy	Includes all points in New York and New Jersey with the Port of New York on the waters inshore of a line between Sandy Hook and Rockaway Point and south of Tappan Zee Bridge on the Hudson and west of Throgs Neck Bridge of the East River. Movements between these and all points within the New York Port District boundaries described in New York Code (Chapter 154, Laws of New York, 1921), are intraport.
1002—Albany*	Includes all points on the Hudson River between Tappan Zee Bridge and the Troy Lock and Dam. Movements between points within this area are intraport.
0901—Buffalo-Niagara Falls	Includes Buffalo Harbor, Black Rock Channel and Tonawanda Harbor, and all points on Cattaraugus Creek, and Dunkirk Harbor. Movements between these points are intraport.
0706—Cape Vincent	
0701—Ogdensburg	
0904—Oswego	
0903—Rochester	
0905—Sodus Point	Includes Little Sodus Bay Harbor, and Great Sodus Bay Harbor.

PORT CODES, NAMES, AND DESCRIPTIONS OF PORTS SUBJECT TO HARBOR MAINTENANCE FEE—Continued

[Section 1402 of PL 99–662, as amended]

Port code, port name and state	Port descriptions and notations
North Carolina	
1511—Beaufort-Morehead City	Includes Ocracoke Inlet. Movements within this area are intraport.
1501—Wilmington	Includes all points on the Cape Fear and Northeast Cape Fear Rivers inshore of the Atlantic Ocean entrance. Movements within this area are intraport.
Ohio	
Lake Erie Ports 4108—Ashtabula 4101—Cleveland 4109—Conneaut 4106—Erie, PA 4111—Fairport 4117-Huron 4121—Lorain 4105—Toledo-Sandusky	Includes Toledo, Sandusky, Huron, Lorain, Cleveland, Fairport, Ashtabula, Conneaut and Erie. Movements between these points are intraport. Fee does not apply at Marblehead.
Oregon	
Columbia River Ports, OR, WA 2901—Astoria, OR 2904—Portland, OR 2909—Kalama, WA 2905—Longview, WA 2908—Vancouver, WA	Includes all points on the Columbia River downstream of Bonneville Dam, and all points on the Willamette River downstream of River Mile 21. Includes the Multnoma Channel, the Skipanon Channel, and Oregon Slough. Movements between points within this area are intraport.
2903—Coos Bay	Includes Port Orford, the Siuslaw River, and Umpaqua River. Movements between these points are intraport.
2902—Newport	Includes Tillamook Bay, and Yaguina Bay and Harbor.
Pennsylvania	
Delaware River Ports, DE, NJ, PA* 1102—Chester, PA 1107—Camden, NJ 1113—Gloucester, NJ 1118—Marcus Hook, PA 1105—Paulsboro, NJ 1101—Philadelphia, PA 1103—Wilmington, DE	Includes all points on the Delaware River from Trenton to the sea at a line between Cape Henlopen and Cape May, all points on the lower four miles of the Christina River, Delaware, and all points on the lower six miles of the Schuykill River, Pennsylvania. Fee applies to all movements on the Chesapeake and Delaware Canal east of U.S. Highway 13. Includes Absecon Inlet (Atlantic City) and Cold Spring Inlet. Movements between these points are intraport.
Puerto Rico	
4907—Mayaguez	
4908—Ponce	Does not include Guayanilla and Tallaboa.
4909—San Juan	Includes Arecibo.
Rhode Island	
0502—Providence	Federal project limit: Providence River East of Prudence Island just above Dyer Island and ending at Hurricane Barrier at Fox Point. The areas west of Prudence Island, including Quonset Point, Patience Island, Warwick Neck and Greenwich Bay are not subject to the fee.
South Carolina	
1601—Charleston	Includes the Ashley River, Cooper River, Shipyard River, and Port Royal Harbor. Movements within this area are intraport.
1602—Georgetown	
Texas	
2301—Brownsville	Includes Port Isabel and Brazos Island Harbor. Movements between these points are intraport.
5312—Corpus Christi	
5311—Freeport	
Galveston Bay Ports*	Includes Port Bolivar and all points on Galveston Bay in Galveston County. Movements between points within this area are intraport.
5301—Houston*	Includes Bayport, Baytown, and all other points on or accessed via the Houston Ship Channel from the Liberty/Chambers county line on the north to the Chambers/Galveston county line to the south. Movements within this area are intraport.
5313—Port Lavaca	Includes Matagorda Ship Channel.
Sabine Ports* 2104—Beaumont 2103—Orange 2101—Port Arthur 2102—Sabine	Includes Port Neches, Sabine Pass and all other points on the Sabine-Neches Waterway. Movements between these points are intraport.

PORT CODES, NAMES, AND DESCRIPTIONS OF PORTS SUBJECT TO HARBOR MAINTENANCE FEE—Continued

[Section 1402 of PL 99–662, as amended]

Port code, port name and state	Port descriptions and notations
Virginia	
Potomac River Ports, DC, MD, VA* ..... 5402—Alexandria, VA 5401—Washington, DC	Includes all points on the Potomac River (see Chesapeake Bay Ports map) from a line between Point Lookout and the Little Wicomico River at Chesapeake Bay to and including Washington and Alexandria. Movements between these points are intraport.
Chesapeake Bay Ports,VA* ..... 1406—Cape Charles 1402—Newport News 1401—Norfolk	Includes all Virginia points on the Chesapeake Bay inshore of a line from Cape Henry to Cape Charles, and tributary waters including the ports of Hampton Roads. Does not include the Potomac River or the James River above the James River Bridge at Newport News. Movements between points within this area are intraport. (Also see Chesapeake Bay Ports, MD.)
James River Ports, VA ..... 1408—Hopewell 1404—Richmond/Petersburg	Includes all points on the James River above the James River Bridge at Newport News. Movements between these points are intraport.
Washington	
3003—Aberdeen	Includes Grays Harbor and Yaguina Bay and Harbor. Movements between these points are intraport.
Puget Sound Ports, WA* ..... 3005—Bellingham 3006—Everett 3007—Port Angeles 3001—Seattle 3002—Tacoma 3026—Olympia	Fee applies only at ports listed. Bellingham includes all of Bellingham Bay and tributary waters north of Chuchanut Bay on the east, and Portage Island on the west. Port Everett includes all of Port Dardner (an arm of Possession Sound) between Elliott Point on the south to, and including, the Snahomish River on the north. The port of Olympia includes all points on Budd Inlet extending from Cooper and Dofflemyer Point on the north to, and including, the city of Olympia on the south. The fee applies to all points within the Inner Harbor of the Port of Seattle, including Salmon Bay, Lakes Union and Washington, the Lake Washington Ship Canal, and Kenmore Navigation Channel. Includes all points on Elliott Bay and tributary waters between West Point on the north and Duwamish Head on the south. Fee applies at all points within Tacoma Harbor including all of Commensement Bay and tributary waters between Browns Point on the east and Point Defiance on the west. Movements between these ports and any other U.S. points on Puget Sound or the Strait of Juan de Fuca east of Cape Flattery are intraport.
3010—Anacortes	Includes only access channel and berthing areas adjacent to Anacortes Industrial Park off 30th Street.
Columbia River Ports, WA, OR ..... 2901—Astoria, OR 2904—Portland, OR 2909—Kalama, WA 2905—Longview, WA 2908—Vancouver, WA	Includes all points on the Columbia River downstream of Bonneville Dam, and all points on the Willamette River downstream of River mile 21. Includes the Multnoma Channel, the Skipanon Channel, and Oregon Slough. Movements between points within this area are intraport.
Wisconsin	
3602—Ashland	See Duluth/Superior Area Ports, MN.
Green Bay/Marinette Area Ports ..... 3703—Green Bay 3702—Marinette	Fee applies to all movements between points along the Sturgeon Bay and Lake Michigan Ship Canal. Fee also applies to Green Bay, Oconto, and Menominee/Marinette. Movements between points from Menominee and points along the Sturgeon Bay and Lake Michigan Ship Canal are intraport.
Western Lake Michigan Ports ..... 3701—Milwaukee 3708—Racine 3707—Sheboygan	Includes the ports of Milwaukee, Racine, and Sheboygan, MN. All movements between these points are intraport.

*Indicates that a map of this area is available from the Budget Division, Office of Finance, U.S. Customs Service, Room 6328, 1301 Constitution Ave., NW., Washington, DC 20229; tel. 202–927–0034.

* * * * *

George J. Weise,

Commissioner of Customs.

Approved: April 17, 1997.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 97–14409 Filed 6–3–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F–0369]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the expanded safe use of triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, as a stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by General Electric Co.

DATES: Effective June 4, 1997; written objections and requests for a hearing by July 7, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 11, 1996 (61 FR 53379), FDA announced that a food additive petition (FAP 6B4522) had been filed by General Electric Co., One Lexan Lane, Mt. Vernon, IN 47620–9364. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, as a stabilizer for olefin polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and (3) the regulations in § 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before July 7, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objection received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for ''Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester'' under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4), which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3).	For use only: 1. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, and items 2.1, 2.2, or 2.3 (where the density of these polymers is not less than 0.94 gram per cubic centimeter), and items 3.1 or 3.2, provided that the finished polymer contacts foods of types I, II, and VI–B as described in Table I of § 176.170(c) of this chapter only under conditions of use B, C, D, E, F, G, and H as described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, that contact food of types III, IV, V, VI–A, VI–C, VII, VIII, and IX as described in Table 1 of § 176.170(c) of this chapter, only under conditions of use C, D, E, F, and G as described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: May 15, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–14602 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 93N–0027]

Neurological Devices; Effective Date of Requirement for Premarket Approval of Cranial Electrotherapy Stimulators

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to revoke a regulation requiring that a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) be submitted for the cranial electrotherapy stimulator (CES), a medical device. This action is being taken in order that FDA may reconsider whether the CES device may be reclassified from class III (premarket approval) into class II (special controls) or class I (general controls). Elsewhere in this issue of the **Federal Register**, FDA is issuing an order requiring manufacturers of these devices to submit information concerning their safety and effectiveness.

EFFECTIVE DATE: July 7, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 4, 1979 (44 FR 51770), FDA published a final rule classifying the CES device into class III (premarket approval). This regulation was codified in § 882.5800 (21 CFR 882.5800). Section 882.5800 applies to: (1) Any CES that was in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295); and (2) any device that FDA has found to be substantially equivalent to the CES and that has been marketed on or after May 28, 1976.

In the **Federal Register** of August 31, 1993 (58 FR 45865), FDA published a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the CES, under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)). In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act and the benefits to the public from the use of the device (58 FR 45865 at 45867). The primary concern expressed in the preamble to the proposed rule was the varying and contradictory results in investigations concerning the effectiveness of the CES device. FDA's conclusion at that time was that: ''FDA believes that CES's should undergo premarket approval to establish effectiveness for any intended use and to determine whether the benefits to the patient are sufficient to outweigh any risk'' (58 FR 45865 at 45868).

The August 31, 1993, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the CES was required to be submitted by September 15, 1993. The comment period closed on November 1, 1993.

FDA received two petitions requesting a change in the classification of the device from class III to class II. FDA reviewed the petitions and found them to be deficient based on a lack of new information relevant to the device's classification. Each petitioner was sent a deficiency letter dated February 4, 1994, requesting a response to the reported deficiencies. Neither petitioner responded to the letter. Accordingly, the petitioners were notified on August 23, 1994, that the petitions were deemed closed.

In the **Federal Register** of August 24, 1995 (60 FR 43967), FDA issued a final rule to require the submission of a PMA or notice of completion of a PDP for the CES device. In that document, FDA also published a final order denying the petitions to reclassify the device. One PMA was submitted and filed for the

device. FDA has since become aware of additional information relevant to the possible reclassification of the CES device from class III to class II or class I. In the **Federal Register** of January 28, 1997 (62 FR 4023), FDA published a proposed rule to revoke the requirement that a PMA or a notice of completion of a PDP be filed for the CES device. FDA explained that it now believes that it is more appropriate to invoke the procedures under section 515(i) of the act for the device.

FDA provided an opportunity for interested persons to comment on the proposed rule. FDA received 41 comments. All but two of these comments directly supported the proposal to revoke the requirement that a PMA or notice of completion of a PDP be filed for the CES device. Many of the comments also requested that the CES device be reclassified into class I or II. Some comments submitted information in support of reclassification of the device. One comment included a paper addressing the government's role in regulating ''alternative medicine'' including, according to the comment, CES. Another comment submitted anecdotal information about a negative experience with CES but did not specifically take a position with respect to revocation of the requirement to submit a PMA. One comment supported the revocation of the requirement to submit a PMA, but suggested that FDA should, in all cases, issue an order under section 515(i) before it issues a proposed rule to require the submission of a PMA.

As noted above, elsewhere in this issue of the **Federal Register**, FDA is issuing an order under section 515(i) of the act to require manufacturers of CES devices to submit information to FDA about the safety and effectiveness of the devices. FDA will review all information submitted in response to that order and in the comments submitted on the proposed revocation to determine whether to reclassify the device.

In response to the suggestion that FDA not issue a rule under section 515(b) of the act without first issuing an order under section 515(i) of the act, as FDA previously stated in the **Federal Register** of May 6, 1994 (59 FR 23731), the Safe Medical Devices Act (SMDA) (Pub. L. 101–629) does not prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of the public health, independent of the procedure in section 515(i) of the act. FDA will consider the suggestion on a case-by-case basis.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule will allow FDA to review information about these devices and determine the least burdensome degree of control needed to provide reasonable assurance of the safety and effectiveness of the CES device, the Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 882.5800 is amended by revising paragraph (c) to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

* * * * *

(c) *Date a PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

Dated: May 28, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–14597 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

POSTAL SERVICE

39 CFR Part 111

Domestic Mail Manual; Miscellaneous Amendments

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This document describes the numerous amendments consolidated in the Transmittal Letter for Issue 52 of the Domestic Mail Manual, which is incorporated by reference in the Code of Federal Regulations, see 39 CFR 111.1. These amendments reflect changes in mail preparation requirements and other miscellaneous rules and regulations not previously published in the **Federal Register**.

EFFECTIVE DATE: July 1, 1997.

FOR FURTHER INFORMATION CONTACT: Neil Berger, (202) 268–2859.

SUPPLEMENTARY INFORMATION: The Domestic Mail Manual (DMM), incorporated by reference in title 39, Code of Federal Regulations, part 111, contains the basic standards of the U.S. Postal Service governing its domestic mail services; descriptions of the mail classes and special services and conditions governing their use; and standards for rate eligibility and mail preparation. The document is amended and republished about every 6 months, with each issue sequentially numbered.

DMM Issue 52, the next edition of the DMM, is scheduled for release on July 1, 1997. That issue will include substantive changes to the following special services: caller service, certified mail, Express Mail insurance, insured mail, post office box service, registered mail, return receipt, return receipt for merchandise, and special delivery. The final rule containing the standards for these changes was published on May 12, 1997, in the **Federal Register** (62 FR 26086–26098), as approved on May 5, 1997, by the Board of Governors to implement the Decision of the

Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on Special Services Fees and Classifications, Docket No. MC96–3. Those standards take effect at 12:01 a.m., June 8, 1997.

DMM Issue 52 will also include new experimental nonletter-size business reply mail categories and fees. The final rule containing the standards for these new categories and fees was published on May 9, 1997, in the **Federal Register** (62 FR 25752–25755), as approved on May 5, 1997, by the Board of Governors to implement the Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Experimental Nonletter-Size Business Reply Mail Categories and Fees, Docket No. MC97–1.

DMM Issue 52 will include the standards for a new ancillary service endorsement system used by mailers to request address correction, return, and forwarding services for undeliverable-as-addressed mail. The final rule containing the standards for this system, which takes effect July 1, 1997, was published on March 28, 1997, in the **Federal Register** (62 FR 15056–15066), with a request for further public comments on the standards for Single-Piece Standard Mail. A subsequent final rule was published on May 5, 1997, in the **Federal Register** (62 FR 24340–24341).

The following excerpt from section I010, Summary of Changes, of the transmittal for DMM Issue 52 covers the minor changes not previously described in final rules or in other interim or final rules published in the **Federal Register**. Announcements of these minor changes were first published in various issues of the Postal Bulletin, an official biweekly document published by the Postal Service. In addition, the revised contents of DMM Issue 52 are also presented.

Domestic Mail Manual Issue 52 Summary of Changes

Ancillary Service Endorsement Placement

Sections A010.4.2 and M012.4.0 clarify the required use and placement of a return address on mail with an ancillary service endorsement and expand from one to four locations on a mailpiece where a mailer may print ancillary service endorsements. Effective February 13, 1997 (Postal Bulletin (PB) 21939 (2–13–97)).

Sections M012.4.3 and M012.4.4 relax the standards for one of the placement locations (to the left of the postage area) and for the clearance space (¼ inch) required for ancillary service endorsements. Effective May 22, 1997 (PB 21946 (5–22–97)).

Business Reply Mail Address Block Barcoding

Sections E060.11.4, S922.4.8, and S922.5.0 give any business reply mail (BRM) permit holder who uses window envelopes or address labels the option of printing ZIP+4 barcodes as part of the delivery address block for prebarcoded BRM letter-size and flat-size pieces. Effective March 1, 1997 (PB 21939 (2–13–97)).

Carrier Route Codes on Container Labels

Exhibit M032.1.3a footnote 2 makes the space between the one-letter carrier route type code (for example, ''R'' for rural route, ''C'' for carrier route) and the required three digits representing the route number optional on barcoded sack and tray labels. Effective July 1, 1997 (PB 21946 (5–22–97)).

Express Mail Corporate Account

Section P500.2.0 ensures proper accounting procedures are in place to reduce uncollectible Express Mail Corporate Account revenue. Effective March 27, 1997 (PB 21942 (3–27–97)).

Section P500.2.3 changes the minimum balance that must be maintained in an Express Mail Corporate Account to the average 1 week's postage and fees or $100, whichever is higher. Effective April 24, 1997 (PB 21944 (4–24–97)).

*FASTforward*SM

Sections E130.3.3 and E140.1.3 are amended, current sections F030.3.0 and F030.4.0 are redesignated as sections F030.4.0 and F030.5.0, respectively, and new section F030.3.0 is added to reflect the introduction of FASTforwardSM, a computerized system developed as an additional method of meeting the move update requirement for Presorted First-Class Mail and automation rate First-Class Mail. Effective July 1, 1997 (PB 21943 (4–10–97)).

Section C830.4.1 clarifies that window envelopes processed on multiline optical character readers (MLOCRs) using FASTforward software must meet the FASTforward standards in section F030.3.3. Effective May 22, 1997 (PB 21946 (5–22–97)).

Internet Version of PS Form 3575

Sections A910.2.4, A910.6.2, C032.2.4, D910.2.2, D920.2.2, F020.1.4, F030.3.2e, R900.8.3, and I021 reflect the approved use of Internet version PS Form 3575-WWW, Change of Address Order. Effective March 27, 1997 (PB 21942 (3–27–97)).

Label Barcode Specifications and Use

Section M031.1.4 clarifies the required information on the origin line (Line 3) of a label. Section M031.1.6 permits the use of the City State File for city and state abbreviations. Section M031.3.2 makes the paper stock specifications the same for barcoded and nonbarcoded labels. Section M032 is reorganized with amendments to the standards and specifications for barcoded tray and sack labels. Effective February 13, 1997 (PB 21939 (2–13–97)).

Sections M032.1.1, M032.2.1, M810.1.1, and M820.1.1 delay by 6 months the required use of barcoded tray and sack labels for automation rate mailings. Originally slated to take effect January 1, 1997, the date of required use is moved to July 1, 1997. Effective January 1, 1997 (PB 21935 (12–19–96)).

Label Content Lines

Sections M031.5.0, M032.1.3, M045.4.4, M073.3.2, M120.2.8, M130.2.3, M130.3.3, M130.4.3, M130.5.4, M200.3.2, M200.4.2, M610.3.3, M610.4.3, M610.5.8, M610.6.3, M620.3.2, M620.4.3, M630.2.7, M630.3.6, M630.4.6, M630.6.3, M630.8.0, M810.2.3, M810.3.2, M820.2.3, M820.3.3, M820.4.4 are amended and new exhibit M032.1.3c (later redesignated as exhibit M032.1.3a) and new section M810.3.3 are added to reflect new content identifier numbers (CINs) for the content line of tray and sack labels. Also revised is the human-readable content line information for most tray and sack labels and for some pallet labels. With these revisions, label instructions for the content line throughout the mail preparation sections of module M match the content line of the label associated with a CIN in new exhibit M032.1.3c (later redesignated as exhibit M032.1.3a). Effective July 1, 1997 (PB 21937 (1–16–97)).

New exhibit M032.1.3c (later redesignated as exhibit M032.1.3a) changes the human-readable content line for certain international mail content identifier numbers (CINs) for barcoded tray and sack labels. Effective July 1, 1997 (PB 21943 (4–10–97)).

Labeling Instructions

Section M032.2.4f corrects the content identifier instructions for barcoded sack labels. Effective July 1, 1997 (PB 21938 (1–30–97)).

Section M120.2.3c corrects the Line 1 labeling instruction for the Priority Mail SCF package sort level from L002,

Column B, to L002, Column C. Effective January 30, 1997 (PB 21938 (1–30–97)).

Labeling Instructions for Standard Mail Mixed BMC

Sections L601, M073.3.1d, M610.6.2d, and M630.6.2d clarify and correct labeling instructions. These amendments specify that ''MXD'' must be added to the beginning of the destination line (Line 1) of labels in section L601 for mixed BMC sort levels. This change standardizes the use of the term ''MXD'' on the destination line for all types of mixed sacks, trays, and pallets. Effective July 1, 1997 (PB 21943 (4–10–97)).

Sections L601, M045.4.1e, M045.4.2d, M073.3.1d, M610.6.2d, and M630.6.2d clarify and correct labeling instructions for Standard Mail prepared at the mixed BMC sortation level (including palletized mail). Effective July 1, 1997 (PB 21944 (4–24–97)).

Labeling List Changes

Sections L004, L102, and L801 reflect changes in mail processing operations. Effective January 16, 1997; mandatory March 16, 1997 (PB 21937 (1–16–97)).

Sections L002, L003, L004, L005, L102, L601, L603, L604, L801, and L803 reflect changes in mail processing operations. Effective April 10, 1997; mandatory July 1, 1997 (PB 21943 (4–10–97)).

Markings on Automation Mail

Sections M810.1.4 and M820.1.4 clarify the required markings on letter-size and flat-size mail sent at automation rates. Effective May 22, 1997 (PB 21946 (5–22–97)).

Merchandise Return Service

Section S923.1.0 transfers standards for postage collection originally contained in Domestic Mail Manual Transition Book (DMMT) section 919.7. Effective January 16, 1997 (PB 21937 (1–16–97)).

Nonprofit Standard Mail Low-Cost Products

Section E670.5.10 increases from $6.75 to $6.93 the permitted amount for low-cost products mailable at Nonprofit Standard Mail rates. Effective January 1, 1997 (PB 21938 (1–30–97)).

Optional Endorsement Lines

Sections M013.1.1 and M013.2.6 require the appropriate 3-digit ZIP Code prefix or 5-digit ZIP Code for the destination area distribution center (ADC) or automated area distribution center (AADC) for optional endorsement lines (OELs) on packages labeled to an ADC, mixed ADC, AADC, or mixed AADC. Effective July 1, 1997 (PB 21943 (4–10–97)).

Penalty Mail Detention

Section E060.5.9 transfers the standard for the detention of penalty mail from Domestic Mail Manual Transition Book (DMMT) 137.23. If suspected misuse of the penalty mail privileges occurs, the USPS does not hold or delay processing the mail but contacts and refers the matter to the affected government agency for investigation and action. Effective January 16, 1997 (PB 21937 (1–16–97)).

Periodicals Additional Entry

Sections D230.1.1 and P200.3.0 are amended and sections E250.1.3 and E250.2.4 are removed to clarify revisions to additional entry standards. Effective April 24, 1997 (PB 21944 (4–24–97)).

Periodicals Documentation

Sections M200.7.0, M810.4.0, M820.5.0, and P012.2.1 change from January 1 to July 1, 1997, the date when Periodicals mailings must be prepared with software certified under the Presort Accuracy Validation and Evaluation (PAVE) program or prepared to meet the criteria for standardized documentation. Effective January 1, 1997 (PB 21934 (12–5–96)).

Sections E230.7.4, E250.1.4, E250.2.6, P012.2.2, P012.2.3, P012.2.4, P012.2.5 and P200.1.5 are amended; section P012.3.0 is redesignated as P012.4.0 and amended; and section E230.1.5 and new section P012.3.0 are added, to reflect the standards for use of Presort Accuracy Validation and Evaluation (PAVE)-certified software or standardized documentation for Periodicals. Originally scheduled to take effect July 1, 1997 (PB 21940 (2–27–97)). A subsequent notice postponed the effective date to August 1, 1997 (PB 21944 (4–24–97)).

Polywrapped Automation Flats Certification

Section C820.3.1 allows mailers who wish to claim automation rates for flat-size polywrapped (plastic-covered) barcoded pieces to have their pieces evaluated and certified by their local USPS mailpiece design analyst (MDA). Effective March 21, 1997 (PB 21940 (2–27–97)).

Postage Meter New Indicia

Exhibit P030.4.1 adds a new postage meter indicia approved for Neopost postage meter Model SM26. Effective May 8, 1997 (PB 21945 (5–8–97)).

Registered Mail Additional Services

Section S911.1.5 is revised, section S911.3.9 is removed, and section S911.3.10 is redesignated as section S911.3.9 to clarify which additional special services are available with registered mail. Effective April 24, 1997 (PB 21944 (4–24–97)).

Reply Mail and Special Mailing Envelopes

Section C100.5.0 is added and sections C810.8.0 and S922.4.10 are amended and reorganized to provide mailers with specific automation standards for business reply, meter reply, and courtesy reply mail. Sections C010.6.0 through C010.9.0 are redesignated as sections C010.7.0 through C010.10.0, respectively. Current sections C024.15.0 through C024.17.0 are redesignated as new sections C010.6.1 through C010.6.3, respectively. These new sections present general mailability standards for envelopes constructed with windows, envelopes printed with green diamond borders, and envelopes configured as reusable mailpieces for two-way mailing. Effective April 10, 1997 (PB 21943 (4–10–97)).

Sexually Oriented Advertisements

Sections C032.2.0, C032.3.1, C032.4.1, C032.6.0, C033.1.0, and C033.3.0 reflect the centralized processing of customer requests not to receive sexually oriented advertisements. Two USPS programs help customers protect themselves and their children against receiving unwanted sexually oriented advertisements in the mail. G043 provides the mailing address for the centralized processing center handling customer requests. I021 adds new Form 1500, Application for Listing and/or Prohibitory Order, which replaces the previously used Form 2201, Application for Listing Pursuant to 39 U.S.C. 3010, and Form 2150, Notice for Prohibitory Order Against Sender of Pandering Advertisement in the Mails. Effective December 5, 1996 (PB 21934 (12–5–96)).

Small Flats Test

Section C820.2.3 allows mailers to claim the automation rate for flats for flat-size pieces prepared as booklets, catalogs, and magazines measuring at least 53/8 inches long when these pieces are no more than 91/2 inches high. These pieces may not be enclosed in polywrap (plastic) material. Effective July 1, 1997 (PB 21946 (5–22–97)).

Tan Label MXD

Sections M130.2.1d, M130.4.1d, M130.5.2d, M200.2.4f, M610.3.1d, M610.5.3d, M820.2.1d, M820.3.1d, and

M820.4.1d change the acronym from ''MS'' (for mixed states) to ''MXD'' (for mixed ADCs) for the tan-colored pressure-sensitive label used to identify packages of mixed ADC mail. Effective January 1, 1997 (PB 21936 (1–2–97)).

Unnumbered Insured Articles

Sections S010.4.1 and S010.4.2 provide that a customer claim for an unnumbered insured article lost or damaged in the mail is adjudicated by the local post office where the claim is received. Section G043 revises the mailing address for the Office of Claims Appeals at the St. Louis Accounting Service Center. Effective March 29, 1997 (PB 21941 (3–13–97)).

Value Added Refunds

Section P014.4.0 clarifies authorization procedures for refunds requested for excess postage at the time of mailing (termed value added refunds). Effective April 10, 1997 (PB 21943 (4–10–97)).

Written Additions—Circulars

Section E612.2.1 clarifies that a circular may be mailed as Standard Mail (A) even if it includes handwritten or typewritten dates or addresses on the piece or handwritten or typewritten corrections of typographical errors. Effective April 10, 1997 (PB 21943 (4–10–97)).

List of Subjects in 39 CFR Part 111

Postal Service.

In consideration of the foregoing, 39 CFR part 111 is amended as set forth below:

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

2. The table at the end of § 111.3(e) is amended by adding at the end thereof a new entry to read as follows:

§ 111.3 Amendments to the Domestic Mail Manual.

* * * * *

(e) * * *

Transmittal letter for issue	Dated	Federal Register publication
52	July 1, 1997	62 FR [insert page number]

* * * * *

3. Section 111.5 is revised to read as follows:

§ 111.5 Contents of the Domestic Mail Manual.

A—Addressing

A000 Basic Addressing

A010 General Addressing Standards
A040 Alternative Addressing Formats
A060 Detached Address Labels (DALs)

A800 Addressing for Automation

A900 Customer Support

A910 Mailing List Services
A920 Address Sequencing Services
A930 Other Services
A950 Coding Accuracy Support System (CASS)

C—Characteristics and Content

C000 General Information

C010 General Mailability Standards
C020 Restricted or Nonmailable Articles and Substances
C021 Articles and Substances Generally
C022 Perishables
C023 Hazardous Matter
C024 Other Restricted or Nonmailable Matter
C030 Nonmailable Written, Printed, and Graphic Matter
C031 Written, Printed, and Graphic Matter Generally
C032 Sexually Oriented Advertisements
C033 Pandering Advertisements
C050 Mail Processing Categories

C100 First-Class Mail

C200 Periodicals

C500 Express Mail

C600 Standard Mail

C800 Automation-Compatible Mail

C810 Letters and Cards
C820 Flats
C830 OCR Standards
C840 Barcoding Standards

D—Deposit, Collection, and Delivery

D000 Basic Information

D010 Pickup Service
D020 Plant Load
D030 Recall of Mail
D040 Delivery of Mail
D041 Customer Mail Receptacles
D042 Conditions of Delivery
D070 Drop Shipment
D071 Express Mail and Priority Mail
D072 Metered Mail

D100 First-Class Mail

D200 Periodicals

D210 Basic Information
D230 Additional Entry

D500 Express Mail

D600 Standard Mail

D900 Other Delivery Services

D910 Post Office Box Service
D920 Caller Service
D930 General Delivery and Firm Holdout

E—Eligibility

E000 Special Eligibility Standards

E010 Overseas Military Mail
E020 Department of State Mail
E030 Mail Sent by U.S. Armed Forces
E040 Free Matter for the Blind and Other Handicapped Persons
E050 Official Mail (Franked)
E060 Official Mail (Penalty)
E070 Mixed Classes
E080 Absentee Balloting Materials

E100 First-Class Mail

E110 Basic Standards
E120 Priority Mail
E130 Nonautomation Rates
E140 Automation Rates

E200 Periodicals

E210 Basic Standards
E211 All Periodicals
E212 Qualification Categories
E213 Periodicals Mailing Privileges
E214 Reentry
E215 Copies Not Paid or Requested by Addressee
E216 Publisher Records
E230 Nonautomation Rates
E240 Automation Rates
E250 Destination Entry
E270 Preferred Periodicals

E500 Express Mail

E600 Standard Mail

E610 Basic Standards
E611 All Standard Mail
E612 Additional Standards for Standard Mail (A)
E613 Additional Standards for Standard Mail (B)
E620 Nonautomation Nonpresort Rates
E630 Nonautomation Presort Rates
E640 Automation Rates
E650 Destination Entry
E651 Regular, Nonprofit, and Enhanced Carrier Route Standard Mail
E652 Parcel Post
E670 Nonprofit Standard Mail

F—Forwarding and Related Services

F000 Basic Services

F010 Basic Information
F020 Forwarding
F030 Address Correction, Address Change, *FASTforward*℠, and Return Services

G—General Information

G000 The USPS and Mailing Standards

G010 Basic Business Information
G011 Post Offices and Postal Services
G013 Trademarks and Copyrights
G020 Mailing Standards
G030 Postal Zones
G040 Information Resources
G041 Postal Business Centers
G042 Rates and Classification Service Centers
G043 Address List for Correspondence
G090 Experimental Classifications and Rates
G091 Barcoded Small Parcels
G092 Nonletter-Size Business Reply Mail

G900 Philatelic Services

L—Labeling Lists

L000 General Use

L002 3-Digit ZIP Code Prefix Matrix
L003 3-Digit ZIP Code Prefix Groups—3-Digit Scheme Sortation

L004 3-Digit ZIP Code Prefix Groups—ADC Sortation
L005 3-Digit ZIP Code Prefix Groups—SCF Sortation

L100 First-Class Mail

L102 ADCs—Presorted Priority Mail

L600 Standard Mail

L601 BMCs—Machinable Parcels
L602 BMCs—DBMC Rates
L603 ADCs—Irregular Parcels
L604 Originating ADCs—Irregular Parcels

L800 Automation Rate Mailings

L801 AADCs—Letter-Size Mailings
L802 BMC/ASF Entry—Periodicals and Standard Mail (A)
L803 Non-BMC/ASF Entry—Periodicals and Standard Mail (A)

M—Mail Preparation and Sortation

M000 General Preparation Standards

M010 Mailpieces
M011 Basic Standards
M012 Markings and Endorsements
M013 Optional Endorsement Lines
M014 Carrier Route Information Lines
M020 Packages and Bundles
M030 Containers
M031 Labels
M032 Barcoded Labels
M033 Sacks and Trays
M040 Pallets
M041 General Standards
M045 Palletized Mailings
M050 Delivery Sequence
M070 Mixed Classes
M071 Basic Information
M072 Express Mail and Priority Mail Drop Shipment
M073 Combined Mailings of Standard Mail Machinable Parcels
M074 Plant Load Mailings

M100 First-Class Mail (Nonautomation)

M120 Priority Mail
M130 Presorted First-Class Mail

M200 Periodicals (Nonautomation)

M500 Express Mail

M600 Standard Mail (Nonautomation)

M610 Single—Piece and Nonautomation Standard Mail (A)
M620 Enhanced Carrier Route Standard Mail
M630 Standard Mail (B)

M800 All Automation Mail

M810 Letter-Size Mail
M820 Flat-Size Mail

P—Postage and Payment Methods

P000 Basic Information

P010 General Standards
P011 Payment
P012 Documentation
P013 Rate Application and Computation
P014 Refunds and Exchanges
P020 Postage Stamps and Stationery
P021 Stamped Stationery
P022 Adhesive Stamps
P023 Precanceled Stamps
P030 Postage Meters and Meter Stamps
P040 Permit Imprints
P070 Mixed Classes

P100 First-Class Mail

P200 Periodicals

P500 Express Mail

P600 Standard Mail

P700 Special Postage Payment Systems

P710 Manifest Mailing System (MMS)
P720 Optional Procedure (OP) Mailing System
P730 Alternate Mailing Systems (AMS)
P750 Plant-Verified Drop Shipment (PVDS)
P760 First-Class or Standard Mail Mailings With Different Payment Methods

R—Rates and Fees

R000 Stamps and Stationery

R100 First-Class Mail

R200 Periodicals

R500 Express Mail

R600 Standard Mail

R900 Services

S—Special Services

S000 Miscellaneous Services

S010 Indemnity Claims
S020 Money Orders and Other Services
S070 Mixed Classes
S500 Special Services for Express Mail

S900 Special Postal Services

S910 Security and Accountability
S911 Registered Mail
S912 Certified Mail
S913 Insured Mail
S914 Certificate of Mailing
S915 Return Receipt
S916 Restricted Delivery
S917 Return Receipt for Merchandise
S920 Convenience
S921 Collect on Delivery (COD) Mail
S922 Business Reply Mail (BRM)
S923 Merchandise Return Service
S930 Handling

I—Index Information

I000 Information

I010 Summary of Changes
I020 References
I021 Forms Glossary
I022 Subject Index

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 97–14571 Filed 6–3–97; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 232

[FRA Docket No. PB–9, Notice No. 7]

RIN 2130–AA73

Two-Way End-of-Train Telemetry Devices

AGENCY: Federal Railroad Administration (FRA).

ACTION: Final rule; response to petitions for reconsideration.

SUMMARY: On January 2, 1997, FRA published a final rule revising the regulations governing train and locomotive power braking systems at 49 CFR part 232 to include provisions pertaining to the use and design of two-way end-of-train telemetry devices (two-way EOTs). *See* 62 FR 278. The revisions were intended to improve the safety of railroad operations by requiring the use of two-way EOTs on a variety of freight trains, in accordance with legislation enacted in 1992, and by providing minimum performance and operational standards related to the use and design of the devices. In this document, FRA responds to concerns raised in two petitions for reconsideration of the final rule.

EFFECTIVE DATE: July 1, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas Peacock, Motive Power and Equipment Division, Office of Safety, RRS–14, FRA, 400 Seventh Street, SW., Washington, DC 20590 (telephone 202–632–3345), or Thomas Herrmann, Trial Attorney, Office of the Chief Counsel, RCC–12, FRA, 400 Seventh Street, SW., Washington, DC 20590 (telephone 202–632–3167).

SUPPLEMENTARY INFORMATION: On January 2, 1997, FRA published a final rule amending the regulations governing train and locomotive power braking systems at 49 CFR part 232 to add provisions pertaining to the use and design of two-way end-of-train telemetry devices (two-way EOTs). *See* 62 FR 278. The purpose of the revisions was to improve the safety of railroad operations by requiring the use of two-way EOTs on a variety of freight trains pursuant to 1992 legislation, and by establishing minimum performance and operational standards related to the use and design of the devices. In response to the final rule, two petitions for reconsideration were submitted.

On February 11, 1997, the Alaska Railroad Corporation (ARC) requested reconsideration of the July 1, 1997, effective date contained in the final rule based on the limited availability of the hardware necessary for compliance. On March 4, 1997, the American Short Line Railroad Association (ASLRA), on behalf of its member railroads, filed a petition for reconsideration seeking an extension of the effective date to December 1, 1997, and seeking elimination of the tonnage limitation contained in the rule's definition of ''local and work train.'' *See* 49 CFR 232.23(a)(3) and 232.23(a)(4). As the ARC is specifically named in the petition submitted by the ASLRA and

because both petitions seek an extension of the effective date of the final rule on similar grounds, FRA will address ARC's petition primarily in the context of the ASLRA's petition for reconsideration.

A. Summary of Concerns Raised in the Petitions for Reconsideration and FRA's Responses

FRA's rules of practice at 49 CFR part 211 state that FRA must decide to grant or deny, in whole or in part, each petition for reconsideration not later than four months after receipt by FRA's Docket Clerk. *See* 49 CFR 211.31. In this case, FRA's decision on the petitions for reconsideration is due no later than June 11, 1997. If FRA grants a petition for reconsideration, a notice of this decision must appear in the **Federal Register**. To provide a fuller explanation of the issues, this document addresses both grants and denials of the petitions for reconsideration. Accordingly, a copy of this document is being mailed to all petitioners.

1. Extension of the Effective Date of the Final Rule to December 1, 1997 for Class II and Class III Railroads

Both the ASLRA and the ARC submitted petitions for reconsideration seeking an extension of the effective date of the final rule. Currently, the final rule becomes effective for all covered railroads on July 1, 1997. The ASLRA requested an extension of the effective date to December 1, 1997 for all Class II and Class III railroads. *See* Surface Transportation Board regulations at 49 CFR part 1201; General Instructions 1–1 for a description of Class II and III railroads. The ASLRA specifically named 12 railroads,[1] including the ARC, in its petition, claiming they are representative of all Class II and Class III railroads affected by the final rule. The petition cites several reasons why an extension of the effective date for these operations is necessary. The petition contends that the current effective date does not provide sufficient time for these smaller railroads to purchase and obtain a sufficient number of two-way EOTs due to the limited number of suppliers and the volume of acquisition orders submitted by Class I railroads. The petition also appears to allege that the current effective date imposes a financial hardship on some small railroads in that these operations are not being provided sufficient time to generate the necessary cash flow needed for the acquisition and installation of the devices. The ASLRA petition further contends that because most smaller railroads have a limited number of locomotives in their fleets, the ability to schedule the out-of-service time necessary for the installation of the front unit of a two-way EOT within the time frame of the current effective date of the final rule imposes additional operational and financial hardships on these smaller railroads. Lastly, although not raised in the ASLRA petition, the ARC notes that smaller railroads need some time to train their employees on the use, installation, and testing of the devices once they are received.

In the preamble to the final rule, FRA recognized that Class I, II, and III railroads voluntarily committed to equip the vast majority of the trains covered by the final rule by the effective date of the requirements. *See* 62 FR 288–289. However, it should be noted that the final rule requires the use of two-way EOTs on a larger number of trains than the industry voluntarily committed to equip by the effective date of the final rule. Furthermore, FRA stated that it would consider extending the effective date of the final rule in the event that manufacturing delays result in a railroad's inability to secure an adequate number of the devices, but would not extend the effective date beyond the statutorily mandated date of December 31, 1997. *Id.*, 49 U.S.C. 20141. The concerns and hardships alleged in the ASLRA and ARC petitions for reconsideration are based on the inability of Class II and III railroads to acquire a sufficient number of devices within a reasonable time period prior to the effective date of the final rule in order to properly install the equipment and adequately train their employees on the use of the devices. Consequently, the burdens that the petitions allege are being imposed on Class II and III railroads are precisely the type of concerns FRA stated it would consider in determining whether to grant an extension of the effective date of the final rule. Furthermore, ASLRA's petition proposes an extension of the effective date only to December 1, 1997, which is still 30 days prior to the statutorily mandated date.

In order to verify the concerns raised in the petitions for reconsideration, FRA conducted its own investigation of the impact of the effective date on Class II and III railroads. Although ASLRA's petition seeks an extension of the effective date for all Class II and Class III railroads, FRA has determined that some larger Class II railroads, particularly those reporting two million or more man-hours to FRA for calendar year 1995, have acquired or will acquire a sufficient number of two-way EOTs to equip all of the trains covered by the final rule well before the July 1, 1997 effective date. Therefore, FRA will not extend the effective date of the final rule for those Class II and III railroads that reported two million or more man-hours for calendar year 1995 pursuant to 49 CFR part 225. Consequently, FRA specifically denies ASLRA's petition as it relates to an extension of the effective date of the final rule for Class II or III railroads reporting two million or more man-hours to FRA for calendar year 1995.

However, as noted above, the final rule does require a greater number of short line trains to be equipped with two-way EOTs than these railroads envisioned and planned for when they voluntarily committed to equip their fleets by July 1, 1997. As a result, many of the short line operations covered by the final rule did not order a sufficient number of devices to equip all the trains that are now covered by the final rule. In addition, some short line operations that were not originally covered by the industry's voluntary commitment have just recently discovered that some of their trains will require the use of the devices. Furthermore, the ability of these smaller operations to generate the capital necessary for acquiring the devices on such short notice is somewhat limited. Therefore, many of the Class II and Class III railroads covered by the final rule have just recently ordered the devices from the manufacturers or, due to financial limitations, will be ordering the devices in the near future as soon as sufficient capital is available.

After discussions with the manufacturers' of two-way EOTs, it appears that the delivery time for the devices from receipt of an order ranges anywhere from 60 to 120 days or more, depending on the manufacturer. Therefore, if the short line railroads were forced to order the devices from the manufacturer with the shortest lead time, then most likely a two or three month extension of the effective date would probably be sufficient. However, FRA recognizes that forcing railroads to acquire the devices based solely on delivery time is not necessarily good business practice and may not enhance safety in the long term. Railroads should not only have the ability to benefit from competitive procurement, but should

[1] The following railroads were specifically named in ASLRA's petition: Birmingham Southern Railroad Company; the Bay Line Railroad, L.L.C.; Iowa Interstate Railroad Ltd.; Central Railroad of Indiana; Central Railroad Company of Indianapolis; Alaska Railroad Corporation; St. Lawrence & Atlantic Railroad Company; Gateway Western Railway; Northeast Kansas & Missouri Railroad; Wheeling & Lake Erie Railway Company; Dequeen & Eastern Railroad Company; and Lake Superior & Ishpeming Railroad Company.

also be afforded the ability to acquire a device which best suits their operation and existing equipment. For example, the most readily available device may not be compatible with the devices a railroad has already acquired or may not provide the options most desired by a railroad.

In addition to a delivery time that could exceed four months, FRA also agrees that these smaller railroads need some extra time to install the devices once they are delivered. As the petition points out, most smaller railroads have very limited locomotive fleets and, thus, will need extra time to schedule out-of-service time in order to install the front units of the devices. Furthermore, some additional time must also be afforded for these smaller railroads to adequately train their employees on the use, installation, and testing of the devices. Consequently, after careful consideration of the petitions for reconsideration and for the reasons set forth above, FRA has decided to grant ARC's petition to extend the effective date of the final rule and ASLRA's petition to extend the effective date of the final rule specifically to December 1, 1997 for all Class II and Class III railroads reporting less than two million man-hours to FRA for calendar year 1995 pursuant to 49 CFR part 225.

2. Eliminate the Tonnage Limitation in the Definitions of Local and Work Trains.

The ASLRA's petition for reconsideration also objects to the final rule's definitions of local and work train, which contain a limitation of 4,000 trailing tons. For the reasons stated below, FRA denies this request in the ASLRA petition. The ASLRA petition contends that the tonnage limitation fails to recognize the inherent operating characteristics of local and work trains and that FRA ignored the clear intent of Congress to exclude these types of operations. The petition further contends there is no basis in the hearing record or any safety statistics that supports the definitions contained in the final rule. The petition stresses the impracticality of requiring the use of two-way EOTs in local train operations. The ASLRA notes that a typical local train will drop off and pick up cars at various points, thus reducing and increasing the train length and tonnage several times throughout its operation. The petition contends that the removal and reinstallation of the rear-end device in each instance is time consuming and creates the potential for damaging the rear-end device. Finally, the petition asserts that FRA should not have used the final rule on two-way EOTs to decide the definition of local train, as it could have unknown consequences in future regulatory proceedings, and should allow the issue to be argued in the pending freight power brake rulemaking.

In the statutory provision, Congress stated that two-way EOTs shall be required ''on road trains other than locals, road switchers, or work trains * * *.'' *See* 49 U.S.C. 20141(b)(1). However, the statute does not define the terms ''locals, road switchers, or work trains'' and does not include them in the specific exclusions contained in the legislation. *See* 49 U.S.C. 20141(c). As stated in the preamble to the final rule, FRA does not believe Congress intended to except trains merely based on a label placed on the operation. FRA believes that Congress intended for the terms ''locals, road switchers, or work trains'' to be narrowly construed by FRA and not so broadly defined that the requirements for two-way EOTs are rendered meaningless in many circumstances. Therefore, contrary to the assertions contained in the petition, FRA has effectuated Congress' intent by narrowly defining the terms ''local'' and ''work train'' to ensure consistent and logical application of the requirements for the use of two-way EOTs.

In the NPRM on power brakes, FRA attempted to narrowly construe the ''local and work train'' exception by proposing to require the use of two-way EOTs on local or work trains that exceeded 30 mph. *See* 59 FR 47726 (September 16, 1994). At the Public Regulatory Conference conducted on March 5, 1996, several parties, including the ASLRA, objected to the speed limitation placed on the local and work train exemption contending it was inconsistent with the statutory mandate. Other participants, however, strongly recommended that the terms local and work trains be narrowly defined in order to prevent the creation of a loophole wherein a carrier could designate all their trains as local and, thus, circumvent the two-way EOT requirements. Furthermore, several commenters also objected to special treatment of local and work trains as they incur similar operational difficulties and pose the same threat to safety as road trains. Therefore, not only did FRA propose a narrow exception for local and work trains in the NPRM but there was substantial discussion regarding the exception of local and work trains at the Public Regulatory Conference conducted prior to the issuance of the final rule. *See* transcript of public hearing, March 5, 1996. Although it is clear from the above that FRA as well as other commenters sought to narrowly construe the local and work train exception, not one commenter in a written submission, including the ASLRA, provided any alternative method for defining the terms which would address the concerns raised by various parties noted above, nor does the ASLRA propose such an alternative in its petition. Consequently, FRA in the final rule reconsidered the exception for local and work trains based upon the limited written comments received on the issue, its own review of the accident data, and its extensive knowledge of railroad operations.

After a review of the available accident data, FRA determined that the trains which are most likely to benefit from the use of two-way EOTs are heavier tonnage trains and trains that operate over heavy grades. The accident data also indicated that the vast majority of the potentially preventable accidents involved trains that were operating with greater than 4,000 trailing tons or that were operating on grades of two percent or greater and that, as the tonnage of the train increased, the steepness of the grade became a more important factor. Furthermore, in FRA's view there is no logical or rational basis for concluding that a local or work train operating with greater than 4,000 trailing tons or in heavy grades is any less susceptible to the operational problems and difficulties faced by any other road train. Consequently, FRA believes the definition of local and work train is consistent with the accident data, Congress' intent, and FRA's rationale expressed with regard to defining heavy grades. Furthermore, FRA believes the definitions recognize the operational necessity for the services these types of trains provide and the nature of the duties they engage in when en route, while preventing the potential for confusion or abuse of the terms local or work train, and ensuring that those trains most likely to benefit from the added safety provided by two-way EOTs are so equipped.

Although FRA recognizes that the final rule's definitions of local and work train may impose some additional operational burdens on the railroads, FRA believes that the ASLRA has overstated the operational impact of the requirements on Class II and III railroads. In its written submissions to FRA, the ASLRA indicated that the vast majority of Class II and III railroads operate trains with less than 4,000 trailing tons. In addition, contrary to the contention contained in the petition, the rear-end unit of an EOT device would not have to be removed and reinstalled every time a local train picks up or drops off cars. If the rear car, on which

the rear unit of the EOT is attached, remains a part of the train after conducting these switching operations, the communication between the front unit and the rear unit should remain intact even after a cut of cars is added or removed from the train. Furthermore, many local trains currently operate with rear-end marking devices or one-way EOTs which would have to be reinstalled if the rear car were removed from the train. Additionally, if a train is not equipped with a one-way EOT then an inspection of the ''set and release'' of the rear car must performed when cars are added or removed from a train; thus, someone would have to be at the rear to conduct this inspection. *See* 49 CFR 232.13. Consequently, in FRA's view, the increased time burdens and the potential damage to the rear units are greatly overstated in the petition when compared with current practice. We believe these actual and potential costs can be greatly minimized and should be incurred in only a limited number of circumstances.

FRA further considers to be without merit the ASLRA's contention that the definition of local train should not have been decided in the context of the proceeding to issue the two-way EOT final rule. The final rule text explicitly states that the definition of local train is intended solely for the purpose of identifying operations subject to the requirements for the use of two-way EOTs. *See* 62 FR 294. FRA does not intend for the definitions used in this final rule to change or otherwise impinge on other possible definitions of the term local train when used in another context. Therefore, the definition used in this final rule should have no impact on future regulatory proceedings. Consequently, after careful consideration of the ASLRA's petition for reconsideration and for the reasons set forth above, FRA has decided to deny ASLRA's request to change the definitions of local and work trains contained in § 232.23(a)(3) and (a)(4) of the final rule on two-way EOTs.

Issued in Washington, DC, on May 29, 1997.

Jolene M. Molitoris,

Federal Railroad Administrator.

[FR Doc. 97–14497 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 74–14; Notice 119]

RIN 2127–AG82

Federal Motor Vehicle Safety Standards; Occupant Crash Protection, Child Restraint Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: This document amends Standard No. 213, ''Child Restraint Systems,'' to modify the air bag warning label that child seats which can be used in a rear-facing position (''rear-facing child seats'') are now required to bear. The required label warns that the rear-facing child restraint must never be placed in the front seat with an air bag. On April 17, 1997, NHTSA issued an interim final rule which allowed the phrase ''unless air bag is off'' to be added to the end of the warning, if the child seat automatically deactivates the air bag and activates a specified telltale light in the vehicle. On further examining the issue in response to a request from Porsche Cars North America Inc. (Porsche), NHTSA has tentatively determined that the phrase ''unless air bag is off'' may be added to child seats regardless of the means by which they deactivate the air bag so long as deactivation can be achieved, and that specified telltale requirements are unnecessary so long as an audible or visual signal is provided to the driver that the air bag has been disabled. This document makes final on an interim basis the amendment requested by Porsche, and supplements the amendments made by the April 17, 1997 interim rule. The agency also solicits comments on today's amendment.

DATES: This rule is effective June 4, 1997. Comments must be received by July 21, 1997. Because this amendment will clarify the required warning label and will relieve a restriction currently imposed by the standard, NHTSA has determined that it is in the public interest to make the changes effective immediately on an interim basis. Assuming that a final rule is issued, the final rule would respond to any comments and would be effective upon publication in the **Federal Register**.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted to: Docket Section, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are 9:30 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For nonlegal issues: Mary Versailles, Office of Safety Performance Standards, NPS–31, telephone (202) 366–2057.

For legal issues: Deirdre Fujita, Office of Chief Counsel, NCC–20, telephone (202) 366–2992.

Both can be reached at the National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC, 20590.

SUPPLEMENTARY INFORMATION: This document amends Standard No. 213, ''Child Restraint Systems,'' on an interim basis to modify the air bag warning label which rear-facing child seats must bear effective May 27, 1997. This document also solicits comments on this amendment. It is the second interim final rule modifying the warning label.

Original Final Rule

The requirement for the label was adopted by a November 27, 1996 final rule (61 FR 60206) [1], which also adopted new warning label requirements for vehicles with air bags. The requirement for the enhanced child seat label is set forth in S5.5.2(k) of Standard 213. The requirement specifies, among other things, the exact content of the message that must be provided by the label. The message of the label must be preceded by a heading (''WARNING''), with an alert symbol, and state the following:

DO NOT place rear-facing child seat on front seat with air bag.
DEATH OR SERIOUS INJURY can occur.

The back seat is the safest place for children 12 and under. Also required for the label is a pictogram showing a rear-facing child seat being impacted by an air bag, surrounded by a red circle with a slash across it. Flexibility as to the content of the label is not provided; thus, wording other than that specified in the standard is not permitted.

First Interim Final Rule

On April 17, 1997 (62 FR 18723), NHTSA amended S5.5.2(k) to permit, for some child restraints, the addition of the phrase ''unless air bag is off'' after the sentence stating ''DO NOT place rear-facing child seat on front seat with air bag.'' The amendment responded to

[1] Corrected December 4, 1996 (61 FR 64297), December 11, 1996 (61 FR 65187), and January 2, 1997 (62 FR 31).

a request from Mercedes-Benz concerning rear-facing child seats that have features enabling the seat to deactivate the passenger-side air bag.

Mercedes developed a rear-facing child seat with a device that automatically cuts off the passenger-side air bag in vehicles designed to respond to such a device. The cutoff feature makes it possible to use a child restraint system on the front seat of these vehicles without subjecting the child to risk of injury from an air bag deployment. Mercedes believed that the first statement (''DO NOT place rear-facing child seat on front seat with air bag'') was inappropriate for child restraints with a feature that turns off the air bag, and could be potentially confusing to owners of child restraints that are marketed as compatible with a complementary air bag system. Mercedes suggested that the amended label should be permitted on a child restraint that is equipped with a cutoff device, if the cutoff device automatically deactivates the passenger-side air bag and activates a telltale light in the vehicle that complies with S4.5.4.3 of Standard No. 208, ''Occupant Crash Protection'' (49 CFR § 571.208).

In the April 17, 1997 interim final rule, NHTSA agreed with Mercedes that adding the phrase ''unless air bag is off'' would clarify the message of the label and reduce the likelihood of confusing owners of child seats that are intended for use on and marketed as appropriate for front seat positions on vehicles equipped with complementary air bag cutoff devices. The agency tentatively agreed that the conditions for (a) automatic deactivation and (b) a telltale meeting S4.5.4.3 of Standard 208, ''reduce[d] the likelihood that a child restraint would be used with an active air bag.'' Because NHTSA saw no diminution of safety resulting from the change, the agency amended the standard to accommodate Mercedes' request.

Today's Interim Rule

After the April 17, 1997 interim final rule was issued, Porsche contacted the agency asking whether the conditions for automatic deactivation and a telltale meeting S4.5.4.3 were necessary requisites to allowing the phrase ''unless air bag is off'' to be added to the child seat warning label.

Porsche has also developed a rear-facing child seat with a device that cuts off the passenger-side air bag in vehicles designed to respond to such a device. However, unlike Mercedes, the device is not automatic. To cut off the passenger-side air bag, a specialized buckle tongue on the child seat must be inserted into a buckle receiver installed under the front passenger seat. The Porsche system does not include a telltale light complying with S4.5.4.3 of Standard No. 208. Instead, the air bag readiness indicator flashes for 10 seconds to inform the driver that the child seat has properly cut off the passenger-side air bag. If the vehicle is on when the special buckle is inserted in the receiver, the warning light flashes upon insertion of the buckle. If the vehicle is off when the special buckle is inserted, the warning light flashes each time the ignition is turned on. Porsche believes that its design, while different from the Mercedes design, also warrants the addition of the phrase ''unless air bag is off'' to the child seat warning label on Porsche's rear-facing child seats.

On reexamining the interim rule, NHTSA has tentatively determined that the phrase ''unless air bag is off'' may be added to a child seat that can deactivate an air bag, whether or not the deactivation is automatic. In addition, the agency has tentatively determined that specified telltale requirements are unnecessary so long as a signal is provided to the driver that the air bag has been disabled.

If an air bag is deactivated by a device incorporated into a child safety seat, the danger that the label on the seat warns against will not be present. This result can be achieved as effectively by non-automatic means as by automatic means. The question raised by a non-automatic device such as Porsche's is whether a person installing the seat in a vehicle will install it correctly. If the likelihood of correct installation is very high, allowing the addition of the phrase ''unless air bag is off'' to the label would help resolve any confusion on the part of the person installing the seat.

In the case of the device employed by Porsche, the child safety seat is equipped with a single buckle that fits into a buckle receiver under the vehicle's seat. The buckle fits no other part of the vehicle. The correctness of its installation is evident, both by the click of the buckle upon its insertion into the receiver and by the activation of a visual signal on the vehicle's dash. These features offer sufficient assurance of correct installation, in the agency's view, to warrant the modification of the label.

The nature of the visual signal is the second issue raised by the Porsche request. The agency considers it essential to have a means of notifying the driver that the air bag has been disabled. In the first interim rule, NHTSA said that the phrase may be added if the child seat has a device that activates a telltale complying with S4.5.4.3 of Standard 208. S4.5.4.3 states:

> A telltale light on the dashboard shall be clearly visible from all front seating positions and shall be illuminated whenever the passenger air bag is deactivated. The telltale:
> (a) Shall be yellow;
> (b) Shall have the identifying words ''AIR BAG OFF'' on the telltale or within 25 millimeters of the telltale;
> (c) Shall remain illuminated for the entire time that the passenger air bag is deactivated;
> (d) Shall not be illuminated at any time when the passenger air bag is not deactived; and,
> (e) Shall not be combined with the readiness indicator required by S4.5.2 of [Standard 208].

Upon reexamining the need for notifying the driver, the agency has tentatively determined that the telltale requirements of Standard 208 are not necessary, as stated in the first interim final rule, to ''reduce the likelihood that a child restraint would be used with an active air bag.'' 62 FR at 18724. The telltale requirements were originally specified for a cutoff device that operates in a way that could allow an adult to use the front passenger seating position with the air bag deactivated. The requirements ensure that there is a reminder that the cutoff device should be reset whenever the vehicle's front seat is no longer carrying an infant, so that the air bag would be ready when needed. The telltale requirements are intended to inform an adult passenger, to enable him or her to see the warning light and understand that the air bag is not activated.

In contrast, air bag deactivation systems of the types developed by Mercedes and Porsche deactivate the air bag when and only when a child restraint is present and reactivate the air bag when the child restraint is removed. Such systems render it highly unlikely that an unknowing adult could be seated in the front seating position with the air bag deactivated. Because of this difference, a telltale meeting S4.5.4.3 of Standard 208 does not appear needed.

NHTSA has tentatively decided, however, that the driver should be signaled as to whether the child seat has deactivated the air bag. The agency has tentatively concluded that the signal must continue for at least 10 seconds after deactivation of the air bag. A visual signal could include a dashboard light.

Because this rule does not require that a dashboard light must remain illuminated for the entire time that the passenger air bag is deactivated, the agency tentatively concludes that the light may be combined with the readiness indicator required by S4.5.2 of

Standard 208. However, such combination must not affect the compliance of the readiness indicator with S4.5.2.

This amendment clarifies a requirement and avoids possible confusion resulting from the required labeling. Accordingly, NHTSA finds for good cause that an immediate amendment of the requirement is in the public interest.

Submission of Comments

Interested persons are invited to submit comments on this rule. 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 interim rule 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. Comments on the interim rule will be available for inspection in the docket. 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 envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under E.O. 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document was not reviewed under E.O. 12866, ''Regulatory Planning and Review.'' This action has been determined to be ''nonsignificant'' under the Department of Transportation's regulatory policies and procedures. The amendments pertain to optional label changes that are minor in nature. The agency concludes that the impacts of the amendments are so minimal that a full regulatory evaluation is not required.

B. Regulatory Flexibility Act

NHTSA has also considered the impacts of this document under the Regulatory Flexibility Act. I hereby certify that this rule does not have a significant economic impact on a substantial number of small entities. The rule will not impose any new requirements or costs on manufacturers, but instead will permit a manufacturer to use an optional label on its child restraint if conditions on the use of the label are met. Further, since no price increases are associated with the rule, small organizations and small governmental units are not be affected in their capacity as purchasers of child restraints.

C. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96–511), there are no requirements for information collection associated with this rule.

D. National Environmental Policy Act

NHTSA has also analyzed this rule under the National Environmental Policy Act and determined that it will not have a significant impact on the human environment.

E. Executive Order 12612 (Federalism)

NHTSA has analyzed this rule in accordance with the principles and criteria contained in E.O. 12612, and has determined that this rule will not have significant federalism implications to warrant the preparation of a Federalism Assessment.

F. Civil Justice Reform

This rule has no retroactive effect. Under 49 U.S.C. 30103, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 30161 sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

In consideration of the foregoing, NHTSA amends 49 CFR Part 571 as set forth below.

1. The authority citation for Part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.50.

2. Section 571.213 is amended by revising S5.5.2(k)(5), to read as follows:

§ 571.213 Standard No. 213, Child Restraint Systems.

* * * * *

S5.5.2 * * *

(k) * * *

(5) If a child restraint system is equipped with a device that deactivates the passenger-side air bag in a vehicle when and only when the child restraint is installed in the vehicle and provides a signal, for at least 10 seconds after deactivation, that the air bag is deactivated, the label specified in Figure 10 may include the phrase ''unless air bag is off'' after ''on front seat with air bag.''

* * * * *

Issued on May 30, 1997.

Philip Recht,

Deputy Administrator.

[FR Doc. 97–14607 Filed 5–30–97; 3:22 pm]

BILLING CODE 4910–59–P

Proposed Rules

Federal Register

Vol. 62, No. 107

Wednesday, June 4, 1997

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

Agricultural Marketing Service

7 CFR Parts 911 and 944

[Docket No. FV97–911–1B PR]

Limes Grown in Florida and Imported Limes; Reopening of Comment Period on Proposed Rule

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Reopening of comment period.

SUMMARY: This rule reopens the period for filing written comments on proposed changes to the minimum size requirements currently prescribed under the lime marketing order and the lime import regulations. The proposed rule covered two proposed changes to the regulations. One proposed change would increase the minimum size requirement from 1⅞ to 2 inches in diameter for the month of June, which would result in the 2 inch minimum being required from January 1 through June 30 of each year. The comment period is only being reopened to solicit comments on the proposal to increase the minimum size. Changes in import requirements would be necessary under section 8e of the Agricultural Marketing Agreement Act of 1937. The other proposed change would revoke the temporary suspension and thereby maintain continuous, year round, implementation of regulations. An interim final rule with an opportunity for comments is being published separately concerning the suspension.

DATES: Comments regarding the minimum size requirements must be received by July 7, 1997.

ADDRESSES: Interested persons are invited to submit written comments concerning this reopened action. Comments must be sent in triplicate to the Docket Clerk, Marketing Order Administration Branch, F&V, AMS, USDA, Room 2525–S, P.O. Box 96456, Washington, DC 20090–6456, FAX: (202) 720–5698. Comments should reference the docket number, the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Aleck Jonas, Southeast Marketing Field Office, Marketing Order Administration Branch, F&V, AMS, USDA, P. O. Box 2276, Winter Haven, Florida 33883; telephone: (941) 299–4770, FAX: (941) 299–5169; or Kathleen M. Finn, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, Room 2530–S., P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–2491, or FAX (202) 720–5698.

SUPPLEMENTARY INFORMATION: The proposed rule was issued under Marketing Agreement No. 126 and Marketing Order No. 911 [7 CFR Part 911], both as amended, regulating the handling of limes, hereinafter referred to as the ''order.'' The marketing agreement and order are authorized by the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The proposed rule was also issued under section 8e of the Act, which provides that whenever certain specified commodities, including limes, are regulated under a Federal marketing order, imports of these commodities into the United States are prohibited unless they meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically produced commodities.

The proposed rule was issued on April 25, 1997, and published in the April 29, 1997, issue of the **Federal Register** (62 FR 23185). It proposed amending §§ 911.311, 911.329, 911.344 of the regulations by removing a scheduled June 1, 1997, through December 31, 1997, suspension of regulations maintaining continuous, year round, handling regulations. This portion of the proposed rule is being handled under a separate rulemaking action.

The rule also proposed amending § 911.344 of the order's rules and regulations by increasing the minimum size requirement from 1⅞ inches to 2 inches in diameter for the month of June. The proposed size increase also would apply to imports, consistent with 8e of the Act. The comment period for this portion of the rule is being reopened for 30 days by this action.

Two comments were filed requesting an extension of time to file comments. One comment was from a Mexican exporter and the other from a Mexican exporters' and packers' union of limes. Both requested that the comment period be extended so that they could adequately analyze the proposal and its impact on their businesses. One commenter requested a 30-day and the other a 90-day extension with one concluding that the proposal would have a negative effect on its business and the other noting that the proposal would have a direct effect on its business.

In light of these comments, the Department has determined that it is in the public interest to reopen the comment period on the proposed rule as it pertains to increasing the minimum size. A 30-day extension is deemed appropriate. A 30-day comment period on the proposal has already been provided. Such action will provide interested persons the opportunity to review the rule and submit additional written views and information pertinent to the potential effect of the action on the lime industry. Accordingly, the comment period is reopened to July 7, 1997.

List of Subjects

7 CFR Part 911

Limes, Marketing agreements, Reporting and recordkeeping requirements.

7 CFR Part 944

Avocados, Food grades and standards, Grapefruit, Grapes, Imports, Kiwifruit, Limes, Olives, Oranges.

Authority: 7 U.S.C. 601–674.

Dated: May 29, 1997.

Robert C. Keeney,

Director, Fruit and Vegetable Division.

[FR Doc. 97–14651 Filed 6–2–97; 10:02 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 918

[Docket No. FV–97–918–1PR]

Fresh Peaches Grown in Georgia; Proposed Termination of Marketing Order No. 918

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposal invites comments on the termination of the Federal marketing order regulating the handling of fresh peaches grown in Georgia (order) and the rules and regulations issued thereunder. The order does not reflect current industry structure and operating procedures and there is no industry support for reactivating the order. Therefore, there is no need to continue this order.

DATES: Comments must be received by July 7, 1997.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456, Fax: (202) 720–5698. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: William G. Pimental, Southeast Marketing Field Office, AMS, USDA, P.O. Box 2276, Winter Haven, Florida 33883–2276; telephone: (941) 299–4770, Fax: (941) 299–5169; or Caroline Thorpe, Marketing Order Administration Branch, F&V, AMS, USDA, room 2522–S, P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–8139, Fax: (202) 720–5698. Small businesses may request information on compliance with this regulation by contacting: Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090-6456; telephone (202) 720–2491, Fax: (202) 720–5698.

SUPPLEMENTARY INFORMATION: This proposal is governed by provisions of section 608(16)(A) of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act and § 918.81 of the order.

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This proposal will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after date of the entry of the ruling.

This proposed rule would terminate the order regulating the handling of peaches grown in Georgia. Sections 918.81 and 918.82 of the order contain the authority and procedures for termination.

The order was initially established in 1942 to help the industry solve specific marketing problems and maintain orderly marketing conditions. It was the responsibility of the Peach Industry Committee (committee), the agency established for local administration of the marketing order, to periodically investigate and assemble data on the growing, harvesting, shipping, and marketing conditions of Georgia peaches. The committee tried to achieve orderly marketing and improve acceptance of Georgia peaches through the establishment of minimum size, maturity and quality requirements.

The Georgia peach industry has not operated under the marketing order for four years. The order and all of its accompanying rules and regulations were suspended March 1, 1993, for two years (58 FR 8209). At the request of the industry, the Department extended the suspension for two more years (60 FR 17633). Regulations have not been applied under the order since 1992, and no committee has been appointed since then. The only regulations the industry is using are for research, promotion, and advertising. This is handled locally by the Georgia Commodity Commission through a State program.

In 1942, when the marketing order was issued, there were over 300 growers of Georgia peaches. Currently, there are approximately 20 peach growers.

The Department contacted many current industry members with respect to the need for reinstating the marketing order. Virtually all the individuals corresponding with the Department stated they were not interested in reestablishing the order. There was a peach industry meeting held on February 6, 1997, in Byron, Georgia where the marketing order was a topic of discussion. There was no support from the attendees for reactivating or amending the order.

There have been changes in industry structure and operating procedures since the order was last amended. Making the marketing order reflect these changes could require further amendments. The steps necessary to amend and reactivate the existing order would be similar to what would be required to establish a new order. The need for a new or amended marketing order would have to be justified and supported by a large majority of Georgia peach growers. This would require a public hearing and a grower referendum. There is no determinable industry support for a marketing order. Thus, there is little justification to continue the current order.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 8 handlers of Georgia peaches who would be subject to regulation under the marketing order and approximately 20 peach growers in the regulated area. Small agricultural service firms have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $5,000,000, and small agricultural producers are defined as those having annual receipts of less than

$500,000. The majority of the Georgia peach growers and handlers may be classified as small entities.

This proposed rule would terminate the order regulating the handling of peaches grown in Georgia. The order and its accompanying rules and regulations have been suspended since March 1, 1993. No regulations have been implemented since the 1990–91 season, and there is no indication that such regulations will again be needed.

The industry has been operating without a marketing order since its suspension. Reestablishing the order would mean additional cost to the industry stemming from assessments to maintain the order and any associated costs generated by regulation. By not reinstating the marketing order, the industry benefits from avoiding these costs. Because the industry has been operating without an order for four years, the termination of the order would have no noticeable effect on either small or large operations.

The Department attempted to solicit as much industry input on this decision as possible. The Department sent a letter to current industry members it was able to identify seeking comments on the need for reinstating the marketing order. There was a peach industry meeting held on February 6, 1997, in Byron, Georgia where the marketing order was a topic of discussion. In addition, this action provides the opportunity for all interested persons to comment on this proposal.

The Department believes that conducting a termination referendum would merely reaffirm the Georgia peach industry's continued lack of interest in reactivating the marketing order and that conducting such a referendum would be wasteful of Departmental and public resources.

Therefore, pursuant to section 608c(16)(A) of the Act and § 918.81 of the order, the Department is considering the termination of Marketing Order No. 918, covering peaches grown in Georgia. If the Secretary decides to terminate the order, trustees would be appointed to continue in the capacity of concluding and liquidating the affairs of the former committee.

Section 608c(16)(A) of the Act requires the Secretary to notify Congress 60 days in advance of the termination of a Federal marketing order. Congress was notified of this proposed termination on April 25, 1997.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 918

Marketing agreements, Peaches, Reporting and recordkeeping requirements.

PART 918—[REMOVED]

For the reasons set forth in the preamble, and under authority of 7 U.S.C. 601–674, 7 CFR part 918 is proposed to be removed.

Dated: May 29, 1997.

Michael V. Dunn,

Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 97–14478 Filed 6–3–97; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

10 CFR Part 711

[Docket No. DP–RM–97–100]

RIN 1992–AA14

Personnel Assurance Program

AGENCY: Department of Energy.

ACTION: Notice of Proposed Rulemaking and Public Hearings.

SUMMARY: The Department of Energy (DOE or Department) today proposes Personnel Assurance Program (PAP) procedures and standards for DOE and DOE contractor employees who are assigned nuclear explosive duties at DOE facilities. The PAP is a systematic program, previously established by internal DOE directive, to prevent accidental or unauthorized detonation of nuclear explosives as a result of assignment of nuclear explosives duties to employees who have become emotionally, mentally, or physically incapacitated. The proposed rule includes medical standards for evaluating DOE and contractor employees in the PAP.

DATES: Written comments (7 copies) on the proposed rule must be received by the Department on or before August 4, 1997.

Oral views, data, and arguments may be presented at public hearings which are scheduled as follows:

1. July 8, 1997, 9 a.m.–12 noon and 5 p.m–8 p.m., Amarillo, TX.

2. July 10, 1997, 10 a.m.–12 noon and 2 p.m–5 p.m., North Las Vegas, NV.

Requests to speak at a hearing should be phoned in to the Department, (202) 586–3012, no later than 4 p.m. on July 3, 1997, for both hearings.

The length of each oral presentation is limited to 10 minutes.

ADDRESSES: Written comments (7 copies) should be mailed to: U.S. Department of Energy, Office of Defense Programs, DP–21, Docket Number DP–RM–97–100, 1000 Independence Ave. SW., Washington, DC 20585. Requests to speak at a hearing may be phoned in to (202) 586–3012. The public hearings will be held at the following locations.

1. Amarillo, TX, Sunset Convention Center, 3701 Plains Blvd (at Western), Suite 135.

2. North Las Vegas, NV, USDOE, 232 Energy Way (off Losee Rd), room A–106/107 (first floor, ''The Great Basin Room'').

Copies of transcripts from hearings and written comments may be inspected and photocopied in the DOE Freedom of Information Reading Room, Room 1E–190, (202) 586–6020, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

For additional information concerning public participation in this rulemaking, see the ''Opportunity for Public Comment'' section in the Supplementary Information section of this proposed rule.

FOR FURTHER INFORMATION CONTACT: For further information concerning the proposed rule: Mr. Randall Weidman, U.S. Department of Energy, Office of Defense Programs (DP–21), 1000 Independence Ave. SW., Washington, DC 20585, (301) 903–3154.

For further information concerning Subpart B, Medical Assessments for PAP Certification and Recertification: Mr. Kenneth O. Matthews, Office of Occupational Medicine and Medical Surveillance (EH–61), 1000 Independence Ave. SW., U.S. Department of Energy, Washington, DC 20585, (301) 903–6398.

For further information concerning the public hearings and submitting written comments: Ms. Andi Kasarsky, (202) 586–3012.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to the Atomic Energy Act of 1954 (Act), DOE owns defense nuclear facilities in various locations in the United States which are operated by management and operating contractors under DOE supervision. These facilities are involved in researching, testing, producing, disassembling, and transporting of nuclear explosives which, when mated with Department of Defense provided delivery systems, become nuclear weapon systems.

Pursuant to section 161 of the Act, 42 U.S.C. 2201 (b), (i)(3), and (p), DOE and its predecessor agencies—the Atomic Energy Commission (AEC) and the Energy Research and Development Administration (ERDA)—have used

some version of the PAP to certify, actively monitor, and periodically recertify personnel as suitable to perform nuclear explosive duties in a safe and reliable manner. PAP provides for disqualification of persons from performance of nuclear explosive duties who fail to meet PAP requirements for emotional, mental, and physical capability. In DOE's internal administrative directives, DOE Order 452.2, formerly DOE Order 5610.11, ''SAFETY OF NUCLEAR EXPLOSIVE OPERATIONS,'' the term ''Nuclear Explosive Duties'' has been defined to include DOE or contractor employees who have custody of or ''access'' to a nuclear explosive. ''Access'' has been defined to mean: ''The proximity to a nuclear explosive that affords a person the opportunity to tamper with it or to cause a detonation.''

All PAP-certified employees are subject to continuous review and evaluation. The certification of such employees is subject to immediate review in light of facts and circumstances about an employee or an employee's behavior indicating a reliability risk that warrants protective action to neutralize a nuclear explosive hazard by having an individual immediately removed from nuclear explosive duties. Immediate removal does not constitute a determination that the individual is unsuitable for nuclear explosive duties, but indicates that the individual's suitability is in question.

The PAP procedures and standards are legally binding on contractors under the terms and conditions of their contractual agreements which require them to comply with applicable DOE directives. They also apply to contractor personnel and could serve as the basis for the contractor to take action affecting an employee's employment rights.

In 1992, the Independent Guard Association of Nevada, Local No. 1, representing PAP-certifiable civilian security guards employed by Wackenhut Security, Inc., at DOE's Nevada Test Site, brought suit challenging DOE Order 5610.11, ''NUCLEAR EXPLOSIVE SAFETY,'' which established the Department's nuclear explosive and weapons safety program, including the PAP. The DOE Order was challenged for failure to promulgate it through public notice and comment in compliance with the Administrative Procedure Act, 5 U.S.C. 553. In *Independent Guard Association of Nevada* v. *O'Leary*, No. CV–S–92–204–LDG–LRL (D. Nev. June 14, 1996), the District Court enjoined DOE from enforcing the requirements section (section 2) of DOE Order 5610.11, Chapter I, against contractor employees pending notice and comment rulemaking under 5 U.S.C. 553. DOE is now publishing this notice of proposed rulemaking to codify the PAP employee certification procedures and standards and other PAP-related policies, including the responsibilities of the Site Occupational Medical Director (SOMD) and other medical personnel. Subject to consideration of comments that are submitted in response to this notice, DOE intends to issue a final rule establishing PAP procedures and standards, including medical assessment requirements applicable to the DOE and contractor employees performing nuclear explosive duties.

Today's notice of proposed rulemaking contains provisions that are similar to those in a notice of interim procedures and standands DOE published in the **Federal Register** on October 9, 1996 (61 FR 53018). DOE published the interim procedures and standards after finding good cause for making them immediately effective pending completion of notice and comment rulemaking. The proposal published today goes beyond the interim procedures and standards by proposing, in Subpart B, more detailed administrative procedures and standards for the conduct of medical assessments used for PAP certification and recertification.

II. Description and Basis for Proposed PAP Procedures and Standards

The program elements of certification, periodic recertification, and physical and psychological evaluation for cause are based on DOE's experience, as well as the experience of DOE's predecessor agencies for over 30 years. Both the AEC and ERDA had provisions in their manuals for the PAP, and DOE has had internal administrative directives setting forth PAP policies. Today's proposed rule contains several modifications of the PAP as set forth in DOE directives. This part of the Supplementary Information section discusses the meaning of, and the basis for, those modifications and other proposed provisions of the proposed rule that require explanation.

A. Discussion of Subpart A: Certification, Recertification, and Revocation of PAP Certification

Subpart A includes, with few substantive changes, the provisions of the interim procedures and standards published by DOE on October 9, 1996, except for section 11 of the interim procedures and standards dealing with medical assessments. The medical assessment provisions have now been incorporated in an expanded set of medical assessment provisions in Subpart B of this proposed rule.

Proposed § 711.3 sets forth definitions that apply to this Part. The definitions of ''access,'' ''custody,'' ''nuclear explosive,'' ''nuclear explosive area,'' ''nuclear explosive duties,'' and ''pit'' were developed in consultation with a variety of interested stakeholders and experts and have been included in internal DOE orders and directives. The term ''alcohol use disorder'' is included as a substitute for the term ''alcohol abuse'' that was used in the interim procedures and standards. The definition of ''alcohol use disorder'' is used in the occupational medical field to describe the condition referred to in the interim procedures and standards as alcohol abuse.

''Hallucinogen'' is defined, for purposes of PAP, as any hallucinogenic drug or substance that causes flashbacks. A definition of ''flashback'' is included. The basis for these terms is discussed more fully in connection with § 711.5, ''General requirements.'' The definition of ''illegal drug'' tracks the definitions of ''illegal drug'' in 10 CFR 707.4 (''Workplace Substance Abuse Programs at DOE Sites'') and 10 CFR 710.54 (applicable to DOE's Personnel Security Assurance Program).

Proposed § 711.4 contains general provisions that describe and define the scope of the PAP. Paragraph (a) Would establish that PAP certification is in addition to any other qualification requirements that may apply to a particular job. Paragraph (b) would preserve the contractor's authority to establish stricter standards, including medical standards, for individuals the contractor nominates for PAP certification or recertification. Paragraph (c) would provide that the failure of an individual to be certified or recertified in the PAP shall not, by itself, be cause for questioning the individual's qualification for non-PAP duties or for loss of pay or other employment benefits. While an individual's failure to be recertified in the PAP would not automatically be cause for denial of non-PAP employment or loss of pay, conduct that leads to an individual's removal from the PAP (e.g., participation in illegal drug activity) may be the basis for an adverse personnel management action (e.g., participation in illegal drug activity). Paragraph (e) would grant broad authority to the operations office manager to delegate most PAP responsibilities to lower-level DOE officials. This delegation would provide necessary flexibility in implementing the PAP.

Proposed § 711.5(b)(3) would require each individual in the PAP to be tested for illegal drugs at least once each calendar year in an unannounced and unpredictable manner. In addition to this random testing, DOE may test an individual for cause or reasonable suspicion of illegal drug use, or after an accident or an unsafe practice involving the individual. Drug testing procedures are dealt with in § 711.42.

Proposed § 711.5(b)(4), and § 711.43 in Subpart B, set forth a special policy for disqualification from the PAP for hallucinogen use. ''Hallucinogen'' is defined in proposed § 711.3 so as to limit PAP-disqualifying hallucinogens to those hallucinogenic drugs or substances that cause flashbacks. The proposed rule provides that hallucinogen use more than 5 years earlier is not, in itself, an adequate basis for denying certification or recertification. The 5-year rule reflects a period of time that should elapse, as a protective practice, to minimize the likelihood of flashbacks. ''Flashback'' is the term used to describe a transient, spontaneous recurrence of certain aspects of a person's hallucinogen experience. Flashbacks typically have all of the qualities of the original experience, and they are strongly felt. Because flashbacks are sudden, often unpredictable, largely involuntary, dramatic alterations of emotional state, perception, sensation, and behavior, an accident would likely result if a flashback were to occur during the performance of a hazardous task. Flashbacks may occur within a few days after hallucinogen use, or they may occur a few weeks, months, or even years later. In developing the proposed 5-year rule, DOE has consulted with experts at the Alcohol, Drug Abuse and Mental Health Administration of the Department of Health and Human Services. DOE has placed the views, and a review of relevant studies, submitted by the National Institute on Drug Abuse, in the docket established for this rulemaking. Although an individual who used a hallucinogen more than 5 years earlier would be considered for nuclear explosive duties, proposed § 711.43 provides that an individual who has used a hallucinogen must undergo a medical evaluation to determine reliability. In addition, the individual must have an acceptable job record and observed behavior.

Proposed § 711.6 sets forth details of the PAP certification process. Paragraph (a) would assign the PAP certifying official the responsibility for making the initial decision to certify or recertify an individual in the PAP. The PAP certifying official may be the operations office manager, but more typically it will be a lower-level official who has been delegated the certification authority by the operations office manager or, on occasion, by the Secretary of Energy. Paragraph (b) would direct each operations office manager who has jurisdiction over PAP certification to issue implementing instructions that accomplish specified objectives. Because of the varied nature of the workforce at DOE sites, the proposed rule does not dictate the implementation details, but rather sets forth performance standards for PAP implementation.

Proposed § 711.7 would require PAP administrators to maintain a list of individuals certified in the PAP. The required list would be used for DOE program administration purposes only, and would not be considered as an authorization for an individual to perform PAP duties.

Proposed § 711.9 would impose an obligation on supervisors to report any observed or reported condition or behavior of a PAP individual that gives rise to a reasonable belief that the individual may not be able to perform assigned tasks in a safe and reliable manner. Proposed § 711.10 would impose the same obligation on individuals in the PAP, including a duty of self-reporting. The non-exclusive list in § 711.9(b) includes a variety of conditions and behavior that may raise PAP concerns. It is emphasized the purpose of this reporting is only to determine whether an individual should be removed from nuclear explosive duties.

Proposed §§ 711.11 through 711.16 would prescribe the procedures that must be followed for resolving issues related to denial of certification or recertification and revocation of PAP certification. Proposed § 711.11 would provide for the immediate removal of any PAP-certified individual from nuclear explosive duties if a question is raised about that individual's suitability.

Proposed § 711.12 deals with the evaluation following temporary removal from nuclear explosive duties; the recommendation of the PAP certifying official; and the operations office manager's initial decision and decision following a request for reconsideration or a hearing before a certification review hearing officer.

Proposed § 711.13 concerns the appointment of a certification review hearing officer and DOE legal counsel. Paragraph (a)(2) would ensure the independence of the hearing officer by providing that the hearing officer may not have prior involvement with the matter for which a hearing is requested, nor be directly supervised by any person who is involved in the matter. Subject to the restrictions in paragraph (a), the operations office manager would have discretion in selecting a hearing officer. Depending on the availability of personnel and the needs of a particular case, the manager may appoint a qualified field office attorney to serve as hearing officer or request the DOE Office of Hearings and Appeals to assign a hearing officer.

Proposed § 711.16 would provide an individual who has been denied certification or recertification the right to appeal the operations office manager's final decision to the Assistant Secretary for Defense Programs within 20 working days after receipt of the manager's decision.

B. Discussion of Subpart B: Medical Assessments for PAP Certification and Recertification

Subpart B includes the substance of the medical assessment provisions in section 11 of the interim procedures and standards, including the requirements for illegal drug and alcohol use disorder evaluation and testing. In addition, Subpart B contains definitions that apply to the medical assessment program; provisions on the responsibilities of PAP-designated physicians and psychologists, the SOMD, and other DOE officials; general medical standards for PAP certification; and administrative requirements for medical assessments, including provisions for the maintenance of medical records.

Proposed § 711.22 includes definitions that are used in Subpart B. The focus of a medical assessment under this subpart is on a PAP individual's fitness for duty. The term ''fitness for duty'' is defined to mean that the physical and mental health of a PAP individual is adequate for the performance of nuclear explosive duties in a safe and reliable manner. It is noted that ''fitness for duty'' is narrower than the concept of ''PAP suitability'' used throughout Subpart A. ''PAP suitability'' is a term of longstanding use in the PAP. It encompasses all of the conditions or behavior listed in § 711.9(b), some of which may not involve the physical or mental health of an individual.

Proposed § 711.30 sets forth the minimum qualifications of designated physicians and their responsibilities. The designated physician at a DOE site may serve multiple functions, including serving as the security designated physician, the Medical Review Officer, and firefighter designated physician. Proposed § 711.31 sets forth the

minimum qualifications and responsibilities of designated psychologists. The designated psychologist reports directly to the SOMD and has the principal responsibility for assessing the psychological fitness of individuals in the PAP. The SOMD's role in nominating designated physicians and psychologists and overseeing the PAP medical assessment program is covered in proposed § 711.32.

Proposed § 711.40 contains the general medical standards that must be met by individuals certified in the PAP. An individual must be free of any mental, emotional, physical or medical condition or behavior that is likely to result in impaired ability to perform assigned duties in a safe and reliable manner. Paragraphs (a) through (f) list conditions or behavior that may disqualify an individual from nuclear explosive duties. A medical assessment, conducted as provided in Subpart B, is required to determine whether an individual will be denied initial certification or recertification because of any of the listed conditions or behaviors.

Proposed § 711.41 establishes requirements for the PAP medical assessment process. Paragraph (a) would give the designated physician the overall responsibility, subject to supervision by the SOMD, for the medical assessment of PAP individuals for certification and recertification. Paragraph (b) would require DOE and contractor employers to provide a job task analysis, as defined in § 711.22, to the designated physician and designated psychologist as a prerequisite to each medical assessment and psychological evaluation. Paragraph (c) would require that medical assessments shall be conducted each time there is a ''medical contact.'' Medical contacts include the medical assessments required for initial recertification, annual recertification, and recertification that occurs following the revocation of an individual's removal from nuclear explosive duties. Medical contacts also occur if an individual is transferred to a different job, is self-referred or referred by his or her employer for evaluation, returns to work after an absence for which an evaluation is required by DOE directives, and if an individual's legal drug use is reviewed.

Paragraph (d) presents details about medical assessments that involve a psychological evaluation. It refers to the use of a ''generally accepted, self-reporting psychological inventory tool'' together with a ''semi-structured interview'', both of which are required initially. Also, the semi-structured interview is part of the annual medical assessment for recertification, while the psychological inventory tool is required every third year as part of the medical assessment for recertification. The Minnesota Multi-phasic Personality Inventory is an example of a psychological inventory tool. A ''semi-structured interview'' means an interview by a designated psychologist who has the latitude to vary the focus and content of the questions depending upon the interviewee's responses.

Paragraph (f) concerns the handling of completed medical assessments. Paragraph (f)(1) applies in cases of initial certification and recertification in which the PAP individual is determined to meet the requirements for recertification. In such cases, the designated physician is directed to submit the completed medical assessment to the SOMD, who shall forward a recommendation based on the assessment to the individual's administrative organization and the PAP certifying official. Paragraph (f)(2) applies to cases in which a currently certified individual fails to meet the requirements for recertification. In such cases, the designated physician is directed to immediately inform the PAP certifying official and the PAP individual's administrative organization.

Proposed § 711.42 deals with policies applicable to detecting and acting with regard to positive indications of drug abuse. ''Drug abuse'' is defined in proposed § 711.22 to mean use of an illegal drug or misuse of a legal drug. Paragraph (b) cross-references 10 CFR part 707 which provides DOE's general policy to promote drug-free workplaces, and applies to DOE contractors performing work at DOE-owned or controlled sites. Paragraph (d) establishes conditions on reinstatement in the PAP following rehabilitation. Proposed § 711.43, ''Evaluation of hallucinogen use,'' is discussed in connection with proposed § 711.5, ''General requirements,'' in Subpart A.

Proposed § 711.44 concerns medical assessments for alcohol use disorder and specifies the blood alcohol concentration level that warrants enforcement action. Based on a review of the practices of the Federal Aviation Administration with regard to airplane pilots (14 CFR 91.17(a)(1); 49 CFR 382.505(b)), DOE has adopted the policy of prohibiting alcohol consumption within an 8-hour period preceding nuclear explosive duties and does not permit an individual to perform nuclear explosive duties for a minimum of 24 hours in the event a confirmatory breath alcohol test result is at or above 0.02 percent. Removal from nuclear explosive duties due to results of a confirmatory breath alcohol test could lead to revocation of PAP certification, but there is provision for reinstatement following completion of an approved alcohol treatment program.

Proposed § 711.45 sets forth requirements that apply to maintenance of medical records. Paragraph (c) would establish stringent protections for psychological records, which are to be maintained separately from other medical records of PAP individuals.

III. Opportunity for Public Comment

A. Written Comment Procedures

Written comments (7 copies) should be identified on the outside of the envelope, and on the comments themselves, with the designation: ''Personnel Assurance Program NOPR, Docket Number DP–RM–97–100'' and must be received by the date specified at the beginning of this notice. In the event any person wishing to submit a written comment cannot provide seven copies, alternative arrangements may be made in advance by calling Ms. Andi Kasarsky at (202) 586–3012.

All comments received on or before the date specified at the beginning of this notice and other relevant information will be considered by DOE before final action is taken on the proposed rule. All comments submitted will be available for examination in the Rule Docket File in DOE's Freedom of Information Reading Room. In addition, a transcript of the proceedings of the public hearings will be filed in the docket.

Pursuant to the provisions of 10 CFR 1004.11, any person submitting information or data that is believed to be confidential, and which may be exempt by law from public disclosure, should submit one complete copy, as well as two copies from which the information claimed to be confidential has been deleted. The DOE will make its own determination of any such claim.

B. Public Hearing Procedures

The time and place of the public hearings are indicated at the beginning of this notice. The Department invites any person who has an interest in the proposed regulation, or who is a representative of a group or class of persons which has an interest, to make a request for an opportunity to make an oral presentation at the hearing. Requests to speak should be sent to the address or phone number indicated in the **ADDRESSES** section of this notice and be received by the time specified in the **DATES** section of this notice.

The person making the request should provide a phone number where they may be reached during the day. Each person selected to speak at a public hearing will be notified as to the approximate time that they will be speaking. They should bring seven (7) copies of their statement to the hearing. In the event any person wishing to testify cannot meet this requirement, alternative arrangements may be made in advance with Ms. Andi Kasarsky, (202) 586–3012.

The DOE reserves the right to select persons to be heard at each hearing, to schedule their presentations, and to establish procedures governing the conduct of the hearing. The length of each presentation will be limited to ten minutes, unless modified based on the number of persons requesting to speak.

A Departmental official will be designated to preside at the hearing. The hearing will not be a judicial or an evidentiary-type hearing, but will be conducted in accordance with 5 U.S.C. 553 and section 501 of the Department of Energy Organization Act, 42 U.S.C. 7191. At the conclusion of all initial oral statements, each person will be given the opportunity to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made.

Any further procedural rules needed for the proper conduct of the hearing will be announced by the Presiding Officer at the hearing.

If DOE must cancel a hearing, DOE will make every effort to publish an advance notice of such cancellation in the **Federal Register**. Notice of cancellation will also be given to all persons scheduled to speak at the hearing. Hearing dates may be canceled in the event no public testimony has been scheduled in advance.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

Today's regulatory action has been determined not to be a ''significant regulatory action'' under Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, this rulemaking has not been reviewed by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

B. Review Under Executive Order 12612

Executive Order 12612 (52 FR 41685, October 30, 1987) requires that regulations, rules, legislation, and other policy actions be reviewed for any substantial direct effect on States, on the relationship between the National Government and the States, or in the distribution of power and responsibilities among various levels of government. If there are substantial effects, then the Executive Order requires the preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing policy action. The Department has analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 12612, and has determined there are no federalism implications that would warrant the preparation of a Federalism Assessment. The rule proposed today would apply to DOE and DOE contractor personnel employed at defense nuclear facilities. The proposed rule would not have a substantial direct effect on States, the relationship between the States and Federal Government, or the distribution of power and responsibilities among various levels of government.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires preparation of an initial regulatory flexibility analysis for every rule which by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. Today's proposed rule would affect a total of approximately 3,300 DOE and contractor employees working at Government-owned or leased facilities. Only a small number of the employees work for a small entity. In addition, the DOE is formalizing a program that has been in place at DOE nuclear explosive facilities for over 30 years, so the economic impact of this proposed rule would be negligible. DOE certifies that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. Public comment on this issue is invited.

D. Review Under the National Environmental Policy Act

The proposed rule would amend the PAP program which has been in existence, pursuant to DOE directives, for approximately 30 years. In addition, it relates to personnel qualifications and, if promulgated, would have no impact on the environment. Categorical exclusions A1 and A5 in Appendix A to Subpart D, 10 CFR part 1021 apply to this rulemaking. The Department has therefore determined that neither an environmental assessment nor an environmental impact statement is required.

E. Review Under the Paperwork Reduction Act

The proposed rule does not contain a collection of information that requires the approval of the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* OMB has defined the term ''information'' to exclude certifications, consents, or acknowledgments that entail only minimal burden. 5 CFR 1320.3(h)(1).

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

List of Subjects in 10 CFR Part 711

Administrative practice and procedure, Alcohol abuse, Drug abuse, Government contracts, Government employees, Health, Nuclear safety, Occupational safety and health.

Issued in Washington, DC on May 23, 1997.

Victor H. Reis,

Assistant Secretary for Defense Programs.

Peter N. Brush,

Principal Deputy Assistant Secretary for Environment, Safety and Health.

For the reasons set forth in the preamble, Chapter III of title 10 of the Code of Federal Regulations is amended by adding new Part 711 to read as set forth below:

PART 711—PERSONNEL ASSURANCE PROGRAM

Subpart A—Certification, Recertification, and Revocation of PAP Certification

Sec.
711.1 Purpose.
711.2 Applicability.
711.3 Definitions.
711.4 General.
711.5 General requirements.
711.6 PAP certification process.
711.7 Maintenance of PAP personnel list.
711.8 PAP training requirements.
711.9 Supervisor reporting.
711.10 Individual reporting.
711.11 Immediate removal from nuclear explosive duties.
711.12 Action following removal from duties.
711.13 Appointment of certification review hearing officer and legal counsel.
711.14 Certification review hearing.
711.15 Hearing officer's submission.
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Subpart B—Medical Assessments for PAP Certification and Recertification

General Provisions

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Responsibilities and Authorities

711.30 Designated physician.
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711.40 Medical standards for certification.
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Authority: 42 U.S.C. § 2201, 7191.

Subpart A—Certification, Recertification, and Revocation of PAP Certification

§ 711.1 Purpose.

The purpose of this part is to establish a PAP in the DOE. The PAP is a human reliability program designed to ensure that individuals assigned to nuclear explosive duties do not have emotional, mental, or physical incapacities that could result in a threat to nuclear explosive safety. The PAP establishes the requirements and responsibilities for screening, selecting, and continuously evaluating employees assigned to or being considered for assignment to nuclear explosive duties.

§ 711.2 Applicability.

(a) This part applies to DOE Headquarters and field elements and DOE contractors that manage, oversee, or conduct nuclear explosive operations and associated activities, and to DOE and contractor employees assigned to nuclear explosive duties.

(b) The provisions of this part do not apply to responses to unplanned events (e.g., Accident Response Group activities), which are addressed in DOE 5530-Series Orders and DOE Order 151.1, ''Comprehensive Emergency Management System.''

§ 711.3 Definitions.

Access means proximity to a nuclear explosive that affords a person the opportunity to tamper with it or to cause it to detonate.

Alcohol use disorder means a maladaptive pattern in which a person's intake of alcohol is great enough to damage or adversely affect physical or mental health or personal, social, or occupational function; or when alcohol has become a prerequisite to normal function.

Contractor means the contractor and subcontractors at all tiers.

Custody means responsibility for control of and access to nuclear explosives.

Flashback means a transient, spontaneous, and often unpredictable recurrence of aspects of a person's use of a hallucinogen that involves dramatic alteration of emotional state, perception, sensation, and behavior.

Hallucinogen means any hallucinogenic drug or substance that has the potential to cause flashbacks.

Illegal drug means a controlled substance, as specified in Schedules I through V of the Controlled Substances Act, 21 U.S.C. 811, 812. The term ''illegal drug'' does not apply to the use of a controlled substance in accordance with the terms of a valid prescription, or other uses authorized by law.

Nuclear explosive means an assembly containing fissionable and/or fusionable materials and main charge high explosive parts or propellants capable of producing a nuclear detonation (e.g., a nuclear weapon or test device).

Nuclear explosive area means any area that contains a nuclear explosive or collocated pit and main charge high explosive parts.

Nuclear explosive duties means work assignments that allow custody of a nuclear explosive or access to a nuclear explosive device or area.

Occupational medical program means a DOE program that:

(1) Assists in the maintenance, monitoring, protection, and promotion of employee health through the skills of occupational medicine, psychology, and nursing; and

(2) Maintains a close interface with allied health disciplines, including industrial hygiene, health physics, and safety.

Operations office manager or manager means the manager of a DOE operations office.

PAP certifying official or certifying official means the operations office manager or the manager's delegate who certifies, recertifies, or reviews the circumstances of an individual's removal from nuclear explosive duties, or another individual who is delegated the certification function by the Secretary of Energy.

PAP individual means an individual being considered for assignment or assigned to perform nuclear explosive duties.

Pit means a fissile component, or a set of fissile components, designed to fit in the central cavity of an implosion system and which if placed therein will create a nuclear explosive.

Site Occupational Medical Director means the physician responsible for the overall direction and operation of the site occupational medical program.

§ 711.4 General.

(a) PAP certification is required of each individual assigned to nuclear explosive duties in addition to any other job qualification requirements that apply.

(b) Nothing in this part shall be construed as prohibiting contractors from establishing stricter suitability standards for selecting candidates for nomination to DOE for certification or recertification in the PAP.

(c) The failure of an individual to be certified or recertified in the PAP shall not, in itself, reflect on the individual's suitability for assignment to other duties or, in itself, be a cause for loss of pay or other benefits or other changes in employment status.

(d) Personnel management actions based on the consideration of technical competence and other job qualification requirements shall be considered only if they are based on behavior that also

affects an individual's suitability for the PAP.

(e) The use of any hallucinogen having the potential to cause flashbacks is incompatible with PAP duties and must be evaluated prior to certification or recertification.

(f) Except for the functions in § 711.12 (d), (e) and (h), an operations office manager may delegate PAP functions to a deputy manager, assistant manager, division director, and/or area office manager.

§ 711.5 General requirements.

(a) Each PAP individual shall be certified in the PAP before being assigned to nuclear explosive duties and shall be recertified annually, not to exceed 12 months between recertifications.

(b) To be certified or recertified in the PAP, an individual shall—

(1) Have an active final DOE Q access authorization;

(2) Sign an acknowledgment and agreement to participate in the PAP on a form provided by DOE;

(3) Be interviewed and briefed on the importance of the nuclear explosive duty assignment and PAP objectives and requirements;

(4) Complete a medical assessment for certification and recertification in accordance with subpart B of this part;

(5) Not have used any hallucinogen in the preceding 5 years, and shall not be susceptible to flashbacks resulting from use of any hallucinogen more than 5 years before applying for certification or recertification; and

(6) Be tested for illegal drugs at least once each calendar year in an unannounced and unpredictable manner; an individual may be tested for cause or reasonable suspicion or after an accident or an unsafe practice involving the individual.

(c) If an individual in the PAP refuses to submit a urine sample for illegal drug testing or attempts deception by substitution, adulteration, or other means, DOE immediately shall remove the individual from nuclear explosive duties.

(d) An individual's PAP certification shall be revoked if use of an illegal drug is confirmed through drug testing, as provided in § 711.42 of subpart B.

(e) An individual whose PAP certification is revoked may be reinstated in the PAP if the individual successfully completes an SOMD-approved drug rehabilitation program, as provided in § 711.42 of subpart B.

(f) If an individual chooses to not participate in the PAP, he or she shall sign a refusal of consent form provided by DOE.

§ 711.6 PAP certification process.

(a) The PAP certifying official shall determine each PAP individual's suitability for certification or recertification in the PAP and review the circumstances concerning an individual's removal from nuclear explosive duties and possible recertification.

(b) Each operations office manager who exercises jurisdiction over PAP certification shall issue instructions for implementing the PAP. At a minimum, the instructions shall provide for:

(1) Conducting a supervisory interview of each PAP individual, during which the supervisor shall determine the individual's willingness to accept the requirements and conditions of the PAP;

(2) Ensuring that each PAP individual undergoes a medical assessment under subpart B of this part;

(3) Ensuring that the personnel security file of each PAP individual is reviewed by a DOE employee trained to identify PAP concerns before the individual is certified or recertified;

(4) Ensuring that other available personnel data or information about each PAP individual is reviewed by an employee trained to identify PAP concerns before the individual is certified or recertified;

(5) Allowing the exchange of information about a PAP individual among responsible DOE officials during the certification, recertification, or certification revocation process;

(6) Requesting certification or recertification of a contractor employee when the contractor has determined, on the basis of all available information, that the individual is suitable for the PAP. The contractor requesting certification or recertification shall, in writing, assure the PAP certifying official that all PAP certification requirements have been met;

(7) Addressing any requirement not met during the recertification process, and requiring a contractor to provide any additional personal data or information in its possession that may have a bearing on recertification of an individual;

(8) Documenting certification and recertification of each PAP individual on a form provided by DOE;

(9) Developing a mechanism for co-workers, supervisors, and managers to communicate concerns about a PAP individual's suitability for nuclear explosive duties;

(10) Ensuring that PAP concerns are reported to an appropriate official, as specified in §§ 711.9 and 711.10, for timely resolution; and

(11) Providing that the processing of a request for certification or recertification of an individual is terminated if the individual is no longer being considered for assignment to nuclear explosive duties or is no longer assigned to such duties. If, subsequently, the individual is considered for assignment to nuclear explosive duties, the certification or recertification process must be completely redone.

§ 711.7 Maintenance of PAP personnel list.

Operations office managers who conduct PAP certification and recertification shall establish procedures for developing and maintaining a current list of DOE and contractor personnel certified in the PAP. The list is to be used for program administration and is not an authorization for personnel to perform nuclear explosive duties. The list shall be promptly updated and verified on a quarterly basis.

§ 711.8 PAP training requirements.

(a) Operations office managers shall ensure that each individual who is assigned to nuclear explosive duties receives special training in PAP objectives, policies, and requirements.

(b) Operations office managers shall ensure that DOE and contractor supervisory personnel and PAP certifying officials receive training that includes:

(1) A detailed explanation of nuclear explosive duties and nuclear explosive safety;

(2) Instruction on PAP objectives, policies, and requirements;

(3) Instruction on the early identification of behavior that may indicate a degradation in reliability or judgment; and

(4) Special emphasis on the importance of timely reporting of any PAP concern to appropriate personnel.

(c) Operations office managers shall ensure that medical personnel who perform medical assessments receive, before performing PAP responsibilities, training that includes:

(1) A detailed explanation of nuclear explosive duties and nuclear explosive safety;

(2) Instruction on PAP objectives, policies, and requirements;

(3) An orientation on nuclear explosive processing and the work environment in nuclear explosive areas;

(4) Annual professional training on current issues and concerns relative to psychological assessment; and

(5) Special emphasis on the importance of timely reporting of any PAP concern to appropriate personnel.

(d) Operations office managers shall establish and maintain a system for documenting the training received by PAP-certified individuals, supervisors of PAP personnel, and medical personnel with PAP-related duties.

§ 711.9 Supervisor reporting.

(a) Supervisors shall document and report to a PAP official and the SOMD, if appropriate, any observed or reported behavior or condition of an individual that causes the supervisor to have a reasonable belief that the individual's ability to perform assigned tasks in a safe and reliable manner may be impaired.

(b) Behavior and conditions that could indicate unsuitability for the PAP include, but are not limited to, the following:

(1) Psychological or physical disorders that impair performance of assigned duties;

(2) Conduct that is illegal or results in arrest or conviction;

(3) Indications of deceitful or delinquent behavior;

(4) Attempted or threatened destruction of property or life;

(5) Suicidal tendencies or attempted suicide;

(6) Use of illegal drugs or the abuse of legal drugs or other substances;

(7) Alcohol use disorder;

(8) Recurring financial irresponsibility;

(9) Irresponsibility in performing assigned duties;

(10) Inability to deal with stress, or the appearance of being under unusual stress;

(11) Failure to understand work directives, hostility or aggression toward fellow workers or authority, uncontrolled anger, violation of safety or security procedures, or repeated absenteeism; and

(12) Significant behavioral changes, moodiness, depression, or other evidence of loss of emotional control.

§ 711.10 Individual reporting.

(a) An individual in the PAP shall report any observed or reported behavior or condition of another PAP individual that could indicate the individual's unsuitability for nuclear explosive duties, including the behaviors and conditions listed in § 711.9, to a supervisor, the SOMD, or a PAP official.

(b) An individual in the PAP shall report any behavior or condition, including any behavior or condition listed in § 711.9, that may affect his or her own suitability for nuclear explosive duties to a supervisor, the SOMD, or a PAP official.

§ 711.11 Immediate removal from nuclear explosive duties.

(a) A supervisor who has a reasonable belief that an individual in the PAP is not suitable for nuclear explosive duties shall immediately remove that individual from those duties pending a determination of the individual's suitability. The supervisor shall, at a minimum, require the individual to stop performing nuclear explosive duties and deny the individual access to nuclear explosive areas.

(b) A supervisor who removes an individual from nuclear explosive duties shall notify the PAP certifying official of the action and the reasons that led to the removal of the individual from nuclear explosive duties as soon as possible, and shall forward this information, in writing, to the PAP certifying official within 24 hours.

(c) Immediate removal of an individual from nuclear explosive duties is an interim, precautionary action and does not constitute a determination that the individual is not fit for nuclear explosive duties. Removal from nuclear explosive duties shall not, in itself, be cause for loss of pay or other benefits or other changes in employment status.

§ 711.12 Action following removal from duties.

(a) *Temporary removal.* If a PAP certifying official receives a supervisor's written notice of the immediate removal of an individual from nuclear explosive duties, the certifying official shall direct the removal of the individual from PAP duties pending an evaluation and determination regarding the individual's suitability for nuclear explosive duties.

(b) *Evaluation.* The PAP certifying official shall conduct an evaluation of the circumstances or information that led the supervisor to remove the individual from nuclear explosive duties. The PAP certifying official shall prepare a written report of the evaluation that includes the certifying official's determination regarding the individual's suitability for continuing PAP certification.

(c) *PAP certifying official's action.* (1) If the PAP certifying official determines that an individual who has been temporarily removed from nuclear explosive duties continues to meet the requirements for certification in the PAP, the certifying official shall:

(i) Notify the operations office manager of the determination; and

(ii) Notify the individual's supervisor of the determination and direct that the individual be allowed to return to nuclear explosive duties.

(2) If the PAP certifying official determines that an individual who has been temporarily removed from PAP duties does not meet the requirements for certification in the PAP, the certifying official shall refer the matter to the operations office manager for action. The certifying official shall submit the evaluation report to the operations office manager and a recommendation that the individual's PAP certification be revoked.

(d) *Operations office manager's initial decision.* After receipt of a PAP certifying official's evaluation report and recommendation for revoking an individual's PAP certification, the operations office manager shall take one of the following actions:

(1) Direct that the individual be reinstated in the PAP and, in writing, explain the reasons and factual basis for the action;

(2) Direct the revocation of the individual's PAP certification and, in writing, explain the reasons and factual basis for the decision; or

(3) Direct continuation of the temporary removal pending completion of specified actions (e.g., medical assessment, security evaluation, treatment) to resolve the concerns about the individual's suitability for the PAP.

(e) *Reinstatement after completion of specified actions.* An individual directed by the operations office manager to take specified actions to resolve PAP concerns shall be reevaluated by the certifying official after those actions have been completed. After considering the PAP certifying official's evaluation report and recommendation, the operations office manager shall direct either:

(1) Reinstatement of the individual in the PAP; or

(2) Revocation of the individual's PAP certification.

(f) *Notification of operations office manager's initial decision.* The operations office manager shall send by certified mail, return receipt requested, a written decision to an individual who is denied certification or recertification. The operations office manager's decision shall be accompanied by notification to the individual, in writing, of the procedures in paragraph (g) of this section and §§ 711.14—711.16 pertaining to reconsideration or review of the manager's decision.

(g) *Request for reconsideration or certification review hearing.* An individual who receives notification of an operation office manager's decision to deny or revoke their PAP certification may choose one of the following options:

(1) Take no action;

(2) Submit a written request to the operations office manager for reconsideration of the decision to deny or revoke certification. The request shall include the individual's response to any information that gave rise to a concern about the individual's suitability for nuclear explosive duties. The statement shall be signed under oath or affirmation before a notary public, and must be received by the operations office manager within 20 working days after the individual received notice of the office manager's decision; or

(3) Submit a written request to the operations office manager for a certification review hearing. The request for a hearing must be received by the operations office manager within 20 working days after the individual receives notice of the office manager's decision.

(h) *Operations office manager's decision after reconsideration or hearing.* (1) If an individual requests reconsideration by the operations office manager but not a certification review hearing, the manager shall, within 20 working days, send by certified mail, return receipt requested, to the individual a final decision as to suitability based upon the individual's response and other relevant information available to the manager.

(2) If an individual requests a certification review hearing, the operations office manager shall decide the matter after receipt of the certification review hearing officer's submission, as provided in § 711.15. The operations office manager shall, within 20 working days, send by certified mail, return receipt requested, the manager's final decision to the individual, accompanied by a copy of the hearing officer's findings and recommendations, and the transcript of the certification review proceedings.

§ 711.13 Appointment of a certification review hearing officer and legal counsel.

(a) After receiving an individual's request for a certification review hearing, the operations office manager shall promptly appoint a certification review hearing officer. The hearing officer shall:

(1) Be a DOE attorney or a hearing official from the DOE Office of Hearings and Appeals and have a DOE Q access authorization; and

(2) Have no prior involvement in the matter or be directly supervised by any person who is involved in the matter.

(b) The operations office manager shall also appoint a DOE attorney as counsel for DOE, who shall assist the hearing officer by:

(1) Obtaining evidence;

(2) Arranging for the appearance of witnesses;

(3) Examining and cross-examining witnesses; and

(4) Notifying the individual in writing, at least 7 working days in advance, of the scheduled place, date, and hour where the hearing will take place.

§ 711.14 Certification review hearing.

(a) The certification review hearing officer shall conduct the proceedings in an orderly and impartial manner to protect the interests of both the Government and the individual.

(b) An individual who requests a certification review hearing shall have the right to appear personally before the hearing officer; to present evidence in his own behalf, through witnesses or by documents, or by both; and be accompanied and represented at the hearing by counsel of the individual's choosing and at the individual's own expense.

(c) In conducting the proceedings, the certification review hearing officer shall:

(1) Receive all information relating to the individual's fitness for PAP certification through witnesses or documentation;

(2) Ensure that the individual is permitted to offer information in his or her behalf; to call, examine, and cross-examine witnesses and other persons who have made written or oral statements, except as provided in paragraph (c)(3) of this section, and to present and examine documentary evidence;

(3) Have the option to receive and consider oral or written statements adverse to the individual without affording the individual the opportunity to cross-examine the person making the statement in either of the following circumstances:

(i) The substance of the statement was contained in the individual's personnel security file before the question as to the individual's fitness for PAP certification arose, and the head of the Federal agency supplying the statement certifies that the person who furnished the information is a confidential informant who has been engaged in obtaining intelligence information for the Government, and that the disclosure of that person's identity would substantially harm the national security; or

(ii) The substance of the statement was contained in the individual's personnel security file before the question as to the individual's fitness for PAP certification arose, and the Assistant Secretary for Defense Programs or designee for that particular purpose has determined, after considering information furnished by the investigative agency concerning the reliability of the person and the accuracy of the statement, that —

(A) The statement appears to be reliable and material;

(B) Failure of the hearing officer to receive and consider such statement would substantially harm the national security; and

(C) The person who furnished the information cannot appear to testify due to death or severe illness, or due to some other good cause as determined only by the Assistant Secretary for Defense Programs;

(4) Ensure that if the procedures in paragraph (c)(3) of this section are used, the individual is given a description of the information, which shall be as comprehensive and detailed as the national security permits. In addition, if a statement is received under paragraph (c)(3)(ii), the identity of the person making the statement and the information to be considered shall be made available to the individual. The hearing officer shall give appropriate consideration to the fact that the individual did not have an opportunity to cross-examine such person;

(5) Require the testimony of the individual and all witnesses be given under oath or affirmation;

(6) Request that the Assistant Secretary for Defense Programs issue subpoenas for witnesses to attend the hearing or for the production of specific documents or other physical evidence; and

(7) Ensure that a transcript of the certification review proceedings is made.

§ 711.15 Hearing officer's submission.

Not later than 30 working days after the conclusion of the hearing, the certification review hearing officer shall forward written findings, a supporting statement of reasons, and recommendations regarding the individual's suitability for certification or recertification in the PAP to the operations office manager. The hearing officer's decision shall be accompanied by a copy of the record of the proceedings.

§ 711.16 Appeal of the operations office manager's final decision.

(a) An individual who has been denied PAP certification or recertification, or whose certification has been revoked, may appeal the operations office manager's decision to the Assistant Secretary for Defense Programs. The appeal must be received by the Assistant Secretary for Defense

Programs no later than 20 working days after the individual receives the operations office manager's decision.

(b) An individual who appeals an operations office manager's decision to the Assistant Secretary for Defense Programs must submit the appeal and a written supporting statement to the Assistant Secretary for Defense Programs through the operations office manager and the Deputy Assistant Secretary for Military Application and Stockpile Management. The individual must also submit:

(1) A copy of the operations office manager's final decision and any related documentation; and

(2) If a certification review hearing was conducted, a copy of the hearing officer's findings and recommendations and the transcript or record of the proceedings.

(c) Upon receipt of an individual's appeal and supporting documents, the Assistant Secretary for Defense Programs shall review all of the information and issue a written decision in the matter. The decision of the Assistant Secretary for Defense Programs shall be final.

(d) If an individual does not appeal to the Assistant Secretary for Defense Programs within the time specified in paragraph (a) of this section, the operations office manager's decision shall be final.

Subpart B—Medical Assessments for PAP Certification and Recertification

General Provisions

§ 711.20 Applicability.

This subpart establishes standards and procedures for conducting medical assessments of DOE and contractor employees in the PAP.

§ 711.21 Purpose and scope.

The standards and procedures set forth in this subpart are necessary for DOE to:

(a) Identify the presence of any mental, emotional, or behavioral characteristics or conditions that present or are likely to present an unacceptable impairment in judgment, reliability, or fitness of an individual to perform nuclear explosive duties safely;

(b) Facilitate the early diagnosis and treatment of disease or impairment and to foster accommodation and rehabilitation of a disabled individual with the intent of returning the individual to assigned nuclear explosive duties;

(c) Determine what functions an employee may be able to perform and to facilitate the proper placement of employees; and

(d) Provide for continuing monitoring of the health status of employees in order to facilitate early detection and correction of adverse health effects, trends, or patterns.

§ 711.22 Definitions.

In addition to the definitions in subpart A of this part, the following definitions apply to this subpart:

Designated physician means a licensed doctor of medicine or osteopathy who has been nominated by the SOMD with the concurrence of the Director, Office of Occupational Medicine and Medical Surveillance, to provide professional expertise in the area of occupational medicine as it relates to the PAP.

Designated psychologist means a licensed Ph.D. or Psy.D. clinical psychologist who has been nominated by the SOMD with the concurrence of the Director, Office of Occupational Medicine and Medical Surveillance, to provide professional expertise in the area of psychological assessment as it relates to the PAP.

Diagnostic and Statistical Manual for Mental Disorders means the current version of the American Psychiatric Association's manual containing definitions of psychiatric terms and diagnostic criteria of mental disorders .

Director, Office of Occupational Medicine and Medical Surveillance, means the chief occupational medical officer of the DOE with responsibility for policy and quality assurance for DOE occupational medical programs.

Drug abuse means use of an illegal drug or misuse of legal drugs.

Fitness for duty means that the physical and mental health of a PAP individual is adequate for the performance of nuclear explosive duties in a safe and reliable manner.

Impairment means a decrease in functional capacity of a worker caused by a physical, mental, emotional, substance abuse, or behavioral disorder.

Job task analysis means a statement outlining the essential functions of a job and the potential exposures and hazards of an individual's specific job.

Medical assessment means an evaluation of a PAP individual's present health status and health risk factors by means of:

(1) A historical review;

(2) The job task analysis;

(3) A physical examination;

(4) Appropriate laboratory tests and measurements; and

(5) Appropriate psychological and psychiatric evaluations.

Medical Review Officer (MRO) means a licensed doctor of medicine or osteopathy who has knowledge of substance abuse disorders and appropriate medical training to interpret drug test results. The MRO may also be the designated physician and/or SOMD.

Semi-Structured Interview means an interview by a designated psychologist who has the latitude to vary the focus and content of the questions depending upon the interviewee's responses.

Responsibilities and Authorities

§ 711.30 Designated physician.

(a) The designated physician shall be qualified to provide professional expertise in the area of occupational medicine as it relates to the PAP. The designated physician may serve in other capacities, including Medical Review Officer.

(b) The designated physician shall:

(1) Be a physician who is a graduate of an accredited school of medicine or osteopathy;

(2) Have a valid, unrestricted state license to practice medicine in the state where PAP medical assessments occur;

(3) Have met the applicable PAP training requirements; and

(4) Be eligible for DOE access authorization to the worksite.

(c) The designated physician shall be responsible for the medical assessments of PAP individuals, including determining which components of the medical assessments may be performed by other qualified personnel. Although a portion of the assessment may be performed by another physician, physician's assistant, or nurse practitioner, the designated physician remains responsible for:

(1) Supervising the evaluation process;

(2) Interpreting the results of evaluations;

(3) Documenting medical conditions that disqualify an individual or that may in the future disqualify an individual from the PAP;

(4) Providing medical assessment information to the designated psychologist to assist in determining psychological fitness;

(5) Determining the location and date of the next required medical assessment, thereby establishing the period of certification; and

(6) Signing a recommendation for certification or recertification of an individual.

(d) The designated physician shall immediately report to the SOMD any of the following about himself or herself:

(1) Initiation of an adverse action by any state medical licensing board or any other professional licensing board;

(2) Initiation of an adverse action by any Federal regulatory board since the last designation;

(3) The withdrawal of the privilege to practice by any institution;

(4) Being named a defendant in any criminal proceedings (felony or misdemeanor) since the last designation;

(5) Being evaluated or treated for alcohol use disorder or drug dependency or abuse since the last designation; or

(6) Occurrence of a physical or mental health condition since the last designation that might affect his or her ability to perform professional duties.

§ 711.31 Designated psychologist.

(a) The designated psychologist shall report to the SOMD and shall determine the psychological fitness of an individual to participate in the PAP. The results of this evaluation shall be provided only to the designated physician or the SOMD.

(b) The designated psychologist shall:

(1) Hold a doctoral degree from a clinical psychology program that included a 1-year clinical internship approved by the American Psychological Association or an equivalent program;

(2) Have accumulated a minimum of 3 years postdoctoral clinical experience with a major emphasis in psychological assessment;

(3) Have a valid, unrestricted state license to practice clinical psychology in the state where PAP medical assessments occur;

(4) Have met the applicable PAP training requirements; and

(5) Be eligible for DOE access authorization to the worksite.

(c) The designated psychologist shall be responsible for the performance of all psychological evaluations of PAP individuals, and otherwise as directed by the SOMD. In addition, the designated psychologist shall:

(1) Designate which components of the psychological evaluation may be performed by other qualified personnel;

(2) Upon request of management, assess the psychological fitness of personnel for PAP duties in specific work settings and recommend referrals as indicated;

(3) Conduct and coordinate educational and training seminars, workshops, and meetings to enhance PAP individual and supervisor awareness of mental health issues;

(4) Establish regular personal workplace contact with supervisors and workers to help them identify psychologically distressed PAP individuals;

(5) Make referrals for psychiatric, psychological, substance abuse, personal or family problems, and monitor the progress of individuals so referred; and

(6) Participate as a member of the hostage negotiations team as required by the emergency management center.

(d) The designated psychologist shall immediately report to the SOMD any of the following about himself or herself:

(1) Initiation of an adverse action by any state medical licensing board or any other professional licensing board;

(2) Initiation of an adverse action by any Federal regulatory board since the last designation;

(3) The withdrawal of the privilege to practice by any institution;

(4) Being named a defendant in any criminal proceeding (felony or misdemeanor) since the last designation;

(5) Being evaluated or treated for alcohol or drug dependency or abuse since the last designation; or

(6) Occurrence of a physical or mental health condition that might affect his or her ability to perform professional duties since the last designation.

§ 711.32 Site Occupational Medical Director (SOMD).

(a) The SOMD shall nominate a physician to serve as the designated physician and a clinical psychologist to serve as the designated psychologist. The nominations shall be sent through the appropriate operations office to the Director, Office of Occupational Medicine and Medical Surveillance. Each nomination shall describe the nominee's relevant training, experience, and licensure, and shall include a curriculum vitae and a copy of the nominee's current state or district license.

(b) The SOMD shall submit a redesignation report biennially through the operations office to the Director, Office of Occupational Medicine and Medical Surveillance. This report shall be submitted at least 60 days before the second anniversary of the initial designation or of the last redesignation, whichever applies. The report shall include:

(1) A statement evaluating the performance of the designated physician and designated psychologist during the previous designation period;

(2) A summary of all PAP-relevant training, including postgraduate education, that the designated physician and designated psychologist has completed since the last designation; and

(3) A copy of the valid, unrestricted license of the designated physician and designated psychologist.

(c) The SOMD shall submit, annually, to the Director, Office of Occupational Medicine and Medical Surveillance, through the operations office manager, a written report summarizing PAP medical activity during the previous year. The SOMD shall comply with any DOE directives specifying the form or contents of the annual report.

(d) The SOMD shall investigate any reports of problems regarding a designated physician or designated psychologist, and the SOMD may suspend either official from PAP-related duties. If the SOMD suspends either official, the SOMD shall notify the Director, Office of Occupational Medicine and Medical Surveillance, and provide supporting documentation and reasons for the action.

§ 711.33 Director, Office of Occupational Medicine and Medical Surveillance.

The Director, Office of Occupational Medicine and Medical Surveillance, shall:

(a) Develop policies, standards, and guidance related to the medical aspects of the PAP, including the psychological testing inventory to be used;

(b) Review the qualifications of designated physicians and designated psychologists, and concur or nonconcur in their designations by sending a statement to the responsible program office and the operations office, with an informational copy to the SOMD;

(c) Provide technical assistance on medical aspects of the PAP to all elements of DOE and DOE contractors; and

(d) Concur or nonconcur with the medical bases of decisions rendered on appeals of PAP certification decisions.

§ 711.34 Operations office managers.

Operations office managers shall approve, upon the nomination of the SOMD and concurrence of the Director, Office of Occupational Medicine and Medical Surveillance, physicians and psychologists to serve as designated physicians and designated psychologists.

Medical Assessment Process and Standards

§ 711.40 Medical standards for certification.

To be certified in the PAP, an individual shall be free of any mental, emotional, or physical condition or behavior likely to result in impaired ability to perform assigned duties in a safe and reliable manner. The designated physician, with the assistance of the designated psychologist, shall determine whether any of the following disqualify an individual from performing nuclear explosive duties:

(a) Physical or medical disabilities such as visual acuity, defective color vision, impaired hearing, musculoskeletal deformities, and neuromuscular impairment;

(b) Mental disorders or behavioral problems as defined in the Diagnostic and Statistical Manual of Mental Disorders;

(c) Past or present use of illegal drugs or the abuse of legal drugs or other substances, as identified by self-reporting, or by medical or psychological evaluation or testing;

(d) Alcohol use disorder;

(e) Past or present threat of suicide, homicide, or physical harm; or

(f) Cardiovascular disease, endocrine disease, cerebrovascular or other neurologic disease, or the use of drugs for the treatment of such conditions that may adversely affect the judgment or ability of an individual to perform assigned duties in a safe and reliable manner.

§ 711.41 Medical assessment process.

(a) The designated physician, under the supervision of the SOMD, shall be responsible for the medical assessment of PAP individuals. In carrying out this responsibility, the designated physician shall integrate the medical evaluations, drug testing results, psychological evaluations, any psychiatric evaluations, and any other relevant information to determine an individual's overall medical qualification for assigned duties.

(b) Employers shall provide a job task analysis for each PAP individual to both the designated physician and the designated psychologist before each medical assessment and psychological evaluation. PAP medical assessments and psychological evaluations shall not be performed if a job task analysis has not been provided.

(c) The designated physician shall consider a PAP individual's fitness for duty at the time of each medical contact, including:

(1) Medical assessments for initial certification, annual recertification, and special evaluations for recertification following temporary removal from the PAP;

(2) Intermediate evaluations, including job transfer evaluations, evaluations upon self-referral, and referral by management;

(3) Routine medical contacts, including routine return-to-work evaluations and occupational and nonoccupational health counseling sessions; and

(4) A review of current, legal drug use.

(d) *Psychological evaluation.* (1) For the initial certification, the psychological evaluation consists of a generally accepted, self-reporting psychological inventory tool approved by the Director, Office of Occupational Medicine and Medical Surveillance, and a semistructured interview.

(2) For recertification, the psychological evaluation consists of a semistructured interview.

(3) Every third year, the medical assessment for recertification shall include a generally accepted self-reporting psychological inventory tool approved by the Director, Office of Occupational Medicine and Medical Surveillance.

(4) Additional psychological evaluations may be required by the SOMD when needed to resolve PAP concerns.

(e) Following absences requiring return-to-work evaluations under applicable DOE directives, the designated physician, with assistance from the designated psychologist, shall determine whether a psychological evaluation is necessary.

(f)(1) Except as provided in paragraph (f)(2) of this section, the designated physician shall forward the completed medical assessment of a PAP individual to the SOMD, who shall send a recommendation based on the assessment simultaneously to the individual's PAP administrative organization and to the PAP certifying official.

(2) If the designated physician determines that a currently certified individual no longer meets the PAP standards, the designated physician shall immediately inform the PAP certifying official and the PAP individual's administrative organization, following up in writing as appropriate.

(g) Only the designated physician, subject to informing the SOMD, shall make a medical recommendation for return to work and work accommodations for PAP individuals.

(h) The following documentation is required for routine use in the PAP program after treatment of a PAP individual for any disqualifying condition:

(1) A summary of the diagnosis, treatment, current status, and prognosis to be furnished to the designated physician;

(2) The medical opinion of the designated physician advising the individual's supervisor on whether the individual is able to return to work in either a PAP or non-PAP capacity; and

(3) Any periodic monitoring plan approved by the designated physician, the designated psychologist, and the SOMD, that is used to evaluate the reliability of the employee.

§ 711.42 Medical assessment for drug abuse.

(a) Except as otherwise provided by this section, a medical assessment for illegal drug use by DOE employees shall be conducted under DOE Order 3792.3, ''Drug-Free Federal Workplace Testing Implementation Program.'' Copies of DOE Orders are available for inspection in the DOE Freedom of Informaiton Reading Room, Washington, DC.

(b) Except as otherwise provided by this section, a medical assessment for illegal drug use by contractor employees shall be conducted under 10 CFR part 707, ''Workplace Substance Abuse Programs at DOE Sites.''

(c) In each case of drug abuse, the SOMD, in consultation with the designated psychologist, shall evaluate the individual for evidence of psychological impairment and make a recommendation to the PAP certifying official as to the individual's reliability.

(d) After successfully completing an SOMD-approved drug rehabilitation program, and subject to SOMD-directed unannounced tests for illegal drugs and relevant counseling for 3 years, DOE may reinstate an individual in the PAP based on the SOMD's follow-up evaluation and recommendation.

§ 711.43 Evaluation of hallucinogen use.

If DOE determines that a PAP individual has used any hallucinogen, the individual shall not be eligible for certification or recertification unless:

(a) Five years have passed since the last use of the hallucinogen;

(b) A medical evaluation is performed to determine that the individual is reliable; and

(c) The individual has a record of acceptable job performance and observed behavior.

§ 711.44 Medical assessment for alcohol use disorder.

(a) If alcohol abuse is suspected, an individual shall be examined for evidence of alcohol use disorder. If the examination produces evidence of alcohol use disorder, additional evaluation shall be conducted, which may include psychological evaluation.

(b) Alcohol consumption is prohibited within an 8-hour period preceding and during the performance of nuclear explosive duties. DOE shall implement or require the contractor to implement procedures that will ensure that persons called in to perform unscheduled work are fit to perform the tasks assigned.

(c) Individuals in the PAP shall be tested at the work site if there is an

indication of alcohol use in violation of the requirements of paragraph (b) of this section.

(d) Tests for alcohol must be administered by a certified Breath Alcohol Technician using an evidential-grade breath analysis device that conforms to the Department of Transportation's (DOT) National Highway Traffic Safety Administration (NHTSA) model specifications, and the most recent ''Conforming Products List'' issued by NHTSA which are available from the Office of Traffic Safety Programs, Washington, DC.

(e) An individual whose confirmatory breath alcohol test result is at or above a blood alcohol concentration of 0.02 percent shall not be allowed to perform nuclear explosive duties for a minimum of 24 hours.

(f) Individuals refusing to submit to a breath alcohol test shall be immediately removed from nuclear explosive duties.

(g) The SOMD, in conjunction with the designated psychologist, shall evaluate each case of alcohol use disorder for evidence of psychological impairment and provide the PAP certifying official a recommendation as to the individual's reliability.

(h) After successfully completing an SOMD-approved alcohol treatment program, DOE may reinstate an individual in the PAP based on the SOMD's follow-up evaluation and recommendation.

§ 711.45 Maintenance of medical records.

(a) Medical records produced or used in the PAP certification process shall be maintained according to established professional standards.

(b) The medical records of PAP individuals shall be maintained in accordance with the Privacy Act, 5 U.S.C.§ 552a, and DOE implementing regulations in 10 CFR part 1008; the Department of Labor's regulations on access to employee exposure and medical records, 29 CFR 1910.20; and applicable DOE orders and directives.

(c) The psychological record of a PAP individual shall be considered a component of the medical record. The psychological record shall —

(1) Contain any clinical reports, test protocols and data, notes of employee contacts and correspondence, and other information pertaining to an individual's contact with a psychologist;

(2) Be stored in a secure location in the custody of the designated psychologist;

(3) Be kept separate from other medical record documents, with access limited to the SOMD, the designated physician, the designated psychologist, or other persons who are authorized by law or regulation to have access; and

(4) Be retained indefinitely.

(d) The records of alcohol and drug testing shall be maintained in accordance with 42 CFR part 2, ''Confidentiality of Alcohol and Drug Abuse Patient Records,'' and 10 CFR part 707, ''Workplace Substance Abuse Programs at DOE Sites.''

[FR Doc. 97–14416 Filed 6–3–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 835

Occupational Radiation Protection; Availability of Draft Guides and Technical Standards

AGENCY: Department of Energy.

ACTION: Extension of notice of availability for draft guides.

SUMMARY: The Department of Energy (DOE) published a notice of availability (62 FR 19940) on April 24, 1997, announcing that drafts of guidance documents that may be used to implement proposed occupational radiation protection regulations were available for public comment. That notice provided the public with the opportunity to submit written comments on these documents on or before May 28, 1997. This notice extends the written comment period for the 13 implementation guides to June 30, 1997.

DATES: Written comments for the 13 draft implementation guides must be submitted by June 30, 1997.

ADDRESSES: A copy of each draft implementation guide is available at the DOE Freedom of Information Reading Room, 1E–190, 1000 Independence Avenue, SW, Washington D.C. 20585, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Submit written comments to Dr. Joel Rabovsky, U.S. Department of Energy, EH–52/GTN/270CC, 19901 Germantown Road, Germantown, Maryland 20874–1290.

FOR FURTHER INFORMATION CONTACT: Dr. Joel Rabovsky, U.S. Department of Energy, EH–52/GTN/270CC, 19901 Germantown Road, Germantown, Maryland 20874–1290, 301–903–2135.

Issued in Washington, DC, on May 27, 1997.

Peter N. Brush,

Principal Deputy Assistant Secretary, Environment, Safety and Health.

[FR Doc. 97–14550 Filed 6–3–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–271–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–600–2B19 (Regional Jet Series 100) Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Bombardier Model CL–600–2B19 (Regional Jet Series 100) airplanes. This proposal would require a one-time inspection of the direct current (DC) power distribution system for reliability, and correction or repair, of any fuse holders and associated electrical wiring, if necessary. This proposal is prompted by a report indicating that a loose fuse holder caused the DC power distribution system to short circuit on one of the affected airplanes, which resulted in a burnt wire between circuit breaker panel CBP–2 and junction box JB7. The actions specified by the proposed AD are intended to prevent such short circuiting, which could result in a burnt wire, smoke entering the cockpit area, and consequent passenger injury due to smoke inhalation.

DATES: Comments must be received by July 14, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–271–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Bombardier, Inc., Canadair Aerospace Group, P.O. Box 6087, Station Centre-ville, Quebec H3C 3G9, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York.

FOR FURTHER INFORMATION CONTACT: Balram Rambrich, Aerospace Engineer,

Systems and Equipment Branch, ANE–172, FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7507; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–271–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–271–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

Transport Canada Aviation, which is the airworthiness authority for Canada, notified the FAA that an unsafe condition may exist on certain Bombardier Model CL–600–2B19 (Regional Jet Series 100) airplanes. Transport Canada Aviation advises that a loose fuse holder caused the direct current (DC) power distribution system on one of the affected airplanes to short circuit. This resulted in a burnt wire between circuit breaker panel CBP–2 and junction box JB7. The actions specified by the proposed AD are intended to prevent such short circuiting, which could result in a burnt wire and smoke entering the cockpit area, and consequent passenger injury due to smoke inhalation.

Explanation of Relevant Service Information

Bombardier has issued Canadair Regional Jet Alert Service Bulletin S.B. A601R–24–056, Revision 'A', dated July 9, 1996, which describes procedures for a one-time inspection of the fuse holders of the DC power distribution system for reliability (proper connection, proper wiring, and to assure there are no damaged wires), and rewiring, correcting, or repairing fuse holders and associated electrical wiring, if necessary. Transport Canada Aviation classified this service bulletin as mandatory and issued Canadian airworthiness directive CF–96–18, dated September 30, 1996, in order to assure the continued airworthiness of these airplanes in Canada.

FAA's Conclusions

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, Transport Canada Aviation has kept the FAA informed of the situation described above. The FAA has examined the findings of Transport Canada Aviation, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require a one-time inspection of the DC power distribution system for reliability, and correction or repair of any fuse holders and associated electrical wiring, if necessary. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Cost Impact

The FAA estimates that 41 Bombardier Model CL–600–2B19 (Regional Jet Series 100) airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 14 work hours per airplane to accomplish the proposed inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $34,440, or $840 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Bombardier, Inc. (Formerly Canadair): Docket 96–NM–271–AD.

Applicability: Model CL–600–2B19 (Regional Jet Series 100) airplanes, serial numbers 7003 through 7105 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the direct current (DC) power distribution system from short circuiting, which could result in a burnt wire, smoke entering the cockpit area, and consequent passenger injury due to smoke inhalation, accomplish the following:

(a) Within 600 hours time-in-service after the effective date of this AD, perform a one-time inspection of the DC power distribution system for reliability in accordance with Canadair Regional Jet Service Bulletin S.B. A601R–24–056, Revision 'A', dated July 9, 1996. Prior to further flight, correct or repair any discrepant fuse holders and associated electrical wiring, in accordance with the service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 28, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–14484 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–CE–68–AD]

RIN 2120–AA64

Airworthiness Directives; Fairchild Aircraft Incorporated Models SA226–AT, SA226–TC, SA227–AC, and SA227–AT Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Fairchild Aircraft Incorporated (Fairchild) Models SA226–AT, SA226–TC, SA227–AC, and SA227–AT airplanes. The proposed action would require inspecting the cargo door lower belt frames at the cargo latch receptacles for cracks in the belt frames, repairing the cracks, and reinforcing the cargo door lower belt frames by installing doublers. A decompression incident during flight caused by fatigue at the bottom of the cargo door on a Fairchild Model SA226–TC prompted the proposed action. The actions specified by the proposed AD are intended to prevent the failure of the cargo door in flight which could cause decompression injuries to passengers and substantial structural damage to the airplane.

DATES: Comments must be received on or before August 7, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–68–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Fairchild Aircraft, P. O. Box 790490, San Antonio, Texas 78279–0490, telephone (210) 824–9421. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Hung Viet Nguyen, Aerospace Engineer, FAA, Fort Worth Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150; telephone (817) 222–5155; facsimile (817) 222–5960.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 96–CE–68–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–68–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

In 1995, the FAA received a report on a Fairchild Model SA226–TC airplane that had a cargo door failure during flight. Upon investigation, the examiners discovered cracking in the cargo door lower belt frames. As a result of the incident, the FAA issued AD 95–18–05 to require replacing the cargo door receptacles to prevent failure of the cargo door. The FAA has since determined that further AD action is necessary to address this condition. This proposed AD does not cancel the actions required in AD 95–18–05.

Relevant Service Information

Fairchild has issued Service Bulletin 227–53–003, Issued: January 29, 1986; Revised: February 13, 1986, and Service

Bulletin 226–53–007, Issued: May 7, 1981; Revised: February 17, 1992 which specifies inspecting the cargo door belt frames for cracks and installing reinforcing doublers.

Differences Between Manufacturer's Service Information and the Proposed Action

Fairchild has suggested different compliance times for repair of the cracks based on total flight hours of each individual airplane. The FAA has determined that there should be one compliance time for all owners/operators of the affected airplanes. These service bulletins also specify reinforcing the area if cracks found are less than one inch, and if the cracks are larger than one inch, contact the manufacturer.

As currently written, the Fairchild service bulletin allows continued flight if cracks are found in the cargo door lower belt frames that do not exceed certain limits. The FAA has established a policy to disallow airplane operation when known cracks exist in primary structure, unless the ability to sustain ultimate load with these cracks is proven. The cargo door and the lower belt frame are considered primary structure, and the FAA has not received any analysis to prove that ultimate load can be sustained with cracks in this area. For this reason, the FAA has determined that the crack limits contained in the service bulletin fall under the policy, and that AD action should be taken to require immediate replacement of any cracked cargo door lower belt frames.

The FAA's Determination

After examining the circumstances and reviewing all available information related to the incident described above, the FAA has determined that AD action should be taken to prevent the failure of the cargo door in flight which could cause decompression injuries to passengers and substantial structural damage to the airplane.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Fairchild Aircraft Models SA226-AT, SA226-TC, SA227-AC, and SA227-AT airplanes of the same type design, the proposed AD would require inspecting the lower belt frames at the cargo latch receptacles for cracks. If cracks are found, the proposed AD would require repairing the cracks, prior to further flight, using a repair scheme provided by the manufacturer through the Airplane Certification Office. If no cracks are found, the proposed action would require reinforcing the cargo door lower belt frames by installing doublers.

Cost Impact

The FAA estimates that 145 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 30 workhours per airplane to accomplish the proposed initial inspection and installation of the reinforcing doubler, and that the average labor rate is approximately $60 an hour. Parts for the installation of the reinforcing doubler cost approximately $710 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $363,950 or $2,510 per airplane. The FAA has no way to determine the number of affected airplanes that have already accomplished the proposed action.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

Fairchild Aircraft Incorporated: Docket No. 96-CE–68-AD. Applicability: The following Models and serial numbered airplanes, certificated in any category.

Models	Serial Nos.
SA226–AT	AT001 through AT074.
SA226–TC ...	TC201 through TC419.
SA227–AC ...	AC406, AC415, AC416, AC420 through AC478, except AC457 and AC470.
SA227–AT	AT423 through AT469.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated within the body of this AD, unless already accomplished.

To prevent failure of the cargo door in flight which could cause decompression injuries to passengers and substantial structural damage to the airplane, accomplish the following:

(a) Within the next 500 hours time-in-service (TIS) after the effective date of this AD, inspect the cargo door lower belt frames at the cargo latch receptacles for cracks in accordance with part A of the Accomplishment Instructions section in the Fairchild Aircraft (Fairchild) Service Bulletin (SB) No. 226–53–007, Issued: May 7, 1981; Revised: February 17, 1992 or Fairchild SB No. 227–53–003, Issued: January 29, 1986; Revised: February 13, 1986, whichever is applicable.

(b) If cracks are found, prior to further flight, contact the FAA Fort Worth Airplane Certification Office for a reinforcement and repair scheme provided by Fairchild Aircraft Incorporated and incorporate this reinforcement and repair scheme.

(c) If no cracks are found, within the next 500 hours after the initial inspection required in paragraph (a) of this AD, reinforce the cargo door lower belt frames by installing doublers in accordance with part B of the Accomplishment Instructions in Fairchild SB

226–53–007, Issued: May 7, 1981; Revised: February 17, 1992 or Fairchild SB 227–53–003, Issued: January 29, 1986; Revised: February 13, 1986, whichever is applicable.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, FAA, Fort Worth Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Fort Worth Airplane Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Fort Worth Airplane Certification Office.

(f) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Fairchild Aircraft, P. O. Box 790490, San Antonio, Texas 78279–0490; or may examine these documents at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on May 29, 1997.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–14544 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–13–U

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

Release No. 34–38672; International Series Release No. IS–1085; File No. S7–16–97 Regulation of Exchanges

AGENCY: Securities and Exchange Commission.

ACTION: Concept release; request for comments.

SUMMARY: The Securities and Exchange Commission (''SEC'' or ''Commission'') is reevaluating its approach to the regulation of exchanges and other markets in light of technological advances and the corresponding growth of alternative trading systems and cross-border trading opportunities. Accordingly, the Commission is soliciting comment on a broad range of questions concerning the oversight of alternative trading systems, national securities exchanges, foreign market activities in the United States, and other related issues. Following receipt of public comment, the Commission will determine whether rulemaking is appropriate.

DATES: Comments must be received on or before September 2, 1997.

ADDRESSES: Interested persons should submit three copies of their written data, views, and opinions to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549. Comments may also be submitted electronically at the following e-mail address: rule-comments@sec.gov. All comment letters should refer to File No. S7–16–97; this file number should be included on the subject line if comments are submitted using e-mail. All submissions will be available for public inspection and copying at the Commission's Public Reference Room, Room 1024, 450 Fifth Street, NW, Washington DC 20549. Electronically submitted comment letters will be posted on the Commission's Internet web site (http://www.sec.gov).

FOR FURTHER INFORMATION CONTACT: For questions or comments regarding this release, contact: Kristen N. Geyer, Special Counsel, at (202) 942–0799; Gautam S. Gujral, Special Counsel, at (202) 942–0175; Marie D'Aguanno Ito, Special Counsel, at (202) 942–4147; Paula R. Jenson, Deputy Chief Counsel, at (202) 942–0073; or Elizabeth K. King, Special Counsel, at (202) 942–0140, Division of Market Regulation, Securities and Exchange Commission, Mail Stop 5–1, 450 Fifth Street, NW, Washington, DC 20549. For questions or comments regarding corporate disclosure and securities registration issues raised in this release, contact David Sirignano, Associate Director, at (202) 942–2870, Division of Corporation Finance, Securities and Exchange Commission, Mail Stop 3–1, 450 Fifth Street, NW, Washington, DC 20549.

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I. Executive Summary

A. Purpose of Concept Release

Stock markets play a critical role in the economic life of the United States. The phenomenal growth of the U.S. markets over the past 60 years is a direct result of investor confidence in those markets. Technological trends over the past two decades have also contributed greatly to this success. In particular, technology has provided a vastly greater number of investment and execution choices, increased market efficiency, and reduced trading costs. These developments have enhanced the ability of U.S. exchanges to implement efficient market linkages and advanced the goals of the national market system (''NMS'').

At the same time, however, technological changes have posed significant challenges for the existing regulatory framework, which is ill-equipped to respond to innovations in U.S. and cross-border trading. Specifically, two key developments highlight the need for a more forward-looking, flexible regulatory framework: (1) The exponential growth of trading systems that present comparable alternatives to traditional exchange trading; and (2) the development of automated mechanisms that facilitate access to foreign markets from the United States.

The Commission estimates that alternative trading systems [1] currently handle almost 20 percent of the orders [2] in over-the-counter (''OTC'') stocks and almost 4 percent of orders in securities listed on the New York Stock Exchange (''NYSE''). The explosive growth of alternative trading systems over the past several years has significant implications for public secondary market regulation. Even though many of these systems provide essentially the same services as traditional markets, most alternative trading systems are regulated as broker-dealers. As a result, they have been subject to regulations designed primarily to address traditional brokerage, rather than market activities. For example, these systems are typically subject to oversight by self-regulatory organizations (''SROs'') that themselves operate exchanges or quotation systems, which raises inherent competitive concerns.

At the same time, alternative trading systems are not fully integrated into the national market system. As a result, activity on alternative trading systems is not fully disclosed to, or accessible by, public investors. The trading activity on these systems may not be adequately surveilled for market manipulation and fraud. Moreover, these trading systems have no obligation to provide investors a fair opportunity to participate in their systems or to treat their participants fairly, nor do they have an obligation to ensure that they have sufficient capacity to handle trading demand. These concerns together with the increasingly important role of alternative trading systems, call into question the fairness of current regulatory requirements, the effectiveness of existing NMS mechanisms, and the quality of public secondary markets.

The impact of technological change has not been limited to domestic markets. Foreign markets, information vendors, and broker-dealers have developed automated systems that enable U.S. persons to trade directly on foreign markets from the United States. The Commission to date has not addressed the regulatory status of entities that limit their activities to providing U.S. investors access to foreign markets. As a result, many foreign markets have been reluctant to provide these services directly to U.S. investors. This has highlighted the need to establish standards that can accommodate U.S. investors' growing interest in cross-border trading, and better ensure that this type of cross-border trading is subject to appropriate safeguards. At the same time, improved foreign market access would mean that U.S. investors can trade securities of companies listed solely on foreign markets as easily as securities of companies that satisfy the Commission's disclosure and reporting requirements. This would raise additional questions as to how to craft a regulatory scheme that provides sufficient information to investors about the securities they trade.

These and other questions raised by the application of the existing regulatory approach to technologically changing markets are only likely to multiply as technology facilitates ways of trading and enables the creation of market structures that were unimaginable a few years ago. In light of these issues, the Commission is now reevaluating its regulation of the markets, particularly its oversight of alternative trading systems, registered exchanges, and foreign market activities in the United States. In doing so, the Commission seeks to develop a forward-looking and enduring approach that will permit diverse markets to evolve and compete, while preserving market-wide transparency, fairness, and integrity. The issues raised by technology in the domestic markets are summarized in Part B below and discussed in greater detail in Sections II through VI. The issues raised by technology in the foreign markets are summarized in Part

[1] Trading systems not registered as exchanges have been referred to in previous Commission releases as ''proprietary trading systems,'' ''broker-dealer trading systems,'' and ''electronic communications networks.'' The latter two terms are defined in Rules 17a–23 and 11Ac1–1 under the Securities Exchange Act of 1934 (''Exchange Act''), 17 CFR 240.17a–23 and 240.11Ac1–1, respectively. The term ''alternative trading systems'' will be used throughout this release to refer generally to automated systems that centralize, display, match, cross, or otherwise execute trading interest, but that are not currently registered with the Commission as national securities exchanges or operated by a registered securities association.

[2] For purposes of this release, the term ''order'' generally means any firm trading interest, including both limit orders and market maker quotations.

C below and discussed in greater detail in Section VII of this release.

B. Alternatives for Revising Domestic Market Regulation

The questions raised by technological developments in the U.S. markets could be addressed in a variety of ways. As an initial matter, the Commission is soliciting comment on whether the current statutory and regulatory framework remains appropriate in light of the myriad new means of trading securities made possible by emerging and evolving technologies. The Commission is also soliciting comment on alternative ways of addressing these issues within the existing securities law framework. The release discusses two alternatives in particular that would integrate alternative trading systems more fully into mechanisms that promote market-wide transparency, investor protection, and fairness.

First, the Commission could continue to regulate alternative trading systems as broker-dealers and develop rules applicable to these systems, and their supervising SROs that would more actively integrate these systems into NMS mechanisms. The Commission could, for example, require alternative trading systems to provide additional audit trail information to SROs, to assist SROs in their surveillance functions, and to adopt standard procedures for ensuring adequate system capacity and the integrity of their system operations. The Commission could then require SROs to integrate trading on alternative trading systems into their ongoing, real-time surveillance for market manipulation and fraud, and to develop surveillance and examination procedures specifically targeted to alternative trading systems they supervise. In addition, the Commission could require alternative trading systems to make all orders in their systems available to their supervising SROs, and require such SROs to incorporate those orders into the public quotation system. The Commission could also require that alternative trading systems provide the public with access to these orders on a substantially equivalent basis as provided to system participants.

Alternatively, the Commission could integrate alternative trading systems into the national market system as securities exchanges, by adopting a tiered approach to exchange regulation. The first tier, under this type of approach, could consist of the majority of alternative trading systems, those that have limited volume or do not establish trading prices, which could be exempt from traditional exchange requirements. For example, exempt exchanges could be required to file an application and system description with the Commission, report trades, maintain an audit trail, develop systems capacity and other operational standards, and cooperate with SROs that inspect their regulated participants. Most alternative trading systems currently regulated as broker-dealers would be exempt exchanges.

The second tier of exchanges under this approach could consist of alternative trading systems that resemble traditional exchanges because of their significant volume of trading and active price discovery. These systems could be regulated as national securities exchanges. The Commission could then use its exemptive authority to eliminate barriers that would make it difficult for these non-traditional markets to register as exchanges, by exempting such systems from any exchange registration requirements that are not appropriate or necessary in light of their business structure or other characteristics. For example, the Commission could exempt alternative trading systems that register as exchanges from requirements that exchanges have a traditional membership structure, and from requirements that limit exchange participation to registered broker-dealers. The Commission could also use its exemptive authority to reduce or eliminate those exchange requirements that are incompatible with the operation of for-profit, non-membership alternative trading systems.

This approach could integrate these alternative trading systems more fully into NMS mechanisms and the plans governing those systems, potentially by requiring these systems to become members of those plans.[3] Because alternative trading systems differ in several key respects from currently registered exchanges, this could require revision of those plans in order to accommodate diverse and evolving trading systems.

Finally, a third tier of exchanges, consisting of traditional membership exchanges, could continue to be regulated as national securities exchanges. The Commission could then use its exemptive authority to reduce overall exchange requirements. In this regard, the Commission is considering ways to reduce unnecessary regulatory requirements that make it difficult for currently registered exchanges to remain competitive in a changing business environment. The Commission, for example, could further accelerate rule filing and approval procedures for national securities exchanges and securities associations, and allow fully automated exchanges to meet their regulatory requirements in non-traditional ways.

One way for the Commission to implement this tiered approach would be to expand its interpretation of the definition of ''exchange.'' For example, the Commission could reinterpret the term ''exchange'' to include any organization that both: (1) Consolidates orders of multiple parties; and (2) provides a facility through which, or sets material conditions under which, participants entering such orders may agree to the terms of a trade.

C. Alternatives for Revising Regulation Applicable to Foreign Market Activities in the United States

The questions raised by the activities of foreign markets in the United States could also be addressed in a number of ways. As an initial matter, any proposal should address questions about the lack of comparable information about securities of non-reporting foreign companies. In addition, any approach to regulating access to foreign markets from the U.S. should address the issue of whether sufficient information is disclosed to U.S. investors regarding the risks of trading on foreign markets and whether the Commission has the ability to enforce the antifraud provisions of the U.S. securities laws.

This release describes a number of different ideas for addressing foreign market activity in the United States, including applying traditional exchange regulation to foreign markets that seek to enter the United States. At the other extreme, the Commission could rely solely on home country regulation of the foreign market. Alternatively, the Commission could take an intermediate approach by establishing regulatory requirements for entities that provide U.S. persons with direct access to foreign markets (''access providers''), regardless of whether the entity is the foreign market itself, a broker-dealer, or another service provider. Such access providers could be required to comply with limited recordkeeping, reporting, and disclosure requirements, as well as the antifraud provisions of the federal securities laws.

Under this type of approach, an access provider that provides a U.S. member of a foreign market with direct access to that foreign market's trading facilities would register as a securities information processor (''SIP'') under section 11A of the Exchange Act. Foreign markets, information vendors,

[3] *See infra* notes 162 to 175 and accompanying text.

and other access providers could be required to register as SIPs, or to conduct their U.S. activities through another registered SIP. As a condition of registration, SIPs could also be limited to trading foreign securities that are registered with the Commission under the Exchange Act or limited to dealing with sophisticated parties.

Broker-dealers that act as access providers could be required to comply with the same, limited recordkeeping, reporting, disclosure, and antifraud requirements as SIPs. The Commission could also permit broker-dealer access providers to provide both retail and sophisticated investors with electronic links to foreign markets, and to provide such links to foreign markets that trade U.S. and foreign securities, regardless of whether those securities are registered with the Commission. This approach might provide adequate protections to U.S. investors trading on foreign markets, while facilitating greater transparency.

In creating an appropriate regulatory scheme to address U.S. investor access to unregistered foreign securities, the Commission seeks to balance the desire to craft a forward-looking and enduring approach to the oversight of the securities markets with concerns that U.S. investors have access to full and complete disclosure about the securities they trade. The Commission has been working directly with fellow regulators around the world on a variety of initiatives to improve the efficiency of cross-border capital flows.

D. Conclusion

Regulation should not be static. Changes in the markets should be accompanied by corresponding changes in market regulation. In light of the rapid pace of technological advancements during the past two decades, it is critical to develop a regulatory framework that both accommodates traditional market structures and provides sufficient flexibility to ensure that markets of the future promote fairness, efficiency, and transparency. The purpose of this release is to facilitate a dialogue as to how this can best be achieved.

II. Regulation of Domestic Markets

A. Technological Advances

Securities markets serve several basic functions that are critical to facilitating investment and, as a result, materially influence the long-term financial security of a large segment of the population.[4] For example, markets provide the forum for individuals to invest in securities and for financial instruments to be readily converted into cash when needed. Securities markets also serve as a fundamental indicator of national and international economic health, in part because they reveal investors' judgments about the potential earning capacity of corporations.[5] They help to raise and efficiently allocate capital by providing a reliable means of valuing assets and facilitating the flow of capital into private enterprise. They also allocate capital toward productive uses by providing a forum where stocks can compete for investment dollars.[6] U.S. securities markets have been highly successful at fulfilling these functions and are consistently the world's largest, most liquid, efficient, and fair.[7] Moreover, U.S. markets have continued to attract foreign listings and investors even as other markets become more competitive.[8] This success has come about, in part, because the strength and stability of U.S. markets have allowed people throughout the world to feel confident investing a large percentage of their personal wealth in the future of companies trading on those markets.

The ability of U.S. markets to use technology to increase efficiency, reduce the costs of trading, and respond to changing investor demands has also contributed significantly to the success of our markets. Over the past three decades, technology has transformed U.S. markets. Investors, particularly the growing institutional investor base, now have numerous alternatives to traditional exchange trading and the OTC market. Similarly, market participants (including broker-dealers, issuers, and service providers) have integrated technological advancements into their trading and marketing activities.[9] For example, some broker-dealers have made communications with retail customers more efficient by offering various services through the Internet.[10]

As technology has broadened the services that can be delivered by both markets and market intermediaries, market services have become unbundled from traditional brokerage or exchange services. While some entities that perform brokerage services have also begun to perform some of the traditional functions of a stock exchange, other entities (including information vendors, service bureaus, and routing services) now provide many of the services historically provided by exchanges and broker-dealers. One significant example of this has been the development and growing popularity of alternative trading systems, such as the Real-Time Trading Service operated by Instinet Corporation (''Instinet''), The Island System (''Island''),[11] Portfolio System

[4] *See generally* SEC, Report of the Special Study of the Securities Markets of the Securities and Exchange Commission, H.R. Doc. No. 95, 88th Cong., 1st Sess. Pt. 1, at 9 (1963) (hereinafter Special Study).

[5] Essentially, securities markets centralize information about buying and selling interest, either by physically or electronically centralizing order interaction, or by centralizing quote and trading information. Because of this interaction of supply and demand, a stock price is considered by many to be the best estimate by investors of the present value of a company's future earnings. As a result of such beliefs, stock prices influence investment calculations, the allocation of resources, company business decisions, and economic planning. *See* 2 Thomas Lee Hazen, Treatise on the Law of Securities Regulation, § 10.1, at 4 (3d ed. 1995); U.S. Congress, Office of Technology Assessment, Pub. No. OTA–CIT–469, Electronic Bulls & Bears: U.S. Securities Markets & Information Technology at 3, 26 (1990) (hereinafter Electronic Bulls & Bears). *See generally* Jack Clark Francis, Investment Analysis and Management 57, 196–97 (4th ed. 1986).

[6] *See generally* ELECTRONIC BULLS & BEARS, *supra* note 5, at ch. 2; Francis, *supra* note 5, at 57.

[7] As of December 31, 1996, there were 3,530 securities trading on the NYSE, representing 2907 NYSE-listed companies. *Market Records Shattered in 1996, The Exchange (NYSE), Jan./Feb. 1997, at 1–2. In addition, as of December 31, 1996, the Nasdaq Stock Market (''Nasdaq'') listed over 6300 stocks of 5556 companies, and dollar volume on that market has grown to almost equal that of the NYSE. Conversation with staff of Corporate Communications, National Association of Securities Dealers, Inc. (''NASD'') (Feb. 21, 1997). In 1996, the average daily share volume on Nasdaq was 543,839,000 shares and the total dollar volume was $3,301.8 billion. During that same period, the NYSE's average daily share volume was 409,893,000 shares and its total dollar volume was $4,063.7 billion. See Market Records Shattered in 1996*, The Exchange (NYSE), Jan./Feb. 1997, at 1–2.

[8] Both the NYSE and Nasdaq have experienced significant growth in foreign company listings. Foreign company listings on the NYSE increased from 106 in 1991 to 290 as of the end of 1996. Similarly, foreign listings on Nasdaq increased from 185 in 1991 to 320 as of the end of 1996. Conversation with staff of NYSE (Feb. 21, 1997); Conversation with staff of Corporate Communications, NASD (Feb. 21, 1997); New York Stock Exchange, Inc., 1995 Annual Report 3 (1995); National Association of Securities Dealers, Inc., 1996 Nasdaq Fact Book 37 (1996).

[9] *See, e.g.*, Letter from Catherine McGuire, Chief Counsel, Division of Market Regulation, SEC, to Jere W. Glover, Chief Counsel for Advocacy, U.S. Small Business Administration, and Gregory J. Dean, Jr., Assistant Chief Counsel for Banking and Finance, U.S. Small Business Administration (Oct. 26, 1996); Letter from Catherine McGuire, Chief Counsel, Division of Market Regulation, SEC, to Bruce D. Stuart, Esq. (Aug. 5, 1996); and Letter from Catherine McGuire, Chief Counsel, Division of Market Regulation, SEC, to Barry Reder, Esq. (June 24, 1996).

[10] *See* Arthur M. Louis, *Schwab Plays Catchup: Broker Faces Tough Internet Competition*, S.F. Chron., Nov. 26, 1996, at C1. *See also* Letter from Richard R. Lindsey, Director, Division of Market Regulation, SEC, to Scott W. Campbell, Vice President and Associate General Counsel, Charles E. Schwab & Co. (Nov. 27, 1996).

[11] Island is operated by Datek Securities Corp., a registered broker-dealer. Island, Instinet, and other ''matching'' systems (such as Tradebook, which is operated by Bloomberg Tradebook LLC) allow participants to display firm, priced orders to other participants and to execute automatically against other orders in the system.

for Institutional Trading (''POSIT''),[12] and the Arizona Stock Exchange (''AZX''),[13] which allow institutions and other market participants to electronically execute trades in a variety of ways.[14] These and other alternative trading systems have grown to account for a significant percentage of the trading volume of the U.S. securities markets, particularly within the last five years. In 1994, the Commission's Division of Market Regulation reported that alternative trading systems accounted for 13 percent of the volume in Nasdaq securities and 1.4 percent of the trading volume in NYSE-listed securities.[15] In comparison, the Commission estimates that alternative trading systems currently handle almost 20 percent of the orders in Nasdaq securities and almost 4 percent of orders in NYSE-listed stocks.

Technology has also significantly altered the operation of exchange and OTC markets. For example, most exchanges have designed systems that allow members to route orders electronically to the exchange for execution.[16] The NYSE has also established after-hours crossing systems that automate the execution of single stock orders and baskets of securities,[17] and the Cincinnati Stock Exchange (''CSE'') is now a fully automated exchange where members effect transactions through computers located in their own offices.[18] Dealer markets have been similarly transformed. Dealer markets traditionally consisted of loosely organized groups of individual dealers that traded securities OTC, without formal consolidation of orders or trading. As individual dealers and associations of dealers have employed technology to make OTC markets more efficient, however, dealer markets in certain instruments have become organized to such an extent that they have assumed many of the characteristics of exchange markets. This is particularly true in markets that trade instruments that are also listed on registered exchanges. For example, the Nasdaq market, operated by the National Association of Securities Dealers, Inc. (''NASD''), consolidates trading interest of multiple dealers on a computer screen that is displayed in real-time to its members and provides a mechanism for dealers to update displayed quotations.[19] Additional services, such as SelectNet, allow dealers in the Nasdaq market to trade electronically. Through this technology, the NASD has been able to coordinate the dealer market more efficiently.

Overall, these developments have benefited investors by increasing efficiency and competition, reducing costs, and spurring further technological advancement of the entire market. In particular, for those market participants that have access to alternative trading systems, these systems have provided opportunities for the direct execution of orders without the active participation of an intermediary. Alternative markets are likely to grow as technology continues to drive the evolution of the equity markets.

B. Market Regulation

Whether trading electronically or through human intervention, investors are more likely to trade on a market when prices are current and reflect the value of securities, when they are confident that they will be able to buy and sell securities easily and inexpensively, and when they believe that they can trade on a market without being defrauded or without other investors having an unfair advantage. The competition for global investment capital among the world's exchanges and the many opportunities available to U.S. and foreign investors make it more important than ever for U.S. exchanges to protect these investor interests in order to attract order flow. Appropriate regulation is often necessary to protect these interests, by helping to ensure fair and orderly markets, to prevent fraud and manipulation, and to promote market coordination and competition for the benefit of all investors.[20]

In the United States, Congress decided that these goals should be achieved primarily through the regulation of exchanges and through authority it granted to the Commission in 1975 (''1975 Amendments'')[21] to adopt rules that promote (1) economically efficient execution of securities transactions, (2) fair competition, (3) transparency, (4) investor access to the best markets, and (5) the opportunity for investors' orders to be executed without the participation of a dealer.[22] In promulgating the Exchange Act, Congress gave the Commission means to achieve these and other goals of regulation,[23] by requiring

[12] POSIT is operated by ITG Inc., a registered broker-dealer. POSIT and other ''crossing'' systems allow participants to enter unpriced orders, which are then executed with matching interest at a single price, typically derived from the primary public market for each crossed security.

[13] AZX and other ''single-price auction'' systems allow participants to enter priced orders, which the system then compares to determine the single price at which the largest volume of orders can be executed. All orders are then matched and executed at that price.

[14] In addition to these systems, more than 140 broker-dealers have notified the Commission that they operate some type of alternative trading system, either internally for their own traders or for their customers and other market participants. Registered broker-dealers that operate or otherwise sponsor alternative trading systems are required to comply with periodic reporting and recordkeeping requirements pursuant to Rule 17a–23 under the Exchange Act. 17 CFR 240.17a–23. *See generally* Division of Market Regulation, Market 2000: An Examination of Current Equity Market Developments app. IV (1994) (hereinafter Market 2000 Study) (general description of proprietary trading systems).

[15] *See* Market 2000 Study, *supra* note 14, at Study II–13.

[16] The NYSE's SuperDOT (Designated Order Turnaround) system enables firms to transmit market and limit orders in all NYSE-listed securities directly to the specialist post for execution. Some NYSE members also allow selected institutional customers to route their orders through the members' connection to SuperDOT. Similar systems are operated by the following exchanges: the American Stock Exchange (''Amex'') (Automated Post Execution Reporting System, or AutoPERS), the Boston Stock Exchange (''BSE'') (BSE Automated Communication and Order Routing Network, or BEACON), the Chicago Board Options Exchange (''CBOE'') (the RAES system), the Chicago Stock Exchange (''CHX'') (Midwest Automatic Execution System, or MAX), the Pacific Exchange (''PCX'') (Pacific Computerized Order Access System, or P/COAST), and the Philadelphia Stock Exchange (''Phlx'') (Phlx Automated Communication and Execution System, or PACE).

[17] *See* Securities Exchange Act Release No. 29237 (May 24, 1991), 56 FR 24853 (May 31, 1991); Securities Exchange Act Release No. 32368 (May 25, 1993), 58 FR 31565 (June 3, 1993).

[18] First organized in 1884, the CSE initially operated with a physical trading floor which it began phasing out in 1976. SEC, Report on the Practice of Preferencing Pursuant to Section 510(c) of the National Securities Markets Improvement Act of 1996, 24 (1997) (hereinafter Preferencing Report).

[19] Like exchange markets, the NASD imposes obligations on market makers to provide a continuous source of liquidity for Nasdaq-traded securities, establishes minimum qualifications that issuers must meet in order for their securities to be quoted on the consolidated computer screen, and sets enforceable rules that govern the priorities dealers must give to certain orders.

[20] Experience in both the United States and world markets has repeatedly shown that commercial incentives alone are insufficient to protect investors adequately and ensure fair markets. In adopting the Exchange Act, Congress noted that, however zealously exchange authorities may supervise the business conduct of their members, the interests with which they are connected frequently conflict with the public interest. H.R. Rep. No. 1383, 73rd Cong., 2d Sess. at 4 (1934); S. Rep. No. 792, 73rd Cong., 2d Sess. (1934). *See also* SEC, Statement of the Securities and Exchange Commission on the Future Structure of the Securities Markets (Feb. 2, 1972), 37 FR 5286 (Feb. 4, 1972) (hereinafter Future Structure Statement). Legislative history to key Exchange Act amendments adopted in 1975 also points to the need for regulation. *See, e.g.*, S. Rep. No. 75 and H.R. Rep. No. 229, *infra* note 22. *See also* SEC, Report Pursuant to Section 21(a) of the Securities Exchange Act of 1934 Regarding the NASD and the Nasdaq Market (1996) (hereinafter NASD 21(a) Report).

[21] Pub. L. No. 29, 89 Stat. 97 (1975).

[22] *See* S. Rep. No. 75, 94th Cong., 1st Sess. 8 (1975); H.R. Rep. No. 229, 94th Cong., 1st Sess. 92 (1975). *See also* Exchange Act section 11A(a)(1), 15 U.S.C. 78k–1(a)(1).

[23] Congress also directed the Commission in the 1975 Amendments to advance the concept of equal regulation so that persons enjoying similar

Continued

every market that meets the definition of ''exchange'' under the Exchange Act to either register as a national securities exchange or be exempted from registration on the basis of limited transaction volume.[24] Congress also gave the exchanges authority to enforce their members' compliance with the goals of the securities laws and, in 1983, required every broker-dealer to become a member of an exchange [25] or securities association.[26] As SROs, every registered exchange and securities association is required to assist the Commission in assuring fair and honest markets, to have effective mechanisms for enforcing the goals of regulation, and to submit their rules for Commission review. This statutory structure has given the Commission ample authority to oversee securities markets and ensure compliance with the Exchange Act. Although regulation cannot prevent all manipulation, fraud, or collusion, it has proven effective in ridding markets of the most egregious of these practices and consequently in inspiring a high degree of investor confidence.

As a result of the technologically-driven developments discussed above, however, the distinctions among market service providers have become blurred, making it more difficult to determine whether any particular entity operates as an exchange, OTC market, broker, or dealer. For example, alternative trading systems incorporate features of both traditional markets and broker-dealers. Like traditional exchanges, alternative trading systems centralize orders and give participants control over the interaction of their orders. Like traditional broker-dealers, alternative trading systems are proprietary and, in some cases, maintain trading desks that facilitate participant trading. Because the activities of alternative trading systems include both traditional exchange and broker-dealer functions, it is often unclear whether such systems should register as exchanges, broker-dealers, or both. Under the existing statutory structure enacted by Congress, however, exchanges and broker-dealers are subject to significantly different obligations and responsibilities.

To date, the Commission has regulated many alternative markets as broker-dealers, rather than as exchanges, in order to foster the development of innovative trading mechanisms within the existing statutory framework.[27] The determination as to whether any particular alternative trading system should be regulated as an exchange or broker-dealer has been decided on a case-by-case basis.[28] This regulatory approach has had two significant, unintended effects: (1) It has subjected alternative trading systems to a regulatory scheme that is not particularly suited to their market activities; and (2) it has impeded effective integration, surveillance, enforcement, and regulation of the U.S. markets as a whole.

1. The Current Regulatory Approach Applies Inappropriate Regulation to Alternative Trading Systems

As broker-dealers, alternative trading systems are subject to regulation designed primarily to address traditional brokerage activities rather than market activities.[29] For example, broker-dealers are required to become members of the Securities Investor Protection Corporation (''SIPC''). While this membership is designed to protect customer funds and securities held by brokers, few alternative trading systems hold customer funds or securities.[30] In addition, broker-dealers are required to be members of an SRO. Thus, alternative trading systems are subject to oversight by exchanges and the NASD, which operate their own markets. Because these markets often compete with alternative trading systems for order flow, there is an inherent conflict between SROs' competitive concerns as markets and their regulatory obligations to oversee alternative trading systems.

Regulating alternative trading systems as traditional broker-dealers, therefore, requires compliance by these systems with obligations that, in many cases, are not pertinent to their principal activities. As discussed below, traditional broker-dealer regulation also fails to address concerns raised by alternative trading systems' market activities.

2. The Current Regulatory Approach Impedes Effective Regulation

The Commission has repeatedly evaluated whether the case-by-case no-action approach has permitted adequate Commission oversight of secondary trading markets, particularly in light of the growth and evolving market significance of such systems. Prior to 1993, the low volume and relatively small number of alternative trading systems appeared to justify such an approach. In 1993, for example, in an attempt to evaluate the effects of regulating alternative trading systems as broker-dealers, the Commission's Division of Market Regulation conducted a study of the U.S. equity markets.[31] This study concluded that, at that time, the Commission did not have sufficient regular information to

privileges, performing similar functions, and having similar potential to affect markets would be treated equally. The Commission was charged with ensuring that no member or class of members had an unfair advantage over other members as a result of a disparity in regulation not necessary or appropriate to further the objectives of the Exchange Act. *See* H.R. Rep. No. 229, *supra* note 22.

[24] There are currently eight registered national securities exchanges and one exempted exchange. AZX (formerly known as Wunsch Auction Systems) was exempted from the registration requirements of Sections 5 and 6 of the Exchange Act, 15 U.S.C. 78e and 78f, based on the exchange's expected limited volume in trading of securities. *See* Securities Exchange Act Release No. 28899 (Feb. 20, 1991), 56 FR 8377 (Feb. 29, 1991) (hereinafter AZX Exemptive Order). *See also* Securities Exchange Act Release No. 37271 (June 3, 1996), 61 FR 29145 (June 7, 1996).

[25] Markets operated by registered securities associations serve many of the same functions as exchanges. Registered securities associations are regulated under section 15A of the Exchange Act, 15 U.S.C. 78*o*–1, and are subject to requirements that are virtually identical to those applicable to registered exchanges under the Exchange Act.

[26] *See* Pub. L. No. 38, 97 Stat. 205 (1983).

[27] *See infra* notes 120 to 124 and accompanying text.

[28] Since 1991, the Commission staff has given operators of trading systems assurances that it would not recommend enforcement action if those systems operated without registering as exchanges. As a result, to date, many automated trading markets have not been required to register as exchanges and have instead been regulated as broker-dealers. For a list of no-action letters issued to system sponsors until the end of 1993 and a short history of the Commission's oversight of such systems, see Securities Exchange Act Release No. 33605, 59 FR 8368, 8369–71 (Feb. 18, 1994) (''Rule 17a–23 Proposing Release''). *See also* Letters from the Division of Market Regulation to: Tradebook (Dec. 31, 1996); The Institutional Real Estate Clearinghouse System (May 28, 1996); Chicago Board Brokerage, Inc. and Clearing Corporation for Options and Securities (Dec. 13, 1995).

[29] Broker-dealers have a responsibility under the Exchange Act for ensuring their own (and their employees') compliance with the federal securities laws and with the rules of all relevant SROs. Broker-dealer requirements generally focus on ensuring adequate employee supervision, financial responsibility and sufficient capital, and fair dealing with customers, including protection of customers' securities and funds, and monitoring sales practices.

[30] Rather than hold customer funds or securities, most alternative trading systems require their customers to arrange for trades executed on the system to be cleared through another broker-dealer. *See, e.g.*, Letter from Brandon Becker, Director, Division of Market Regulation, SEC, to Lloyd H. Feller, Esq., Morgan, Lewis & Bockius (Sep. 9, 1993) (Lattice trading system to have trades cleared and settled by a registered broker-dealer designated by respective system participants); Letter from Larry E. Bergmann, Associate Director, Division of Market Regulation, SEC, to Larry E. Fondren, Intervest Financial Services, Inc. (Nov. 24, 1992) (CrossCom Trading Network to use WFS Clearing Services, Inc.); Letter from William H. Heyman, Director, Division of Market Regulation, SEC, to Daniel T. Brooks, Cadwalader, Wickersham & Taft (Nov. 25, 1991) (LIMITrader to use Mabon Securities Corp. as its initial clearing broker); and Letter from William H. Heyman, (then) Deputy Director, Division of Market Regulation, SEC, to Richard S. Soroko, Esq., Lippenberger, Thompson & Welch (May 16, 1991) (Portfolio Trading Services, Inc. to use Ernst & Company as its clearing broker).

[31] *See* Market 2000 Study, *supra* note 14.

evaluate the effects of alternative trading systems on the U.S. securities markets. Therefore, the Division of Market Regulation recommended that the Commission closely monitor the impact of the proliferation of such systems. In response to this recommendation, the Commission adopted a recordkeeping and reporting rule, Rule 17a–23, specifically for broker-dealers that operate alternative trading systems.[32]

Because traditional broker-dealer regulation is not designed to apply to markets such as alternative trading systems, gaps have developed in the structures designed to ensure marketwide fairness, transparency, integrity, and stability. As discussed in greater detail below, the regulation of the most significant alternative trading systems under traditional broker-dealer regulation calls into question the accuracy of public quotation and trade information, and the fairness of the public secondary markets.[33] In addition, such regulation may impair the detection and elimination of fraudulent and manipulative trading, and the mechanisms to ensure fair and equitable oversight and competition among markets.

a. Market Access and Fairness

While institutional investors are now the dominant players in U.S. financial markets,[34] the United States still has the highest percentage of direct individual participation in the stock markets.[35] Because the needs and interests of small individual investors, money managers, wealthy speculators, and large pension plans are not always the same,[36] market regulation is intended to ensure that these diverse investors are treated fairly and have fair access to investment opportunities.

Specifically, the Exchange Act requires registered exchanges and securities associations to consider the public interest in administering their markets, to allocate reasonable fees equitably,[37] and to establish rules designed to admit members fairly.[38] While these provisions are based on the principle that qualified market participants should have fair access to the nation's securities markets, they are not intended to limit exchanges from having reasonable standards for access.[39] Rather, fair access requirements are intended to prohibit unreasonably discriminatory denials of access. A denial of access would be reasonable, for example, if it were based on unbiased standards, such as capital and credit requirements, and if these standards were applied fairly.

The Exchange Act also requires registered exchanges and securities associations to establish rules that assure fair representation of members and investors in selecting directors and administering their organizations.[40] The purpose of this requirement is to protect the rights and interests of the diverse members of registered exchanges and securities associations. In addition, because registered exchanges and securities associations are also SROs, they exercise governmental powers, such as the imposition of disciplinary sanctions on their members. Fair representation on the body responsible for disciplining members is, therefore, critical to the impartial enforcement of SRO rules.

Market regulation is also designed to remove barriers to fair competition, by prohibiting the rules of registered exchanges and securities associations from being anticompetitive,[41] and by providing for Commission review of the rules of registered exchanges and securities associations.[42] To further emphasize the goal of vigorous competition, Congress required the Commission to consider the competitive effects of exchange rules,[43] as well as the Commission's own rules.[44]

The Commission's authority to review the actions of registered exchanges and securities associations has prevented the implementation of numerous rules that would have been anticompetitive or otherwise detrimental to the market. For example, in December 1990, the American Stock Exchange (''Amex'') submitted a rule proposal to the Commission that would have excluded the orders of competing dealers (*i.e.*, regional exchange specialists and third market makers) from its order routing system and would have imposed trading restrictions on competing dealers in Amex securities. Because the exclusions and restrictions applied only to competing dealers and not to other off-floor broker-dealers trading for their own accounts, the proposal raised market access and competitive concerns.[45] After receiving numerous negative public comments regarding the Amex's proposal, the Commission staff recommended that the Amex either amend or withdraw the proposal.[46] Similarly, several exchanges have proposed prohibiting customer orders from being executed through the

[32] Rule 17a–23 under the Exchange Act generally requires U.S. broker-dealers that sponsor broker-dealer trading systems to provide a description of their systems to the Commission and report transaction volume and other activity to the Commission on a quarterly basis. This rule also requires that such broker-dealers keep records regarding system activity and to make such records available to the Commission. 17 CFR 240.17a–23. *See also* Securities Exchange Act Release No. 35124 (Dec. 20, 1994), 59 FR 66702 (Dec. 28, 1994).

[33] Commenters have repeatedly suggested that the regulatory disparity between exchanges and broker-dealers gives a competitive advantage to alternative trading systems. Concern about this regulatory dichotomy has been voiced by many commenters. Industry and congressional commenters at various times since 1991 have questioned whether regulating alternative trading systems differently from exchanges is advisable. The NYSE, for example, has stated that: ''[R]egulation of participants in our securities markets should be governed by the principle of ''functional regulation'': entities that perform similar functions should be subject to similar regulation * * * firms that establish a market place for providing execution of transactions in securities pursuant to their own trading rules should be regulated in a manner similar to exchanges, regardless of whether they are also brokers and dealers. The name given an entity should not control the manner in which it is regulated.'' Testimony of Edward A. Kwalwasser, Exec. V.P., NYSE, before the Telecommunications and Finance Subcommittee, Committee on Energy and Commerce, U.S. House of Representatives, at 5–6 (May 26, 1993) (hereinafter Testimony of Edward A. Kwalwasser).

[34] In 1960, institutions owned only 14.2 percent of the total $425 billion outstanding U.S. equity securities. By the end of the third quarter of 1996, the percentage had grown to 52.3% of the total $9,387 billion of outstanding U.S. equity securities. Conversation with staff of the Securities Industry Association (Feb. 21, 1997).

[35] From 1989 to 1995, the percentage of U.S. households having direct or indirect stock holdings jumped from 31.7% to over 41%. *See* Arthur B. Kennickell and Annika E. Sunden, *Family Finances in the U.S.: Recent Evidence from the Study of Consumer Finances,* Fed. Reserve Bull., Jan. 1997, at 1.

[36] Electronic Bulls & Bears, *supra* note 5, at 29.

[37] Exchange Act section 6(b)(4), 15 U.S.C. 78f(b)(4); Exchange Act section 15A(b)(5), 15 U.S.C. 78*o*–3(b)(5).

[38] Exchange Act sections 6(b)(2) and 6(c), 15 U.S.C. 78f(b)(2) and (c); Exchange Act section 15A(b)(8); 15 U.S.C. 78*o*–3(b)(8).

[39] ''[R]estraints on membership cannot be justified as achieving a valid regulatory purpose and, therefore, constitute an unnecessary burden on competition and an impediment to the development of a national market system.'' H.R. Rep. No. 123, 94th Cong., 1st Sess. 53 (1975).

[40] Exchange Act section 6(b)(3), 15 U.S.C. 78f(b)(3); Exchange Act section15A(b)(4), 15 U.S.C. 78*o*–3(b)(4).

[41] Exchange Act section 6(b)(8), 15 U.S.C. 78f(b)(8); Exchange Act section 15A(b)(9), 15 U.S.C. 78*o*–3(b)(9).

[42] Exchange Act section 19(b)(1), 15 U.S.C. 78s(b)(1). *See infra* notes 188 to 205 and accompanying text (discussion of obligations of exchanges and securities associations to file rules and rule changes with the Commission).

[43] Exchange Act sections 6(b)(6), 15 U.S.C. 78f(b)(6).

[44] Exchange Act section 23(a), 15 U.S.C. 78w(a)(2).

[45] Securities Exchange Act Release No. 28741 (Jan. 3, 1991), 56 FR 1038 (Jan. 10, 1991). The proposal would have required that orders for the account of competing dealers: (1) Yield priority and parity to all other off-floor orders; (2) accept parity with orders for an account of an Amex specialist; and (3) be excluded from the Amex's order routing system, the Post Executions Reporting system. The Amex subsequently amended its proposal. Securities Exchange Act Release No. 30161 (Jan. 7, 1992), 57 FR 1502 (Jan. 14, 1992).

[46] *See* Market 2000 Study, *supra* note 14, at app. III, at 11. In 1994, the Amex withdrew its proposal.

exchanges' automated systems for guaranteed execution of small customer orders, if those customers used computer and communications technology to generate and transmit those orders. Such a proposal, if implemented, would have had the effect of discouraging the use of new, innovative technology. The tendency to try to discourage innovation in order to protect existing practices is not new. In 1987, for example, the Commission set aside the NYSE's denial of the requests of two of its members for permission to install telephone connections on the floor to enable the members to communicate with their customers.[47]

The fair access and treatment requirements in the Exchange Act are intended to ensure that exchanges and securities associations operating markets treat investors and their participants fairly. Under the current regulatory approach, however, there is no regulatory redress for unfair denials or limitations of access by alternative trading systems, or for unreasonably discriminatory actions taken against, or retaliatory fees imposed upon, participants in these systems. The availability of redress for such discriminatory actions may not be critical when alternative trading systems disclose any discriminatory practices to their participants and when market participants are able to substitute the services of one alternative trading system with those of another. However, when an alternative trading system has no other serious competitor, such as when it has a significantly large percentage of the volume of trading, discriminatory actions may be anticompetitive because market participants must use such trading system to remain competitive. Similarly, significant changes in the operations of alternative trading systems are not subject to either Commission or SRO review—even those changes that may be anticompetitive, unfair to a particular group of market participants, or that have significant effects on the primary public markets.

b. Market Transparency and Coordination

Securities markets have become increasingly interdependent because of the opportunities technology provides to link products, implement complex hedging strategies across markets, and trade on multiple markets simultaneously. While these opportunities benefit many investors, they can also create misallocations of capital, widespread inefficiency, and trading fragmentation if markets do not coordinate. Moreover, a lack of coordination among markets can increase system-wide risks. Congress adopted the 1975 Amendments, in part, to address these potential negative effects of a proliferation of markets.[48] In the 1975 Amendments, Congress specifically endorsed the development of a national market system, and sought to clarify and strengthen the Commission's authority to promote the achievement of such a system. Because of uncertainty as to how technological and economic changes would affect the securities markets, Congress explicitly rejected mandating specific components of a national market system.[49] Instead, Congress granted the Commission ''maximum flexibility in working out the specific details'' and ''broad discretionary powers'' to implement the development of a national market system in accordance with the goals of the 1975 Amendments.[50] The SROs and the Commission have worked hard to achieve these goals. [51]

Recent evidence suggests that the failure of the current regulatory approach to fully coordinate trading on alternative trading systems into national market systems mechanisms has impaired the quality and pricing efficiency of secondary equity markets, particularly in light of the explosive growth in trading volume on such alternative trading systems. Although these systems are available to some institutions, orders on these systems frequently are not available to the general investing public. The ability of market makers and specialists to display different and potentially superior prices on these alternative trading systems than those displayed to the general public created, in the past, the potential for a two-tiered market.[52]

For example, during the Commission's recent investigation of Nasdaq trading,[53] analyses of trading in the two most significant trading systems for Nasdaq securities (Instinet and SelectNet) revealed that the majority of bids and offers displayed by market makers in these systems were better than those posted publicly on Nasdaq.[54] Moreover, the Commission found that, because they could trade with other market professionals through non-public alternative trading systems, market makers did not have a sufficient economic incentive to adjust their public quotations to reflect more competitive prices.[55] Ultimately, the wider spreads quoted publicly by market makers increased the transaction costs paid by public customers, impaired the ability of some institutional investors to obtain favorable prices in those securities, and placed institutions at a potential disadvantage in price negotiations.[56]

In response to these findings, the Commission recently took steps to bring greater transparency into the trading environment of certain alternative trading systems. In September 1996, the Commission adopted rules that require a market maker or specialist to make

[47] *See In the Matter of the Application of William J. Higgins and Michael D. Robbins,* Admin. Proc. No. 3–6609, Securities Exchange Act Release No. 24429 (May 6, 1987).

[48] *See generally* S. Rep. No. 75 and H.R. Rep. No. 229, 94th Cong., *supra* note 22.

[49] S. Rep. No. 75, *supra* note 22, at 2, 8; H.R. Rep. No. 229, *supra* note 22. ''(T)he increasing tempo and magnitude of the changes that are occurring in our domestic and international economy make it clear that the securities markets are due to be tested as never before,'' and that it was, therefore, important to assure ''that the securities markets and the regulations of the securities industry remain strong and capable of fostering (the) fundamental goals [of the Exchange Act] under changing economic and technological conditions.'' S. Rep. No. 75, *supra* note 22, at 3.

[50] S. Rep. No. 75 and H.R. Rep. No. 229, *supra* note 22.

[51] For example, the Intermarket Communications Group links the Commission, the Commodity Futures Trading Commission, and the SROs for the major securities and futures markets. During periods of market stress this interagency and intermarket coordination helps to minimize uncertainty and improve communication for the benefit of investors trading in all U.S. markets. In addition, market-wide trading halts imposed by circuit breaker procedures limit credit risk by providing a brief respite amid frenetic trading, which allows market participants to ensure the solvency of their counterparties. These planned, coordinated trading halts also facilitate price discovery by providing an opportunity to publicize order imbalances in order to attract value traders, and cushion the impact of market movements that would otherwise damage a market's infrastructure.

[52] *See* Securities Exchange Act Release No. 36310 (Sept. 29, 1995), 60 FR 52792 (Oct. 10, 1995) (hereinafter Order Handling Rules Proposing Release).

[53] Following the filing of several class action lawsuits alleging collusion among Nasdaq market makers and public allegations that Nasdaq market makers routinely refused to trade at their published quotes, intentionally reported transactions late in order to hide trades from other market participants, and engaged in other market practices detrimental to individual investors, the Commission opened a formal inquiry to investigate the functioning of the Nasdaq market and to determine whether the NASD was complying fully with its obligations as an SRO. In 1996, as a result of the investigation, the Commission instituted enforcement proceedings against the NASD pursuant to section 19(h) of the Exchange Act and issued a report under section 21(a) of the Exchange Act detailing the Commission's findings. *See* NASD 21(a) Report, *supra* note 20.

[54] These conclusions are based on Instinet and SelectNet data for the months April through June 1994. *See* NASD 21(a) Report, *supra* note 20, at notes 48 to 52 and accompanying text.

[55] The Commission found that ''the ability of market makers to attract trading interest through Instinet allowed them to trade without using odd-eighth quotes and narrowing the Nasdaq spread.'' NASD 21(a) Report, *supra* note 20, at 20.

[56] NASD 21(a) Report, *supra* note 20, at 18.

publicly available any superior prices that it privately offers through certain types of alternative trading systems known as electronic communications networks, or ECNs.[57] The new rules permit an ECN to fulfill these obligations on behalf of market makers using its system, by submitting its best market maker bid/ask quotations to an SRO for inclusion into public quotation displays (''ECN Display Alternative'').

These rules, however, were not intended to fully coordinate trading on alternative trading systems with public market trading. While these rules will help integrate orders on certain trading systems into the public quotation system, they only affect trading that is conducted by market makers and specialists; activity of other participants on alternative trading systems remains undisclosed to the public market unless the system voluntarily undertakes to disclose all of its best bid/ask prices.[58] Moreover, whether an ECN reflects the best bid/ask quotations on behalf of market makers and specialists that participate in its system is wholly voluntary.[59] Specifically, ECNs are under no obligation to integrate orders submitted into their systems into the public quotation system, and the central quotation system is not currently required to accept ECNs as participants.

Because a majority of trading interest on alternative trading systems is not integrated into the national market system, price transparency is impaired and dissemination of quotation information is incomplete. These developments are contrary to the goals the Commission enunciated over twenty years ago when it noted that an essential purpose of a national market system

> is to make information on prices, volume, and quotes for securities in *all* markets available to *all* investors, so that buyers and sellers of securities, wherever located, can make informed investment decisions and not pay more than the lowest price at which someone is willing to sell, and not sell for less than the highest price a buyer is prepared to offer.[60]

This development also thwarts congressional goals for a national market system, where the best trading opportunities are to be made accessible to *all customers,* not just those customers who, due to their size or sophistication, may avail themselves of prices in alternative trading systems not currently available in the public quotation system.

c. Market Surveillance

Market regulation critically enhances the Commission's ability to surveil market activity as a whole in order to prevent fraud and manipulation, which can jeopardize market integrity and stability. Exchanges and securities associations such as the NASD act as SROs and, as such, are responsible not only for complying with the Exchange Act, but also for carrying out the purposes of the Exchange Act, principally by enforcing member compliance with the provisions of the Exchange Act and the rules promulgated thereunder, as well as the exchanges' or associations' own rules.[61] This requires exchanges and securities associations to establish rules and procedures to prevent fraud and manipulation and promote just and equitable principles of trade, typically by establishing audit trails, surveillance, and disciplinary programs. It also requires exchanges and securities associations to enforce the antifraud provisions of the federal securities laws.[62] These requirements are essential to ensure that SROs implement the goals established by Congress vigilantly and effectively. In addition, exchanges and securities associations serve a critical regulatory function by establishing and enforcing just and equitable principles of trade, and by providing a mechanism for preventing inappropriate behavior that damages market integrity, even if such behavior does not rise to the level of fraud under the Exchange Act. As a result of these requirements, exchanges and securities associations carry out much of the day-to-day surveillance for, and initial investigation of, trading improprieties, rule violations, and fraud.

Although the broker-dealers that operate many of the alternative trading systems have certain obligations to individual customers, because these systems are not SROs, they do not have the same market-wide enforcement and surveillance obligations as registered exchanges and the NASD. Moreover, SROs' current programs to surveil their own markets for fraud, insider trading, and market manipulation do not extend to observing quote activity on alternative trading systems. Specifically, although trades executed through certain alternative trading systems are reported to the NASD by either broker-dealer participants in such systems or by the broker-dealer operating the market,[63] the NASD may not receive a consolidated picture of trading activity on alternative trading systems. Because activity on alternative trading systems is only reported to an SRO after a trade has been executed, SROs cannot fully supervise SROs' members' activities on those systems.[64] In addition, because alternative trading systems are often reported as the counterparty to all trades between institutions executed through their systems, SRO surveillance mechanisms may not be able to identify the true counterparties of those trades. As a result, fraudulent or manipulative activity that an institution is carrying on through an alternative trading system may be masked by the overall activities of the system's other participants, and go uninvestigated. As more institutions use alternative trading systems to trade with each other, rather than with

[57] ECNs include any automated trading mechanism that widely disseminates market maker orders to third parties and permits such orders to be executed through the system, other than crossing systems. *See* Securities Exchange Act Release No. 37619A (Sept. 6, 1996), 61 FR 48290 (Sept. 12, 1996) (hereinafter Order Handling Rules Adopting Release). Currently, all ECNs are broker-dealer trading systems, as defined in Exchange Act Rule 17a–23, and are sponsored through registered broker-dealers.

[58] Because such trading interest remains undisclosed, within certain alternative trading systems non-market maker participants are able to display prices that lock and cross the public quotations. If the quotes of such participants were also disclosed to the public, it could result in improved price opportunities for public investors. There is already divergence among ECNs in the extent to which they have chosen to integrate non-market maker orders into the prices they display to the public. Of the four ECNs that are currently linked to Nasdaq, two ECNs display to the public the best prices of any orders entered into their systems (including both market makers and institutions). One ECN displays to the public the best price of any visible order entered into its system by market makers or institutions, but does not display any orders that are designated as ''reserve orders'' (which may interact with orders entered into the ECN's system, but are not generally displayed to participants in the ECN). The fourth ECN displays to the public only orders of market makers and those institutional customers that affirmatively choose to have their orders so displayed.

[59] To date, four trading systems have elected to display quotes under the ECN alternative. *See* Letters dated January 17, 1997 from Richard R. Lindsey, Director, SEC to: Charles R. Hood, Senior V.P. and General Counsel, Instinet Corporation (recognizing Instinet as an ECN); Joshua Levine and Jeffrey Citron, Smith Wall Associates (recognizing the Island System as an ECN); Gerald D. Putnam, President, Terra Nova Trading, LLC (recognizing the TONTO System, now known as Archipelago, as an ECN); and Roger D. Blanc, Wilkie Farr & Gallagher (counsel to Bloomberg) (recognizing Bloomberg Tradebook as an ECN).

[60] Future Structure Statement, *supra* note 20, at 9–10 (emphasis added). *See also,* SEC, Policy Statement of the Securities and Exchange Commission on the Structure of a Central Market System 25–28 (1973).

[61] Exchange Act section 6(b) (1), (5), and (6), 15 U.S.C. section 78f(b) (1), (5), and (6); Exchange Act 15A(b)(2), 15 U.S.C. 78*o*–3(b)(2).

[62] *Id.*

[63] Broker-dealers that operate trading systems have the same reporting obligations as other broker-dealers. For trades executed on an alternative trading system, this means that, depending on the circumstances, market makers and broker-dealers trading on the system will report their own trades, and that the broker-dealer sponsor of the system will undertake to report trades between non-broker-dealers.

[64] *See* NASD 21(a) Report, *supra* note 20.

intermediaries, this could result in significant volume that is not integrated into SRO surveillance operations. Finally, alternative trading systems that compete with systems operated by SROs have repeatedly questioned whether particular SRO actions were driven by competitive, rather than regulatory motives. Thus, adequate oversight of alternative trading systems by SROs may be hindered by competitive concerns.

d. Market Stability and Systemic Risks

SROs have substantial, ongoing commitments to maintain sufficient system capacity, integrity, and security. The Commission has instituted a program to monitor capacity planning at SROs, so that it can take preemptive action if necessary, and meets with the SROs on a regular basis and reviews various aspects of their computer operations. In contrast, the Division of Market Regulation's experience in administering the Order Handling Rules and other broker-dealer rules has revealed that, in many cases, ECNs and other alternative trading systems may have serious capacity problems.[65] Even though they have significant trading volume, under the current regulatory scheme ECNs and other alternative trading systems are not required to have sufficient computer capacity to meet ongoing trading demand or to withstand periods of extreme market volatility or other short-term surges in trading volume. Failure to integrate alternative trading systems into the Commission's programs to review and enhance the capacity of alternative trading systems jeopardizes efforts to ensure that all trade execution centers will remain operational during periods of market stress.

C. Conclusion

In sum, the current regulation of alternative trading systems does not address the market activities performed by such systems. As a result, such regulation may not have effectively met the congressional goals of protecting market participants from fraud and manipulation, promoting market coordination and stability, and ensuring regulatory fairness and fair competition.

Question 1: The Commission seeks comment on the concerns identified above and invites commenters to identify other issues raised by the current approach to regulating alternative trading systems.

Question 2: Are the concerns raised in this release with regard to the operation of alternative trading systems under the current regulatory approach unique to such systems? To what extent could these concerns be raised by broker-dealers that do not operate alternative trading systems, such as a broker-dealer that matches customer orders internally and routes them to an exchange for execution or a broker-dealer that arranges for other broker-dealers to route their customer orders to it for automated execution?

III. Approaches to Market Oversight

The Commission recognizes that, in order to promote efficiency, competition, and capital formation in the securities industry, creation of new markets or the evolution of existing ones must not be inhibited. At the same time, the Commission continues to believe that fair and measured market oversight is valuable to protect investors, ensure the integrity and fairness of markets, and otherwise promote the goals reflected in the Exchange Act.

As the problems discussed above illustrate, the current approach for regulating alternative trading systems may not effectively accomplish these objectives. New technologies are continually facilitating innovative means of trading securities, resulting in qualitatively different market structures. In the next decade, the continued growth of the Internet will present even more opportunity for change in financial services. This release solicits comment on whether the current statutory and regulatory framework is appropriate in light of these myriad developments and new means of trading securities made possible by emerging technologies. The release then seeks comment on specific alternatives for addressing these objectives within the existing securities law framework.

A. Regulatory Structure

As technology continues to drive the evolution of markets, the variety and combinations of services offered by markets and intermediaries will continue to blur the distinctions among these entities. Under the Exchange Act, such distinctions determine the obligations and responsibilities of each entity towards customers and the market as a whole. In particular, the Exchange Act categorizes market participants based on their primary activities, such as an ''exchange'' function or a ''broker-dealer'' function. Although Congress defined the terms ''exchange,'' ''broker,'' and ''dealer'' broadly enough to accommodate changes in how these entities carry out their business, they could not anticipate the variety of entities that would develop. The Commission invites commenters to analyze whether, in light of technological advances, market participants might be appropriately regulated without reference to distinctions between markets and intermediaries. In the alternative, the Commission solicits comment on whether new regulatory categories are needed for entities that combine both market and intermediary functions. The Commission also solicits comment on what oversight should apply to these categories.

In addition, as explained above, exchanges and broker-dealer intermediaries each play critical roles in supervising securities activities. The Commission solicits comment on how any changes to the regulatory approach would affect these roles.

Finally, the Commission solicits comment on how any changes to the current statutory and regulatory structure made to accommodate market innovations could be accomplished without undue cost to existing market participants, which have invested significantly to comply with the existing structure.

Question 3: What regulatory approaches would best address the concerns raised by the growth of alternative trading systems and the needs of the market? Is the current approach the most appropriate one?

Question 4: What should be the objectives of market regulation? Are the goals and regulatory structure incorporated by Congress in the Exchange Act appropriate in light of technological changes? Are business incentives adequate to accomplish these goals?

Question 5: Are the regulatory categories defined in the Exchange Act sufficiently flexible to accommodate changes in market structure? If not, what other categories would be appropriate? How should such categories be defined?

B. Regulatory Tools

Technological changes also have significant implications for the tools the Commission relies on to achieve the goals incorporated by Congress into the Exchange Act. As discussed in greater detail in Sections IV and V below, the Commission currently regulates markets largely through its registration, rule filing, examination, and enforcement programs. In light of the changes

[65] The Commission is aware of several occasions on which significant alternative trading systems had to stop disseminating market maker quotations in order to keep from closing altogether due to insufficient system capacity. In one recent occurrence, an interruption in service at an ECN immediately following a key market announcement appears to have seriously affected options market makers' ability to trade the equities underlying their options.

discussed above, the Commission solicits comment on whether these are effective means of accomplishing congressional goals, and, if not, what other means might be more appropriate.

For example, many Commission regulations require market participants to deliver written documents. In order to give broker-dealers and investment advisers the flexibility to comply with these requirements in the most cost-effective and efficient manner, the Commission has issued interpretative guidance regarding the use of electronic communications to fulfill the delivery requirements of the federal securities laws.[66] Rather than specifying acceptable types of electronic delivery, the Commission specified the standards that entities had to achieve in meeting their delivery requirements electronically, leaving it to each entity to determine the best way to meet each standard. This approach allows broker-dealers and investment advisers to avail themselves of technological innovations without first obtaining regulatory approval. The Commission solicits comment on whether such a standard-oriented approach would be appropriate for the regulation of markets, and, if so, what these standards should be.

Question 6: Can the Commission regulate markets effectively through standard-oriented regulation of the type described above?

Question 7: How could the Commission enforce compliance with the Exchange Act under such a standard-oriented approach?

Question 8: Is the current regulatory framework an effective form of oversight, in light of technological changes? Are there other regulatory techniques that would be comparably effective? If so, would the implementation of such techniques be consistent with congressional goals reflected in the Exchange Act?

IV. Proposals Under Consideration To Integrate Alternative Trading Systems into the Existing Regulatory Structure for Market Oversight

Within the existing regulatory framework, the issues currently associated with alternative trading systems could be addressed in large part by integrating alternative trading systems more effectively into national market system mechanisms. Discussed below are two alternative means of effecting such integration. First, the Commission could continue to regulate alternative trading systems as broker-dealers and attempt to integrate these systems more effectively into market regulation mechanisms through a series of rules applicable to broker-dealers operating such systems and to SROs overseeing such systems. Second, the Commission could regulate alternative trading systems as exchanges by expanding the interpretation of the term ''exchange'' to cover those alternative trading systems that engage in many of the same activities as currently registered exchanges, such as operating an electronic limit order book, or matching or crossing participant orders. The Commission could then follow a tiered approach to regulating those alternative trading systems classified as exchanges. The first tier under this approach would consist of those alternative trading systems that have low volume or a passive pricing structure. These trading systems would not be required to register as national securities exchanges (or as broker-dealers, to the extent that such trading systems do not also perform customary brokerage functions),[67] but would be subject to limited requirements. The second tier under this approach would consist of those alternative trading systems with a large volume of trading and active price discovery, but that do not have membership structures. The Commission could require these trading systems to register as exchanges, but would use its new exemptive authority to eliminate unnecessary or inappropriate requirements.[68] Finally, the third tier under this approach would consist of those traditional exchanges that have membership governance structures.

Any new regulatory approach to oversight of alternative trading systems should promote efficiency, competition, and capital formation in the securities industry, without inhibiting the development of new markets. At the same time, it is critical to address the problems discussed above. The Commission solicits comment on the two alternatives for addressing these issues discussed below, and on whether there are other alternatives that may address the Commission's concerns.

Question 9: Are there viable alternatives within the existing Exchange Act structure, other than those discussed below, that would address the concerns raised by the growth of alternative trading systems and congressional goals in adopting the Exchange Act?

A. Integrating Alternative Trading Systems into the National Market System Through Broker-Dealer Regulation

In order to rectify the shortcomings discussed in Section II of this release, the Commission could build upon its current regulation of alternative trading systems as broker-dealers. In particular, alternative trading systems could be overseen and integrated into the NMS through a combination of broker-dealer regulation and regulation of the SROs that supervise these systems. The Commission took a similar approach in its recent adoption of the Order Handling Rules (which are designed to integrate a portion of the trading on ECNs into market transparency mechanisms) and in its adoption of Rule 17a–23 (which established recordkeeping and reporting requirements specifically tailored to broker-dealers operating trading systems).

As discussed below, these broker-dealer regulations could include requiring those broker-dealers that operate alternative trading systems to make all orders of participants in those systems available to the public quotation system. The Commission could also require alternative trading systems to provide the public with access to such systems in order to interact with the orders posted by participants of such systems. In addition, the Commission could impose additional requirements on both the broker-dealers that operate alternative trading systems and their SROs in order to more effectively integrate these systems into SRO surveillance mechanisms. For example, the Commission could require broker-dealers that operate alternative trading systems to provide more audit trail

[66] *See* Securities Exchange Act Release No. 36345, 60 FR 53458 (Oct. 6, 1995); Securities Exchange Act Release No. 36346, 60 FR 53468 (Oct. 6, 1995); Securities Exchange Act Release No. 37183 (May 9, 1996), 61 FR 24652 (May 15, 1996).

[67] *See infra* notes 183 to 184 and accompanying text.

[68] The National Securities Markets Improvement Act of 1996 (hereinafter 1996 Amendments), Pub. L. 104–290, added Section 36 to the Exchange Act, 15 U.S.C. 78mm, which authorizes the Commission to conditionally or unconditionally exempt any person, security, or transaction, or any class thereof, from any provision of the Exchange Act or rule thereunder, so long as the exemption is necessary or appropriate in the public interest and is consistent with the protection of investors. Section 36 of the Exchange Act does not authorize the Commission to exempt persons, securities, transactions, or classes thereof from section 15C of the Exchange Act or rules and regulations issued under that section. Section 15C establishes registration requirements for government securities brokers and government securities dealers and gives the U.S. Department of the Treasury authority to promulgate rules governing the activities of these entities. All of the exemptions pursuant to section 36 of the Exchange Act that the Commission is considering in this concept release could be granted by rule or regulation. If the Commission determined instead to issue orders granting exemptive applications, it would need to adopt procedures for doing so pursuant to section 36.

information to their SROs, which would help SROs execute their oversight functions, and could require SROs to use this additional information to integrate these systems into their surveillance programs. Finally, the Commission could adopt measures that would help to ensure that alternative trading systems have adequate systems capacity.

Question 10: What types of alternative trading systems would it be appropriate to regulate in this manner?

1. Fully Integrating the Orders of All Market Participants into the Public Quotation System and Facilitating Public Access to Such Orders

In its efforts to increase competition and transparency in the market, the Commission has encouraged the development of NMS mechanisms, such as the Consolidated Tape Association (''CTA''), the Consolidated Quotation System (''CQS'') and the Intermarket Trading System (''ITS''). These mechanisms make information about trading interest, prices, and volume widely available to market participants. The Commission has worked to continuously update and improve the NMS to reflect technological advances. For example, the new Order Handling Rules require market makers and specialists to make available publicly any superior prices they privately offer through ECNs. As an alternative, the new rules permit, but do not require, an ECN to fulfill these obligations on behalf of the market maker or specialist by submitting the ECN's best bid and offer to an SRO for inclusion into the public quotation system.

As discussed above,[69] however, these rules were not intended to integrate all trading on alternative trading systems into the NMS. These rules focus only on ensuring that market maker and specialist activity on alternative trading systems is reflected in their public quotations. As a result, institutional orders on ECNs remain largely undisclosed to the public, thus hiding the aggregate trading interest on alternative trading systems from public view. Therefore, it might be appropriate to require broker-dealers that operate alternative trading systems to report all orders[70] submitted by participants, including those of non-broker-dealer participants, for integration into the public quotation system.

If alternative trading systems are required in some manner to publicly display the orders of all participants, they could also be required to provide the public with the ability to execute against those orders. Under the Order Handling Rules, an ECN that voluntarily displays market makers' and specialists' quotations to the public must also provide an equal opportunity for participants and non-participants to execute their orders against such quotations. Non-participants, however, may only access market maker and specialist quotations on those ECNs. Alternative trading systems could be required to provide non-participants with the ability to execute against all orders in their system, including those of institutions, in a manner equivalent to that offered participants of the systems. Non-participants would be granted access on a real-time basis under this approach and could be charged reasonable fees for such access.

Question 11: If the Commission decided to further integrate alternative trading systems into the NMS through broker-dealer regulation, should it require alternative trading systems to submit all orders displayed in their systems into the public quotation system? If not, how should the Commission ensure adequate transparency?

Question 12: If the Commission requires alternative trading systems to submit all orders displayed in their systems into the public quotation system, how can duplicate reporting by alternative trading systems and their participant broker-dealers be prevented?

Question 13: Are there other methods for integrating all orders submitted into alternative trading systems into the public quotation system?

Question 14: Are there any reasons that orders available in alternative trading systems should not be available to the public?

Question 15: If the Commission requires alternative trading systems to allow non-participants to execute against orders of system participants, how should it ensure that non-participants are granted equivalent access?

Question 16: If the Commission requires alternative trading systems to allow non-participants to execute against orders of system participants, how should it determine whether the fees charged to non-participants by such systems are reasonable and do not have the effect of denying access to orders?

Question 17: Are there any reasons that non-participants should not be able to execute against orders of participants in alternative trading systems?

2. Improving the Surveillance of Trading Conducted on Alternative Trading Systems

As discussed below, alternative trading systems may not be subject to real-time surveillance for market manipulation and fraud. Broker-dealers that operate these systems are not required to actively surveil the conduct of system participants to ensure against fraud and manipulation. Instead, as discussed above, these surveillance responsibilities lie with the SROs. SROs, however, do not actively incorporate alternative trading systems into their real-time surveillance programs, and broker-dealer trade reporting conventions restrict SRO surveillance capabilities.

Trading by institutions on alternative trading systems is effectively hidden from SRO programs designed to detect fraud and manipulation. SRO surveillance systems generate ''alerts'' that, in their most basic form, indicate when trading in a particular security is outside of normal trading patterns, such as when a previously inactive entity suddenly begins actively trading. Broker-dealers operating alternative trading systems, however, are not required to report the identities of the counterparties to a trade to their supervising SRO. Instead, the broker-dealer may report the trade to the SRO as its own trade. Therefore, SRO surveillance programs do not ''look through'' the alternative trading system to the actual counterparties conducting the trading on such systems. Because the SRO system views the broker-dealer operating the system as the counterparty to trades, unusual trading activity of a participant in an alternative trading system may not trigger an alert. While the anonymity provided by the broker-dealer trading system reporting the trade may be desirable to some because it allows traders to hide their trading strategies from other market participants, it also represents an opportunity for market manipulation that is increasingly difficult for SROs to detect.

In addition, SRO surveillance programs typically are constructed around activity in particular securities. Several alternative trading systems are designed to provide a liquid market in securities that are not traded on exchanges or Nasdaq, such as limited partnerships and certain derivatives.

[69] *See supra* notes 57 to 60 and accompanying text.

[70] Firm prices for securities, whether such firm prices are labeled as ''orders,'' ''quotes,'' or otherwise, could be included in the public quotation system. Priced orders entered into alternative trading systems where the orders are widely disseminated and executable could be viewed as the functional equivalent of quotations, and like quotations, would play a key role in the price discovery process. *See also* Order Handling Rules Adopting Release, *supra* note 57, at 116.

Because SRO surveillance currently focuses primarily on trading in securities listed or approved for trading on the market operated by that SRO, activity on systems trading other securities (particularly non-equity securities) may not receive adequate surveillance for fraud and market manipulation.

Finally, although a broker-dealer is generally obligated to report a trade executed on an alternative trading system to its SRO,[71] the SRO does not receive a composite picture of orders available on that alternative trading system on a real-time basis. Consequently, the SRO is not able to integrate the activity on an alternative trading system into its information about activity in that security on its own market.

For these reasons, if alternative trading systems continue to be regulated as broker-dealers, it may be appropriate to require such systems to provide their SRO, on an automated basis, with real-time information about trading on the systems (including, where appropriate, parties to a trade), in order to enable the SRO to improve its surveillance of such trading. The Commission notes that the identities of the counterparties to a trade would not be made publicly available, but would be provided solely to the market surveillance department of an SRO. In addition, in order for SROs to incorporate the trading on alternative trading systems into their real-time surveillance programs, SROs would have to understand in much greater detail than they do today the manner in which prices are established on alternative trading systems. This would probably require SROs, for example, to examine the trading algorithms, including the programming code, of alternative trading systems. Alternative trading systems would also have to notify SROs of changes to their system. Further, because alternative trading systems that trade non-NMS securities are not currently included within SROs' primary surveillance programs, SROs may have to broaden the scope of their surveillance activities to include more active surveillance of trading in securities not listed or quoted on the market operated by the SRO.

Under this approach, the surveilling SRO would integrate the additional data provided by the alternative trading systems into the SRO's audit trail and real-time surveillance function. The SROs could use this data to enhance their ongoing, real-time surveillance of these alternative systems by developing specifically tailored surveillance and examination procedures to detect fraud and manipulation on particular systems and among systems.

Question 18: Should the Commission require alternative trading systems to provide additional information (such as identifying counterparties) to their SRO in order to enhance the SRO's audit trail and surveillance capabilities?

Question 19: What other methods could the Commission use to enhance market surveillance of activities on alternative trading systems?

Question 20: Should SROs be required to surveil trading by their members in securities that are not listed or quoted on the market operated by that SRO?

3. Ensuring Adequate Capacity of Alternative Trading Systems

As alternative trading systems play an increasingly important role in the securities markets, their ability to continue to operate during periods of high volume or volatility becomes critical. Existing standards regarding the review of the capacities and other operational requirements of markets could apply to alternative trading systems if they continue to be regulated as broker-dealers.[72]

The Commission currently receives limited information regarding the operational procedures of alternative trading systems under Rule 17a–23.[73] Although that Rule requires system operators to provide the Commission with a brief description of their trading systems, including significant systems changes and procedures for reviewing systems capacity, security, and contingency planning, it does not require alternative trading systems to adopt such procedures. The Commission in the past has issued guidance to SROs on developing and implementing policies for assessing the capacity, security, and contingency planning of their systems.[74] To ensure that alternative trading systems have adequate capacity for order execution and other services they provide, the Commission could consider whether broker-dealers that operate such systems should be required to follow similar guidelines. For example, alternative trading systems could be required to arrange for independent systems reviews, including an assessment of anticipated capacity requirements, contingency protocols, and processes for preventing, detecting, and controlling threats to their systems. In addition, alternative trading systems could be required to report significant systems outages to the Commission and their SRO on a real-time basis.

Question 21: Should alternative trading systems be required to follow guidelines regarding the capacity and integrity of their systems? If not, how should the Commission address systemic risk concerns associated with potentially inadequate capacity of alternative trading systems, particularly those systems with significant volume?

Question 22: With what types of standards regarding computer security, capacity, and auditing of systems, should alternative trading systems be required to comply?

Question 23: To what extent would complying with systems guidelines similar to those implemented by exchanges and other SROs require modification to the current procedures of alternative trading systems? What costs would be associated with such modifications? How much time would be required to implement the necessary modifications and systems enhancements? Please provide a basis for these estimates.

4. Potential Problems with Regulating Alternative Trading Systems Under the Broker-Dealer Regulatory Scheme

Although broker-dealer regulation provides a framework for integrating alternative trading systems into the most significant aspects of the NMS, such an

[71] *See, e.g.,* NASD Manual Rules 4630–32.

[72] In particular, the Commission is considering adopting certain additional procedures, pursuant to section 15(b)(7) of the Act, 15 U.S.C. 78*o*(b)(7), to ensure that alternative trading systems have adequate facilities and operational capabilities for the services they provide.

[73] *See* Item 5, Part I of Form 17A–23, 17 CFR 249.636.

[74] *See* Securities Exchange Act Release No. 29185 (May 9, 1991), 56 FR 22490 (May 15, 1991); Securities Exchange Act Release No. 27445 (Nov. 16, 1989), 54 FR 48703 (Nov. 24, 1989). These releases encourage SROs to establish comprehensive planning and assessment programs that accomplish three objectives: (1) Each SRO should establish current and future capacity estimates; (2) each SRO should conduct capacity stress tests periodically; and (3) each SRO should obtain an annual independent assessment of whether the affected systems can perform adequately in light of estimated capacity levels and possible threats to the systems. An ''independent review'' might be performed by any qualified party that has the organizational status and objectivity such that it operates separately from and is not controlled by the SRO's technology staff. The Commission recommended that these independent reviews evaluate the following areas: computer operations; telecommunications; systems development methodology; capacity planning and testing; and contingency planning. The Commission also presented the SROs with guidelines for additional means for providing the Commission with information regarding automation developments or enhancements and system outages, specifically: (1) Annual reports through which SRO technical staff would describe for Division staff the current automated system operations and planned changes; (2) SRO notification of the Division of significant changes to automated systems; and (3) real-time notification of significant interruptions of service in SRO automated trading systems.

approach may not address certain of the regulatory gaps discussed above in Section II. First, the broker-dealer approach may not ensure the fair treatment of investors by alternative trading systems. Second, as broker-dealers, these systems would continue to be required to comply with regulations designed for more traditional brokerage activities. For example, the operators of alternative trading systems would be subject to oversight and heightened surveillance by SROs, which may operate competing trading systems. Third, alternative trading systems, even those with a significant share of trading volume, would not be subject to provisions designed to address anticompetitive activities.

a. Alternative Trading Systems Would Not Be Subject to Requirements Designed to Assure Fair Treatment of Investors

In contrast to national securities exchanges, no regulatory redress exists for unreasonably discriminatory action taken by a broker-dealer operating an alternative trading system against a system participant or an applicant.[75] As discussed above,[76] the ability of these systems to unreasonably discriminate can have adverse ramifications for market participants. For example, if a significant percentage of institutional orders are entered into an alternative trading system, broker-dealers denied access to that system would lose the opportunity to interact with that institutional trading interest. They may also be denied the opportunity to display customer limit orders in a forum where they are most likely to be executed. Similarly, an alternative trading system that trades illiquid securities, such as limited partnerships or real estate derivatives, may provide the only efficient means of locating counterparties with which to trade in those securities. Investors denied access to such a system may have limited opportunity to trade those securities, particularly if other participants in the market primarily trade those securities through the alternative trading system.

Fair treatment of potential and actual participants becomes more important as alternative trading systems capture a larger percentage of overall trading volume and display consistently superior prices, particularly if there are no viable alternatives to trading on such systems. The importance of fair treatment by such systems is heightened during periods of significant market activity. Broker-dealer regulation may not provide meaningful redress for unfairly discriminatory acts taken by the operators of these systems. Even if the Commission were to require reporting of denials of access to a system or its services, investors might continue to be without regulatory redress for discriminatory actions.

Question 24: Is access to alternative trading systems an important goal that the Commission should consider in regulating such systems? If so, are there circumstances in which alternative trading systems should be able to limit access to their systems (for example, should the Commission be concerned about access to an alternative trading system that has arranged for its quotes to be displayed as part of the public quotation system)?

Question 25: If alternative trading systems were to continue to be regulated as broker-dealers and were subject to a fair access requirement, should the Commission consider denial of access claims brought by participants and non-participants in alternative trading systems? If not, are there other methods that could adequately address such claims?

Question 26: Are commenters aware of any unfair denials of access by broker-dealers operating alternative trading systems, where there were no alternative trading venues available to the entities denied access?

b. Broker-Dealers that Operate Alternative Trading Systems Will Still Be Required to Comply with Potentially Inapplicable Regulation and Be Subject to Oversight by SROs

Alternative trading systems are currently required to comply with regulation intended for traditional broker-dealer activities (*e.g.*, recommending investment strategies and holding customer funds and securities).[77] Moreover, they are subject to surveillance by SROs that operate their own trading systems that may compete with alternative trading systems. In the past, broker-dealers that operated alternative trading systems have been reluctant to comply with SRO requests for compliance data because of their concern that the SRO will use this confidential business data for purposes unrelated to regulatory oversight.

The broker-dealer approach described above contemplates enhancement of SRO oversight to integrate these systems into the mechanisms of the NMS, provide for adequate market surveillance of trading activity on these systems, and prevent fraud and manipulation. SROs may have concerns about the resources that would have to be dedicated to enhance surveillance of alternative trading systems. In addition, alternative trading systems may object to surveillance by the regulatory arm of those entities with which they compete for order flow. For example, alternative trading systems may be reluctant to fully disclose information about the operation of their trading systems to SROs that operate competing markets. Strict separation of market and regulatory functions within an SRO (which some SROs have already undertaken) may help alleviate concerns over whether information provided to the regulatory arm of an SRO could be used for competitive purposes.

It may be more desirable for alternative trading systems to be surveilled by an SRO not under the control of an entity that also operates a competing market. For example, under Section 15A of the Exchange Act, an association of brokers and dealers could establish an SRO that does not operate a market. Such an SRO could be established solely for purposes of overseeing the activities of unaffiliated markets. The Commission seeks comment on the advisability and feasibility of such an approach.

Question 27: Would enhanced surveillance of alternative trading systems by their SROs raise competitive concerns that could not be addressed through separation of the market and regulatory functions of the SROs?

Question 28: If alternative trading systems continue to be regulated as broker-dealers, are there other ways to integrate the surveillance of trading on alternative trading systems?

Question 29: What is the feasibility of establishing an SRO solely for the purpose of surveilling the trading activities of broker-dealer operated alternative trading systems, that does not also operate a competing market?

c. Alternative Trading Systems Will Be Free to Engage in Anticompetitive Activities

Broker-dealer regulation is not designed to address anticompetitive activities. If a traditional broker-dealer acts in an anticompetitive manner, investors and other market participants always have the option of dealing with another broker-dealer. If an alternative trading system operated by a broker-dealer captures a large market share and is a major forum for price discovery in a particular security, however, other

[75] Rule 17a–23 requires a sponsor of a broker-dealer trading system to provide the Commission with a description of the sponsor's criteria for granting access to the system. The Rule does not directly require meaningful disclosure of the underlying reasons for particular denials of access.

[76] *See supra* Section II.B.2.a.

[77] *See supra* Section II.B.1.

trading venues may not be comparable. As a result, anticompetitive activities by that system may have significant effects on investors and other markets.[78]

Because broker-dealers, unlike SROs, are not subject to non-discriminatory standards for access or fees, or prevented under the Exchange Act from using their market position to impose anticompetitive conditions, alternative trading systems that are regulated as broker-dealers would not be restricted from engaging in anticompetitive activities that have a negative impact on investors and other markets.[79]

Question 30: If alternative trading systems continue to be regulated as broker-dealers, how can the Commission address anticompetitive practices by such systems?

5. Conclusion

The approach to regulating alternative trading systems discussed above, which would continue to regulate alternative trading systems as broker-dealers, appears to address some of the Commission's concerns regarding transparency, surveillance, and capacity of alternative trading systems, while balancing business needs of the alternative trading systems. In addition, regulation of the operators of alternative trading systems as broker-dealers has in the past been supported by sponsors of such systems as an appropriate way to regulate, and as a means of fostering the development of, these systems.[80] Similarly, some SROs have expressed their support for basing the regulation of alternative trading systems on the regulation of their sponsors as broker-dealers.[81]

Question 31: Would this approach be an effective means of addressing the issues raised by the growth of alternative trading systems? What would be the benefits of such an approach? What would be the drawbacks of such an approach?

B. Integrating Alternative Trading Systems into Market Regulation Through Exchange Regulation

As discussed above, regulation of alternative trading systems as broker-dealers may not address all of the issues raised by the activities of such systems. A second approach might integrate such systems more fully into market regulation: Rather than continuing to regulate alternative trading systems as broker-dealers, the Commission could use the exemptive authority granted under the 1996 Amendments[82] to explore new approaches to the regulation of exchanges.[83] In particular, under this approach, the interpretation of the term ''exchange'' could be broadened to include *any organization that both: (1) Consolidates orders of multiple parties; and (2) provides a facility through which, or sets material conditions under which, participants entering such orders may agree to the terms of a trade.* This expanded interpretation would significantly broaden the entities that are considered to be exchanges to include currently registered exchanges, certain broker-dealer trading systems (including matching and crossing systems), currently exempted exchanges, certain dealer markets, and other alternative trading systems. For example, this interpretation would capture systems such as Instinet, Tradebook, Island, and Terra Nova's Archipelago system, that operate as electronic limit order books, allowing participants to display buy and sell offers in particular securities and to obtain execution against matching offers contemporaneously entered or stored in the system. In addition, systems that consolidate orders internally for crossing or matching with display to participants such as POSIT, and organized dealer markets (unless operated by a registered securities association) that consolidate orders and set material conditions under which orders can be executed, would also be encompassed by such an interpretation. While interdealer brokers in municipal and government securities could be exempted from any revised interpretation of ''exchange,'' fully automated interdealer brokers would be covered by this interpretation.[84] Any such reinterpretation of ''exchange'' presumably would not be intended to include customary brokerage activities or the activities of information vendors.

The Commission could then use its exemptive authority under section 36 of the Exchange Act[85], as described below, to create a new category of exchanges that are exempt from most statutory exchange registration requirements and are subject only to limited obligations designed to address specific concerns related to their market activities. More significant alternative trading systems could be integrated into the exchange regulatory scheme, with exemptions for such systems from those exchange requirements that are unnecessary or inappropriate for proprietary, automated systems.

At the same time, this type of an approach could potentially open the door for competing exchanges to use national market systems as a vehicle to inhibit innovation by alternative trading systems. For example, it is possible that existing exchanges could try to use participation in joint national market system mechanisms to set marketwide operational standards (as conditions of participation in the national market system plans) that have the effect of inhibiting innovation by alternative

[78] For example, following adoption of the 1975 Amendments, the Commission reviewed SRO rules to confirm that they were in compliance with the Exchange Act as amended. Among other things, the Commission identified several rules that it considered to be anticompetitive in violation of the Exchange Act, such as rules that restricted the types of entities with which their members could trade. *See* Securities Exchange Act Release No. 13027 (Dec. 1, 1976), 41 FR 53557 (Dec. 7, 1976).

[79] Exchange regulation addresses potentially anticompetitive activities through the Commission's oversight of SROs and through the rule filing process. For example, a primary registered market could institute an after-hours trading halt for purposes of news dissemination, but fail to remove that halt until the re-opening of its own facilities the following trading day, even if sufficient time has passed to permit the dissemination of the news. In that situation, the Commission could act to ensure that the registered market was not instituting a trading halt to prevent competitors from engaging in after-hours trading in its securities.

[80] *See, e.g.,* Letter from Daniel T. Brooks, Cadwalader, Wickersham & Taft (counsel to Instinet), to Jonathan G. Katz, SEC (Aug. 2, 1989) at 29 (''When properly analyzed * * * market structure concerns dictate that Instinet be regulated as a broker.'')

[81] *See, e.g.,* Memorandum accompanying Letter from James E. Buck, Senior V.P., NYSE, to Jonathan Katz, SEC (Aug. 2, 1989) at 2 (stating that a rule based approach to regulating alternative trading systems ''strikes a near optimal balance. It represents a significant improvement over the 'no-action' approach, and is significantly superior to the 'no-filing' approach, in retaining minimal regulatory 'costs' and yet maximizing the benefit to the markets.'').

[82] *See supra* note 68.

[83] In adopting the general exemptive authority included in the 1996 Amendments, the Report of the Senate Committee on Banking, Housing and Urban Affairs made specific reference to alternative trading systems: ''The Committee recognizes that the rapidly changing marketplace dictates that effective regulation requires a certain amount of flexibility. Accordingly, the bill grants the SEC general exemptive authority under both the Securities Act and the Securities Exchange Act. This exemptive authority will allow the Commission the flexibility to explore and adopt new approaches to registration and disclosure. It will also enable the Commission to address issues related to the securities market more generally. For example, the SEC could deal with the regulatory concerns raised by the recent proliferation of electronic trading systems, which do not fit neatly into the existing regulatory framework.'' S. Rep. No. 293, 104th Cong., 2d Sess. 15 (1996).

[84] A more detailed discussion of the effects of a revised interpretation of ''exchange'' is provided in Section IV.B.3 *infra.*

[85] *See supra* note 68 for a discussion of the Commission's exemptive authority under Section 36 of the Exchange Act.

trading systems.[86] As discussed below,[87] the Commission would anticipate working with existing exchanges and Nasdaq to integrate alternative trading systems into the national market system without stifling their innovation.

Question 32: If the Commission reinterpreted the term ''exchange,'' are the factors described above (*i.e.*, (1) consolidating orders of multiple parties and (2) providing a facility through which, or setting conditions under which, participants entering such orders may agree to the terms of a trade) sufficient to include the alternative trading systems described above?

Question 33: Is broadening the Commission's interpretation of ''exchange'' to cover diverse markets, and then exempting all but the most significant of these new exchanges from registration, the most appropriate way to address the regulatory gaps discussed above and provide the Commission with sufficient flexibility to oversee changing market structures?

1. Creating a New Category Called ''Exempted Exchanges'' for Smaller and Passive Alternative Trading Systems

The Commission could create a new tier of exchange regulation for most alternative trading systems by expanding its interpretation of the term ''exchange,'' as discussed in greater detail in Section IV.B.3. below, and by exempting from registration alternative trading systems that, although captured within a broader interpretation of ''exchange,'' do not need to be subject to full exchange regulation (''exempted exchanges''). The Commission could then establish limited and narrowly tailored requirements for these exempted exchanges. Regulation as exempted exchanges could be appropriate for two types of alternative trading systems: (1) Systems that are small, start-up entities; and (2) systems that match or cross orders at a price that is primarily or wholly derived from trading on another market (''passive markets''). To the extent that these types of alternative trading systems have a sufficiently low impact on the market or do not establish the price of securities, they should have an insignificant effect on the market as a whole, which would not warrant exchange regulation.[88] At this time, all except the most significant alternative trading systems would appear to fall within one of these two categories.

These exempted exchanges could then be subject to limited requirements that are more appropriate than current broker-dealer regulation for the market activities of such systems, as discussed in Section IV.B.1.c. below. This approach also could address concerns regarding system capacity, confidentiality, integrity, and would clarify the regulatory treatment of alternative trading systems that fall within such a structure. Moreover, treating smaller alternative trading systems and systems with passive pricing mechanisms as exempted exchanges would provide an environment conducive to innovation, which could, in turn, reduce the cost of experimenting with innovative trading techniques.

Question 34: Are there any other categories of alternative trading systems that have sufficiently minimal effects on the public secondary market that they should be treated as exempted exchanges?

a. Low Impact Markets

Small alternative trading systems could be regulated as exempted exchanges under this approach. If the Commission expands its interpretation of ''exchange'' to include alternative trading systems, it would be able to exempt small markets from all exchange registration requirements under either Section 5 or section 36 of the Exchange Act.

Under section 5 of the Exchange Act, the Commission has the authority to exempt any exchange with a limited volume of transactions from registration as a national securities exchange, provided that it is not practicable and not necessary or appropriate in the public interest or for the protection of investors to require registration.[89] As noted in the Commission's 1991 order granting an exemption to AZX under this provision, the Exchange Act does not provide specific guidance as to the standard to use in determining whether an exchange has a limited volume of transactions. In considering the limited volume test, the Commission looked to anticipated transaction volume on AZX and compared this to the transaction volume of fully regulated national securities exchanges.[90] While the Commission's AZX order provides useful guidance, the Commission also is considering other ways of assessing whether an exchange has a limited impact on the overall market. In many circumstances, the impact that a particular volume has on the market will depend upon a number of factors, including the size and liquidity of the market for the type of security traded. For example, the Commission could use its authority under the 1996 Amendments to exempt small exchanges based on a market's limited share of the relevant market as a whole, rather than the number of its transactions. Similarly, the Commission could base an exemption determination on the dollar value of transactions effected on an exchange, or on other factors.

While an exemption would allow a new market to develop without unnecessary and costly regulatory burdens, if that market achieved a greater market presence, its exemption would no longer apply. Once a market has attained more than a significant level of business, such that it no longer can be considered to have a low impact on the securities market, it would no longer be eligible for treatment as an exempted exchange. Instead, it would be required to register as a national securities exchange and be subject to greater regulatory responsibilities and oversight. In order to give exempted exchanges that attain significant volume sufficient time to prepare for registration as a national securities exchange, it might be appropriate to allow exempted exchanges to delay registration as an exchange for up to one year after they consistently attain more than *de minimis* volume. Treatment of low impact markets as exempted exchanges could also allow existing exchanges that consistently fall below minimum volume levels for an extended period of time to deregister and instead comply with any requirements applicable to exempted exchanges.

Question 35: Should low impact markets be regulated as exempted exchanges, rather than as broker-dealers?

[86] For example, as discussed below, national securities exchanges participate in national market systems plans, which are jointly drafted and operated, and the terms of these plans must be approved by all of the markets that are plan participants. *See infra* Section IV.B.4. By specifying operational requirements that each exchange must meet in order to participate in the national market system mechanisms, these plans can have the effect of setting marketwide standards. As a result, these plans could be used to require newly registered exchanges to comply with particular trading increments, reporting methods, and fee arrangements, for example.

[87] *See infra* notes 163 to 169 and accompanying text.

[88] The integration of trading on exempted exchanges with public trade and quote reporting mechanisms could be accomplished by continuing to require broker-dealer participants in exempted exchanges to report trades to the primary market on which a security trades and to comply with the Commission's rules. Similarly, as a condition of exemption, these exchanges could be required to report trades between non-SRO member participants to an SRO designated by the Commission.

[89] 15 U.S.C. 78(e). In 1991, the Commission used this authority to exempt AZX from the requirement to register as an exchange. *See* AZX Exemptive Order, *supra* note 24.

[90] *Id.*

Question 36: What measure or measures should be used in determining whether a market has a low impact? What is the level above which an alternative trading system should not be considered to have a low impact on the market? At what level should an already registered exchange be able to deregister?

Question 37: Should an alternative trading system be considered to have a low impact on the market and be treated as an exempted exchange if it trades a significant portion of the volume of one security, even if the trading system's overall volume is low in comparison to the market as a whole?

Question 38: In determining whether an alternative trading system has a low impact, what factors other than volume should the Commission consider? Should this determination be affected if the operator of an alternative trading system was the issuer of securities traded on that system?

b. Passive Markets

The Commission also could treat passive markets as exempted exchanges. Passive markets are alternative trading systems that match or cross orders at a price that is primarily or wholly derived from trading on another market. For example, the POSIT system allows participants to enter unpriced orders, which other participants cannot view, and periodically crosses the orders. Any orders that match other trading interest in this periodic cross are executed at the mid-point of the bid/ask spread on the primary market for the security. Like traditional exchanges, these systems centralize orders and set the conditions under which participants agree to trade. Unlike active pricing markets, however, passive pricing systems do not establish the price at which securities trade on the system through the interaction of priced orders of sellers with priced orders of buyers, or through participant dissemination of quotes.

Question 39: Should passive markets be regulated as exempted exchanges, rather than as broker-dealers?

c. Requirements for Exempted Exchanges

As a general matter, regardless of their regulatory status, markets should comply with certain minimum requirements designed to clarify their obligations as markets and to prevent harm to investors or overall market integrity.[91] These requirements could be less burdensome than the broker-dealer regulation to which these markets are currently subject. This would continue to encourage the robust development of U.S. markets. In cases in which alternative trading systems do not also conduct customary brokerage activities, these conditions could replace the broker-dealer regulation to which alternative trading systems are now subject.[92]

Specifically, alternative trading systems seeking an exemption from exchange registration could file an application for exemption (including a system description) with the Commission prior to operation. The Commission could establish a time period in which an alternative trading system's application would automatically become effective, unless disapproved by the Commission. Under this procedure, disapproval of a system's exemptive application would probably be rare and limited to specific circumstances, such as where a controlling person of the system is subject to a statutory disqualification or where the system fails to meet one of the requirements to be an exempted exchange. In addition to an initial application, an exempted exchange could also be required to: (1) Notify the Commission in the event of a material change in operations or control; (2) maintain a record of trading through the system and make such information available to the Commission upon request; (3) implement procedures for surveillance of employees' trading comparable to those adopted by existing SROs to ensure that employees do not misuse confidential customer information for insider or manipulative trading; (4) cooperate with registered SRO investigations and examinations of the exempted exchange's participants; (5) report trades to one or more designated SROs, unless a trade is reported by a trade participant pursuant to its SRO membership obligations; and (6) require participants to make adequate clearance and settlement arrangements prior to participation in trading on the exempted exchange.[93]

Question 40: Are the requirements described above appropriate to ensure the integrity of secondary market oversight?

Question 41: Should any other requirements be imposed upon exempted exchanges, such as requirements that an exempted exchange provide fair access or establish procedures to ensure adequate system capacity, integrity, and confidentiality?

Question 42: Should requirements vary with the type of alternative trading system (*e.g.*, should passive systems be subject to different conditions than systems exempted on the basis of low impact)?

Question 43: Should the Commission require that securities traded on exempted exchanges be registered under section 12 of the Exchange Act? Should different disclosure standards be applicable to such securities if they are only traded on such exchanges?

2. The Application of Exchange Regulation to Alternative Trading Systems That Are Not Exempted Exchanges

If the term ''exchange'' is expanded to include alternative trading systems, alternative trading systems that have active pricing mechanisms and significant volume could be required to register as national securities exchanges.

In the past, the Commission avoided requiring alternative trading systems to register as exchanges because it had limited authority to tailor exchange regulation to diverse market structures and because the volume and number of alternative trading systems was relatively small.[94] In particular, prior to the adoption of the 1996 Amendments, the Commission had limited authority to reduce or eliminate the consequences of exchange registration for innovative systems.[95] In light of these limitations,

[91] The only currently exempted exchange, AZX, is subject to a number of exemption conditions. Among other things, it is required to provide the Commission with regular activity reports, adopt and implement procedures to surveil for potential insider trading or manipulative abuses by participants, and cooperate with the registered SROs. *See* AZX Exemptive Order, *supra* note 24, 56 FR at 8383.

[92] Based on the information that the Commission currently has regarding the activities of alternative trading systems, it believes that only a few of the systems that would be exempted exchanges also conduct customary brokerage functions. Regulation of broker-dealer activities and market activities being conducted by the same alternative trading system could be integrated. *See infra* Section IV.B.4.d.

[93] 15 U.S.C. 78*l*.

[94] Throughout the past 60 years, the Commission has attempted to accommodate market innovations within the existing statutory framework to the extent possible in light of investor protection concerns, without imposing regulation that would stifle or threaten the commercial viability of such innovations. For example, at various times prior to 1991, the Commission considered the implications of evolving market conditions on exchange regulation. *See* Securities Exchange Act Release No. 8661 (Aug. 4, 1969), 34 FR 12952 (initially proposing Rule 15c2–10); Securities Exchange Act Release No. 11673 (Sep. 23, 1975), 40 FR 45422 (withdrawing then-proposed Rule 15c2–10 and providing for registration of securities information processors); Securities Exchange Act Release No. 26708 (Apr. 13, 1989), 54 FR 15429 (reproposing Rule 15c2–10); and Securities Exchange Act Release No. 33621 (Feb. 14, 1994), 59 FR 8379 (withdrawing proposed Rule 15c2–10).

[95] Prior to adoption of the 1996 Amendments, the Commission's authority under the Exchange Act to reduce or eliminate negative consequences of

Continued

the Commission believed that regulating alternative trading systems as exchanges would stifle the development of such systems.

The 1996 Amendments, however, provide the Commission with considerable authority to exempt markets from provisions of the Exchange Act. Given this expanded authority, the Commission's past concerns that classification as an exchange would stifle innovation may no longer outweigh competing concerns regarding the need to establish a consistent, long-term approach to the regulation of alternative trading systems and to better integrate the most significant of these systems into the NMS.

a. Using the Commission's Exemptive Authority To Encourage Innovation and To Eliminate Barriers to Non-Traditional Exchanges

Alternative trading systems encompassed by a revised interpretation of the term ''exchange'' and not eligible for treatment as an exempted exchange could be subject to fundamental statutory requirements applicable to national securities exchanges, in order to ensure that the goals of market regulation are met. These non-traditional exchanges could be required, for example, to file an application for registration,[96] be organized and have the capacity to carry out the purposes of, and comply and enforce compliance with, the Exchange Act, the rules thereunder, and their own rules. These non-traditional exchanges may also need to ensure that they have rules designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to refrain from imposing any unnecessary or inappropriate burden on competition. In addition, they could be required to assure regulatory oversight of their participants, participate in national market systems, and take the public interest into account in administering their markets.

The Commission recognizes that these responsibilities would have significant consequences for non-traditional markets. For example, imposing SRO oversight obligations on existing proprietary systems would change the relationship between such systems and their participants significantly, and could raise transaction costs for participants. Alternative trading systems have adopted different corporate structures than the traditional non-profit, membership exchanges and generally have entered into primarily commercial relationships with their participants.[97] While expanding the common understanding of how exchanges operate and the functions that they perform, these developing market structures do not fit easily into the current regulatory scheme, which has been designed and applied primarily to non-profit, membership exchanges.

Prior to adoption of the 1996 Amendments, it was difficult to reconcile the private, commercial structure of these markets with the membership structure and public obligations traditionally assigned to national securities exchanges under the Exchange Act. For example, one reason the Commission has been hesitant to adopt an expansive interpretation of the term ''exchange'' is that it would impose a participant-controlled board of directors on these markets.[98] Applying exchange regulation to new markets could dictate their structure and could prevent them from adopting innovative means of carrying out exchange obligations.

There does not appear to be an overriding regulatory reason to require markets to adopt homogenous structures. To the contrary, Congress clearly intended the 1975 Amendments to encourage innovation by exchanges and recognized that future exchanges may adopt diverse structures.[99] Accordingly, the Commission could use its exemptive authority to relieve alternative markets from requirements it does not believe are critical to achieving the objectives of the Exchange Act. In particular, the Commission could permit institutions to access registered exchange facilities directly. In addition, the Commission could consider ways in which exchanges that are not participant-owned can meet fair representation requirements.

(i) The Commission Could Consider Permitting Institutional Access to Exchanges

Without exemptive relief, exchange registration would prevent alternative trading systems from serving their institutional customers. Historically, exchange members were individuals (and broker-dealers and other organizations affiliated with those individuals) that traded directly on the exchange floor and had an ownership interest in the exchange.[100] In keeping with this structure, many requirements applicable to registered exchanges pertain to their relationship with their ''members.'' [101] In addition, in order to

exchange registration was limited. For example, the Commission could only exempt an exchange from registration if the exchange had limited transaction volume. *See* Exchange Act section 5, 15 U.S.C. 78e. Once an exchange was registered, the Commission only had authority to exempt an exchange from a limited number of requirements relating to an exchange's obligations as an SRO. Although the Commission has authority under various sections of the Exchange Act (including Sections 17 and 19) to exempt a registered exchange from specific provisions, its exemptive authority under these sections relates only to an exchange's obligations as an SRO to oversee its members. These sections do not give the Commission flexibility with respect to other requirements, such as the obligation of an exchange to file rule changes with the Commission for approval. The Exchange Act also did not give the Commission the flexibility or authority to tailor regulation to reflect technological and economic differences among markets. For example, although Congress gave the Commission greater flexibility to address rapidly changing market and technological conditions when it added Section 11A to the Exchange Act in the 1975 Amendments, that section does not provide the Commission with authority to reduce or eliminate existing exchange requirements for innovative trading structures. S. Rep. No. 75, *supra* note 23, at 3.

[96] Pursuant to Section 19(a)(1) of the Exchange Act, when an applicant submits an application to register as a national securities exchange under section 6 of the Exchange Act, the Commission must publish a notice of the filing and within ninety days must either grant the registration or institute proceedings to determine whether the registration should be denied. Proceedings for a denial of registration must be concluded within one hundred eighty days, with an extension period available of up to another ninety days. 15 U.S.C. 78s(a)(1).

[97] This effect has not been limited to U.S. alternative trading systems. In the seven years since the Delta Decision, *see infra* note 124, a growing number of stock exchanges throughout the world have adopted fully automated structures similar to those of alternative trading systems and appear to conduct trading without a specialist or market maker structure. The Commission determined in the Delta Release, *see infra* note 121, that the definition of the term exchange in section 3(a)(1) of the Exchange Act requires the Commission to view an entity as an exchange *only if*, in ''bringing together purchasers and sellers,'' the entity performs the functions commonly understood to be performed by exchanges. This reading is based on the view that the words ''bringing together purchasers and sellers'' in the definition cannot be read in a vacuum, but must be read in the context of how exchanges commonly operate. At the time that the Delta Release was issued, few exchanges had adopted structures similar to alternative trading systems.

[98] *See* Delta Release, *infra* note 121, at 1900. The court in the Delta Decision stated that: ''The Delta system cannot register as an exchange because the statute requires that an exchange be controlled by its participants, who in turn must be registered brokers or individuals associated with such brokers. So all the financial institutions that trade through the Delta system would have to register as brokers, and [the system sponsors] would have to turn over the ownership and control of the system to the institutions. The system would be kaput.'' Delta Decision, *infra* note 124, at 1272–73.

[99] *See* S. Rep. No. 75, *supra* note 22, at 7–9.

[100] *See* Special Study, *supra* note 4, at 11–13.

[101] The Exchange Act defines an exchange 'member' as: ''The term ''member'' when used with respect to a national securities exchange means (i) any natural person permitted to effect transactions on the floor of the exchange without the services of another person acting as broker, (ii) any registered broker or dealer with which such a natural person is associated, (iii) any registered broker or dealer permitted to designate as a

give the Commission adequate authority over persons trading on exchanges under section 6(c)(1) of the Exchange Act, Congress prohibited exchanges from granting membership to any person that is not, or is not associated with, a registered broker-dealer.[102] Taken together, these statutory provisions have traditionally been interpreted to mean that all persons trading on an exchange would be members of that exchange, and would be registered as, or associated with, broker-dealers.[103]

Alternative trading systems do not fit neatly into this structure for several reasons. Unlike traditional exchanges that restrict membership to broker-dealers, most alternative trading systems give comparable access and trading privileges to both institutions and broker-dealers.[104] If all entities that have access to an alternative trading system are treated as ''members'' under the Exchange Act, section 6(c)(1) would prevent these systems from continuing to provide direct access to their institutional participants. On the other hand, if institutional entities that have access to an alternative trading system are not treated as members, the system's statutory obligations that pertain expressly to its ''members'' under the Exchange Act would not apply to those institutions, and provisions of the Exchange Act that apply primarily to exchange members, such as prohibitions regarding the trading of unlisted securities under section 12, would no longer apply to all participants on an exchange. This could result in neither the Commission nor the market having sufficient authority to enforce trading rules against those participants. It could also lessen the effectiveness of oversight of trading on those markets. In either case, if such systems were registered as exchanges, the statute's reliance on the term ''member'' and the prohibition against exchange members that are not affiliated with a broker-dealer would make it difficult for alternative trading systems to continue meeting the trading needs of institutional investors. The Commission also notes that, as markets evolve, exchanges may ultimately wish to not only allow institutions to access their trading facilities along with broker-dealers, they may wish to provide trading facilities exclusively to institutions or other non-broker-dealer participants (such as retail investors).

There is no direct evidence that Congress intended these provisions to prohibit institutional investors from accessing the facilities of an exchange. On the contrary, in the course of adopting the 1975 Amendments, Congress saw no overriding regulatory reason to prohibit non-broker-dealers from obtaining direct access to the execution facilities of exchanges.[105] There also does not appear to be a regulatory need to require entities to register as broker-dealers in order to obtain direct access to exchanges.[106] Because institutions primarily trade for their own account, do not execute orders for unaffiliated customers, and do not undertake to maintain orderly markets for the exchange, institutional trading on an exchange does not necessarily raise the type of concerns that broker-dealer regulation was designed to address.[107]

Congress did, however, provide the Commission and exchanges with sufficient authority in such circumstances to oversee the trading of non-members on exchanges. Section 6(f) of the Exchange Act authorizes the Commission to require any non-member that is effecting transactions on an exchange without the services of another person acting as broker to comply with the rules of such exchange.[108] In addition, any person required by the Commission to comply with an exchange's rules pursuant to section 6(f) would be deemed a ''member'' of such exchange for most relevant provisions of the Exchange Act.[109] Congress therefore envisioned

representative such a natural person, and (iv) any other registered broker or dealer which agrees to be regulated by such exchange and with respect to which the exchange undertakes to enforce compliance with the provisions of this title, the rules and regulations thereunder, and its own rules.'' 15 U.S.C. 78c(a)(3)(A). The Commission notes that this definition does not require an entity to participate in the ownership of an exchange in order to be considered a statutory ''member'' of that exchange.

[102] Section 6(c)(1), 15 U.S.C. 78f(c)(1), prohibits exchanges from granting new memberships to non-broker-dealers. At the time this Section was adopted in 1975, one non-broker-dealer maintained membership on an exchange. This non-broker-dealer was not affected by the prohibition and continues to maintain its membership. Section 15(e) of the Exchange Act, 15 U.S.C. 78*o*(e), gives the Commission authority to require any member of a registered exchange that is not required to register with the Commission as a broker-dealer to comply with any provision of the Exchange Act (other than section 15(a)) and rules thereunder that regulate or prohibit any practice by a broker-dealer.

[103] As discussed below, however, despite this prohibition on non-broker-dealer membership in exchanges, Section 6(f) of the Exchange Act, 15 U.S.C. 78f(f), grants the Commission authority to require non-broker-dealers to comply with the rules of the exchange.

[104] Alternative markets also do not have ''members'' as that term has been traditionally understood and interpreted by existing exchanges. In particular, most alternative markets do not give their participants voting rights or other ownership interests. The Commission does not consider a non-profit membership structure to be an inherent requirement for performing the trading functions of an exchange.

[105] In the legislative history of the 1975 Amendments, Congress expressly noted that advances in communication technologies could permit an entity to trade on an exchange without the services of a member acting as a broker, and without itself becoming a member of that exchange. Reports by both the House of Representatives Committee on Interstate and Foreign Commerce and the Senate Committee on Banking, Housing and Urban Affairs noted the potential for technology to permit non-members (both broker-dealers and institutions) to effect transactions on exchanges without the intermediation of a broker. *See* S. Rep. No. 75, *supra* note 22, at 99 (1975) (''The Committee recognizes that it is impossible at this time to define precisely the manner in which investors, particularly large institutional investors will or should have access to execution facilities in a national market system.''); H.R. Rep. No. 123, *supra* note 39, at 66 (''[I]t is conceivable, that the regulatory reach could be extended to investors or money managers who are not themselves brokers or dealers but who have been permitted the means of making direct executions on an exchange'').

[106] *See, e.g.*, Securities Exchange Act Release No. 35030 (Nov. 30, 1994), 59 FR 63141 (Dec. 7, 1994) (order approving Chicago Match, an electronic matching system operated by the CHX, which provided for the crossing of orders entered by CHX members and non-members, including institutional customers).

[107] For example, expanding the Commission's interpretation of what constitutes an exchange to include alternative trading systems with institutional participants could subject such institutions to the constraints of section 11(a) of the Exchange Act. Section 11(a) generally prohibits exchange members from effecting transactions on such exchanges for their own accounts or the accounts of their associated persons, or for their own managed accounts or the managed accounts of their associated persons. 15 U.S.C. 78k(a). Section 11(a) was intended to encourage fair dealing and fair access in the exchange markets by restricting exchange members' proprietary trading, which Congress believed created a conflict between a member's interests as a principal and the member's fiduciary obligations when representing customer trades. Both Congress and the Commission provided exceptions to the rule to accommodate principal trading that does not conflict with the public interest.

Section 11(a) also granted the Commission broad authority to regulate exchange members' trading. Congress explained that it gave the Commission broad authority under section 11(a) for two reasons. First, Congress recognized that it lacked expertise in this area, and thus believed that any doubts should be resolved in favor of maintaining present business practices. Second, Congress wanted the Commission to have sufficient flexibility to accomplish the purposes of the Exchange Act. *See* S. Rep. No. 75, *supra* note 22, at 68.

[108] 15 U.S.C. 78f(f)(1).

[109] Section 3(a)(3)(A) of the Exchange Act provides that: ''For purposes of sections 6(b)(1), 6(b)(4), 6(b)(6), 6(b)(7), 6(d), 17(d), 19(d), 19(e), 19(g), 19(h), and 21 of this title, the term 'member' when used with respect to a national securities exchange also means, to the extent of the rules of the exchange specified by the Commission, any person required by the Commission to comply with such rules pursuant to section 6(f) of this title.'' 15 U.S.C. 78c(a)(3)(A). This would require a registered exchange that permitted institutions to effect transactions without the services of a broker, among other things, to: (1) Enforce compliance by such institutions with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the exchange; (2) allocate equitably its dues, fees, and other charges among its members, issuers, and such institutions; and (3) provide fair procedures for the disciplining of such institutions.

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that it would be possible to allow entities to have electronic access to an exchange without becoming a member, and at the same time, to ensure through section 6(f) that the exchange and the Commission have adequate authority to regulate such electronic access participants.

The development of fully automated markets has revealed an inconsistency in this scheme, however. Both the Commission and Congress have recognized that the ''floor'' of an exchange could include a non-physical trading system operated by such exchange.[110] As a result, any natural person with direct access to an exchange's alternative trading system would appear to be effecting transactions on the ''floor'' of such exchange and, therefore, would be a ''member'' of that exchange under the statute. Despite congressional intent not to unnecessarily restrict non-member access to exchanges under this interpretation, there would appear to be no circumstances in which institutions could electronically access an automated exchange without being considered ''members'' of that exchange.

In order to make it possible for alternative markets to register as exchanges, therefore, congressional intent to allow entities to have access to exchanges without becoming traditional members must be reconciled with the existence of non-physical ''floors.'' Any method of doing so must also ensure that, as Congress intended, exchanges and the Commission have sufficient authority to supervise and oversee all persons accessing an exchange's facilities.

There are at least two ways in which the Commission could achieve this. First, the Commission could interpret the term ''member'' narrowly, to apply only to natural persons who are permitted to effect transactions on a *physical* exchange floor.[111] Under this interpretation, no entity that accesses a fully automated exchange would be deemed a ''member'' of that exchange. In addition, both broker-dealers and institutions could electronically access exchanges that maintain physical floors without being deemed members of those exchanges. With respect to any such non-member participants on an exchange, the Commission could exercise its authority under section 6(f) of the Exchange Act to require the non-member participants of an exchange to comply with that exchange's rules to the extent appropriate. In addition, these non-member participants could be deemed members of such exchanges for certain purposes of the Exchange Act. Depending upon the extent to which the Commission exercised its authority under section 6(f), therefore, there may be little practical difference in an exchange's obligations to surveil traditional members and its obligation to surveil entities that are members by virtue of a Commission order pursuant to section 6(f).[112]

In the alternative, the Commission could interpret the term ''member'' broadly, to apply to any natural persons that are permitted to effect transactions through an exchange's facilities and any persons associated with such natural persons. Under this interpretation, the Commission could then use the exemptive authority granted by the 1996 Amendments to exempt exchanges from the prohibition on non-broker-dealer membership in section 6(c)(1) of the Exchange Act. The Commission could then allow exchanges to revise any rules that would not appropriately apply to non-broker-dealer members. Using this approach, the Commission would not be called upon to exercise its authority under section 6(f).

Question 44: Should the Commission allow institutions to be participants on registered exchanges to the same extent as registered broker-dealers? If so, should the Commission adopt rules allowing registered exchanges to have institutional participants, or should the Commission issue exemptive orders on a case-by-case basis, upon application for relief by registered exchanges?

Question 45: Should the Commission allow exchanges to provide services exclusively to institutions?

Question 46: If the Commission allows institutions to participate in exchange trading, should the Commission view all entities that have electronic access to exchange facilities as ''members'' under the Exchange Act and then exempt exchanges from section 6(c)(1)?

Question 47: Is it foreseeable that exchanges will wish to permit retail investors to be participants in their markets? If so, should the Commission allow retail participation on registered exchanges to the same extent as registered broker-dealers?

Question 48: Should the Commission allow registered exchanges to provide services exclusively to retail investors?

Question 49: Could exchanges have various classes of participants, as long as admission criteria and means of access are applied and allocated fairly? Would it be in the public interest if new or existing exchanges sought to operate primarily or exclusively on a retail basis? What would be the advantages and disadvantages if new or existing exchanges were to admit as participants only highly capitalized institutions or only highly capitalized institutions and broker-dealers?

(ii) The Commission Could Consider Ways in Which Alternative Exchanges Can Meet Fair Representation Requirements

An exchange's obligation to establish fair representation of investors and participants in its decisionmaking process could also significantly affect the structure of proprietary systems. Section 6(b)(3) of the Exchange Act compels an exchange to have rules that: (1) Provide that one or more directors is representative of issuers and investors, and not associated with a member of the exchange, or with any broker-dealer; and (2) ''assure a fair representation of its members in the selection of its directors and administration of its affairs.'' [113] Securities associations have identical fair representation requirements.[114] Because many alternative trading systems are operated as for-profit, non-membership

Exchange Act sections 6(b)(1), (4), (7) and 19(g), 15 U.S.C. 78f(b)(1), (4), (7), and 19(g). Further, an exchange imposing any disciplinary sanction on, denying participation to, or prohibiting or limiting access to any institution would be required to file notice of such action with the Commission. The Commission would have authority to review any such action. Exchange Act sections 19(d) and 19(e), 15 U.S.C. 78s(d) and 78s(e). The Commission would have the same authority to allocate among SROs regulatory responsibilities with respect to institutions effecting transactions on an exchange without the services of a broker as it currently does with respect to exchange members. Exchange Act section 17(d), 15 U.S.C. 78q(d). The Commission would also have the authority to sanction an exchange for failure to enforce compliance with the Exchange Act, the rules thereunder, or the exchange's rules by institutions that were permitted to effect transactions on the exchange, and to commence an investigation under section 21 to determine whether any such institution has violated the Exchange Act. Exchange Act section 21, 15 U.S.C. 78u.

[110] *See* Committee on Interstate and Foreign Commerce Report, H.R. Rep. No. 123, *supra* note 39, at 66 (1975) (''As the market systems make greater use of communications and data processing techniques, the concept of a physical 'floor' of an exchange will disappear. Instead we will have a communications network which will serve as the 'floor' of the future marketplace'').

[111] Persons trading on the physical floor of an exchange, such as floor brokers and specialists, would continue to be ''members'' of that exchange under any construction of the Exchange Act.

[112] In these circumstances, it is not clear how provisions of the Exchange Act that are by their terms applicable only to exchange members or broker-dealers would apply to non-broker-dealers that access exchange facilities. For example, sections 11(a) and 9(b) would not appear to apply directly to non-member participants in exchanges.

[113] Exchange Act section 6(b)(3), 15 U.S.C. 78f(b)(3).

[114] Exchange Act section 15A(b)(4), 15 U.S.C. 78*o*–3(b)(4).

corporations, complying with these representation obligations would potentially change the nature of their operations and relationship with their participants.

With respect to the first requirement, the public's interest in ensuring the fairness and stability of significant markets was of paramount importance to Congress, which adopted a structure that seeks to ensure this through public representation on an exchange's board of directors. Under this structure, fair representation of the public on an oversight body that has substantive authority and decisionmaking ability therefore may be critical to ensure that an exchange actively works to protect the public interest and that no single group of investors has the ability to systematically disadvantage other market participants through use of the exchange governance process.[115]

The second requirement, that of fair representation of an exchange's members, also serves to ensure that an exchange is administered in a way that is equitable to all market members and participants. Because a registered exchange is not solely a commercial enterprise, but also has significant regulatory powers with respect to its members,[116] competition between exchanges may not be sufficient to ensure that an exchange carries out its regulatory responsibilities in an equitable manner. The fair application of an exchange's authority to bring and adjudicate disciplinary procedures may be particularly important in this respect, because these actions can have significant and far-reaching ramifications for broker-dealers. Accordingly, under the Exchange Act structure, it may be essential to give exchange participants equitable and enforceable input into disciplinary and other key processes to prevent them from being conducted in an inequitable, discriminatory, or otherwise inappropriate fashion.

The Commission has not, however, interpreted an exchange's obligation to provide fair representation of its members to mean that all members must have equal rights. Instead, the Commission has allowed registered SROs a degree of flexibility in complying with this requirement. For example, Pacific Exchange ''electronic access members'' (''ASAP Members'') do not have voting rights, and therefore are not represented on the board of that exchange.[117] In addition, with respect to clearing agencies, the Commission has stated that registered clearing agencies may employ several methods to comply with the fair representation standard.[118] Other structures may also provide independent, fair representation for an exchange's constituencies in its material decisionmaking processes, for exchanges that are not owned by their participants. For example, an alternative trading system that registers as an exchange might be able to fulfill this requirement by establishing an independent subsidiary that has final, binding responsibility for bringing and adjudicating disciplinary proceedings and rule making processes for the exchange, and ensuring that the governance of such subsidiary equitably represents the exchange's participants.[119]

Question 50: Should non-membership exchanges (including alternative trading systems that may register as exchanges) be exempt from fair representation requirements?

Question 51: Should all exchanges be required to comply with section 6(b)(3) by having a board of directors that includes participant representation?

Question 52: If not, are there alternative structures that would provide independent, fair representation for all of an exchange's constituencies (including the public)?

3. Expanding the Commission's Interpretation of ''Exchange''

To create a new category of exempted exchanges and to apply exchange registration requirements to the most significant alternative trading systems, the Commission would have to expand its current interpretation of ''exchange'' to encompass many more trading systems than are currently considered ''exchanges.'' Although the Exchange Act definition of ''exchange'' is potentially quite broad,[120] the Commission currently interprets this definition to include only those organizations that are ''designed, whether through trading rules, operational procedures or business incentives, to centralize trading and provide buy and sell quotations on a regular or continuous basis so that purchasers and sellers have a reasonable expectation that they can regularly execute their orders at those price quotations.'' [121] The Commission analyzed how the definition of exchange applies to alternative trading systems in a 1991 release, explaining its decision not to register a government options trading system as an exchange (''Delta Release'').[122] The Commission concluded that, in light of congressional emphasis on the ''generally understood'' meaning of stock exchange and the Exchange Act as a whole, the definition of exchange should be applied narrowly, to include only those entities that enhanced liquidity in traditional ways through market makers, specialists, or a single price auction structure.[123] Because most alternative

[115] *See* NASD 21a Report, *supra* note 20.

[116] *See supra* Section II.B.1.

[117] *See* Securities Exchange Act Release No. 28335 (Aug. 13, 1990), 55 FR 34106 (Aug. 21, 1990) (order approving rule change establishing electronic access memberships on the PSE, since renamed PCX).

[118] These methods include: (1) Solicitation of board of directors nominations from all participants; (2) selection of candidates for election to the board of directors by a nominating committee which would be composed of, and selected by, the participants or representatives chosen by participants; (3) direct participation by participants in the election of directors through the allocation of voting stock to all participants based on their usage of the clearing agency; or (4) selection by participants of a slate of nominees for which stockholders of the clearing agency would be required to vote their share. *See* Securities Exchange Act Release No. 14531 at 24 (March 6, 1978), 43 FR 10288 (March 10, 1978). *See also* Securities Exchange Act Release No. 16900 (June 17, 1980), 45 FR 41920 (June 23, 1980).

[119] The Commission notes that the proprietary exchange Easdaq, a recognized secondary market in Belgium, has established a ''regulatory authority'' that has a degree of independence from Easdaq's board of directors.

[120] The Exchange Act defines an ''exchange'' as: ''any organization, association, or group of persons, whether incorporated or unincorporated, which constitutes, maintains, or provides a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange as that term is generally understood, and includes the market place and the market facilities maintained by such exchange.'' 15 U.S.C. 78c(a)(1).

[121] *See* Securities Exchange Act Release No. 27611 (Jan. 12, 1990), 55 FR 1890, 1900 (Jan. 19, 1990).

[122] *Id.* In 1988, the Commission granted Delta Government Options Corporation (''Delta'') temporary registration as a clearing agency to allow it to issue, clear, and settle options executed through a trading system operated by RMJ Securities (''RMJ''). Concurrently, the Commission's Division of Market Regulation issued a letter stating that the Division would not recommend enforcement action against RMJ if its system did not register as a national securities exchange. Subsequently, the Board of Trade of the City of Chicago and the Chicago Mercantile Exchange petitioned the U.S. Court of Appeals for the Seventh Circuit for review of the Commission's actions. Both challenges were premised on the view that RMJ's system unlawfully failed to register as an exchange or obtain an exemption from registration. The Seventh Circuit vacated Delta's temporary registration as a clearing agency, pending publication of a reasoned Commission analysis of whether or not RMJ's system was an exchange within the meaning of the Exchange Act. *Board of Trade v. SEC*, 883 F.2d 525 (7th Cir. 1989). In 1989, the Commission solicited comment on the issue, and in 1990 published its interpretation of the term ''exchange'' and its determination that RMJ's system did not meet that interpretation. *See* Delta Release, *supra* note 121.

[123] *See* Delta Release, *supra* note 121, at 1900. The Commission stated: ''In summary, employing an expansive interpretation of section 3(a)(1) results

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trading systems do not have these features, this narrow interpretation effectively excluded most alternative trading systems from exchange regulation.[124] Thus, many alternative trading systems have not been required to register as exchanges to date and have instead been regulated as broker-dealers.

There are, however, several alternative ways in which the definition of ''exchange'' could be applied more broadly.[125] For example, a large variety of services performed by existing markets and intermediaries could be considered to be functions that are commonly understood to be performed by exchanges within the meaning of section 3(a)(1) of the Exchange Act. Those services include: (1) Centralizing trading interest; (2) providing the opportunity for multiple parties to participate in trading; (3) specifying time, price, size, or other priorities governing the sequence or interaction of orders; (4) providing an opportunity for active price formation (either through interaction of buy and sell interest or through competing dealer quotes); (5) specifying material conditions under which participants may post quotations or trading interest (such as requiring participants to maintain firm, two-sided, or continuous quotes); (6) creating mechanisms for enhancing liquidity, such as giving certain participants special privileges in exchange for assuming market obligations; (7) giving participants control over setting the trading rules; and (8) setting qualitative standards for listing instruments or otherwise standardizing the material terms of instruments traded. Various commenters have identified these and other functions as central characteristics of exchanges.[126]

Each of these functions is performed by existing exchanges and could be incorporated into the Commission's interpretation of the term ''exchange.''[127] Because alternative trading systems do not always offer each of these services, however, if alternative trading systems are integrated into market regulation mechanisms through exchange regulation, a revised interpretation of the term ''exchange'' based on whether a market offers all, or many, of these functions would continue to exclude many alterative trading systems. For example, the application of the term exchange could be broadened to include those entities that provide the opportunity for multiple parties to participate in centralized trading. While many alternative trading systems provide a central execution system, others organize trading by centralizing the display of participant trading interest, and then specifying the sequence or priorities under which participants must trade with each other. Although orders may not directly interact on such markets, the order and price at which they are executed is determined by the market. The fairness of this procedure

in potential conflicts with other central regulatory definitions under the (Exchange) Act as well as adverse effects on innovation and competition. Rather, each system must be analyzed in light of the statutory objectives and the particular facts and circumstances of that system. In conducting such an analysis, the central focus of the Commission's inquiry should be whether the system is designed, whether through trading rules, operational procedures or business incentives, to centralize trading and provide buy and sell quotations on a regular or continuous basis so that purchasers and sellers have a reasonable expectation that they can regularly execute their orders at those price quotations. The means employed may be varied, ranging from a physical floor or trading system (where orders can be centralized and executed) to other means of intermediation (such as a formal market making system or systemic procedures such as a consolidated limit order book or regular single price auction).'' *Id.*

[124] The Commission's authority to adopt this narrow interpretation was subsequently upheld by the U.S. Court of Appeals for the Seventh Circuit. *Board of Trade of the City of Chicago v. SEC,* 923 F.2d 1270 (7th Cir. 1991)*, reh'g en banc, den'd,* (7th Cir. 1991) (hereinafter Delta Decision). The court noted that ''the Delta system differs only in degree and detail from an exchange . . . Section 3(a)(1) (of the Exchange Act) is broadly worded. No doubt . . . this was to give the Securities and Exchange Commission maximum control over the securities industry. So the Commission could have interpreted the section to embrace the Delta system. But we do not think it was compelled to do so.'' *Id.* at 1273 (quoting *Chevron v. Natural* Resources Defense Council, 467 U.S. 837, 844–45 (1984)). In reaching its decision, the court gave weight to the Commission's belief that classifying the Delta system as an exchange would have destroyed its commercial viability. The court also relied in part on the Commission's position that, because Delta would be registered as a clearing agency and the system sponsor would be a registered broker-dealer, there did not appear to be any overriding regulatory need to regulate the system as an exchange. Delta Decision, *supra* at 1273. The court stated that the Commission ''can determine . . . whether the protection of investors and other interests within the range of the statute is advanced, or retarded, by placing the Delta system in a classification that will destroy a promising competitive innovation in the trading of securities.'' *Id.* Since 1991, the Commission staff has given operators of trading systems assurances, based on the interpretation upheld by the court in *Delta,* that it would not recommend enforcement action if those systems operated without registering as exchanges. For a list of no-action letters issued to system sponsors until the end of 1993 and a short history of the Commission's oversight of such systems, see Securities Exchange Act Release No. 33605 (Feb. 14, 1994), 59 FR 8368, 8369–71 (Feb. 18, 1994) (hereinafter Rule 17a–23 Proposing Release). *See also* Letters from the Division of Market Regulation to: Niphix Investments Inc. (Dec. 19, 1996); Tradebook (Dec. 3, 1996); The Institutional Real Estate Clearinghouse System (May 28, 1996); Chicago Board Brokerage, Inc. and Clearing Corporation for Options and Securities (Dec. 13, 1995).

[125] The Exchange Act, coupled with relevant legislative history, appears to provide the Commission with ample authority to revise its interpretation of an exchange. Courts have consistently upheld an agency's discretion to revise earlier interpretations when a revision is reasonably warranted by changed circumstances. *See, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 186 (1991). In *Rust,* the Court stated that ''an initial agency interpretation is not instantly carved in stone, and the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis. *Id.* at 186 (quoting *Chevron* v. *Natural Resources Defense Council,* 467 U.S. 837, 844–45 (1984)). The Court also stated that ''an agency is not required to 'establish rules of conduct to last forever,' but rather 'must be given ample latitude to adapt its rules and policies to the demands of changing circumstances.'' ' *Id.* at 186–87 (quoting *Motor Vehicles Mfrs. Ass'n of United States* v. *State Farm Mut. Automobile Ins. Co.,* 463 U.S. 29, 42 (1983)).

[126] *See, e.g.,* Robert A. Schwartz, *Technology's Impact on the Equity Markets* (Future Markets: How Information Technology Shapes Competition (C. Kremerer ed., forthcoming 1997)) (''In the U.S., an exchange is an environment where broker/dealer *intermediaries,* not natural buyers and sellers meet. In contrast, broker/dealer member firms provide the services (information analysis and dissemination, provision of dealer capital, order handling, account handling etc.) that bring the customer to the market to trade.''); Ruben Lee, *What is an Exchange?* (1992) (available from author) (regulators should consider 25 attributes when determining whether a trading system is an exchange, including price discovery, liquidity, competition of orders, price priority, secondary priorities, information access, and centralized order execution); Therese Maynard, *What is an ''Exchange''?—Proprietary Electronic Securities Trading Systems and the Statutory Definition of an Exchange,* 49 Wash. & Lee L. Rev. 833 (1991); J. Harold Mulherin et al, *Prices are Property: The Organization of Financial Exchanges from a Transaction Cost Perspective,* 34 J. of Law & Econ. 591 (Oct. 1991) (the establishment of property rights to price quotes is a central function of financial exchanges, although the authors do not discount the fact that exchanges accomplish many other functions); Lawrence Harris, *Liquidity, Trading Rules, and Electronic Trading Systems* (1990) (available from author) (exchanges provide services by creating an environment that encourages traders to offer liquidity, often by establishing a set of rules that provide liquidity suppliers protection in proportion to the service that they provide to the market); Jonathan Macey & Hideki Kanda, *The Stock Exchange as a Firm: The Emergence of Close Substitutes for the New York and Tokyo Stock Exchanges,* 75 Cornell L. Rev. 1007 (1990) (in addition to liquidity, organized stock exchanges offer three other services (monitoring, devising standard form contracts, and lending reputational capital to listing firms) that listing firms view as valuable); Ian Domowitz, *An Exchange is a Many Splendored Thing: The Classification and Regulation of Automated Trading Systems,* in The Industrial Organization and Regulation of the Securities Industry 93 (Andrew W. Lo ed., 1996) (the price discovery process with the associated dissemination of price information, and centralization for the purpose of trade execution are the basic functions of trading systems). *See also* Ruben Lee & Ian Domowitz, *The Legal Basis for Stock Exchanges: The Classification and Regulation of Automated Trading Systems* (1996) (available from authors) (there should be no distinction in the regulation of market structure issues between institutions now classified as exchanges and those now classified as broker-operated trading systems).

[127] For example, as noted above, the Commission's current interpretation captures the functions of centralizing trading interest, providing the opportunity for multiple parties to participate in trading, and providing mechanisms to enhance liquidity, such as giving certain participants special privileges in return for assuming market obligations.

will affect participants in those markets no less than the fairness of procedures on an exchange that allows orders to interact centrally.

Similarly, an exchange could be defined as only those entities that provide an opportunity for active price formation (either through interaction of buy and sell interest or through competing dealer quotes). This criteria would capture automated matching systems, such as Instinet, Tradebook, Island and Terra Nova's Archipelago system, but would not include crossing systems that establish a price based on the price already established in another market, such as POSIT, within the term ''exchange.'' Whether or not a market engages in active price formation, however, is not the sole factor that may determine a market's potential to harm investors through unfair treatment or vulnerability to manipulation. Moreover, markets without active price discovery still have the potential to affect the integrity of trading and surveillance on other markets. Depending upon its configuration, for example, a passive pricing system can provide incentives for its participants to manipulate prices in the market from which the passive price is derived in order to affect the outcome of a cross. Finally, while there is general consensus that active price formation occurs through the interaction of orders, there is little consensus on whether the interaction of orders through negotiation, such as occurs within a broker-dealer, should also be considered to be price formation.[128] As market changes continue to affect how securities trade, basing the interpretation of the term ''exchange'' on whether a market engages in price discovery could generate significant uncertainties for markets that develop innovative pricing mechanisms.[129] Therefore, if the Commission expands its interpretation of the term ''exchange,'' it could be appropriate to include passive markets in such an interpretation. Under such an approach, passive markets could be integrated into market regulation by regulating such systems as exempted exchanges.

Reinterpreting the term ''exchange'' based on other traditional exchange functions may have similar drawbacks. For example, unlike existing exchanges, few alternative markets give certain participants special privileges in return for assuming market obligations, give participants control over setting the trading rules, or set listing standards.[130] Moreover, while many exchanges currently provide the services noted above, it is not certain that exchanges will always do so in the future.[131] As a result, if alternative trading systems were integrated into market regulation through exchange regulation, rather than broker-dealer regulation, basing a revised interpretation of ''exchange'' on these traditional functions could result in the same regulatory gaps and lack of flexibility that the current situation has created.

For these reasons, if the Commission were to revise its interpretation of ''exchange,'' it would also consider focusing such a reinterpretation primarily on those essential functions commonly provided by registered exchanges and alternative markets, in order to achieve congressional intent to regulate central marketplaces for securities trading. For example, the Commission could revise its interpretation of the term ''exchange'' to include *any organization that both: (1) Consolidates orders*[132] *of multiple parties; and (2) provides a facility through which, or sets material conditions under which, participants entering such orders may agree to the terms of a trade.* This revised interpretation would closely reflect the statutory concept of ''bringing together'' buying and selling interests. It would also broaden the Commission's concept of what is ''generally understood'' to be an exchange to reflect changes in the U.S. and world markets brought about by automated trading.[133]

Question 53: Would the revised interpretation of ''exchange'' being considered by the Commission adequately and clearly include alternative trading systems that operate open limit order execution systems (even those that also provide brokerage functions)?

Question 54: In light of the decreasing differentiation between market maker quotes and customer orders in trading, should the Commission consider an ''order'' to include any firm trading interest, including both limit orders and market maker quotes?

Question 55: What should the Commission consider to be ''material conditions'' under which participants entering orders may agree to the terms of a trade? For example, should an alternative trading system be considered to be setting ''material conditions'' when it standardizes the material terms of instruments traded on the market, such as standardizing option terms or requiring participants that display quotes to execute orders for a minimum size or to give priority to certain types of orders?

a. Effects of Expanding the Commission's Interpretation of ''Exchange'' on Selected Types of Alternative Trading Systems

One of the principal advantages of expanding the Commission's interpretation of the term ''exchange'' would be to provide sufficient flexibility within the concept of an exchange to encompass both currently registered exchanges and significant existing alternative trading systems, as well as unforeseen alternative trading systems that may arise in the future. At the same time, the Commission has consistently maintained that the definition of exchange should not be interpreted so

[128] *Compare* Lawrence A. Cunningham, *From Random Walks to Chaotic Crashes: The Linear Genealogy of the Efficient Capital Market Hypothesis,* 52 Geo. Wash. L. Rev. 546, 597 (1994) (''price discovery in capital markets arises solely as the result of traders'' orders meeting in the market''); *with* M. Perry, *A Challenge Postponed: Market 2000 Complacency in Response to Regulatory Competition for International Equity Markets,* 34 Va. J. Int'l L. 701, 740 (1994) (''It is not clear whether 'price discovery' means price negotiation between the trading parties or price determination by the market'').

[129] For example, one trading system currently in development, OptiMark, allows participants to enter entire portfolios of securities at a range of prices and sizes at which they would be willing to trade if a variety of other factors are met. It is not clear whether this type of contingent pricing mechanism could be considered ''active price formation.''

[130] Although many alternative trading systems limit trading to securities traded on a registered exchange or Nasdaq, they do not establish or enforce qualitative or quantitative independent listing standards or require that securities be registered under the Exchange Act.

[131] *See, e.g.,* Gerald Novak, *A Failure of Communications: An Argument for the Closing of the NYSE Floor,* 26 U. Mich. J.L. Reform 485, 503 (1993) (while specialists may create enough benefit to the market to allow them to exist within the current regime, the benefits do not seem substantial enough to maintain the physical exchanges solely for the purpose of perpetuating the role of the specialist.) *See also* Norman S. Poser, *Restructuring the Stock Markets: A Critical Look at the SEC's National Market System,* 56 N.Y.U.L. Rev. 883, 956–57 (1981) (arguing for the elimination of the present specialist system in favor of an institutionalized specialist function).

[132] As noted above, the term ''orders'' in this release is intended to be read broadly, to include any firm trading interest. This would include both limit orders and market maker quotations.

[133] *See, e.g.,* AZX Exemptive Order, *supra* note 24; Internet Site of the Australian Stock Exchange, address: http://www.azx.com.au (Dec. 5, 1996) (orders entered on the Australian Stock Exchange are automatically matched and executed through SEATS, a screen based trading system); Internet Site of SIMEX, address: http://www.simex.com (Nov. 6, 1996) (the Singapore International Monetary Exchange is a complete, integrated electronic trading system, which uses an order matching system based upon the use of a matching algorithm reflecting strict price/time priority for all orders entered into the system). In addition, Tradepoint, a recognized investment exchange in the United Kingdom, operates as an order driven, automated system for the trading of shares of U.K. issuers listed on the London Stock Exchange without the use of market makers or specialists.

broadly as to overlap or interfere with other sections of the Exchange Act, such as those governing broker-dealer activities or securities associations. For example, at the time of the Delta Release, the Commission sought to avoid interpreting the term ''exchange'' in a way that could unintentionally and inappropriately subject many broker-dealers to exchange regulation.[134] Therefore, if the Commission decides to broaden its interpretation of ''exchange'' to encompass alternative trading systems, it would have to take into account the potential effects of such an interpretation on entities regulated under other sections of the Exchange Act. This may include entities that provide traditional brokerage activities (*e.g.,* traditional block trading desks or internal programs that allow traders within a firm to search and match orders with customer orders of other traders within the same firm), information vendors, and markets operated by the NASD. For example, the Commission would not intend any revised interpretation of ''exchange'' to capture traditional brokerage activities or the internal automation of traditional brokerage activities. Similarly, it may be inappropriate for a revised interpretation of ''exchange'' to capture certain alternative trading systems, such as interdealer brokers in exempted securities, that are regulated under separate regulatory schemes. Discussed below are the possible effects of an expanded interpretation of ''exchange'' on these market participants.

(i) Broker-Dealer Activities

In light of the blurring distinctions between the services offered by markets and market participants described above,[135] the differences between modern exchange and broker-dealer activities are not easily articulated. Some firms have integrated technology into their activities in ways that appear to have much in common with the trading systems used by modern exchanges. Nonetheless, broker-dealer activities can be distinguished from those of an exchange for several reasons.

First, unlike organized markets, traditional broker-dealer activities do not involve the systematic interaction of customer orders where the customers themselves are informed of and have an opportunity to agree to the terms of their trades (or agree to the priorities under which the terms will be set). For example, broker-dealers may automate part of their intermediary function (such as block trading desk activity) by developing internal programs that allow traders within a firm to search and match orders with customer orders of other traders within the same firm, or with orders and quotes of other traders. Similarly, technologically sophisticated firms may create an internal process for centralizing information regarding customer orders. Such systems, however, generally serve as a means of providing information regarding a firm's customer orders solely to the employees of the broker-dealer operating the system to facilitate the employees' crossing of customer orders on a discretionary basis. In other words, the only participant in such a system is the broker-dealer that operates it. Similarly, while block trading desks provide a central location where employees of a single broker-dealer trade side-by-side, they do not systematically consolidate the customer orders handled by those employees. Although an employee may ultimately match its customer order with a customer order held by a trader sitting across the room, this does not operate as an organized mechanism for ensuring that customer orders are matched, crossed, or otherwise centralized.

Second, a broker-dealer traditionally retains discretion in determining how to handle customer orders. Unlike an exchange, which customers access in part to participate in a particular market or market structure, a customer that gives its order to a broker-dealer typically gives discretion to that broker-dealer regarding which market the order will ultimately be executed in, how the order may be split up or ''worked,'' or whether the broker-dealer will choose to execute the order as principal or as agent. Although a broker-dealer may disclose its standard practices to customers, ultimately these execution decisions are left to the discretion of the broker-dealer, consistent with the responsibilities imposed on broker-dealers. For example, a block positioner may ''shop'' the order around to other traders in his own firm in an attempt to find a contra-side order that has been placed with another trader. In some cases, the block positioner may take the other side of the order, keeping the block as a proprietary position. This decision is dictated by market conditions and typically lies within the block positioner's discretion. Unless otherwise agreed, customers have no rights regarding the system other than the expectation that the broker-dealer will handle the order according to its broker-dealer obligations.

Finally, a sophisticated market maker that develops a system to broadcast its own quotations to the public, or to allow its customers to direct orders for execution solely against that market maker's inventory, is conducting broker-dealer activity. Such systems automate the order routing and execution mechanisms of a single market maker and guarantee that the market maker will execute orders submitted to it at its own posted quotation for the security or, for example, at the inside price quoted on Nasdaq. Single market maker systems merely provide a more efficient means of communicating the trading interest of separate customers to one dealer and thus would not be considered exchange activities.

As noted above, much of this analysis assumes that these activities are being engaged in ''systematically,'' or in a ''traditional'' or ''typical'' fashion. The Commission recognizes that these concepts are not easily defined and that this approach will leave many issues and gray areas to be resolved. The Commission is soliciting comment on how any revised interpretation of the term exchange could clearly distinguish between these activities and those of alternative trading systems.

Question 56: Is it appropriate for the Commission to consider the activities described above as broker-dealer activities?

Question 57: How should a revised interpretation of exchange adequately and clearly distinguish broker-dealer activities, such as block trading and internal execution systems, from market activities?

Question 58: Are the distinctions discussed above accurate reflections of exchange and broker-dealer activities? Are there other factors that may better distinguish a broker-dealer from an exchange?

(ii) Organized Dealer Markets

The term ''exchange,'' as articulated above, would encompass organized dealer markets that operate systems to consolidate participant orders for display, and set material conditions under which orders can be executed (including automatically executing

[134] One key factor in the Commission's decision not to regulate the Delta system as an exchange was the concern that, absent greater exemptive authority, doing so would subject traditional broker-dealer activities to exchange regulation. Delta Release, *supra* note 121. Although some alternative trading systems claim to be the modern analog of traditional brokerage activity, the Commission believes that, while some are, the nature of systems that combine the functions of brokers and exchanges cannot be so readily simplified.

[135] *See supra* notes 14 and 14 and accompanying text.

orders).[136] As discussed in the Delta Release, dealer markets have traditionally consisted of loosely organized groups of individual dealers that trade securities OTC, without formal consolidation of orders or trading. Historically, the majority of trading in corporate, government, and municipal debt instruments has been conducted through such OTC dealers. Individual dealers in such markets generally do not directly ''bring together'' public purchasers and sellers. The court and the parties in the Delta Decision[137] assumed that the term ''exchange,'' as that term is generally understood, would not apply to such a loosely organized market. The approaches described above continue the notion that the definition of ''exchange'' should not cover such loosely organized traditional dealer markets and that broker-dealer regulation should continue to govern individual dealers in those markets.[138] As individual dealers and associations of dealers have employed technology to make OTC markets more efficient, however, dealer markets in certain instruments have become organized to such an extent that they have assumed many of the characteristics of exchange markets. This is particularly true in markets that trade instruments that are also listed on registered exchanges, such as equity securities. For example, Nasdaq consolidates trading interest of multiple dealers on a screen that is displayed real-time to its members, and provides a mechanism for dealers to update displayed quotations. The NASD also imposes obligations on market makers in Nasdaq National Market and SmallCap securities to provide a continuous source of liquidity in Nasdaq, establishes minimum qualifications that issuers must meet in order for their securities to be quoted on the consolidated screen, and sets enforceable rules that govern the priorities dealers must give to certain orders. Through additional services, such as SelectNet, Nasdaq also allows dealers to trade with orders electronically. In other words, a group of market participants, through Nasdaq, act in concert to centralize and disseminate trading interest and establish the basic rules by which securities will be traded on Nasdaq. Because the NASD is already registered as a securities association, the Nasdaq market would not need to be regulated as an exchange. The Commission, however, could consider whether entities that operate similar markets in the United States should be considered exchanges under any expanded interpretation if they are not operated by a registered securities association.

Question 59: How should a revised interpretation of the term ''exchange'' adequately and clearly distinguish broker-dealer activities, such as block trading and internal execution systems, from market activities?

Question 60: What factors should the Commission consider in determining whether an organization of dealers is sufficiently ''organized'' to require exchange registration?

(iii) Information Vendors and Bulletin Boards

The Commission is also concerned that any revised interpretation of the term ''exchange'' not be so broad as to encompass those entities that provide information, but do not provide a central facility for executing trades or set conditions governing trading. Information vendors and ''bulletin boards'' often provide a centralized display of general trading interest, comments, or other information regarding trading, but they generally do not enable customers to communicate directly with each other, execute orders, or otherwise agree to the terms of a trade through their facilities. These entities also do not establish the conditions under which customers negotiate or trade based on displayed information.[139] Because these entities centralize information without standardizing trading based on such information, the approach described above would not regulate these entities as exchanges if they do not allow for execution through their system or set conditions of trading.

The Commission recognizes that the difference between an exchange and an electronic bulletin board depends on the functions that they make available. For instance, a passive bulletin board that merely provides names and addresses of prospective buyers and sellers and the prices at which they are willing to buy or sell would not be an exchange because it would not set priorities that govern trades, and transactions resulting from posted indications of interest, if any, would be executed outside the system. If a system created an electronic link between multiple potential buyers (*e.g.*, a ''chat room''), however, it could be considered to be providing a facility through which participants entering orders may agree to the terms of a trade (*e.g.*, an exchange). The Commission requests comment on whether such a system should be considered to be an exchange, particularly if the customer orders displayed on the system are firm, or if the system specifies the priorities for customer interaction through the electronic linkage or ''chat room.''[140]

Question 61: Does the revised interpretation of ''exchange'' described above clearly exclude information vendors, bulletin boards, and other entities whose activities are limited to the provision of trading information? How should the Commission distinguish between information vendors, bulletin boards, and exchanges?

(iv) Interdealer Brokers

Certain markets that are not centrally organized by a single entity are nonetheless informally organized around interdealer brokers,[141] which display the bids and offers of other dealers anonymously. The importance and role of these interdealer brokers has changed significantly in the past twenty years. While interdealer brokers traditionally had relatively small volume, they are now key players in the government and municipal securities

[136] The only dealer market in the United States that currently appears to both consolidate participant quotes and set conditions governing execution is the Nasdaq market, operated by the NASD. As discussed below, because the NASD is already registered as a securities association, the Commission would not intend for any revised interpretation of ''exchange'' to include the Nasdaq market. The Commission, however, could consider whether other entities that operate similar markets in the United States should be considered exchanges under any expanded interpretation, unless they were also operated by a registered securities association.

[137] *See* Delta Decision, *supra* note 124.

[138] For example, commercial paper trades through several large dealers that disseminate their own quotes to their customers and make a two-sided market in the paper of various issuers. Trading in the commercial paper market is highly concentrated among a few large dealers, some of which provide automated quotation screens for their customers. Unlike an exchange market, however, no entity currently attempts to centralize trading interest by reflecting multiple dealer quotes, or by setting conditions under which the commercial paper of differing issuers may be traded by dealers.

[139] Commission staff has previously indicated that it would not recommend enforcement action if a system operated by an issuer that does not allow transactions to be executed on the system, and that is designed to provide limited information to buyers and sellers of stock, does not register as an exchange. *See* Letter from Catherine McGuire, Martin Dunn, and Jack Murphy, SEC, to Barry Reder, Coblentz, Cahen, McCabe & Breyer, LLP (June 24, 1996) (counsel to Real Goods Trading Corporation).

[140] In addition, it is possible for an information vendor to provide its services by linking its screens to execution facilities provided by other entities with which the vendor has a contractual arrangement. In these circumstances, the information vendor may be captured by the proposed revised interpretation of the term ''exchange,'' depending upon the nature of the services provided.

[141] As used in this release, the term ''interdealer brokers'' includes entities that are referred to as brokers'' brokers and blind brokers in certain markets.

markets,[142] and have begun to operate in other instruments as well. Today, interdealer brokers provide liquidity by providing a central mechanism to display the bids and offers of multiple dealers and by allowing dealers and investors to trade large volumes of securities anonymously and efficiently based on those bids and offers. In the government securities market, for example, interdealer brokers compile and display the anonymous bids and offers of other government securities dealers and traders on screens located in the dealers' offices. Dealers call an interdealer broker via telephone to display their quote information or to execute against a displayed quotation.[143] Automated brokers' brokers in the secondary market for municipal securities operate in a similar manner, disseminating centralized quotation information and executing trades for their customers by telephone.[144]

Operating in this manner, interdealer brokers centralize trading interest and provide a mechanism for agreeing to the terms of a trade in much the same way as registered exchanges and alternative markets do. Interdealer brokers in these markets may also determine certain trading practices.[145] This is a significant change from the way interdealer brokers operated just 30 years ago, when they disseminated last sale information to customers individually, rather than centrally, and operated under less formalized procedures.

Like block trading desks, interdealer brokers now have certain elements in common with markets, but have also retained some of their traditional characteristics. For example, although interdealer brokers do not give advice, they exercise some discretion in matching and executing orders of their dealer customers.[146] Commenters have suggested that these features should distinguish traditional interdealer brokers to some extent from markets that establish priorities for executing participant orders or that otherwise set conditions governing trading between participants. Because interdealer brokers have begun to display quotations in real-time to their customers, centralize the negotiation of trading, and establish conventions under which trading will occur, the issue is whether this difference has become primarily one of degree.[147] Individual brokers at an interdealer broker, in many respects, perform similar functions to exchange specialists. Moreover, if an interdealer broker automated its activities fully, there would appear to be little difference between its activities and those of existing alternative trading systems. Given this evolution, the Commission could consider whether interdealer brokers should be considered exchanges under a revised interpretation.

If the Commission determines that the activities of interdealer brokers should be encompassed by a revised interpretation of ''exchange,'' it could consider whether to use its exemptive authority to exclude those interdealer brokers that trade exempted securities [148] from exchange registration requirements. As noted in the Delta Release, Congress has given no indication that it intended to subject traditional interdealer brokers in the government and municipal securities markets to exchange regulation.[149] Moreover, regulation of traditional interdealer brokers in government and municipal securities as exchanges may not be necessary or appropriate in the public interest at this time, in light of the specialized oversight structures for these markets. Both the government and municipal securities markets are overseen through special regulatory schemes that are tailored to the particular features of those debt markets. Government securities broker-dealers are overseen jointly by the U.S. Department of the Treasury (''Treasury''), the Commission, and federal banking regulators, under the Exchange Act (particularly the provisions of the Government Securities Act of 1986) and the federal banking laws.[150] Municipal securities broker-

[142] Trading by interdealer brokers began to become popular in the government securities market, after trading had moved from the NYSE to the over-the-counter market in the 1920s and the demise of trading agreements in the mid-1950s that had previously provided a foundation for interdealer business. *See* U.S. Congress, Joint Economic Committee, a Study of the Dealer Market for Federal Government Securities 21–26, 49–53 (1960); U.S. Department of the Treasury and U.S. Federal Reserve, Treasury-Federal Reserve Study of the Government Securities Markets 95–100 (1959). By 1972, interdealer brokers handled approximately 14% of the trading of government securities by dealers; by 1990, interdealer brokers handled more than 50% of such business. *See* Marcia Stigum, The Money Market 644–56 (3d ed. 1990).

[143] Dealers and other customers have direct telephone lines to the various individual brokers working at an interdealer broker. The individual brokers typically handle one to three customers each, depending upon activity levels. When customers wish to buy or sell a security through an interdealer broker, they call the individual broker assigned to them at that interdealer broker. Through their assigned broker, customers can hit a bid or take an offer already shown on the screen, tell the broker to post a new, better bid or offer on the screen, or give the broker other information about their activities and trading needs. When customers wish to hit a quote on the screen or enter a new quote, the broker taking that information announces the hit or new bid/offer to other brokers (who are taking information from other customers), and the broker or other staff enter the information so that it is displayed on internal and customer screens. Trading supervisors within the interdealer broker mediate disputes, such as which broker called out an order first. *See generally* U.S. Department of the Treasury, Report of the Secretary of the Treasury on Specialized Government Securities Brokers and Dealers (1995) (hereinafter 1995 Treasury Report); U.S. Securities and Exchange Commission, 1994 Annual Report 29–30 (1994); U.S. Department of the Treasury, U.S. Securities and Exchange Commission, and Board of Governors of the Federal Reserve System, Joint Report on the Government Securities Market 26 (1992) (hereinafter 1992 Joint Report); Stigum, *supra* note 142; U.S. General Accounting Office, U.S. Government Securities: More Transaction Information and Investor Protection Are Needed, 19, 97–100 (1990); U.S. General Accounting Office, U.S. Government Securities: An Examination of Views Expressed About Access to Brokers' Services 28–35 (1987).

[144] See Division of Market Regulation, U.S. Securities and Exchange Commission, Staff Report on the Municipal Securities Market 17–22 (1993) (hereinafter Municipal Securities Report). *See also* Securities Exchange Act Release No. 37998 (Nov. 29, 1996), 61 FR 64782 (Dec. 6, 1996) (Commission approval order for Municipal Securities Rulemaking Board proposals to increase transparency in the municipal securities market); U.S. Securities and Exchange Commission, 1995 Annual Report 31 (1995).

[145] Generally, a broker considers a bid or offer placed with it good until canceled, but the conditions under which they are subject to variation is a matter left up to each interdealer broker. For example, usually, ''when the (Federal Reserve) comes into the market, all bids and offers (become subject to reaffirmation). However, when some key economic number is released, some brokers make the market (subject to reaffirmation), others don't; in this area, there are no formal rules.'' Stigum, *supra* note 142, at 647.

[146] *See* 1992 Joint Report, *supra* note 143, at A9–A11.

[147] ''The government brokers run what amounts to an unlicensed exchange. In the 20-odd years that governments have been brokered, the way in which that exchange operates has slowly changed. At the outset, brokers phoned runs to dealers, then in 1977 to 1978, the era of screens began.'' Stigum, *supra* note 142, at 655. The following quote from a dealer also supports the Commission's view: ''Also, dealers came to view the brokers as just one more place, along with the Chicago pits, to trade—just another place to get business done.'' *Id.* at 652.

[148] Exempted securities are defined in section 3(a)(12) of the Exchange Act to include government securities and municipal securities, among other things. 15 U.S.C. 78c(a)(12).

[149] *See* Delta Release, *supra* note 121, at 1898 n.87.

[150] *See* 1995 Treasury Report, *supra* note 143. ''Under the regulatory structure established by the Government Securities Act of 1986, as amended in 1993, the Treasury was given rulemaking authority over all brokers and dealers in government securities. Specifically, the Treasury was designated by Congress as the sole rulemaker for specialized government securities brokers and dealers (33 firms as of March 1995) and was given rulemaking authority for the government securities activities of financial institutions that filed notice as government securities brokers and dealers (approximately 300 as of January 1995). The Treasury and the SEC have overlapping rulemaking responsibilities for the government securities activities conducted by general securities brokers and dealers (15(b) firms) which numbered about 2,231 as of March 1995. The (Government Securities Act) granted the Treasury the authority

dealers and transactions in municipal securities are overseen by the Commission, the Municipal Securities Rulemaking Board (''MSRB''), the NASD, and the federal banking regulatory authorities under the Exchange Act (particularly section 15B) and the federal banking laws. Unlike equities and other instruments traded primarily on registered exchanges,[151] surveillance of trading in government and municipal securities is not conducted by entities that operate competing markets in those instruments. Instead, surveillance of the government securities market is coordinated among the Treasury, the Commission, and the Board of Governors of the Federal Reserve System. In the municipal securities market, Congress established the MSRB as an SRO for broker-dealers in municipal securities; unlike SROs in other markets, however, the MSRB does not operate a market and was not given inspection or enforcement powers. Surveillance of the municipal securities market for fraud and market manipulation is conducted by the Commission and the NASD.[152]

As a result of these specialized oversight structures, regulation of particular market participants in the government and municipal securities markets as broker-dealers, rather than as exchanges, is not likely to weaken coordination of overall market oversight or create competitive inequities among differently regulated entities that perform similar functions. For these reasons, if the Commission expands its interpretation of ''exchange'' to cover interdealer brokers generally, it could consider expressly exempting traditional government and municipal securities interdealer brokers that trade exempted securities from exchange registration.

It should be noted that the above analysis is based on existing mechanisms for supervising trading in government and municipal securities markets, and on current trading practices of interdealer brokers in such markets. In the event that an interdealer broker automates its services more completely, or operates in a manner more similar to an equity market, for example, this analysis could be reevaluated. Similarly, the above analysis would not apply to derivatives of government and municipal securities.

Question 62: If the Commission expands its interpretation of ''exchange,'' should the Commission exempt interdealer brokers that deal only in exempted securities from the application of exchange registration and other requirements?

Question 63: How could the Commission define interdealer brokers in a way that would implement congressional intent not to regulate traditional interdealer brokers as exchanges, without unintentionally exempting other alternative trading systems operated by brokers?

4. Effect of Broadening the Definition of ''Exchange''

Reinterpreting the definition of ''exchange'' to apply to a broader range of entities would have significant effects, not only on those alternative trading systems classified as exchanges, but also on the securities trading on those exchanges, currently registered exchanges, the NMS, clearance and settlement mechanisms, and market participants. In particular, substantial work would be necessary to ensure that newly registered exchanges could be smoothly integrated into existing market structures.

a. Regulation of Securities Trading on Alternative Trading Systems

Classifying alternative trading systems as exchanges could affect the trading of securities on these systems, particularly on those systems that are required to register as national securities exchanges. Securities traded on a national securities exchange must be registered with the Commission and approved for listing on the exchange, or traded pursuant to Commission regulations governing trading of securities listed on another exchange (''unlisted trading privileges'' or ''UTP''). These requirements are critical to ensuring that securities trading on exchanges provide investors with adequate information and that all relevant trading activity in a security is reported to, and surveilled by, the exchange on which such security is listed.

Specifically, section 12(a) of the Exchange Act makes it unlawful for any member, broker, or dealer to effect any transaction in any security (other than an exempted security) on a national securities exchange unless a registration statement is in effect as to such security for such exchange in accordance with the provisions of the Exchange Act and the rules and regulations thereunder.[153] Under this requirement, upon registration as exchanges, alternative trading systems that are currently trading unregistered securities could no longer freely trade those securities.[154]

In addition, national securities exchanges are permitted to trade securities listed on other exchanges and Nasdaq only pursuant to UTP regulations, which limit the range of securities that they may trade.[155] Like all exchanges, a newly registered exchange would be required to have in place rules for trading the class or type of securities it seeks to trade.[156] To trade Nasdaq/National Market (''NM'') securities, a newly registered exchange would also be required to become a signatory to an existing plan governing such trading.[157] Moreover, under section 12(f) of the Exchange Act, exchanges cannot trade securities not registered on an exchange or classified as NM securities (such as Nasdaq SmallCap or other OTC securities) without Commission action. Section 12(f) of the Exchange Act authorizes the Commission to permit the extension of UTP to any security registered otherwise than on an exchange. The OTC–UTP plan,[158] which permits UTP for Nasdaq/NM securities, is the only extension approved to date by the Commission.[159] Thus, exchanges cannot currently trade Nasdaq SmallCap, other OTC securities, or exempted securities that are not separately listed on the exchange. This restriction would also apply, absent Commission action, to alternative

to promulgate rules and regulations for each of these entities concerning financial responsibility, protection of investor securities and funds, recordkeeping and financial reporting, and audits.''

Id. at 3.

[151] Although all marketable Treasury notes, bonds, and zero-coupon securities are listed on the NYSE, exchange trading volume is a small fraction of the total over-the-counter volume in these instruments. *See* 1992 Joint Report, *supra* note 143.

[152] Coordinated surveillance of secondary trading in municipal securities is still developing. The MSRB, under the Commission's supervision, has authority to issue rules governing, among other things, professional qualifications, recordkeeping, quotations, and advertising of municipal securities broker-dealers. Enforcement of MSRB rules is divided between banking regulatory agencies (for banks) and the NASD (for non-bank firms), with the Commission having authority over all municipal securities dealers, as well as non-bank municipal securities broker-dealers. *See* Municipal Securities Report, *supra* note 144, at 37. Recently, the Commission approved an MSRB rule change designed to increase the information available about municipal securities and to provide a centralized audit trail of municipal securities transactions. *See* Securities Exchange Act Release No. 37998 (Nov. 29, 1996), 61 FR 64782 (Dec. 6, 1996).

[153] 15 U.S.C. 78*l*(a). Section 12(b), 15 U.S.C. 78*l*(b), contains procedures for the registration of securities on a national securities exchange.

[154] Section 12(a) does not apply to exchanges that the Commission has exempted from registration as national securities exchanges, although the Commission could consider whether it would be appropriate to limit trading on exempted exchanges to securities registered under section 12 of the Exchange Act. *See* AZX Exemptive Order, *supra* note 24. *See also* Securities Exchange Act Release No. 37271 (June 3, 1996), 61 FR 29145 (June 7, 1996).

[155] Exchange Act § 12(f), 15 U.S.C. 78l(f).

[156] Exchange Act Rule 12f–5, 17 CFR 240.12f–5.

[157] *See* OTC–UTP plan, *infra* note 168.

[158] *See infra* note 168 and accompanying text.

[159] *Id.*

trading systems newly registered as exchanges.[160]

These restrictions would have a significant effect on newly registered exchanges. Most alternative trading systems do not independently list securities; securities traded on such systems are generally unlisted or listed on another market. As a result, in order to comply with Exchange Act requirements applicable to national securities exchanges, such systems would need to establish listing procedures and comply with Commission regulations governing unlisted trading privileges. Under the tiered approach to regulating alternative trading systems, the ability of such systems to trade a wide range of securities would be subject to the same UTP conditions as currently registered exchanges. In order to minimize some of these effects, the Commission could consider expanding the category of securities that would be available for UTP trading.

Integrating a broader range of entities into the UTP structure could also affect existing exchange rules, such as NYSE Rule 390 and similar offboard trading restrictions, designed to limit members from effecting OTC transactions in exchange-listed stocks.[161] For example, transactions that are executed through alternative trading systems currently may be considered to be OTC transactions. If significant alternative trading systems were to register as exchanges, activity on those systems could no longer be considered to be OTC. Consequently, rules that expressly prohibit OTC transactions in listed securities by their terms would no longer apply to activity on those alternative trading systems and, as a result, the number of transactions subject to the prohibition of such rules would decrease. The Commission is soliciting comment on whether there would be any customer protection or competitive reasons to preserve these offboard trading restrictions if the interpretation of ''exchange'' is broadened to include alternative trading systems and highly organized dealer markets.

Question 64: How could the Commission foster the continued trading of all securities currently traded on alternative trading systems if these systems are classified as exchanges under the interpretation described above and some of these systems are required to register as national securities exchanges? For example, what would be the effect on alternative trading systems that wish to trade securities exempted from registration under Rule 144A if those systems are required to register as national securities exchanges?

Question 65: How would the requirement to have rules in place for trading unlisted securities affect the viability of alternative trading systems that are required to register as national securities exchanges?

Question 66: Would the specifications in the OTC–UTP plan relating to the trading of Nasdaq/NM securities pose particular problems for systems that are required to register as national securities exchanges?

Question 67: Should the Commission extend UTP to securities other than NM securities, such as Nasdaq SmallCap securities? What effect would an inability to trade Nasdaq SmallCap and other non-Nasdaq/NM securities have upon alternative trading systems that are required to register as national securities exchanges?

Question 68: What effect would the prohibition on UTP trading of newly listed stock until the day following an initial public offering have upon systems that are required to register as national securities exchanges?

Question 69: How should existing exchange rules designed to limit members from effecting OTC transactions in exchange-listed stock be applied, if the Commission's interpretation of exchange were expanded to include alternative trading systems and organized dealer markets? What customer protection and competitive reasons might there be to preserve these rules if alternative trading systems are classified as exchanges?

b. Integration with National Market System Mechanisms and Existing Exchange Practices

A revised interpretation of the term ''exchange'' would not only affect currently registered exchanges and alternative trading systems required to register as exchanges, it could also have a significant impact on the NMS, coordination of market-wide trading policies, listing arrangements, and exchange rules governing member trading in the OTC market. There could also be significant effects on coordination of market-wide surveillance and enforcement efforts among national securities exchanges.

Because alternative trading systems differ in several key respects from currently registered exchanges, a number of issues would need to be resolved before these systems could be integrated into national market system mechanisms. Integrating newly registered national securities exchanges into the NMS mechanisms should not cause the homogenizing of all markets—to the contrary, it is as important today as it was in 1975 to cultivate an atmosphere in which innovation is welcome and possible. Such integration therefore could require revision of NMS mechanisms so that they could accommodate diverse and evolving markets. The Commission solicits comment, as discussed in greater detail below, on what revisions to the structure of NMS mechanisms might be necessary to accommodate alternative trading systems. The Commission also solicits comment on the costs and potential effects on innovation if alternative trading systems were linked to NMS mechanisms. In addition, the Commission solicits comment on the costs and potential effects if revisions to the NMS mechanisms were not effective.

Question 70: What effects would linking alternative trading systems to NMS mechanisms have on those systems? For example, how would such linkages affect the ability of alternative trading systems to operate with trading and fee structures that differ from those of existing exchanges or to alter their structures? To what extent could revision of the NMS plans alleviate these effects?

(i) Inter-Market Plans

If certain alternative trading systems were required to register as national securities exchanges, these systems would be expected to become participants in market-wide plans currently subscribed to and operated by registered exchanges and the NASD. All of the currently registered exchanges and the NASD participate in joint plans for transaction and quotation reporting: the CQS, the CTA, the ITS,[162] the

[160] National securities exchanges are also prohibited, pursuant to Exchange Act Rule 12f–2, from extending UTP to a security subject to an initial public offering (''IPO'') until the trading day following commencement of the IPO. Currently, pursuant to NASD rules, participants in the OTC market, including alternative trading systems, may trade securities subject to an IPO immediately after trading has opened on the listing exchange. NASD Manual Section 6440(j). If registered as an exchange, such entities would be subject to the one-day waiting period prior to trading securities subject to an IPO.

[161] For example, NYSE Rule 390 prohibits NYSE members from effecting certain transactions in NYSE-listed stocks in the OTC market. Exchange Act Rule 19c–1, however, prohibits the application of off-board trading restrictions to trades effected by a member as agent. 17 CFR 240.19c–1. Moreover, Exchange Act Rule 19c–3 prohibits the application of off-board trading restrictions to securities listed on an exchange after April 26, 1979. 17 CFR 240.19c–3.

[162] The CTA provides vendors and other subscribers (including alternative trading systems) with consolidated last sale information for stocks

Options Price Reporting Authority (''OPRA''),[163] and the Nasdaq/National Market System/Unlisted Trading Privileges (''OTC–UTP'').[164] These plans form an integral part of the NMS for the trading of securities, and contribute greatly to the operation of linked, transparent, efficient, and fair markets. In order for any newly registered national securities exchanges to become fully integrated into the NMS, it would be essential that the operations of those new exchanges and the market linkage systems be compatible. If the Commission revises its approach to regulation of alternative trading systems by requiring those with active pricing mechanisms and significant volume to register as national securities exchanges, it may have to take action to ensure the suitable and timely inclusion of new exchanges into the NMS.

(A) Quotation and Transacting Reporting

If certain alternative trading systems are required to register as national securities exchanges, they would be required to have effective quote and transaction reporting plans and procedures in place under section 11A of the Exchange Act.[165] The CTA and CQS plans, which are now operated by the eight national securities exchanges and the NASD, make quote and transaction information in exchange-listed securities available to the public. Both the CTA and the CQS plans have provisions governing the entry of participants to the plans.[166] According to the terms of the CTA plan, any national securities exchange or registered national securities association may become a participant of the CTA by subscribing to the CTA plan[167] and paying to the existing participants an appropriate amount for the ''tangible and intangible assets'' created under the plans that will be made available to the new participant. The CQS Plan has similar terms. Participants in the CTA and CQS plans share in the income and expenses associated with the provision of quotation information according to the terms of the plans.

Under the terms of the OTC–UTP plan governing trading of Nasdaq/NMS securities,[168] any national securities exchange where Nasdaq/NMS securities are traded may become a full participant thereunder. The plan specifically states that a new signatory must pay a share of development costs to become a participant in the plan. The plan provides for the collection, consolidation, and dissemination of quotation and transaction information for Nasdaq/NM securities, sets forth specifications for transmission of data to Nasdaq, and establishes procedures for market access, regulatory trading halts, cost allocation, and revenue sharing. Similarly, the OPRA plan approved by the Commission[169] provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. Under the terms of the plan, any national securities exchange whose rules governing the trading of standardized options have been approved by the Commission may become a party to the OPRA plan. The plan provides that any new party, as a condition of becoming a party, must pay a share of OPRA's start-up costs. It also provides for revenue sharing among all parties.

Given the breadth of these plans, existing plan participants would need to work expeditiously with newly registered exchanges to facilitate inclusion of these new exchanges into the NMS plans. Participation in these transaction reporting plans should not seriously impair the functioning of most alternative trading systems. If the Commission revised its approach to regulation of alternative trading systems by requiring those with active pricing mechanisms and high volume to register as national securities exchanges, it may have to take action to ensure the suitable and timely inclusion of new exchanges into these quotation and transaction reporting plans.

Question 71: Are there any insurmountable technical barriers to admission of alternative trading systems into the CTA, CQS, OPRA, or OTC–UTP plans?

Question 72: What costs are associated with the admission of new applicants to these plans?

Question 73: Are there any CTA, CQS, OPRA, or OTC–UTP plan rules that would prevent newly registered national securities exchanges from obtaining fair and equal representation on these entities?

Question 74: What effect would the admission of newly registered national securities exchanges to the CTA, CQS, OPRA, and OTC–UTP plans have upon the governance and administration of those plans?

Question 75: Do admissions fees for new participants required by the terms of the plans present a barrier to admission to the plans? Do the plans' provisions that all participants are eligible to share in the revenues generated through the sale of data affect commenters' views on this issue?

(B) Intermarket Trading System

It has been the Commission's longstanding policy that market centers trading listed stocks be linked. The current linkage, ITS, enables a broker or dealer who participates in one market to execute orders, as principal or agent, in an ITS security at another market center, by sending a commitment to execute with another market through the system. ITS also establishes a procedure that allows specialists to solicit pre-opening interest in a security from specialists and market makers in other markets, thereby allowing these specialists and market makers to participate in the opening transaction. Participation in an opening transaction can be especially important when the price of a security has changed since the previous close. Finally, ITS rules require that the members of participant markets avoid initiating a purchase or sale at a worse price than that available on another ITS

admitted to dealings on any exchange. The CQS gathers quotations from all market makers in exchange-listed securities and disseminates them to vendors and other subscribers. The ITS is a communications system designed to facilitate trading among competing markets by providing each market participating in the ITS pursuant to a plan approved by the Commission (''ITS plan'') with order routing capabilities based on current quotation information. *See, e.g.,* Securities Exchange Act Release Nos. 37191 (May 9, 1996), 61 FR 24842 (May 16, 1996); 17532 (Feb. 10, 1981), 46 FR 12919 (Feb. 18, 1981); 23365 (June 23, 1986), 51 FR 23865 (July 1, 1986) (Cincinnati Stock Exchange / ITS linkage); 18713 (May 6, 1982) 47 FR 20413 (May 12, 1982) (NASD's CAES / ITS linkage); 28874 (Feb. 12, 1991), 56 FR 6889 (Feb. 20, 1991) (Chicago Board Options Exchange / ITS linkage).

[163] *See infra* note 169 and accompanying text for a description of the OPRA plan.

[164] *See infra* note 168 and accompanying text for a description of the OTC–UTP plan.

[165] *See also* Exchange Act Rules 11Ac1–1(b)(1), 17 CFR 240.11Ac1–1(b)(1); 11Aa3–2(c), 17 CFR 240.11Aa3–2(c).

[166] The CTA plan also contains a provision for entities other than participants to report directly to the CTA as ''other reporting parties.'' Pursuant to this provision, parties other than a national securities exchange or association may be permitted to provide transaction data directly to the CTA.

[167] *See* Securities Exchange Act Release No. 37191 (May 9, 1996), 61 FR 24842 (May 16, 1996).

[168] *See* Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Exchange-listed Nasdaq/National Market System Securities and for Nasdaq/National Market System Securities Traded on Exchanges on an Unlisted Trading Privilege Basis (''OTC–UTP plan''). Securities Exchange Act Release No. 24407 (Apr. 29, 1987), 52 FR 17349 (May 7, 1987). Currently, the NASD, the CHX, and the Phlx are participants in the OTC–UTP plan. The BSE is a limited participant, and as such only reports quotation and transaction information for Nasdaq/NM securities that are also listed on the BSE. *See* Securities Exchange Act Release No. 36985, 61 FR 12122 (March 18, 1996).

[169] The OPRA plan was approved pursuant to Section 11A of the Exchange Act and Rule 11a3–2 thereunder. *See* Securities Exchange Act Release No. 17638 (Mar. 18, 1981) (hereinafter OPRA plan). The five exchanges which are participants in the OPRA plan are the Amex, the CBOE, the NYSE, the PCX, and the Phlx.

participant market (''trade-throughs'').[170] Participation in the ITS will give users of these new exchanges full access to, and enable them to execute transactions on other ITS participant markets. Moreover, participation in ITS will require new exchanges to comply with other applicable ITS rules and policies on matters such as, for example, trade-throughs, locked markets,[171] and block trades.[172]

Under an approach that involved broadening the interpretation of ''exchange,'' entities newly registered as national securities exchanges would be expected to sign the plan and become participants in ITS, or an equivalent system if one were developed.[173] Alternative trading systems, however, have developed differently than exchanges and often serve different constituencies. Some practices of alternative trading systems would undoubtedly conflict with the current provisions of the ITS plan, or would be incompatible with participation in ITS. For example, many alternative trading systems allow participants to trade in smaller increments than those available on current plan participants. Similarly, many alternative trading systems have institutional participants who may prefer to trade at an inferior price in order to trade in a larger size, resulting in a locked or crossed market. These characteristics are potentially incompatible with current ITS provisions. If the Commission were to adopt a revised approach to the regulation of alternative trading systems, it likely would be necessary to work with plan participants to accommodate diverse market structures in the plan.

Question 76: What effect would the admission of new, highly automated participants have upon the operation of the ITS?

Question 77: How would compliance with the current ITS rules and policies affect trading on alternative systems that may be regulated as exchanges? How appropriate are these rules and policies for alternative trading systems?

Question 78: What costs would be associated with newly registered exchanges joining ITS? Would those costs represent a barrier for newly registered exchanges to join ITS?

Question 79: Are there any ITS plan rules or practices that would prevent newly registered national securities exchanges from obtaining fair and equal representation on the ITS?

Question 80: What effect would the admission of newly registered national securities exchanges to the ITS plan have upon the governance and administration of the plan?

(ii) Uniform Trading Standards

The Commission is also considering how policies governing market-wide trading, such as trading halts and circuit breakers, would apply to alternative trading systems that register as exchanges. Registered national securities exchanges, the NASD, and the Commission each have the authority to impose trading halts for individual securities, for classes of securities, and on markets as a whole.[174] There are four types of trading halts: (1) Halts due to primary or regional market order imbalance, or operational problems; (2) regulatory halts (as a result of dissemination of material news); (3) halts due to data processing or telecommunications problems (*e.g.*, the inability to disseminate quotations or trade reports); and (4) Commission ordered halts. The existing registered exchanges and the NASD currently have different rules and procedures in place for applying trading halts, and a new interpretation of the term ''exchange'' would result in a broader application of these trading halts in some instances. Because many alternative trading systems are currently operated by registered broker-dealers, they are subject to NASD rules, including rules requiring them to comply with trading halts imposed by the NASD. If registered as national securities exchanges, however, such systems would be required to impose their own trading halts.[175] In addition, a trading system that was regulated as an exchange, would need to implement circuit breaker rules for extraordinary market volatility.

Question 81: What effect would the requirements to impose trading halts or circuit breakers in some circumstances have upon alternative trading systems if such systems were regulated as exchanges?

c. Oversight of Non-Broker-Dealers That Have Access to Exchanges and Clearance and Settlement of Non-Broker-Dealer Trades

As discussed above, Congress intended for an exchange that allowed non-broker-dealers to access its facilities to be responsible for overseeing the trading of such non-broker-dealers.[176] The scheme of self-regulation and market oversight codified in the Exchange Act relies primarily on trading markets to implement and operate market mechanisms for enforcing the federal securities laws and for ensuring that all market participants have adequate access to market information. This system may be able to function effectively only if all significant trading activity and market participants are supervised by an SRO. If entities can participate directly in the market in a significant way without being overseen by an SRO, market mechanisms designed to ensure transparency and to surveil for fraud and manipulation may not be fully effective. The Commission's findings in the NASD 21(a) Report, discussed above, demonstrate the problems that arise when trading occurs on markets that are not subject to effective market oversight.[177] Therefore,

[170] A trade-through occurs when an ITS participant purchases securities at a lower price or sells at a higher price than that available in another ITS participant market. For example, if the NYSE is displaying a bid of 20 and an offer of 20 ⅛ for an ITS security, the prohibition on trade-throughs would prohibit another ITS participant market from buying that security from a customer at 19 ⅞ or selling that security to a customer at 20 ½. *See* ITS plan, *supra* note 162, at Exhibit B. In addition, each participant market has in place rules to implement the ITS Trade-Through Rule. *See, e.g.*, NASD Rule 5262. The plan also provides a mechanism for satisfying a market aggrieved by another market's trade-through. *See* ITS plan, *supra* note 162, at Exhibit B(b)(2).

[171] A locked market occurs when an ITS participant disseminates a bid for an ITS security at a price that equals or exceeds the price of the offer for the security from another ITS participant or disseminates an offer for an ITS security at a price that equals or is less than the price of the bid for the security from another ITS participant. The plan provides a mechanism for resolving locked markets.

[172] The ITS block trade policy provides that the member who represents a block size order shall, at the time of execution of the block trade, send or cause to be sent, through ITS to each participating ITS market center displaying a bid (or offer) superior to the execution price a commitment to trade at the execution price and for the number of shares displayed with that market center's better priced bid (or offer).

[173] To become a participant in ITS, an exchange or association must subscribe to, and agree to comply and to enforce compliance with, the provisions of the plan. *See* ITS plan, *supra* note 162, at section 3(c).

[174] *See, e.g.*, Amex Rule 117, NASD Rule 4120(a)(3), NYSE Rules 80B and 717. Pursuant to Exchange Act sections 12(k)(1)(A) and (B), the Commission may suspend trading in any security for up to 10 days, and all trading on any national securities exchange or otherwise, for up to 90 days. 15 U.S.C. 78*l*(k)(1)(A) and (B).

[175] For example, a newly registered exchange would be required under Exchange Act Rule 11Ac1–1, 17 CFR 240.11Ac1–1 (the ''Quote Rule''), to halt trading when neither quotation nor transaction information can be disseminated.

[176] As noted above, Congress adopted section 6(f) specifically to ensure that the Commission and exchanges have sufficient authority both to limit the ability of non-members to utilize exchange facilities and to ensure that transactions on that exchange are effected in accordance with applicable exchange rules regardless of whether the particular transaction is brought to the exchange by a broker-dealer that is not an exchange member or by an investor who is not utilizing a broker. *See supra* section II.B.2.a.(i).

[177] *See* NASD 21(a) Report, *supra* note 20.

it would probably be necessary for any registered exchange to supervise the trading of non-broker-dealer participants in the same manner as it supervises broker-dealer trading. For example, as part of its obligations under the Exchange Act, each exchange currently maintains procedures to surveil for insider trading and manipulation on that exchange. These procedures, while differing among exchanges, generally identify trading anomalies based on historical and current data, review trading data to isolate suspicious activity and, if suspicious activity is found, refer the matter for enforcement proceedings.[178] If an exchange permitted institutions to directly participate in trading as members, the Commission, pursuant to its authority under section 6(f) of the Exchange Act, could require that exchange to enforce its rules with respect to such non-broker-dealers by conducting equivalent surveillance procedures.

Nevertheless, it may not be appropriate to enforce exchange rules for non-broker-dealers in precisely the same manner as for broker-dealers. For example, although an exchange would have to maintain surveillance procedures for all of its participants, an exchange may require a non-broker-dealer participant to provide different information in the course of cooperating with investigations than would be required from broker-dealer participants. Similarly, in addition to the Commission's net capital requirements for broker dealers,[179] each registered exchange currently requires their broker-dealer members to maintain minimum levels of capital.[180] Exchanges could consider applying different financial requirements to non-broker-dealer participants than they currently apply to broker-dealers.

In any case, institutions that trade for accounts other than their own, maintain custody of customer funds or securities, act as specialists or market makers, or otherwise act as brokers or dealers would be required to register as broker-dealers under the Exchange Act. Entities that engage in broker-dealer activities would continue to be required to comply with broker-dealer registration requirements, Exchange Act and SRO capital and books and records requirements, as well as prohibitions under section 11(a) and other provisions of the Exchange Act designed to protect against conflicts of interest between an exchange member trading for its own account on an exchange and its trading on an agency basis for other accounts.[181]

In addition, integration of alternative trading systems that have institutional participants into exchange registration will raise issues regarding clearance and settlement of the trades of those participants. Currently, institutions do not participate directly in the clearance and settlement process at registered clearing agencies such as the National Securities Clearing Corporation (''NSCC'') or The Depository Trust Company (''DTC'').[182] There is, however, no statutory prohibition against the admission of institutions as members of registered clearing agencies.[183] Conversely, there are no provisions under the Exchange Act, the rules thereunder, or current SRO rules, that require a member conducting trades on an exchange to be a direct member of a clearing agency. Currently, for example, broker-dealer members of an exchange may use a clearing broker for processing trades conducted on an exchange. Similarly, the Commission anticipates that institutions that conduct trades on newly registered exchanges could continue to use separate entities for clearance and settlement of trades.

In order to provide future institutional members the same clearance and settlement choices available to current broker-dealer exchange members, it may be appropriate for clearing agency membership to be open to institutions. Such admission would be subject to corresponding clearing agency rules assuring appropriate safeguards and qualifications.

Question 82: What impact would registration of an alternative trading system as an exchange have on the institutional participants of that trading system, including registered investment companies?

Question 83: If the Commission allows institutions to effect transactions on exchanges without the services of a broker, to what extent should an exchange's obligations to surveil its market and enforce its rules and the federal securities laws apply to such institutions?

Question 84: How could an exchange adequately supervise institutions that effect transactions on an exchange without the services of a broker?

Question 85: What, if any, accommodations should be made with respect to an exchange's surveillance, enforcement, and other SRO obligations with respect to institutions that transact business on that exchange?

Question 86: How could institutions that directly access exchanges be integrated into existing systems for clearance and settlement?

d. Application of Broker-Dealer Regulation to Certain Exchanges

Under the alternative discussed above, most alternative trading systems would be regulated as exempted exchanges. A few alternative trading systems, however, combine both the services of a market and those of a broker-dealer. For example, some systems perform market functions by operating electronic limit order books or crossing sessions. These same systems employ persons to actively search for buyers and sellers[184] or use their discretion in executing orders.[185]

Just as broker-dealer regulation has not effectively integrated alternative trading systems into market regulation, the current framework for regulating exchanges is not well-suited to address concerns raised by traditional broker or dealer activities. As a result, the Commission would consider whether markets that are regulated as either exempted exchanges or as registered national securities exchanges, but that also provide traditional brokerage services, should be subject to broker-dealer regulation as well. Application of broker-dealer regulation in such circumstances may not be inappropriate or necessarily duplicative.

[178] An exchange's surveillance depends on the nature of trading that occurs, and the type of securities that are traded on the exchange.

[179] 17 CFR 240.15c3–1. Capital requirements help to ensure that broker-dealers maintain liquid assets in sufficient amounts to enable them to satisfy their obligations promptly and to provide a cushion of liquid assets to protect against potential market and credit risks.

[180] *See, e.g.*, NYSE Rule 325.

[181] For example, broker-dealers are prohibited from trading ahead of a customer's order, frontrunning, free-riding and withholding, and maintaining accounts for the employees of other broker-dealers without notifying such broker-dealers.

[182] Institutions will generally hire a bank or broker-dealer that is a member of DTC to act as custodian on their behalf. Institutions can be members of DTC's Institutional Delivery system for purposes of the confirmation/affirmation process, but the actual settlement of securities transactions (*i.e.*, the transfer of money and securities) at DTC occurs between the institutions' broker-dealers and custodians. Similarly, NSCC is designed to process street-side settlement between financial intermediaries such as broker-dealers. Therefore, institutions are not members of NSCC for the purposes of settlement of trades.

[183] In fact, Section 17A of the Exchange Act requires that registered investment companies and insurance companies be permitted to become members of clearing agencies. 15 U.S.C. 78q–1(b)(3)(B).

[184] The system employee, for example, negotiates or assists in negotiating the terms of a particular trade on behalf of a participant by initiating communications with potential counterparties.

[185] These additional broker-dealer services may include directing the order to another market or broker-dealer for execution, or executing the order as principal.

This approach is consistent with the way in which exchanges and the persons that trade on those exchanges have traditionally been regulated. For example, specialists are registered broker-dealers that carry on a business for themselves while also serving the exchange as a whole. Among other things, specialists help to ensure the maintenance of a continuous and liquid market. They also often provide individualized services to their customers, such as alerting customers to market movements and forwarding orders to other markets. Although they perform many services for exchanges, specialists are regulated as broker-dealers. There is no reason, however, why an exchange could not choose to perform these activities itself rather than rely on third parties to perform them.

In such a situation, the Commission would have to consider how best to integrate the regulation of these broker-dealer activities with the regulation of the exchange's market activities. To the extent that exchange and broker-dealer regulations overlap, the Commission could determine which requirements a dually registered entity would follow.[186]

The Commission does not anticipate that a revised interpretation of the term ''exchange'' would include other entities that currently provide services to participants in the U.S. securities markets without being registered as broker-dealers or as exchanges. Examples of such service providers are those that restrict their activities to providing communication links between exchanges and broker-dealers and between broker-dealers and customers. Entities that only provide such message routing services likely would not be required under this approach to register with the Commission as either broker-dealers or as national securities exchanges.[187] Entities that provide such communication links and also have affiliates that use those links to perform market functions, however, could be deemed to be facilities of an exchange. In general, in determining whether broker-dealer or exchange regulation would be appropriate for a particular entity, communication links offered in conjunction with other services would have to be viewed in their entirety.

Question 87: Under what conditions should an entity be subject to both exchange and broker-dealer regulation?

Question 88: Should a dually registered entity be required to formally separate its exchange operations from its broker-dealer operations (*e.g.*, through use of separate subsidiaries)?

C. Conclusion

The exchange-based approach described above might address the gaps created by the current approach to oversight of alternative trading systems, as well as many of the concerns raised by the broker-dealer based approach, and could result in more consistent market protections over time. In addition, such an approach might contribute substantial regulatory certainty and the application of fair and equitable principles of trade to alternative trading systems. As noted above, however, such an approach might also have significant effects on existing exchanges, alternative trading systems, and market participants. To some extent, many alternative trading systems that would be considered exempted exchanges under this approach would be subject to less regulation than they currently are, while the few significant alternative trading systems would be subject to more substantial regulatory requirements. This approach would also potentially require greater adjustment to existing NMS mechanisms to accommodate newly registered exchanges than would a broker-dealer based approach.

Question 89: Would this approach be an effective means of addressing the issues raised by the growth alternative trading systems? What would be the benefits of such an approach? What would be the drawbacks of such an approach?

V. The Commission Could Consider Ways in Which Requirements Might Be Reduced or Expedited for Registered Exchanges

The effects of technology on domestic markets have not been limited to alternative trading systems. Registered exchanges and Nasdaq are also engaged in applying technology to respond to the fast changing competitive pressures of modern securities markets. In addition to considering the regulatory position of alternative trading systems, the Commission could therefore consider whether there are other areas of its approach to regulation of markets that would benefit from reevaluation. Specifically, the Commission could examine ways to reduce unnecessary regulatory requirements that make it difficult for these registered entities to remain competitive in changing business environments. The Commission has tried to fulfill its obligation under the Exchange Act to oversee the activities of exchanges and securities associations in a manner that is flexible and responsive to market developments and that allows for innovation by these entities. This has entailed ongoing consideration of additional ways in which the obligations imposed by the Exchange Act on registered exchanges and securities associations may be streamlined, without sacrificing investor protection or market integrity.

The Commission could consider what changes might be made to expedite exchanges' and securities associations' procedures for changing their rules, and how automation might be used to lower the costs and improve the effectiveness of their surveillance and enforcement responsibilities. The Commission could also consider what changes might be made to give exchanges and securities associations greater flexibility in determining how to fulfill their regulatory obligations. For example, while it is generally in the public interest for each exchange to retain ultimate responsibility for fulfilling its statutory obligations, it is clear that smaller SROs do not benefit from the economies and efficiencies of scale available to SROs that supervise larger memberships. In addition, larger SROs may obtain greater cost efficiencies by offering their services to other SROs for a fee. This type of ''outsourcing'' could be a useful tool for exchanges and securities associations.

A. Ways to Further Expedite Rule Filings

Section 19(b)(1) of the Exchange Act requires SROs to file copies of proposed rules and rule amendments with the Commission, accompanied by a concise general statement of the basis and purpose of the proposed rule change.[188] Once a proposed rule change is filed, the Commission is required to publish notice of it and provide an opportunity for public comment. This process serves a critical role in giving the Commission sufficient oversight authority to ensure

[186] For example, certain broker-dealer trading systems, which are subject to Exchange Act Rule 17a–23, would be exchanges under the proposed new interpretation of the term ''exchange.'' To prevent an alternative trading system from being subject to the requirements of both Rule 17a–23 and an exempted exchange or a national securities exchange, the Commission could amend Rule 17a–23 as necessary to avoid duplicative regulation.

[187] *See, e.g.*, Letter from Richard R. Lindsey, Director, Division of Market Regulation, SEC, to Scott W. Campbell, V.P. & Assoc. General Counsel, Charles Schwab & Co., Inc. (Nov. 27, 1996).

[188] The scope of this requirement depends upon what constitutes a ''rule'' under the Exchange Act. If something does not rise to the level of a ''rule,'' section 19(b)(1) does not apply. sections 3(a)(27) and (29) of the Exchange Act define the rules of an SRO broadly to include not only the constitution, articles of incorporation, and bylaws, but also any stated policies, practices, and interpretations that the Commission, by rule, determines to be rules of an SRO. *See* Exchange Act Rule 19b–4, 17 CFR 240.19b–4.

that exchanges and securities associations carry out their self-regulatory obligations vigilantly and effectively.

Between 1934 and 1975, the Exchange Act did not give the Commission adequate authority over SRO rulemaking to act promptly and effectively where a rule or proposed rule might be injurious to the public interest.[189] During that time, the Commission carried out this responsibility by relying on inspections and by conducting administrative proceedings to effect needed changes in exchange rules.[190] The Commission had limited authority to prevent the adoption of a particular exchange rule, or to amend rules once they had been adopted; section 19(b) of the Exchange Act only gave the Commission the authority to amend exchange rules related to certain enumerated matters.[191] As a result, with respect to the majority of exchange rules, although exchanges would consider concerns raised by the Commission or its staff, exchanges were not obligated to address those concerns.[192] Moreover, persons with a significant stake were not provided with notice or an opportunity to comment on a proposed rule change or on the need or justification for a proposal.[193]

The 1975 Amendments established a new uniform procedure for both exchanges and securities associations that required SRO rule changes to be justified to, and reviewed by, the Commission after an opportunity for public comment.[194] In addition, Congress expanded the Commission's authority to permit it to amend all SRO rules.[195] The legislative history of the 1975 Amendments indicates that Congress intended to clarify and strengthen the Commission's oversight role with respect to SROs and, specifically, to ensure that the Commission had the tools it needed to provide meaningful oversight of SRO rules and the rulemaking process.[196] Congress intended that the Commission would conduct a comprehensive review of proposed rule changes, including the justification for the change, any burden on competition and the public interest that the change may impose, and public comments received concerning the rule change.[197] The Commission staff fulfills this responsibility by conducting a careful review of every rule filing it receives. This review often requires the Commission staff to weigh complex and serious issues raised by the proposed changes. The rule filing process also gives the public an opportunity to express its views as to the competitive and other effects of any significant rule changes. For all these reasons, it may be appropriate for all exchanges, including newly registered alternative trading systems, to comply with the rule filing requirements of section 19(b).

Nonetheless, the Commission understands that the time required for solicitation and review of public comments can delay exchanges' and securities associations' implementation of innovative proposals and administrative or non-controversial filings. In response to this concern, the Commission has already streamlined its internal process for reviewing and approving SRO rule filings. This has reduced the average number of days between the filing of a proposed rule change by an SRO and the approval, withdrawal, or disapproval of the rule filing from 349 days at the beginning of fiscal year 1994 to 74 days at the end of fiscal year 1996.

In addition, to respond to SRO requests that the rule review process be expedited, in December 1994, the Commission adopted amendments to Rule 19b–4, which expanded the scope of proposed rule changes that may become effective immediately upon filing pursuant to section 19(b)(3)(A) of the Exchange Act.[198] These amendments permitted SRO rule changes concerning routine procedural and administrative modifications to existing order-entry and trading systems to become effective immediately upon filing. Certain non-controversial filings were also permitted to become operational 30 days after filing with the Commission, provided the SRO gave written notice to the Commission five business days prior to the filing.[199] These amendments to Rule 19b–4, in part, were intended to enhance SROs' ability to implement prompt, flexible, and innovative systems changes.[200] The Commission

[189] *See* SEC, Study of Unsafe and Unsound Practices of Brokers and Dealers, H.R. Rep. No. 231, 92d Cong., 1st Sess. 6 (1971).

[190] The Commission's effort to eliminate fixed commission rates is illustrative of this process and why it was problematic. *See* Securities Exchange Act Release No. 11203 (Jan. 23, 1975), 40 FR 7394 (Feb. 20, 1975).

[191] Before 1975, exchanges were allowed to adopt, without Commission approval, any rule not inconsistent with either the Exchange Act or a Commission rule, and were required to furnish the Commission with copies of rule amendments only upon their adoption. The Commission, however, could alter or supplement exchange rules that related to certain enumerated matters pursuant to defined procedures. In contrast, registered securities associations were required to file rule changes with the Commission 30 days before they became effective, and the Commission had the authority to prevent proposals from taking effect. The Commission could also alter, supplement, or abrogate an association's rule in certain circumstances. *See* generally Special Study, *supra* note 4, at 703–06.

[192] *See* Special Study, *supra* note 4, at 711.

[193] *See* Securities Industry Study, Subcomm. on Securities, Senate Committee on Banking, Housing & Urban Affairs, S. Doc. No. 13, 93d Cong., 1st Sess. 156–7, 198 (1973); Note, *Informal Bargaining Process: An Analysis of the SEC's Regulation of the New York Stock Exchange*, 80 Yale L.J. 832 (1971).

[194] In order to provide interested persons with an opportunity to obtain accurate information on rule proposals and to participate in the review and evaluation of SROs' proposed rule changes, the 1975 Amendments required SROs to file an explanation or justification for their proposals and the Commission to publish notice of the SROs' proposed rule changes. Congress intended this requirement to hold the SROs to the same standards of policy justification that the Administrative Procedures Act imposes on the Commission. *See* Exchange Act section 19(b)(1), 15 U.S.C. 78s(b)(1); S. Rep. No. 75, *supra* note 22, at 29–32.

[195] Exchange Act section 19(c), 15 U.S.C. 78s(c).

[196] *See, e.g.*, S. Rep. No. 75, *supra* note 22. ''In the new regulatory environment created by this bill, self-regulation would be continued, but the SEC would be expected to play a much larger role than it has in the past to ensure that there is no gap between self-regulatory performance and regulatory need, and, when appropriate, to provide leadership for the development of a more coherent and rational regulatory structure to correspond to and to police effectively the new national market system.'' *Id.* at 2.

[197] *Id.*

[198] Section 19(b)(3)(A) of the Exchange Act sets forth certain specified categories of rule changes that may become effective upon filing. These include rule changes that: (1) Constitute a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the SRO; (2) establish or change a due, fee, or other charge imposed by the SRO; or (3) are concerned solely with the administration of the SRO. In addition, consistent with the public interest and the purposes of this subsection, the Commission may specify other categories of rule filings that may become effective upon filing. 15 U.S.C. 78s(b)(3)(A).

[199] *See* Securities Exchange Act Release No. 35123 (Dec. 20, 1994), 59 FR 66692 (Dec. 28, 1994). Particularly in the area relating to new exchange-traded products, the Commission continues to reduce the number of days between filing and allowed trading of those products that do not raise significant regulatory issues or concerns. For example, when an exchange seeks to trade a product that meets generic criteria for listing options on narrow-based indexes, the time period between filing and allowed trading of the product can be shortened considerably. *See, e.g.*, Securities Exchange Act Release No. 38307 (Feb. 19, 1997), 62 FR 8469 (Feb. 24, 1997) (options on The de Jager Year 2000 Index); Securities Exchange Act Release No. 38207 (Jan. 27, 1997), 62 FR 5268 (Feb. 4, 1997) (options and LEAPS on the Phlx Oil Service Index); Securities Exchange Act Release No. 37312 (June 14, 1996), 61 FR 31570 (June 20, 1996) (options on The Morgan Stanley Commodity Related Equity Index); Securities Exchange Act Release No. 37115 (Apr. 15, 1996), 61 FR 17741 (Apr. 22, 1996) (options on the CBOE Gold Index); Securities Exchange Act Release No. 37026 (Mar. 26, 1996), 61 FR 4502 (Apr. 3, 1996) (options on the Chicago Board Options Exchange Computer Networking Index). The exchange may trade the new product 30 days after the date the rule change is filed with the Commission.

[200] It appears that SROs, including exchanges, could take better advantage of the expedited process available under section 19(b)(3)(A) of the Exchange Act. In fiscal year 1996, for example, out of a total of 552 rule changes filed with the Commission, only 18 (or 3.5%) were filed under the expanded

Continued

staff has also taken a flexible approach in applying the expedited procedures under Rule 19b–4. For example, filings that are virtually identical to an SRO filing already approved by the Commission can often be approved on an accelerated basis, particularly in the context of new product listing standards that duplicate listing standards already approved for an identical product on another exchange.[201]

Nonetheless, there may be additional ways in which the Commission could reduce rule filing requirements to facilitate a rapid response by SROs to changing market conditions and competitive pressures. For example, the Commission could consider further expanding the scope of proposed rule changes eligible for effectiveness immediately upon filing to include, for example, any proposed changes to listing standards to accommodate new products. In expanding the scope of rules eligible for this treatment, it may be appropriate to require an SRO to make an affirmative statement that it has undertaken a review of the Commission's eligibility criteria for immediate effectiveness under Rule 19b–4 and is satisfied that the rule filing being submitted conforms to such requirements.

The Commission could also consider exempting certain SRO programs designed to implement innovative new trading systems or mechanisms from rule filing requirements during development and initial operating stages. In the past several years, a few SROs have attempted to implement innovative trading structures for their members. For example, in 1991, the NYSE established after-hours crossing systems that automate the execution of single stock orders and baskets of securities,[202] and in 1994, the CHX developed the Chicago Match system.[203] Although neither program has generated significant trading activity,[204] in both cases, the exchanges submitted rule filings prior to operation. Because of the innovative nature of such systems for the sponsoring exchanges, the approval process was protracted. Alternative trading systems that offer similarly innovative, start-up services today are not required to follow the same procedures prior to operation of the services. In addition, SROs have indicated that revealing the business plans for such innovative programs prior to operation makes it more difficult for them to compete effectively with alternative trading systems in offering start-up services to their members.

The Commission believes that markets should be encouraged to innovate. One way of facilitating innovation by exchanges and securities associations, as well as vigorous competition among these markets, would be to enable exchanges and securities associations to establish innovative trading programs, apart from their other operations. For example, an exchange may wish to establish an electronic book for the trading of securities not traded on the exchange's primary system. Such programs could then be subject to similar oversight as that applied to small, start-up alternative trading systems, to the extent appropriate in light of investor protection. Under such an approach, the Commission could exempt pilot programs from rule filing requirements until such time as the program obtained significant volume, was integrated with an exchange's or securities association's other trading mechanisms, or otherwise began to have significant market impact.

Any such proposal would require careful consideration as to the types of programs that might be eligible for exemption, and other conditions that might be appropriate in light of investor protection concerns, national market system goals, and just and equitable principles of trade. As noted above, one reason that Congress required SROs to submit rule filings was to ensure that the interests of investors were considered in SRO actions, and that persons with a significant stake were provided with notice and an opportunity to comment on a proposed rule change. For example, pilot programs that might be eligible for exemption could potentially function as alternatives to trading through a market's primary system. In such circumstances, these programs would affect not only investors whose orders are executed on such systems, but also investors and traders who were not given the opportunity to use the pilot program. Moreover, customers who placed orders in the exchange's main trading system could also be affected, *e.g.*, if their orders did not have an opportunity to interact with orders executed through the pilot program. For these reasons, it may not be appropriate to make a rule filing exemption available for pilot programs that trade the same securities, operate during the same time of day, or have similar trading structures as a market's main trading system or are otherwise linked to a market's primary operations.

In addition, the Commission could consider the appropriate standards for determining whether a particular proposal would qualify as a pilot program. Other issues to be considered would include whether any exemption for pilot programs should be limited in duration, even if the programs did not reach significant volume, and what would be the appropriate measure for determining when a program would have limited volume in light of all relevant factors.[205] Finally, the Commission could consider how SROs would notify the Commission and the SROs' participants prior to implementing a pilot program, and disclose to participants in the pilot program whether the quality or type of execution capabilities of the pilot system differ from those of the exchange's established systems.

Question 90: Would it be feasible for the Commission to expand the scope of rules eligible for expedited treatment pursuant to Section 19(b)(3)(A) without jeopardizing the investor protection and

expedited process. Similarly, in fiscal year 1995, only 12 out of a total of 593 rule changes (2%) were filed under the expanded expedited process. SROs could also facilitate the prompt publication of notices of proposed rule changes by submitting rule filings in such a form that enables the staff to expedite their review. The Commission strongly encourages SROs to evaluate their internal procedures for drafting, reviewing, and submitting rule filings to take greater advantage of expedited procedures and to ensure complete filings that will enable the Commission to respond promptly.

[201] *See* Securities Exchange Act Release No. 36296 (Sept. 28, 1995), 60 FR 52234 (Oct. 5, 1995) (relating to listing and trading of broad-based index warrants on Nasdaq); Securities Exchange Act Release No. 36165 (Aug. 29, 1995), 60 FR 46653 (Sept. 7, 1995) (establishing the NYSE's uniform listing and trading guidelines for stock index, currency, and currency index warrants); Securities Exchange Act Release No. 36166 (Aug. 29, 1995), 60 FR 46660 (Sept. 7, 1995) (establishing PCX's uniform listing and trading guidelines for stock index, currency, and currency index warrants); Securities Exchange Act Release No. 36167 (Aug. 29, 1995), 60 FR 46667 (Sept. 7, 1995) (establishing Phlx's uniform listing and trading guidelines for stock index, currency, and currency index warrants); Securities Exchange Act Release No. 36169 (Aug. 29, 1995), 60 FR 46644 (Sept. 7, 1995) (establishing CBOE's uniform listing and trading guidelines for stock index, currency, and currency index warrants).

[202] *See* Securities Exchange Act Release No. 29237 (May 24, 1991), 56 FR 24853 (May 31, 1991); Securities Exchange Act Release No. 32368 (May 25, 1993), 58 FR 31565 (June 3, 1993).

[203] *See, e.g.*, Securities Exchange Act Release No. 35030 (Nov. 30, 1994), 59 FR 63141 (Dec. 7, 1994) (order approving Chicago Match, an electronic matching system operated by the CHX, which provided for the crossing of orders entered by CHX members and non-members, including institutional customers).

[204] The NYSE's crossing sessions continue to generate volume that is well below that of POSIT and the smallest registered exchange. The CHX determined not to continue operating Chicago Match in 1996. *See* Sarah Gates, *Will Anyone Miss Chicago Match*, Wall Street & Technology, Apr. 1996, at 26.

[205] As discussed above, whether a trading system has enough volume to have significant market impact will differ depending upon, among other things, the size and liquidity of the market for the instruments traded.

market integrity benefits of Commission oversight of exchange and other SRO rule changes? If so, to what types of rule filings should immediate effectiveness, pursuant to Section 19(b)(3)(A), be extended?

Question 91: If the Commission expands the scope of rule filings eligible for treatment under Section 19(b)(3)(A) to include, for example, certain types of new products, what conditions or representations should be required of an SRO to ensure that the proposed rule change is eligible for expedited treatment under Rule 19b–4?

Question 92: Should the Commission exempt markets' proposals to implement new trading systems, separate from their primary trading operations, from rule filing requirements? If so, should SROs be permitted to operate pilot programs under such an exemption if they trade the same securities, operate during the same hours, or utilize similar trading procedures as the SRO's main trading system? Should there be a limit on the number of pilot programs an SRO can operate under an exemption at any one time? What other conditions should apply to such exemption?

B. Surveillance and Enforcement

Technological advances have greatly increased an exchange's ability to fulfill its enforcement obligations under the Exchange Act efficiently and cost effectively. Some sponsors of trading systems have suggested that automated trading activity requires less extensive surveillance, and that markets with fully automated trading should not be required to conduct the same surveillance as non-automated exchanges. This suggestion may be based in part on the view that automation of trading algorithms may make it more difficult for participants to trade in violation of the trading rules embedded in those algorithms. While automation and embedded algorithms alone cannot prevent insider trading or market manipulation,[206] automation may make it easier to detect potential and attempted abuses by providing a full audit trail of trading activity. By circumscribing participant trading activity, automation can also reduce the resources that must be devoted to monitoring trading activities, which, consequently, would reduce the costs of exchange regulation. For example, failures by market makers to fulfill their obligation to honor quotations are easier to detect in a fully automated environment.[207] Accordingly, the Commission is considering whether fully automated markets may be able to fulfill their regulatory obligations in non-traditional ways.

Existing Commission initiatives and SRO plans that coordinate supervision of broker-dealers that are members of more than one SRO (''common members'') could also apply to newly registered exchanges. For example, while exchanges are required to enforce compliance by their members (and persons associated with their members) with applicable laws and rules, the Commission has used its authority under sections 17 and 19 of the Exchange Act to allocate oversight of common members to particular exchanges, and to exempt exchanges from enforcement obligations with respect to persons that are associated with a member, but that are not engaged in the securities business.[208] In order to avoid unnecessary regulatory duplication, the Commission appoints a single SRO as the designated examining authority (''DEA'') to examine common members for compliance with the financial responsibility requirements.[209] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with applicable financial responsibility rules.[210] Consistent with past Commission action, the Commission could continue to designate one SRO, such as the NASD or the NYSE, as the primary DEA for common members of exchanges. The Commission has also permitted existing SROs to contract with each other to allocate non-financial regulatory responsibilities.[211] For example, the Commission has approved a regulatory plan filed by the Amex, CBOE, NASD, NYSE, PCX, and the Phlx that designates, with respect to each common member, an SRO participating in the plan as a broker-dealer's options examination authority. This designated SRO has sole regulatory responsibility for certain options-related trading matters.[212] An SRO participating in a regulatory plan is relieved of regulatory responsibilities with respect to a broker-dealer member of such an SRO, if those regulatory responsibilities have been designated to another SRO under the regulatory plan. These programs could also be applicable to newly registered exchanges.

These plans permit an SRO to allocate its oversight obligations with respect to certain members' compliance with various requirements. They do not permit an SRO to allocate its oversight obligations with respect to the activities taking place on its market. Currently, enforcement and disciplinary actions for

[206] While automation may reduce the cost and increase the effectiveness of a market's surveillance program, a responsible party must still be able to recognize potentially manipulative activity and, in many cases, review trading records.

[207] *See* NASD 21(a) Report, *supra* note 20, at 28 and 45 for discussion of failures by market makers on the Nasdaq market to honor their quotations or to ''back away,'' and steps that the NASD undertook, as part of its settlement with the Commission, to upgrade its capabilities to detect and prevent such backing away.

[208] *See* 17 CFR 240.17d–2; 17 CFR 240.19g2–1.

[209] With respect to a common member, Section 17(d)(1) of the Exchange Act authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules and regulations, or to perform other specified regulatory functions. 15 U.S.C. 78q(d)(1).

[210] *See* Securities Exchange Act Release No. 23192 (May 1, 1986) 51 FR 17426 (May 12, 1986). Moreover, Section 108 of the 1996 Amendments, *supra* note 68, adds a provision to Section 17 of the Exchange Act that calls for improving coordination of supervision of members and elimination of any unnecessary and burdensome duplication in the examination process.

[211] Rule 17d–2 under the Exchange Act permits SROs to establish joint plans for allocating the regulatory responsibilities imposed by the Exchange Act with respect to common members. Securities Exchange Act Release No. 12935 (Oct. 28, 1976), 41 FR 49093 (Nov. 8, 1976). In addition to the regulatory responsibilities it otherwise has under the Exchange Act, the SRO to which a firm is designated under these plans assumes regulatory responsibilities allocated to it. Under Rule 17d–2(c), the Commission may declare any joint plan effective if, after providing notice and opportunity for comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among the SROs, to remove impediments to and foster the development of a national market system and a national clearance and settlement system, and in conformity with the factors set forth in section 17(d) of the Exchange Act. The Commission has approved plans filed by the equity exchanges and the NASD for the allocation of regulatory responsibilities pursuant to Rule 17d–2. *See, e.g.,* Securities Exchange Act Release No. 13326 (Mar. 3, 1977), 42 FR 13878 (Mar. 14, 1977) (NYSE/Amex); Securities Exchange Act Release No. 13536 (May 12, 1977), 42 FR 26264 (May 23, 1977) (NYSE/BSE); Securities Exchange Act Release No. 14152 (Nov. 9, 1977), 42 FR 59339 (Nov. 16, 1977) (NYSE/CSE); Securities Exchange Act Release No. 13535 (May 12, 1977), 42 FR 26269 (May 23, 1977) (NYSE/CHX); Securities Exchange Act Release No. 13531 (May 12, 1977), 42 FR 26273 (May 23, 1977) (NYSE/PSE); Securities Exchange Act Release No. 14093 (Oct. 25, 1977), 42 FR 57199 (Nov. 1, 1977) (NYSE/Phlx); Securities Exchange Act Release No. 15191 (Sep. 26, 1978), 43 FR 46093 (Oct. 5, 1978) (NASD/BSE, CSE, CHX and PSE); and Securities Exchange Act Release No. 16858 (May 30, 1980), 45 FR 37927 (June 5, 1980) (NASD/BSE, CSE, CHX and PSE).

[212] *See* Securities Exchange Act Release No. 20158 (Sept. 8, 1983), 48 FR 41265 (Sept. 14, 1983). The SRO designated under the plan as a broker-dealer's options examination authority is responsible for conducting options-related sales practice examinations and investigating options-related customer complaints and terminations for cause of associated persons. The designated SRO is also responsible for examining a firm's compliance with the provisions of applicable federal securities laws and the rules and regulations thereunder, its own rules, and the rules of any SRO of which the firm is a member. *Id.*

violations relating to transactions executed in an SRO's market or rules unique to that SRO must be retained by that SRO. Existing exchanges generally employ personnel and establish extensive programs to fulfill this responsibility. Fully automated exchanges, however, might be able to contract with other exchanges to perform these activities while retaining ultimate responsibility for ensuring that these activities are performed. Fully automated exchanges can produce comprehensive, instantaneous automated records that can be monitored remotely. As a result, it may be possible for such an exchange to contract with another exchange to perform its day-to-day enforcement and disciplinary activities. The Commission could consider whether allowing an automated market to do so would be consistent with the public interest.

Another approach would be for fully automated exchanges to form a separate SRO solely for the purpose of overseeing the activities of their markets. This SRO, rather than the automated exchanges, would have the responsibility for bringing enforcement and disciplinary actions for violations relating to transactions executed on those exchanges. The Commission seeks comment on the advisability and feasibility of such an approach.

Question 93: Do differences between automated and non-automated trading require materially different types or degrees of surveillance or enforcement procedures?

Question 94: Which Exchange Act requirements applicable to registered exchanges, if any, could be minimized or eliminated without jeopardizing investor protection and market integrity?

Question 95: If an automated exchange contracts with another SRO to perform its day-to-day enforcement and disciplinary activities, should this affect the exchange's requirement to ensure fair representation of its participants and the public in its governance?

Question 96: If an exchange contracts with another entity to perform its oversight obligations, should that exchange continue to have responsibility under the Exchange Act for ensuring that those obligations are adequately fulfilled?

VI. Costs and Benefits of Revising the Regulation of Domestic Markets

The two alternatives discussed in Section IV could provide significant benefits to U.S. securities markets and market participants. By integrating all significant markets in the market regulatory framework, these proposals would bolster the effectiveness of the national market system by better protecting market participants. For example, if the Commission were to continue to regulate alternative trading systems as broker-dealers, but adopted additional regulations (the first approach discussed in Section IV), the market as a whole would benefit from the additional transparency provided by the public reporting of all orders submitted to alternative trading systems. Moreover, enhancing the surveillance of trading on alternative trading systems would benefit the public by preventing fraud and manipulation. Similarly, by regulating alternative trading systems under a tiered approach to exchange regulation, investors and other market participants could benefit because, as exchanges, significant alternative trading systems would be prohibited from unfairly denying access, taking discriminatory action against participants, imposing unreasonably discriminatory fees, or establishing anticompetitive rules. In addition, because significant alternative trading systems would be required to directly participate in market-wide plans such as the CQS, CTA, OPRA, and ITS, investors could benefit from reductions in misallocations of capital, inefficiency, and trading fragmentation. Moreover, under the proposed reinterpretation of ''exchange,'' investors and the integrity of the market generally could benefit from alternative trading systems sharing SRO responsibilities with currently registered exchanges. In particular, the Commission's ability to prevent fraud and manipulation would be strengthened.

The Commission also recognizes that the proposals discussed in this release would have a substantial impact on the allocation of regulatory costs among market participants. In particular, the additional obligations contemplated under both alternative proposals to revise domestic market regulation could impose costs on alternative trading systems. For example, alternative trading systems could be required to adopt rules to prevent fraud and manipulation, promote just and equitable principles of trade, and not impose any unnecessary or inappropriate burden on competition. Alternative trading systems could also be required to establish mechanisms to assure regulatory oversight of their participants and review their listing procedures. In addition, there would also be costs associated with joining market-wide plans, such as the CQS, CTA, ITS, OPRA, and OTC–UTP. These costs, however, would at least partially be offset because most alternative trading systems would no longer be regulated as broker-dealers. In addition, because alternative trading systems, as exchanges, would share the responsibilities of self-regulation, the regulatory burden carried by currently registered exchanges should be reduced. In contrast, integrating these alternative trading systems into the mechanisms of the national market system through broker-dealer regulation could entail additional costs for the trading systems as well as their supervising SROs.

Question 97: What costs to investors and other market participants are associated with the current regulation of alternative trading systems as broker-dealers? Specifically, what costs are associated with the potential denial of access by an alternative trading system?

Question 98: What costs are associated with each of the alternatives for revising market regulation discussed above? For example, would either of the two principal alternatives discussed in Section IV above impose costs by limiting innovation? Would these costs be greater than those imposed by the current regulatory approach?

Question 99: What regulatory costs can be shared by markets operating simultaneously as self-regulatory organizations, and what regulatory costs must be borne by each market individually? What are the relative magnitudes of these costs (as a proportion of total costs)?

Question 100: Are there innovations or adjustments that can be made to market wide plans such as CQS, CTA and ITS that will lead to lower regulatory costs for exchanges under any of the alternatives for regulating domestic markets?

Question 101: Total regulatory costs vary with a variety of factors (e.g., volume of trade, degree of technology applied in trade). Of these factors, which are most relevant in considering the alternatives discussed above? For example, recognizing that some market mechanisms may rely on some factors more than others, to what extent are regulatory costs greater for particular mechanisms than others?

Question 102: What costs are associated with the responsibilities of an SRO? Will the costs to existing SROs be reduced by registering significant alternative trading systems as exchanges?

Question 103: What regulatory burdens currently inhibit innovation of trading systems? How will the alternatives discussed above change the incentives for innovation?

Question 104: Will the alternatives discussed above impose costs on systems that differ depending on the nature of the trade? For example, will the proposed regulatory revisions change the costs of trades directly between customers relative to the costs of trades between a customer and a dealer?

VII. Regulation of Foreign Market Activities in the United States

A. The Need for a Clear Regulatory Structure to Address U.S. Investors' Electronic Cross-Border Trading

In addition to significantly changing the way domestic markets operate, technology has given U.S. investors new and varied options for accessing foreign markets. The desire of many investors to diversify their portfolios through foreign investment has already resulted in an exponential increase in trading in foreign securities by U.S. persons.[213] The use of advanced technology by broker-dealers, markets, and other entities has the potential to greatly increase institutions' and other U.S. investors' cross-border trading opportunities, to make cross-border trading both more efficient and more affordable, and to promote competition among global markets and intermediaries.

Until recently, in order to obtain current information regarding foreign market activity and to purchase or sell securities on a foreign market, a U.S. investor typically contacted a U.S. broker-dealer by telephone or facsimile. The U.S. broker-dealer would then give the investor current information and transmit the investor's order to a foreign broker-dealer member of the foreign market[214] on which the security was traded. Alternatively, the U.S. investor could contact a foreign broker-dealer member of the foreign market directly. Today, however, it is possible for U.S. investors to obtain real-time information about trading on foreign markets from a number of different sources and to enter and execute their orders on those markets electronically from the United States.

For example, an investor that is not a member of a foreign market can nonetheless trade directly on that market using electronic interfaces, by linking to the market through a member of that market (typically the investor's broker-dealer). The market member provides a direct, automated link between the customer and the foreign market by connecting the customer's computer system directly to its own, which is also connected with the foreign market. This may be accomplished in a variety of ways, including through the use of proprietary software, leased lines or a public network such as the Internet. The member's systems will then automatically distribute market information to the U.S. investor and route the investor's orders directly to the market. Through these types of ''pass-through'' linkages, the non-member customer can enjoy electronic trading capabilities that are equivalent to the trading privileges of a member of the foreign market. From the broker-dealer's and customer's perspectives, this type of ''pass-through'' service enables the investor to send orders through the electronic interface without the broker-dealer having prior knowledge of each order or manually interpositioning itself in the trading process. As a result, orders routed electronically by a customer to the exchange remain under the customer's control until the moment of execution. This is in contrast to traditional brokerage activities involving orders that are routed from a customer to a foreign market member (or its affiliate), and from the member to the exchange. From the perspective of the foreign market, orders sent by a broker-dealer customer through a member's electronic interface may be indistinguishable from orders placed directly by the member.[215] Some broker-dealers have also begun to facilitate trading directly on the facilities of foreign markets in which those broker-dealers are not members, for their U.S. customers or affiliates. This is typically accomplished through agreement or affiliation with a local member of that market.

In addition to allowing investors that are not members to trade directly on foreign markets, technological advances have enabled market members themselves to trade from remote locations outside of particular markets' home countries. Many foreign markets have integrated new technology into their trading processes in recent years, either by using computers in combination with traditional floor trading procedures,[216] or by completely automating their trading facilities.[217] This enhanced technology enables members of those markets to trade without being physically present on a market ''floor'' or establishing a physical

[213] Between 1980 and 1995, the total activity by U.S. persons in foreign securities grew from $53.1 billion to $2,573.6 billion, representing over a 4700% increase. Securities Industry Association, 1996 Securities Industry Fact Book 67 (forthcoming June 1997).

[214] As used in this release, a ''member'' of a foreign market includes any person to which a foreign market provides access for the purpose of effecting transactions on that market. This would include any person that is a full or limited member of a foreign market or that the foreign market allows to electronically access its trading facilities.

[215] Although orders originate from a non-member, they are electronically identified, or ''stamped,'' as coming from the member providing the interface.

[216] For example, in September 1994, the Amsterdam Stock Exchange introduced a new electronic trading system that permits banks and broker-dealers to effect wholesale trades on-screen using the Automatic Interprofessional Dealing System Amsterdam (''AIDA''). This system permits exchange participants to enter bids and offers and to execute trades via a remote computer located in their offices. *The Netherlands,* Institutional Investor, Inc., Sept. 16, 1996, at 11; *The Amsterdam Stock Exchange—An Overview—Amsterdam Stock Exchange,* Business Monitor, Mar. 30, 1995. Similarly, Frankfurt's Deutsche Borse provides remote access in London, Amsterdam, Paris, and Zurich, and has attracted 44 remote members. The number of remote members of the Deutsche Borse is predicted to swell to at least 100 within three to five years. Laura Covill, *Survival of the Fittest,* ABI/INFORM, Aug. 1996, at 60. In addition, the Athens Stock Exchange has installed an electronic trading system that allows members to execute orders via exchange-owned terminals. Internet Site of the Athens Stock Exchange, address: http://www.ase.gr/waser.htm (Dec. 5, 1996).

[217] For example, since 1989, OM Stockholm (formerly the Stockholm Stock Exchange) has been completely electronic, and has remote members in London, Denmark, Norway, Finland, and Switzerland. OMLX, the London Securities & Derivatives Exchange, which is owned by the same company as OM Stockholm, is also a completely electronic trading system. *See* Laura Covill, *Survival of the Fittest,* ABI/INFORM, Aug. 1996, at 60; Hugh Carnegy, *Survey—Swedish Banking; Two Dynamic Exchanges,* Fin. Times, June 20, 1996, at 6. Tradepoint, a London-based electronic stock exchange, started trading in September 1995. *See* Henry Harrington, *Survey of European Stock Exchanges,* Fin. Times, Feb. 16, 1996. The Paris Bourse is now an entirely computerized stock market. Supercac, a system linked to member firms and other intermediaries collecting client orders, went on line in April 1995 and allows for continuous, automated trade execution to take place on the Paris Bourse. *See* Internet Site of The Paris Stock Exchange, address: http://www.bourse-de-paris.fr (Nov. 6, 1996); Henry Harrington, *Survey of European Stock Exchanges,* Fin. Times, Feb. 16, 1996. The purchase by the Toronto Stock Exchange (''TSE'') of the Paris Bourse's Supercac software enabled the TSE to close its floor on April 24, 1997. See *Toronto Stock Exchange Closes its Trading Floor,* The Wall Street J., Apr. 24, 1997, at C15. Other examples of completely automated exchanges include the MEFF Renta Fija and MEFF Renta Variable in Spain, the New Zealand Stock Exchange, the Korean Stock Exchange, the Philippine Stock Exchange, the Singapore Stock Exchange, and the Thailand Stock Exchange. Foreign futures and options markets have also embraced electronic trading systems. For example, the Tokyo International Financial Futures Exchange, the Osaka Futures and Options Exchange, the Swiss Options and Financial Futures Exchange, the Irish Futures and Options Exchange, and the New Zealand Futures and Options Exchanges are completely electronic. *See* Hughes Levecq & Bruce W. Weber, *Electronic Markets and Floor Markets: Competition for Trading Volumes in Futures and Options Exchanges,* Center for Research on Information Systems, Working Paper Series No. IS–95–20, June 15, 1995; Allan D. Grody & Hughes Levecq, *Past, Present and Future: The Evolution and Development of Electronic Financial Markets,* Center for Research on Information Systems, Working Paper Series No. IS–95–21, Nov. 1993.

presence in a market's home country. As a result, several foreign markets have begun to offer their members in non-U.S. jurisdictions ''remote'' access to their trading facilities, typically by installing proprietary market terminals in the members' offices, by providing data feeds or codes for use with software operated through the members' own computers, or by allowing members to access a market's trading facilities through third party service vendors or public networks (such as the Internet). In recent years, several foreign markets have proposed permitting U.S. broker-dealers and institutional investors to become market members through similar remote access arrangements.[218] If this remote access were offered in the United States, U.S. investors would have the ability to trade directly on foreign markets and to bypass broker-dealers.

These are examples of ways in which U.S. investors might access foreign markets. As technology evolves and investor comfort with electronic trading increases, other types of access will likely develop as well, including those that may make greater use of the Internet.

1. The Applicability of the U.S. Regulatory Structure to the Activities of Access Providers Has Not Been Expressly Addressed

When a foreign market, broker-dealer, or other entity provides the type of direct foreign market access described above to investors located in the United States (hereinafter referred to as an ''access provider''), its activities typically differ from both traditional brokerage activities and the activities of exchanges. The Commission to date has not expressly addressed the regulatory status of entities that provide U.S. persons with the ability to trade directly on foreign markets from the United States. While some access providers may be registered as U.S. broker-dealers because of their other activities, the lack of regulatory guidance in this context has discouraged other parties from offering U.S. persons foreign market access. Similarly, foreign markets have been reluctant to permit U.S. persons to become members of their markets without assurances from the Commission that they would not be required to register as national securities exchanges.[219] The Commission therefore is soliciting comment on how best to address U.S. investors' increasing access to foreign markets. Specifically, the Commission requests comment on whether investors could benefit from a clearer regulatory framework for entities that provide U.S. investors with the technological capability to trade directly on foreign markets from the United States.

2. U.S. Investors' Ability to Trade Directly on a Foreign Market And Investor Protection Concerns Under the Federal Securities Laws

In addressing issues raised by cross-border trading, it is important to ensure that investors are provided with certain key protections under the federal securities laws. From an investor's perspective, trading on a foreign market through an access provider is often indistinguishable from trading on a domestic market. These similarities could lead many investors to expect that such trading would be subject to the same protections provided by the U.S. securities laws. There are, however, significant differences in the protections available to investors trading on domestic U.S. markets, and those available to investors trading on foreign markets from the United States. For example, the U.S. securities laws provide significant protections to investors trading on U.S. markets. These protections include assurances that markets and intermediaries will disclose information regarding the rules governing trading operations, as well as requirements regarding transaction reporting and issuer disclosure practices. In addition, U.S. securities laws provide the Commission with the tools to detect and deter fraud and manipulation. Because foreign securities laws are generally not designed to provide these protections to U.S. investors that directly trade on their markets, in the absence of disclosure these differences have the potential to mislead U.S. investors that have come to rely on the U.S. securities laws.

The Commission has been examining alternative regulatory frameworks for addressing these concerns. As an initial matter, the optimal framework for addressing these issues should not impose unnecessary obligations on foreign markets that could effectively preclude U.S. investors from taking advantage of an otherwise efficient, cost-effective investment alternative. Cross-border trading opportunities may raise concerns, however, that U.S. investors may not receive sufficient disclosure about foreign markets or foreign issuers and their securities. As foreign markets are made increasingly accessible to U.S. investors through technological advances, therefore, the Commission should examine how to ensure that investors will receive sufficient information to make informed decisions.

B. Regulating Foreign Market Activities in the United States

The Commission's goal is to initiate a dialogue as to how to develop a consistent, long-term approach that clarifies the application of the U.S. securities laws to the U.S. activities of foreign markets. Any such approach must not impose unnecessary regulatory costs on cross-border trading and, at the same time, must allow the Commission to oversee foreign markets' activities in the United States and protect U.S. investors under the U.S. regulatory framework. There are several ways to achieve these goals. As discussed below, for example, the Commission could (1) rely solely on a foreign market's home country regulator; (2) require all foreign markets to register as national securities exchanges or apply for an exemption from registration; or (3) develop a tailored regulatory scheme designed to regulate the entity that provides U.S. investors with the ability to trade directly on foreign markets, rather than regulating the foreign market itself. The Commission solicits comments on whether any other alternatives could achieve the goals discussed above.

Question 105: What regulatory approaches would best address the concerns raised by the development of automated access to foreign markets? Would these approaches differ if U.S. investors accessed foreign markets in ways other than those described above, such as through the Internet? Are there any other alternative approaches that could be more appropriate?

1. Sole Reliance on Foreign Markets' Home Country Regulation

One option could be for the Commission to rely solely on the laws of the primary regulators of foreign

[218] For example, Deutsche Terminbörse (''DTB''), Germany's electronic futures and options market, installed computer terminals in the United States for trading non-U.S. futures products. *See* Letter from Andrea M. Corcoran, Director, Division of Trading and Markets, Commodity Futures Trading Commission, to Lawrence H. Hunt, Jr., Esq., Sidley & Austin (Feb. 29, 1996) (no-action letter authorizing DTB to install and use computer terminals in the United States in connection with the purchase and sale of certain futures and options contracts). The no-action letter explicitly did not address securities law issues. See also Mark J. Arend, *Securities Trading: How Electronic Markets Empower Institutional Investors,* Global Investment, Dec. 1996, at 30; *The Netherlands,* Institutional Investor, Inc., Sept. 16, 1996, at 11; Laura Covill, *Survival of the Fittest,* ABI/INFORM, Aug. 1996, at 60; *Business, Legal News from Around Europe,* Buraff Publications, May 13, 1996.

[219] Several foreign markets have proposed to provide U.S. investors with direct electronic access to their trading systems. In conjunction with these proposals, the foreign markets have requested certain relief from U.S. exchange and broker-dealer registration requirements.

markets, if those foreign markets are subject to regulation comparable to U.S. securities regulation. Under this approach, the Commission could specify foreign markets that it determines are subject to comparable regulation. In determining whether a foreign market is subject to comparable regulation, the foreign regulatory structure could be viewed as a whole to determine whether it, in its design and implementation, adequately addresses the key protections provided by U.S. securities laws. The Commission could make this determination on a case-by-case basis or it could establish certain standards governing the determination. Under the latter approach, if a foreign market met those enumerated standards, the foreign market could be considered subject to ''comparable'' regulation.[220]

This approach might have several advantages. First, it could provide regulatory certainty to foreign markets entering the United States. Second, it would not impose any additional regulatory costs on foreign markets. As a result, foreign markets would be able to provide their services to U.S. investors at lower cost. Third, this approach would recognize that principles of international comity support reasonable deference to a home country's governance of its own markets, particularly with respect to trading in the securities of home country issuers.

Despite these advantages, an approach that relies solely on foreign regulation has significant drawbacks. As discussed above, a U.S. investor trading on a foreign market through an access provider may incorrectly assume that such trading is subject to the same protections as trading on U.S. markets. Foreign laws, however, may differ significantly from U.S. securities laws.[221] For example, under the federal securities laws, a registered exchange must establish rules that describe its trading processes, file those rules with the Commission (which publishes them for comment), and enforce those rules fairly among its members. These requirements are designed to enable investors to make informed decisions about the risks and benefits of trading in a particular market. U.S. investors rely on the availability and accuracy of the information provided by markets, as well as the information provided by intermediaries, when making their investment decisions. Many foreign markets, however, do not require a similar level of disclosure.

The practices of foreign markets in areas that affect market integrity can also differ significantly from those of U.S. exchanges. For example, some foreign markets are not subject to laws designed to prevent insider trading or other forms of market manipulation that are prohibited in the United States. In addition, U.S. securities laws require market makers and specialists to have firm quotes,[222] and to display certain customer limit orders.[223] They also require U.S. markets and certain participants to report most trades for public dissemination within 90 seconds.[224] On the other hand, many foreign markets do not require market participants to report trading activity as quickly as under U.S. law,[225] and do not publicly disseminate such information as promptly as U.S. markets. Some foreign markets also do not require companies to provide financial and other material information to investors as often or as completely as is required under U.S. law. Moreover, the methods of calculating and reporting financial information that are used on foreign markets often differ from U.S. standards. U.S. investors trading electronically on foreign markets from the United States may not have access to complete information regarding these transaction reporting and issuer disclosure practices so as to evaluate whether published information is current.

Foreign markets also may not be subject to regulations designed to provide regulators with the tools to detect and deter behavior that is prohibited under U.S. securities laws, such as fraud, manipulation, or insider trading. For example, unlike domestic exchanges, which are required to comply with federal securities laws and to enforce compliance with such laws by their members,[226] foreign markets may have less comprehensive surveillance, examination, or enforcement capabilities. In addition, many foreign markets are not required under the laws of their home countries to preserve the trading information that would enable an investigation to be commenced under U.S. law. Without adequate recordkeeping, it could be difficult for the Commission to detect fraudulent or other illegal activity being conducted through access providers.[227]

An equally important component of the Commission's ability to detect and investigate violations of the federal securities laws is *access* to trading information. Even if a foreign market maintains comprehensive trading records, it may be constrained by local law from sharing these records or other market information with U.S. regulators.[228] Unless the Commission has access to trading records, its ability to fully investigate and bring enforcement actions for violations of the U.S. securities laws could be undermined.

U.S. investors may also expect that, because they are trading on foreign markets from the United States, they will be able to file private actions to recover losses arising from trading on those markets. In reality, the foreign nature of such trading may prevent U.S. investors from filing such claims in U.S. courts, from obtaining evidence to support their claims, from serving process on defendants, or from enforcing judgments.

In sum, although relying on foreign market regulation could provide regulatory certainty and allow foreign markets and access providers to provide their services to U.S. investors, it may not provide U.S. investors with certain essential protections they have come to expect. The Commission seeks comment on whether this option is feasible and consistent with the federal securities laws.

Question 106: If the Commission were to rely solely on a foreign market's primary regulator, how could it address the investor protection and enforcement concerns discussed above?

[220] It could be appropriate to permit foreign markets regulated solely under the laws of their home country to trade only foreign securities with U.S. persons. Possible definitions of the term ''foreign securities'' are discussed below.

[221] *See supra* Section VII.A.2.

[222] Exchange Act Rule 11Ac1–1, 17 CFR 240.11Ac1–1.

[223] Exchange Act Rule 11Ac1–4, 17 CFR 240.11Ac1–4.

[224] Pursuant to the terms of the CTA Plan, *see supra* notes 166 and 167, it is the responsibility of all participant exchanges and the NASD to report all sales transactions as promptly as possible, and establish collection procedures to ensure that 90% of such last sale reports are provided within 90 seconds of execution. CTA Plan, Section VIII. Market rules also require participants to report trades within 90 seconds after execution or designate them as being late. *See, e.g.,* NASD Rule 4632. A pattern or practice of late reporting without exceptional circumstances may be considered inconsistent with high standards of commercial honor and just and equitable principles of trade in violation of NASD Rule 2110.

[225] Other foreign markets allow market participants to delay reporting of certain trades. For example, the London Stock Exchange allows members to delay publication of certain large block trades for up to 60 minutes.

[226] *See supra* Section II.B.1.

[227] As the Commission staff stated in its 1994 report on the U.S. equity markets, the Commission also has a significant regulatory interest in ensuring that foreign markets are not used by U.S. broker-dealers to circumvent the application of U.S. regulatory requirements to the detriment of U.S. persons complying with those requirements. *See* Market 2000 Study, *supra* note 14, at VII–4.

[228] *See generally* Technical Committee of the International Organization of Securities Commissions (IOSCO), Report on Issues Raised for Securities and Futures Regulators by Under-Regulated and Uncooperative Jurisdictions 5 (Oct. 1994).

2. Requiring Foreign Markets to Register as National Securities Exchanges

A second option could be to require foreign markets with U.S. activities to register as national securities exchanges under the Exchange Act or to satisfy criteria for exemption from exchange registration.[229] Foreign markets that offer their services to U.S. persons would have to comply with the same regulatory obligations as U.S. exchanges. Under this approach, U.S. investors trading on foreign markets would be provided with the same protections they have when trading on U.S. markets. This could address the concern that, because trading on a foreign market may be indistinguishable from trading on a domestic market, investors may be led to expect that such trading would be subject to the same protections provided by the U.S. securities laws. This approach also could ensure that any foreign markets that offer services to U.S. investors would provide the same protections as registered or exempted exchanges, such as disclosure of trading rules, transparency, timely transaction reporting, and T+3 clearance and settlement.

The U.S. regulatory scheme applicable to exchanges, however, is not necessarily designed to accommodate entities that only engage in limited activities in the United States and that are primarily regulated in foreign jurisdictions. It may not be feasible, therefore, to regulate a foreign market's activities under a regulatory scheme that applies to domestic markets, particularly if a foreign market's only activity in the United States is to provide its U.S. members with the ability to trade directly on its facilities or to allow its members to provide U.S. persons with electronic linkages to trade outside of the United States. For example, U.S. exchange regulation could conflict with the regulation to which these markets are already subject in their home countries or could subject these markets to unnecessarily duplicative and expensive obligations. Any approach to regulating the U.S. activities of these foreign markets should attempt to minimize conflict with obligations imposed by their primary regulators. There may also be limits on the Commission's jurisdiction to impose exchange requirements on foreign markets that have remote access arrangements with U.S. persons. The Commission seeks comment on whether this option is feasible and consistent with the federal securities laws.

Question 107: Should the Commission require foreign markets with only limited activities in the United States to register as national securities exchanges or obtain an exemption from such registration? How would this affect U.S. persons trading directly on foreign markets?

3. Regulating Access Providers to Foreign Markets

A third approach could be to regulate the access providers to foreign markets, including broker-dealers, rather than regulating the foreign markets themselves. Entities that provide U.S. investors with the technological capability to trade directly on a foreign market's facilities appear to fall into two basic categories. The first category includes those entities that distribute or publish information regarding transactions on a foreign market, and provide a direct electronic link on behalf of the U.S. *members* of that foreign market. This category of access providers could be regulated as SIPs.[230] Under this approach, foreign markets, information vendors, and other parties that provide U.S. members with the ability to trade directly on foreign markets could either register as SIPs themselves, or could choose instead to have another registered SIP provide this capability to U.S. persons. This approach could also provide a safe harbor from exchange registration for foreign markets regulated abroad that choose to conduct their limited U.S. activities through a registered SIP.

The second category of access providers consists of those U.S. and foreign broker-dealers that provide U.S. persons who are not members of a foreign market with the technological capability to trade directly on a foreign market. Through their own or another broker-dealer's electronic linkage to a foreign market, broker-dealer access providers enable their customers to trade directly on the facilities of those foreign markets.[231] Because this access is provided in a manner that is functionally equivalent to that provided by SIP access providers, it presents the same risks to U.S. investors. Therefore, similar basic requirements, such as recordkeeping, reporting, disclosure, and antifraud requirements, could be applied to both SIP and broker-dealer access providers.

Such an approach, based on the regulation of access providers, might have several advantages over the two alternatives discussed above. First, regulating only the U.S. activities of foreign markets and other entities might reduce the likelihood of conflict with foreign markets' home country regulations. Second, creating a regulatory framework tailored for foreign markets could ensure appropriate protections for U.S. investors and clarify the regulatory status of foreign markets and other entities with only limited activities in the United States. Third, establishing a regulatory structure that focuses on the limited activities occurring in the United States, rather than on the activities that a foreign market or third party conducts primarily in a foreign country, may be more consistent with the Commission's mandate under the Exchange Act.[232] Finally, this approach recognizes that U.S. investors trade directly on foreign markets through a variety of sources, and could permit the Commission to regulate, in a similar manner, all entities that provide this service.

Question 108: How can the Commission best achieve its goal of regulating the U.S. activities of foreign markets? Commenters should take into consideration that foreign markets are regulated abroad, that there is a potential for international conflicts of law, and that the Commission has jurisdictional limits. Given the difficulties of surveilling public networks such as the Internet, would an access provider approach be workable?

a. Access Providers to U.S. Members of Foreign Markets

Entities that provide U.S. members of foreign markets with the technological capability to trade directly on these markets from remote locations could be regulated as SIPs under section 11A of the Exchange Act. Section 11A was enacted by Congress more than twenty years ago to create a statutory framework for the integration of automation into the securities markets.[233] Through this section, Congress sought to ensure that ''the securities markets and the regulations of the securities industry remain strong

[229] Currently, the only available exemption from exchange registration is based on limited volume of transactions. 15 U.S.C. 78(e). As discussed in Section IV.B. above, however, the Commission is soliciting comment on using its exemptive authority under section 36 of the Exchange Act to create a new category of exempted exchanges.

[230] *See infra* note 235 and accompanying text for a discussion of the statutory definition of SIP. Registered SIPs are required to comply with Section 11A of the Exchange Act.

[231] A broker-dealer would not be considered an access provider to a foreign market's trading facilities, however, if it handled the execution of its customer orders on foreign markets as part of its traditional brokerage activities.

[232] *See generally* 15 U.S.C. 78dd(b).

[233] Section 11A of the Exchange Act was adopted as part of the 1975 Amendments. Pub. L. No. 29, 89 Stat. 97 (1975).

and capable of fostering [the] fundamental goals [of the Exchange Act] under changing economic and technological conditions.''[234]

While Congress did not focus on cross-border trading specifically, Section 11A provides a regulatory basis to address changes in the markets that result from the development of a global, electronic marketplace. Section 11A extended the Commission's oversight authority to ''any person engaged in the business of (i) collecting, processing, or preparing for distribution or publication, or assisting, participating in, or coordinating the distribution or publication of, information with respect to transactions in or quotations for any security . . . or (ii) distributing or publishing . . . on a current and continuing basis, information with respect to such transactions or quotations.''[235] Congress gave the Commission authority to require such entities—referred to as SIPs—to register with the Commission and to establish rules governing SIP activities. All registered SIPs must carry out their functions in a manner consistent with the Exchange Act and report to the Commission denials or limitations of access to the services they provide. The Commission has the authority to review those decisions in much the same manner as it reviews denials or limitations of access to the services offered by registered U.S. exchanges.

Because information processing and dissemination are critical components of today's automated market, the definition of SIP potentially covers a broad range of entities that facilitate communications among investors, intermediaries, and markets. To date, however, only SIPs that process information exclusively on behalf of a U.S. exchange or securities association (known as ''exclusive processors'')[236] have been required to register with the Commission. Congress exempted non-exclusive SIPs from the Section 11A registration requirements until such time as the Commission, by rule or order, finds that the registration of such non-exclusive SIPs is necessary or appropriate in the public interest, for the protection of investors, or for the achievement of the purposes of section 11A. The Commission has not yet promulgated any such rules or orders.[237]

The Commission could use its authority to register and oversee non-exclusive SIPs in order to establish a regulatory framework that could accommodate U.S. investors' and intermediaries' participation in foreign markets from the United States. For example, any non-exclusive SIP could be required to register with the Commission under section 11A if it met the statutory definition of a SIP with respect to securities traded or approved for trading on a foreign market and if it provided a facility or means through which a U.S. person could transmit orders to a foreign market of which the U.S. person is a member.

This approach may have several advantages. For example, it would clarify the regulatory status of foreign markets that arrange for U.S. investors to be members of their trading facilities from the United States. As discussed above, several foreign markets have been reluctant to provide U.S. persons with direct trading capability without receiving assurances from the Commission that they would not be required to register as national securities exchanges under section 5 of the Exchange Act. If the Commission's concerns regarding the effects of U.S. investors' direct trading on foreign markets could be addressed through SIP regulation, there might be no overriding interest in regulating these limited activities of foreign exchanges in the United States under section 5. The Commission therefore solicits comment on the advantages of this approach. The Commission is also soliciting comment on whether it would be appropriate to create a ''safe harbor'' from exchange registration for *bona fide*[238] foreign markets that conduct all their securities activities in the United States through a registered SIP.

Question 109: What would be the best way for the Commission to regulate the limited U.S. activities of foreign markets that provide remote access to U.S. members?

Question 110: When should an entity be required to register with the Commission as a non-exclusive SIP under section 11A of the Exchange Act? For example, should the activities described above require registration as a SIP?

Question 111: If the SIP approach were adopted, is it likely that U.S. members of foreign markets would wish to transmit their orders to such markets through more than one SIP registered with the Commission? If so, should all but one of those SIPs be exempt from registration?

Question 112: Under the SIP approach, should foreign markets that allow their U.S. members to transmit their orders solely through a registered SIP have a safe harbor from registration as national securities exchanges?

Question 113: What type of activities should a registered SIP be permitted to conduct on behalf of a foreign market without the SIP or the foreign market registering as an exchange?

b. Broker-Dealer Access Providers

A U.S. or foreign broker-dealer that provides U.S. persons with terminals, software, access codes, or other means of directly trading on the facilities of a foreign market through a member's interface with that market, provides those U.S. persons with trading capabilities that are functionally equivalent to those of market members, as described above. These types of arrangements therefore present the same risks to U.S. investors and investor protection concerns as described above. An example of this type of arrangement is where a broker-dealer's customer is provided with the technological capability to direct the execution of its orders by viewing a foreign exchange's central limit order book and then transmitting, modifying, or subsequently cancelling an order based on the information in the limit order book.[239] Although the customer's trading on the foreign exchange may be technically or legally considered to be routed by the foreign market member, the customer has the ability to use the facilities of the exchange as though it were a member. By providing U.S persons with the capability to transmit directly, and to direct the execution of, orders to a foreign market, the broker-dealer is providing services that go

[234] S. Rep. No. 75, *supra* note 22, at 3.

[235] Exchange Act section 3(a)(22), 15 U.S.C. 78c(a)(22).

[236] Exchange Act section 3(a)(22)(B), 15 U.S.C. 78c(a)(22)(B). An ''exclusive processor'' is any securities information processor (which is defined in Section 3(a)(22)(A)) that: ''directly or indirectly, engages on an exclusive basis on behalf of any national securities exchange or registered securities association or, any national securities exchange or registered securities association which engages on an exclusive basis on its own behalf, in collecting, processing, or preparing for distribution or publication any information with respect to (i) transactions or quotations on or effected or made by means of any facility of such exchange or (ii) quotations distributed or published by means of any electronic system operated or controlled by such association.'' *Id.*

[237] Exchange Act section 11A(b)(1), 15 U.S.C. 78k–1(b)(1). In 1975, the Commission adopted Rule 11Ab2–1 and Form SIP, which provide that each SIP that is required to be registered pursuant to Section 11A(b)(1) of the Exchange Act (*i.e.*, exclusive SIPs) must file an application for registration on Form SIP. Securities Exchange Act Release No. 11673 (Sept. 23, 1975), 40 FR 45448 (October 2, 1975). Currently, there are five exclusive processors registered under Section 11A: (1) The Consolidated Tape Association, (2) the Consolidated Quotation System, (3) the Securities Industry Automation Corporation, (4) Nasdaq, and (5) the Options Price Reporting Authority.

[238] *See infra* Section VII.B.1.c.(i).

[239] This type of arrangement is commonly referred to in this context as a broker-dealer ''give-up.''

beyond traditional brokerage services.[240] Because these services are a relatively recent development, it appears that only a small number of registered broker-dealers provide this type of direct automated service to their institutional customers.[241] In view of these developments, it may be appropriate to regulate, in the manner just described for SIP access providers, both foreign and U.S. broker-dealers that provide U.S. persons with access to an automated facility or means through which they can directly transmit, and direct the execution of, orders on a foreign market.

In some cases, broker-dealers provide their customers with this type of direct linkage to U.S. exchanges through systems such as the NYSE's SuperDOT system.[242] Although a U.S. exchange has obligations under the federal securities laws and is subject to Commission oversight, a foreign market does not have similar obligations. The ability to trade directly on foreign markets, therefore, may raise investor protection concerns.

U.S. registered broker-dealers are also subject to a panoply of regulations and supervisory requirements intended to protect both the capital markets and investors,[243] and have general agency obligations to their customers under the federal securities laws. Nevertheless, these requirements, in their current form, do not necessarily address concerns raised when broker-dealers provide automated means for U.S. persons to trade directly on foreign markets. Consequently, the Commission could separately regulate the activities of U.S. broker-dealers that act as access providers.

Foreign broker-dealers that engage in activities as broker-dealer access providers are, in most cases, exempt from broker-dealer registration pursuant to Rule 15a–6 under the Exchange Act.[244] These access providers therefore are not subject to the same requirements under the U.S. securities laws as registered broker-dealers. The question thus arises of whether the Commission should require foreign broker-dealers to register as U.S. broker-dealers if they act as access providers to foreign markets on behalf of U.S. persons. Traditional broker-dealer regulation could subject foreign broker-dealers to requirements that are not necessary to address concerns raised by the activities of access providers. Such requirements could include the maintenance of specified capital, and SIPC and SRO membership. Under an approach that applied to broker-dealer access providers, however, the Commission could subject foreign broker-dealers that enable U.S. investors to trade directly on foreign markets to a regulatory framework tailored to their access provider activities.

Question 114: What types of automated broker-dealer systems, both operational and contemplated, would be encompassed within the above description of access providers to foreign markets? How widespread are these activities?

Question 115: Would the above description of broker-dealer access providers adequately and clearly exclude traditional brokerage activities, particularly handling the execution of customer orders on foreign markets? If not, how should such activities be distinguished from traditional brokerage activities, particularly traditional cross-border activities? Should U.S. broker-dealers that provide investors with access to foreign markets be subject to any additional requirements?

Question 116: Should foreign broker-dealers that provide U.S. investors with automated access to foreign markets be required to register as broker-dealers on the basis of that activity?

c. Requirements Applicable to Access Providers

If the Commission were to regulate foreign market access providers, there are a number of conditions that could be applied to these entities. For example, as discussed further below, the Commission could subject registered SIP and broker-dealer access providers to recordkeeping, reporting, disclosure, or antifraud requirements.

Question 117: What types of conditions, if any, should the Commission place on access providers if it were to pursue that approach?

(i) Conditions Relating to the Type of Foreign Market

Any new regulatory approach developed by the Commission to address the unique concerns raised by access providers would not be intended as an alternative regulatory scheme for U.S. exchanges. Accordingly, any such approach would be applicable only to *bona fide* foreign markets. There are a variety of ways the Commission could define a *bona fide* foreign market. For example, a *bona fide* foreign market could be any entity that meets the definition of an exchange under Section 3(a)(1) of the Exchange Act or that otherwise conducts the business of an exchange, but that is organized and has its principal place of business outside of the United States. Any national securities exchange, national securities association, or exchange exempt from registration pursuant to a Commission rule or order would not be considered a *bona fide* foreign market. The Commission could also exclude from the definition of a *bona fide* foreign market an exchange that operates a trading facility or provides terminals in the United States.

Another issue is whether SIP and broker-dealer access providers should be permitted to transmit orders for U.S. persons only to foreign markets that would be able to share information with the Commission in connection with an investigation. As discussed above, the ability to access trading and other market information is an essential component of the Commission's ability to detect and deter fraud. Therefore, the Commission could require a level of information sharing that could ensure that the Commission has the ability to obtain necessary information from a foreign regulatory authority and to obtain meaningful assistance in the case of fraud or manipulation involving U.S. persons and a foreign market's participants.[245] For example, the Commission could require access providers to enter into private contractual agreements with foreign markets to which orders are transmitted, under which foreign markets represent

[240] This type of electronic ''pass-through'' arrangement would not encompass customer orders executed on foreign markets by broker-dealers on behalf of their customers as part of a broker-dealers' traditional brokerage activities.

[241] The principal additional requirement with which registered broker-dealers that are access providers to foreign markets would have to comply under this type of approach, would be disclosure of the specific risks relating to the trading on foreign markets. Registered broker-dealers are already subject to most of the recordkeeping, reporting, and antifraud requirements discussed in Section VII.B.1.c.(iii).

[242] *See supra* note 16.

[243] For example, a broker-dealer is required to register with the Commission, become a member of an SRO and SIPC, maintain certain minimum levels of net capital, segregate customer funds, maintain certain books and records, and make periodic reports to the Commission. In addition, broker-dealers are subject to statutory disqualification standards and the Commission's disciplinary authority. *See* Exchange Act section 15, 15 U.S.C. 78o; Securities Investor Protection Act of 1970, 15 U.S.C. 78aaa. *See also* 17 CFR 240.15a–6.

[244] This release does not address any issues that may be raised regarding the applicability of Rule 15a–6 under the Exchange Act or a foreign broker-dealer's obligations thereunder. 17 CFR 240.15a–6.

[245] Some U.S. exchanges that trade derivative products based on securities primarily traded on foreign markets already have surveillance sharing agreements in place. These surveillance sharing agreements typically require signatories to provide to each other, upon reasonable request, information about market trading activity, clearing activity, and, in some instances, the identities of the purchasers and sellers of securities.

that they are not prohibited by local law from sharing information with the Commission and, as a condition of registration, agree to provide information to the Commission upon request. Alternatively, the Commission could designate certain foreign markets that, in its experience, are able to share information with the Commission.

Question 118: If the Commission decides to regulate access providers to foreign markets, what criteria should the Commission use in determining whether an exchange is a *bona fide* foreign market? Should a market be required to have at least a majority of foreign members in order to be a *bona fide* foreign market? Should the Commission exclude exchanges that provide terminals in the United States?

Question 119: Should the Commission regulate as a U.S. exchange any market that, although organized and having its principal place of business outside of the United States, is under common control with or controlled by U.S. persons, or whose decisions regarding trading rules, practices, or procedures are made by U.S. persons?

Question 120: What factors should the Commission use in determining whether an exchange is operating a trading facility in the United States and is not a *bona fide* foreign market? If exchange-owned terminals are located in the United States, should this constitute operating a trading facility in the United States?

Question 121: What effect would a reinterpretation of the term ''exchange'' under section 3(a)(1) of the Exchange Act have on any Commission proposal to regulate SIP and broker-dealer access providers?

Question 122: If the Commission decides to regulate access providers to foreign markets, should the Commission require access providers to transmit orders only to foreign markets that are willing to share, and capable of sharing, information with the Commission in connection with investigations involving violations of U.S. securities laws? If so, what standard should the Commission use in determining whether a foreign market would provide meaningful assistance to the Commission? If commenters believe that SIP and/or broker-dealer access providers should be permitted to transmit orders to any foreign market, indicate how the Commission could ensure that it has the ability to enforce the applicable provisions of the federal securities laws.

Question 123: Should the Commission require access providers to transmit orders only to foreign markets that are located in countries that have entered into arrangements with the Commission to provide enforcement and information sharing assistance?

(ii) Conditions Relating to Type of Persons and Securities

Access providers could be limited to providing their services only to certain sophisticated U.S. institutional investors. Another alternative could be to permit broker-dealer access providers to provide their services to all U.S. investors, but restrict the type of investors to which SIP access providers could provide their services. The Commission is soliciting comment on whether both SIP and broker-dealer access providers should provide their services only to certain sophisticated U.S. institutional investors. In addition, the Commission solicits comment on whether the additional customer protection requirements to which registered broker-dealers are subject should mean that broker-dealer access providers should be allowed to provide their services to all U.S. investors.

Another issue to be considered is whether it would be appropriate to permit SIP and broker-dealer access providers to transmit orders from U.S. persons to foreign markets only for foreign securities. On the whole, transactions in securities of domestic issuers have a greater potential to affect the U.S. securities markets than transactions in securities of non-U.S. issuers, where the primary market is typically overseas. Moreover, when a U.S. access provider is used to trade the securities of domestic issuers on a foreign market, the foreign market could be required to register as a U.S. exchange under section 5 of the Exchange Act.[246]

Question 124: If the Commission regulated access providers through the approach described above, should SIP access providers be limited to providing their services to sophisticated institutions or should they be allowed to provide any U.S. investor with the capability of directly trading on foreign markets as members? If so, should broker-dealer access providers be subject to similar requirements?

Question 125: If the Commission permits SIP access providers to offer their services only to broker-dealers and certain sophisticated institutions, how should this category of sophisticated institutions be defined?

Question 126: Should the Commission permit SIP and broker-dealer access providers to transmit orders to foreign markets for the securities of U.S. issuers or only for the securities of non-U.S. issuers?

Question 127: Should the Commission limit the ability of SIP and broker-dealer access providers to transmit orders to foreign markets for the securities of non-U.S. issuers if the ''principal market'' for those securities is located in the United States? If so, how should the Commission determine when the ''principal market'' of a non-U.S. security is located in the United States?

Question 128: If the Commission permits SIP and broker-dealer access providers to transmit orders to foreign markets only for securities of non-U.S. issuers, how should the Commission distinguish between U.S. and non-U.S. issuers?

(iii) Recordkeeping, Reporting, Disclosure, and Antifraud Requirements

Recordkeeping and reporting requirements, generally, are an important component of the Commission's oversight role. Adequate trading records are invaluable to the Commission's efforts to enforce the antifraud provisions of the Exchange Act. Without adequate records and reports, the Commission would be unable to effectively monitor, evaluate, and examine the activities of registered SIP and broker-dealer access providers.

If the Commission decides to adopt a regulatory framework for access providers, such recordkeeping and reporting requirements could be crucial elements in enhancing Commission oversight of their activities, and in identifying areas where surveillance is needed to detect fraudulent, deceptive, and manipulative practices. Records and periodic reports could also assist the Commission in gaining an understanding of the effects of foreign markets' activities in the United States and with U.S. persons. For example, these recordkeeping and reporting requirements could be similar to the requirements currently imposed on broker-dealers under Exchange Act Rule 17a–23.[247] Specifically, the Commission could require access providers to keep (i) records regarding the identity of their

[246] U.S. courts have interpreted the extraterritorial application of the Exchange Act more expansively when the securities that are the subject of the transaction are issued by a U.S. corporation. *See* ITT v. Cornfeld, 619 F.2d 909 (2d Cir. 1980); ITT v. Vencap, Ltd., 519 F.2d 1001, 1017 (2d Cir. 1975) (''We believe that Congress intended the Exchange Act to have extraterritorial application in order . . . to protect the domestic securities market from the effects of improper foreign transactions in American securities.'') (quoting Schoenbaum v. Firstbrook, 405 F.2d 215, 206 (2d Cir. 1968)).

[247] 17 CFR 240.17a–23. To the extent that an access provider that is a U.S. broker-dealer is already subject to Rule 17a–23, that access provider would not be subject to duplicative requirements.

U.S. users; (ii) records regarding daily summaries of trading and time-sequenced records of each transaction effected through the access provider; (iii) information disseminated to U.S. investors, such as quotation and transaction information regarding foreign securities traded on foreign markets; and (iv) copies of the membership standards used by each foreign market to which the SIP provides the U.S. members of the market with the ability to trade directly.

In addition, access providers could be required to file periodic reports. Such periodic reports could contain information regarding (i) the types of securities for which orders are transmitted; (ii) the names of users of the access provider; and (iii) certain transaction information, such as the total volume, number, and monetary value of transactions for each foreign market to which orders are transmitted.

If certain entities that provide U.S. investors with the ability to trade directly on foreign markets were required to register as SIPs, they would, by operation of section 11A of the Exchange Act, be required to notify the Commission, and the Commission would be required to review, any limitations or prohibitions of access to the services offered by such SIPs.[248] Pursuant to Section 11A, the Commission would be required to set aside any action only if it determined that such action was unfairly exclusionary.

In addition to recordkeeping and reporting requirements, the Commission is soliciting comment on whether access providers could be required to make certain disclosures to U.S. investors. Disclosure has always been a cornerstone of the Commission's efforts to protect investors. The question becomes what types of specific disclosures are needed to ensure that U.S. persons have sufficient information regarding foreign securities traded on a particular foreign market through an access provider. For example, SIP and broker-dealer access providers could be required to disclose information about the material risks of trading on foreign markets, as well as the risks of using their own facilities. Such disclosure could include information about trading priorities on a foreign market and notification that the nature and timeliness of pre-trade and post-trade information provided by a foreign market differs from that provided by U.S. registered securities exchanges. In addition, access providers could be required to disclose that there is no guarantee under U.S. law that clearance or settlement of securities trades will occur. SIP and broker-dealer access providers could also be required to disclose system-related risks, including limitations affecting the access providers' capacity to disseminate timely information or to handle users' orders during peak periods.

The Commission could also consider specific antimanipulation rules for registered SIP and broker-dealer access providers in order to clarify the obligations imposed upon these entities under the antifraud provisions of the federal securities laws. The Commission has promulgated rules applicable specifically to registered broker-dealers that prohibit them from engaging in manipulative, deceptive, or other fraudulent activities.[249] It would initially appear that SIP and broker-dealer access providers should be similarly prohibited from engaging in fraudulent, deceptive, or manipulative activities. For this reason, the Commission could consider the need for rules supplementing the general prohibition against fraud in section 10(b) of the Exchange Act, and Rule 10b–5 thereunder.[250] For example, it could specifically prohibit access providers from distributing or publishing information that they have reasonable grounds to believe is fraudulent, deceptive, or manipulative, or from colluding to promote certain stocks without the knowledge of U.S. investors.

Question 129: If the Commission decides to regulate access providers to foreign markets, should they be required to make and keep records? What records should registered SIP and broker-dealer access providers be required to maintain?

Question 130: Should access providers be required to file periodic reports? If so, what information should those contain?

Question 131: Should broker-dealer access providers be required to keep records of denials of access to their services? Should they be required to notify the Commission of such denials of access?

Question 132: What types of risks should be disclosed to users of SIP and broker-dealer access providers? For example, should SIP and broker-dealer access providers be required to disclose the listing and maintenance standards of foreign markets to which they transmit orders on behalf of U.S. persons? What would be the costs associated with such a requirement?

Question 133: Should access providers be required to make disclosures to sophisticated institutions?

Question 134: What market information should SIP and broker-dealer access providers be required to provide to the users of their services?

C. Addressing the Differences Between U.S. and Foreign Markets' Listed Company Disclosure Standards

As the Commission develops an approach to the appropriate regulation of the U.S. activities of foreign markets, it must also address the issues that arise because most securities traded on foreign markets are not registered under the Securities Act or the Exchange Act, and the issuers of those securities do not file reports with the Commission. Section 5 of the Securities Act makes it unlawful for any person, through the use of interstate commerce or the mails, to offer or sell a security in a public distribution prior to the effective date of the registration statement.[251] Unless an exemption applies, securities offered or sold in the United States by issuers (whether domestic or foreign) must be registered with the Commission pursuant to section 5 of the Securities Act.[252] In some cases, foreign securities issued abroad, but later sold in the United States, may be eligible for the exemption under section 4(1) of the Securities Act for ''transactions by any person, other than an issuer, underwriter or dealer.'' [253] However, to the extent that a foreign issuer effects a distribution over the facilities of a foreign market, SIP access providers to that market could be required to ensure that U.S. investors may not purchase

[248] Exchange Act section 11A(b)(5), 15 U.S.C. 78k–1(b)(5). The Senate Committee on Banking, Housing and Urban Affairs report on the Securities Acts Amendments of 1975 indicates that one of the purposes of expanding the Commission's regulatory authority over the processors and distributors of market information was ''to assure that these communications networks are not controlled or dominated by any particular market center, to guarantee fair access to such systems * * * and to prevent any competitive restriction on their operation not justified by the purposes of the Exchange Act.'' S. Rep. No. 75, 94th Cong., 1st Sess. 9 (1975). Under Section 11A(b)(5)(A) of the Exchange Act, registered SIPs are required to file notices of denial or limitation of access with the Commission. 15 U.S.C. 78k–1(b)(5)(A).

[249] *See* 17 CFR 240.15c1–2 through 240.15c1–9.

[250] 15 U.S.C. 78j(b); 17 CFR 240.10b–5.

[251] Securities Act section 5, 15 U.S.C. 77e.

[252] For example, section 3(a) of the Securities Act enumerates 12 categories of exempted securities to which the registration requirements of section 5 do not apply, including securities issued by the U.S. Government, religious and benevolent organizations, savings and loan associations, and cooperative banks. 15 U.S.C. 77c(a). Securities of foreign private and sovereign issuers are not exempted securities. In addition, section 4 of the Securities Act sets forth a number of exempted transactions. 15 U.S.C. 77d.

[253] Securities Act section 4(1), 15 U.S.C. 77d(1).

that security during the distribution, absent registration or an available exemption under the Securities Act. Similarly, the Commission requests comment on whether broker-dealer access providers should be required to ensure that U.S. investors do not purchase the securities of a foreign issuer effecting a distribution on a foreign market, unless there is an effective registration statement or an applicable exemption.

As noted, U.S. investors historically have been able to purchase unregistered securities traded on foreign markets by placing orders through one or more domestic and foreign broker intermediaries, which in turn have direct or indirect access to the foreign exchange or market. U.S. and foreign broker-dealers are today providing certain U.S. investors with automated links to foreign markets. As technology facilitates the ability of U.S. investors to conduct transactions directly on foreign securities exchanges and markets, the distinctions between the domestic and foreign trading markets may quickly disappear.

In the Exchange Act, Congress has set the threshold for requiring registration and reporting either upon a company's listing on a U.S. exchange [254] or, in the case of a class of equity securities, upon having at least 500 record holders (in the case of foreign issuers, 300 of which are in the United States) and assets over a specified dollar amount.[255] These disclosure requirements provide transparency with respect to the business, management, operating results and financial condition of the issuers of the traded securities. This is different from the market transparency provided by the Commission's regulatory and disclosure requirements applicable to markets and their members.

The Commission has accommodated the legitimate interest of foreign issuers whose shares come to be held in the United States by providing an exemption from registration under Exchange Act Rule 12g3–2(b) [256] if those shares are not listed on a U.S. exchange or quoted on Nasdaq and if the issuer has not registered an offering of securities under the Securities Act. These issuers need not register so long as they provide the Commission with the information that they make available to their securityholders in their home countries. The exemption is grounded in the jurisdictional and comity concerns that the Commission could not require a foreign company to register and file reports if the company has not affirmatively taken steps to enter our markets, regardless of the level of interest by U.S. investors in the company's securities.

These concerns directly relate to issues raised by the extensive trading in this country of unregistered foreign securities in the U.S. over-the-counter markets, bulletin boards, and alternative trading systems. Despite the extensive U.S. ownership and trading in these foreign securities, registration under the Exchange Act is not required by virtue of the Rule 12g3–2(b) exemption.

As noted in Section IV.B., if the Commission decides to regulate certain domestic alternative trading systems as exchanges, foreign securities traded on those exchanges would have to be registered. By excluding foreign markets from the definition of exchange, however, absent Commission action, Rule 12g3–2(b) would continue to provide an exemption for the foreign issuers of the securities traded on those markets from registration under the Exchange Act. By facilitating U.S. investor access to foreign markets, the SIP or broker-dealer approach described above could promote a real time market in the United States for the securities of potentially thousands of foreign companies without those companies meeting U.S. disclosure and accounting standards. The question thus becomes whether the access provided by SIPs to trading in foreign markets should be limited to securities that are registered with the Commission pursuant to section 12 of the Exchange Act. In addition, there is a question as to whether the Commission should also limit broker-dealer access providers to providing U.S. investors with access to securities trading in foreign markets that are registered under section 12, or whether a distinction should be made between SIP access providers and broker-dealer access providers. The Commission is soliciting comment on whether the approach described above adequately protects the interests of U.S. investors.

Question 135: Should direct trading in foreign listed companies be limited to those that satisfy U.S. disclosure standards in order to better protect U.S. investors?

Question 136: Is it sufficient to merely disclose to investors that the information available about a foreign security may significantly differ from the information that would be available about U.S. securities? Do public policy concerns dictate that the Commission make distinctions based on whether investors receive adequate information?

Question 137: Are there circumstances under which unregistered foreign securities should be permitted to trade on foreign markets through an access provider? For example, should the Commission establish some *de minimis* threshold for a foreign security based on the dollar value of the U.S. float or trading volume in that security, or on the relative percentage of U.S. float or trading volume compared to that of the home or worldwide markets?

Question 138: Should the exemption from registration under Exchange Act Rule 12g3–2(b) be available if a significant portion of an issuer's float is traded in the United States?

Question 139: Given that broker-dealers currently trade unregistered securities for customers, should the Commission reconsider its approach to securities registration requirements in this context? Are there other viable alternatives that would ensure adequate disclosure to U.S. investors trading on foreign markets?

Question 140: Is trading in unregistered foreign securities through an access provider to a foreign market appropriate if access is limited to sophisticated investors? For example, should access providers be permitted to transmit orders for unregistered foreign securities to a foreign market on behalf of qualified institutional buyers as defined in Rule 144A of the Securities Act?

Question 141: Are there uniform procedures that the Commission should impose on foreign markets or on access providers to assure that securities are not sold to U.S. investors in circumstances that result in a public distribution of securities in the United States that are not registered under the Securities Act?

Question 142: What are the consequences to SEC reporting companies if unregistered foreign securities listed on foreign markets are available to be purchased or sold through access providers?

D. Costs and Benefits of Revising Regulation of Foreign Market Activities in the United States

Direct U.S. investor access to foreign markets could provide significant benefits to U.S. investors. Such access may provide these investors with entirely new investment opportunities, and may significantly reduce their transaction costs. The Commission generally solicits comment on the expected costs and benefits of the three alternative approaches to regulating the

[254] Section 12(a) of the Exchange Act.

[255] Section 12(g) of the Exchange Act, 15 U.S.C. 78*l*(g), and Rules 12g–1 and 12g3–2(a), 17 CFR 240.12g–1 and 240.12g3–2(a).

[256] 17 CFR 240.12g3–2(b).

activities of foreign markets in the United States, as discussed above.

E. Conclusion

The increasing globalization of the securities markets has created new opportunities for U.S. investors. The establishment of new securities markets coupled with the enhancement of corporate disclosure and trade transparency in many stock exchanges throughout the world has dramatically increased their range of viable investment opportunities. At the same time, advancements in technology have made foreign investment opportunities more accessible and affordable to U.S. investors. Although these are positive developments, they also raise concerns that the activities of foreign markets in the United States could adversely affect not only U.S. investors, but also the U.S. securities markets.

The Commission believes it is critical to address the regulatory issues raised by U.S. investors' use of technology to trade directly on foreign markets. The Commission hopes to develop a consistent, long-term approach to address these issues, while ensuring that key protections for U.S. investors, as well as U.S. markets, are in place. Discussed above are three alternatives. The Commission is seeking comment on each of these alternatives, along with commenters' ideas about other viable alternatives.

Question 143: Would any of the approaches described above provide an effective means of addressing the issues raised by foreign market activities in the United States, including providing key protections for U.S. investors? What would be the benefits of each approach? What would be the drawbacks of each approach?

VIII. Summary of Requests for Comment

Following receipt and review of comments, the Commission will determine whether rulemaking or other action is appropriate. Commenters are invited to discuss the broad range of concepts and approaches described in this release concerning the Commission's registration and oversight of national securities exchanges, alternative trading systems, and foreign market activities in the United States. In addition to responding to the specific questions presented in this release, the Commission encourages commenters to provide any information to supplement the information and assumptions contained herein regarding the functioning of secondary markets, the roles of market participants, the advantages and disadvantages of the suggested reforms, the expectations of investors, and cross-border trading. The Commission also invites commenters to provide views and data as to the cost and benefits associated with possible changes discussed above in comparison to the costs and benefits of the existing statutory framework. In order for the Commission to assess the impact of changes to the Exchange Act's regulatory scheme, comment is solicited, without limitation, from investors, broker-dealers, exchanges, and other persons involved in the securities markets. In sum, the Commission requests comment on the following questions:

Question 1: The Commission seeks comment on the concerns identified above and invites commenters to identify other issues raised by the current approach to regulating alternative trading systems.

Question 2: Are the concerns raised in this release with regard to the operation of alternative trading systems under the current regulatory approach unique to such systems? To what extent could these concerns be raised by broker-dealers that do not operate alternative trading systems, such as a broker-dealer that matches customer orders internally and routes them to an exchange for execution or a broker-dealer that arranges for other broker-dealers to route their customer orders to it for automated execution?

Question 3: What regulatory approaches would best address the concerns raised by the growth of alternative trading systems and the needs of the market? Is the current approach the most appropriate one?

Question 4: What should be the objectives of market regulation? Are the goals and regulatory structure incorporated by Congress in the Exchange Act appropriate in light of technological changes? Are business incentives adequate to accomplish these goals?

Question 5: Are the regulatory categories defined in the Exchange Act sufficiently flexible to accommodate changes in market structure? If not, what other categories would be appropriate? How should such categories be defined?

Question 6: Can the Commission regulate markets effectively through standard-oriented regulation of the type described above?

Question 7: How could the Commission enforce compliance with the Exchange Act under such a standard-oriented approach?

Question 8: Is the current regulatory framework an effective form of oversight, in light of technological changes? Are there other regulatory techniques that would be comparably effective? If so, would the implementation of such techniques be consistent with congressional goals reflected in the Exchange Act?

Question 9: Are there viable alternatives within the existing Exchange Act structure, other than those discussed below, that would address the concerns raised by the growth of alternative trading systems and congressional goals in adopting the Exchange Act?

Question 10: What types of alternative trading systems would it be appropriate to regulate in this manner?

Question 11: If the Commission decided to further integrate alternative trading systems into the NMS through broker-dealer regulation, should it require alternative trading systems to submit all orders displayed in their systems into the public quotation system? If not, how should the Commission ensure adequate transparency?

Question 12: If the Commission requires alternative trading systems to submit all orders displayed in their systems into the public quotation system, how can duplicate reporting by alternative trading systems and their participant broker-dealers be prevented?

Question 13: Are there other methods for integrating all orders submitted into alternative trading systems into the public quotation system?

Question 14: Are there any reasons that orders available in alternative trading systems should not be available to the public?

Question 15: If the Commission requires alternative trading systems to allow non-participants to execute against orders of system participants, how should it ensure that non-participants are granted equivalent access?

Question 16: If the Commission requires alternative trading systems to allow non-participants to execute against orders of system participants, how should it determine whether the fees charged to non-participants by such systems are reasonable and do not have the effect of denying access to orders?

Question 17: Are there any reasons that non-participants should not be able to execute against orders of participants in alternative trading systems?

Question 18: Should the Commission require alternative trading systems to provide additional information (such as identifying counterparties) to their SRO in order to enhance the SRO's audit trail and surveillance capabilities?

Question 19: What other methods could the Commission use to enhance

market surveillance of activities on alternative trading systems?

Question 20: Should SROs be required to surveil trading by their members in securities that are not listed or quoted on the market operated by that SRO?

Question 21: Should alternative trading systems be required to follow guidelines regarding the capacity and integrity of their systems? If not, how should the Commission address systemic risk concerns associated with potentially inadequate capacity of alternative trading systems, particularly those systems with significant volume?

Question 22: With what types of standards regarding computer security, capacity, and auditing of systems, should alternative trading systems be required to comply?

Question 23: To what extent would complying with systems guidelines similar to those implemented by exchanges and other SROs require modification to the current procedures of alternative trading systems? What costs would be associated with such modifications? How much time would be required to implement the necessary modifications and systems enhancements? Please provide a basis for these estimates.

Question 24: Is access to alternative trading systems an important goal that the Commission should consider in regulating such systems? If so, are there circumstances in which alternative trading systems should be able to limit access to their systems (for example, should the Commission be concerned about access to an alternative trading system that has arranged for its quotes to be displayed as part of the public quotation system)?

Question 25: If alternative trading systems were to continue to be regulated as broker-dealers and were subject to a fair access requirement, should the Commission consider denial of access claims brought by participants and non-participants in alternative trading systems? If not, are there other methods that could adequately address such claims?

Question 26: Are commenters aware of any unfair denials of access by broker-dealers operating alternative trading systems, where there were no alternative trading venues available to the entities denied access?

Question 27: Would enhanced surveillance of alternative trading systems by their SROs raise competitive concerns that could not be addressed through separation of the market and regulatory functions of the SROs?

Question 28: If alternative trading systems continue to be regulated as broker-dealers, are there other ways to integrate the surveillance of trading on alternative trading systems?

Question 29: What is the feasibility of establishing an SRO solely for the purpose of surveilling the trading activities of broker-dealer operated alternative trading systems, that does not also operate a competing market?

Question 30: If alternative trading systems continue to be regulated as broker-dealers, how can the Commission address anticompetitive practices by such systems?

Question 31: Would this approach be an effective means of addressing the issues raised by the growth of alternative trading systems? What would be the benefits of such an approach? What would be the drawbacks of such an approach?

Question 32: If the Commission reinterpreted the term ''exchange,'' are the factors described above (*i.e.*, (1) consolidating orders of multiple parties and (2) providing a facility through which, or setting conditions under which, participants entering such orders may agree to the terms of a trade) sufficient to include the alternative trading systems described above?

Question 33: Is broadening the Commission's interpretation of ''exchange'' to cover diverse markets, and then exempting all but the most significant of these new exchanges from registration, the most appropriate way to address the regulatory gaps discussed above and provide the Commission with sufficient flexibility to oversee changing market structures?

Question 34: Are there any other categories of alternative trading systems that have sufficiently minimal effects on the public secondary market that they should be treated as exempted exchanges?

Question 35: Should low impact markets be regulated as exempted exchanges, rather than as broker-dealers?

Question 36: What measure or measures should be used in determining whether a market has a low impact? What is the level above which an alternative trading system should not be considered to have a low impact on the market? At what level should an already registered exchange be able to deregister?

Question 37: Should an alternative trading system be considered to have a low impact on the market and be treated as an exempted exchange if it trades a significant portion of the volume of one security, even if the trading system's overall volume is low in comparison to the market as a whole?

Question 38: In determining whether an alternative trading system has a low impact, what factors other than volume should the Commission consider? Should this determination be affected if the operator of an alternative trading system was the issuer of securities traded on that system?

Question 39: Should passive markets be regulated as exempted exchanges, rather than as broker-dealers?

Question 40: Are the requirements described above appropriate to ensure the integrity of secondary market oversight?

Question 41: Should any other requirements be imposed upon exempted exchanges, such as requirements that an exempted exchange provide fair access or establish procedures to ensure adequate system capacity, integrity, and confidentiality?

Question 42: Should requirements vary with the type of alternative trading system (*e.g.*, should passive systems be subject to different conditions than systems exempted on the basis of low impact)?

Question 43: Should the Commission require that securities traded on exempted exchanges be registered under section 12 of the Exchange Act? Should different disclosure standards be applicable to such securities if they are only traded on such exchanges?

Question 44: Should the Commission allow institutions to be participants on registered exchanges to the same extent as registered broker-dealers? If so, should the Commission adopt rules allowing registered exchanges to have institutional participants, or should the Commission issue exemptive orders on a case-by-case basis, upon application for relief by registered exchanges?

Question 45: Should the Commission allow exchanges to provide services exclusively to institutions?

Question 46: If the Commission allows institutions to participate in exchange trading, should the Commission view all entities that have electronic access to exchange facilities as ''members'' under the Exchange Act and then exempt exchanges from section 6(c)(1)?

Question 47: Is it foreseeable that exchanges will wish to permit retail investors to be participants in their markets? If so, should the Commission allow retail participation on registered exchanges to the same extent as registered broker-dealers?

Question 48: Should the Commission allow registered exchanges to provide services exclusively to retail investors?

Question 49: Could exchanges have various classes of participants, as long as admission criteria and means of

access are applied and allocated fairly? Would it be in the public interest if new or existing exchanges sought to operate primarily or exclusively on a retail basis? What would be the advantages and disadvantages if new or existing exchanges were to admit as participants only highly capitalized institutions or only highly capitalized institutions and broker-dealers?

Question 50: Should non-membership exchanges (including alternative trading systems that may register as exchanges) be exempt from fair representation requirements?

Question 51: Should all exchanges be required to comply with section 6(b)(3) by having a board of directors that includes participant representation?

Question 52: If not, are there alternative structures that would provide independent, fair representation for all of an exchange's constituencies (including the public)?

Question 53: Would the revised interpretation of ''exchange'' being considered by the Commission adequately and clearly include alternative trading systems that operate open limit order execution systems (even those that also provide brokerage functions)?

Question 54: In light of the decreasing differentiation between market maker quotes and customer orders in trading, should the Commission consider an ''order'' to include any firm trading interest, including both limit orders and market maker quotes?

Question 55: What should the Commission consider to be ''material conditions'' under which participants entering orders may agree to the terms of a trade? For example, should an alternative trading system be considered to be setting ''material conditions'' when it standardizes the material terms of instruments traded on the market, such as standardizing option terms or requiring participants that display quotes to execute orders for a minimum size or to give priority to certain types of orders?

Question 56: Is it appropriate for the Commission to consider the activities described above as broker-dealer activities?

Question 57: How should a revised interpretation of exchange adequately and clearly distinguish broker-dealer activities, such as block trading and internal execution systems, from market activities?

Question 58: Are the distinctions discussed above accurate reflections of exchange and broker-dealer activities? Are there other factors that may better distinguish a broker-dealer from an exchange?

Question 59: How should a revised interpretation of the term ''exchange'' adequately and clearly distinguish broker-dealer activities, such as block trading and internal execution systems, from market activities?

Question 60: What factors should the Commission consider in determining whether an organization of dealers is sufficiently ''organized'' to require exchange registration?

Question 61: Does the revised interpretation of ''exchange'' described above clearly exclude information vendors, bulletin boards, and other entities whose activities are limited to the provision of trading information? How should the Commission distinguish between information vendors, bulletin boards, and exchanges?

Question 62: If the Commission expands its interpretation of ''exchange,'' should the Commission exempt interdealer brokers that deal only in exempted securities from the application of exchange registration and other requirements?

Question 63: How could the Commission define interdealer brokers in a way that would implement congressional intent not to regulate traditional interdealer brokers as exchanges, without unintentionally exempting other alternative trading systems operated by brokers?

Question 64: How could the Commission foster the continued trading of all securities currently traded on alternative trading systems if these systems are classified as exchanges under the interpretation described above and some of these systems are required to register as national securities exchanges? For example, what would be the effect on alternative trading systems that wish to trade securities exempted from registration under Rule 144A if those systems are required to register as national securities exchanges?

Question 65: How would the requirement to have rules in place for trading unlisted securities affect the viability of alternative trading systems that are required to register as national securities exchanges?

Question 66: Would the specifications in the OTC–UTP plan relating to the trading of Nasdaq/NM securities pose particular problems for systems that are required to register as national securities exchanges?

Question 67: Should the Commission extend UTP to securities other than NM securities, such as Nasdaq SmallCap securities? What effect would an inability to trade Nasdaq SmallCap and other non-Nasdaq/NM securities have upon alternative trading systems that are required to register as national securities exchanges?

Question 68: What effect would the prohibition on UTP trading of newly listed stock until the day following an initial public offering have upon systems that are required to register as national securities exchanges?

Question 69: How should existing exchange rules designed to limit members from effecting OTC transactions in exchange-listed stock be applied, if the Commission's interpretation of exchange were expanded to include alternative trading systems and organized dealer markets? What customer protection and competitive reasons might there be to preserve these rules if alternative trading systems are classified as exchanges?

Question 70: What effects would linking alternative trading systems to NMS mechanisms have on those systems? For example, how would such linkages affect the ability of alternative trading systems to operate with trading and fee structures that differ from those of existing exchanges or to alter their structures? To what extent could revision of the NMS plans alleviate these effects?

Question 71: Are there any insurmountable technical barriers to admission of alternative trading systems into the CTA, CQS, OPRA, or OTC–UTP plans?

Question 72: What costs are associated with the admission of new applicants to these plans?

Question 73: Are there any CTA, CQS, OPRA, or OTC–UTP plan rules that would prevent newly registered national securities exchanges from obtaining fair and equal representation on these entities?

Question 74: What effect would the admission of newly registered national securities exchanges to the CTA, CQS, OPRA, and OTC–UTP plans have upon the governance and administration of those plans?

Question 75: Do admissions fees for new participants required by the terms of the plans present a barrier to admission to the plans? Do the plans' provisions that all participants are eligible to share in the revenues generated through the sale of data affect commenters' views on this issue?

Question 76: What effect would the admission of new, highly automated participants have upon the operation of the ITS?

Question 77: How would compliance with the current ITS rules and policies affect trading on alternative systems that may be regulated as exchanges? How

appropriate are these rules and policies for alternative trading systems?

Question 78: What costs would be associated with newly registered exchanges joining ITS? Would those costs represent a barrier for newly registered exchanges to join ITS?

Question 79: Are there any ITS plan rules or practices that would prevent newly registered national securities exchanges from obtaining fair and equal representation on the ITS?

Question 80: What effect would the admission of newly registered national securities exchanges to the ITS plan have upon the governance and administration of the plan?

Question 81: What effect would the requirements to impose trading halts or circuit breakers in some circumstances have upon alternative trading systems if such systems were regulated as exchanges?

Question 82: What impact would registration of an alternative trading system as an exchange have on the institutional participants of that trading system, including registered investment companies?

Question 83: If the Commission allows institutions to effect transactions on exchanges without the services of a broker, to what extent should an exchange's obligations to surveil its market and enforce its rules and the federal securities laws apply to such institutions?

Question 84: How could an exchange adequately supervise institutions that effect transactions on an exchange without the services of a broker?

Question 85: What, if any, accommodations should be made with respect to an exchange's surveillance, enforcement, and other SRO obligations with respect to institutions that transact business on that exchange?

Question 86: How could institutions that directly access exchanges be integrated into existing systems for clearance and settlement?

Question 87: Under what conditions should an entity be subject to both exchange and broker-dealer regulation?

Question 88: Should a dually registered entity be required to formally separate its exchange operations from its broker-dealer operations (*e.g.*, through use of separate subsidiaries)?

Question 89: Would this approach be an effective means of addressing the issues raised by the growth alternative trading systems? What would be the benefits of such an approach? What would be the drawbacks of such an approach?

Question 90: Would it be feasible for the Commission to expand the scope of rules eligible for expedited treatment pursuant to section 19(b)(3)(A) without jeopardizing the investor protection and market integrity benefits of Commission oversight of exchange and other SRO rule changes? If so, to what types of rule filings should immediate effectiveness, pursuant to section 19(b)(3)(A), be extended?

Question 91: If the Commission expands the scope of rule filings eligible for treatment under section 19(b)(3)(A) to include, for example, certain types of new products, what conditions or representations should be required of an SRO to ensure that the proposed rule change is eligible for expedited treatment under Rule 19b–4?

Question 92: Should the Commission exempt markets' proposals to implement new trading systems, separate from their primary trading operations, from rule filing requirements? If so, should SROs be permitted to operate pilot programs under such an exemption if they trade the same securities, operate during the same hours, or utilize similar trading procedures as the SRO's main trading system? Should there be a limit on the number of pilot programs an SRO can operate under an exemption at any one time? What other conditions should apply to such exemption?

Question 93: Do differences between automated and non-automated trading require materially different types or degrees of surveillance or enforcement procedures?

Question 94: Which Exchange Act requirements applicable to registered exchanges, if any, could be minimized or eliminated without jeopardizing investor protection and market integrity?

Question 95: If an automated exchange contracts with another SRO to perform its day-to-day enforcement and disciplinary activities, should this affect the exchange's requirement to ensure fair representation of its participants and the public in its governance?

Question 96: If an exchange contracts with another entity to perform its oversight obligations, should that exchange continue to have responsibility under the Exchange Act for ensuring that those obligations are adequately fulfilled?

Question 97: What costs to investors and other market participants are associated with the current regulation of alternative trading systems as broker-dealers? Specifically, what costs are associated with the potential denial of access by an alternative trading system?

Question 98: What costs are associated with each of the alternatives for revising market regulation discussed above? For example, would either of the two principal alternatives discussed in section IV above impose costs by limiting innovation? Would these costs be greater than those imposed by the current regulatory approach?

Question 99: What regulatory costs can be shared by markets operating simultaneously as self-regulatory organizations, and what regulatory costs must be borne by each market individually? What are the relative magnitudes of these costs (as a proportion of total costs)?

Question 100: Are there innovations or adjustments that can be made to market wide plans such as CQS, CTA and ITS that will lead to lower regulatory costs for exchanges under any of the alternatives for regulating domestic markets?

Question 101: Total regulatory costs vary with a variety of factors (e.g., volume of trade, degree of technology applied in trade). Of these factors, which are most relevant in considering the alternatives discussed above? For example, recognizing that some market mechanisms may rely on some factors more than others, to what extent are regulatory costs greater for particular mechanisms than others?

Question 102: What costs are associated with the responsibilities of an SRO? Will the costs to existing SROs be reduced by registering significant alternative trading systems as exchanges?

Question 103: What regulatory burdens currently inhibit innovation of trading systems? How will the alternatives discussed above change the incentives for innovation?

Question 104: Will the alternatives discussed above impose costs on systems that differ depending on the nature of the trade? For example, will the proposed regulatory revisions change the costs of trades directly between customers relative to the costs of trades between a customer and a dealer?

Question 105: What regulatory approaches would best address the concerns raised by the development of automated access to foreign markets? Would these approaches differ if U.S. investors accessed foreign markets in ways other than those described above, such as through the Internet? Are there any other alternative approaches that could be more appropriate?

Question 106: If the Commission were to rely solely on a foreign market's primary regulator, how could it address the investor protection and enforcement concerns discussed above?

Question 107: Should the Commission require foreign markets with only limited activities in the

United States to register as national securities exchanges or obtain an exemption from such registration? How would this affect U.S. persons trading directly on foreign markets?

Question 108: How can the Commission best achieve its goal of regulating the U.S. activities of foreign markets? Commenters should take into consideration that foreign markets are regulated abroad, that there is a potential for international conflicts of law, and that the Commission has jurisdictional limits. Given the difficulties of surveilling public networks such as the Internet, would an access provider approach be workable?

Question 109: What would be the best way for the Commission to regulate the limited U.S. activities of foreign markets that provide remote access to U.S. members?

Question 110: When should an entity be required to register with the Commission as a non-exclusive SIP under section 11A of the Exchange Act? For example, should the activities described above require registration as a SIP?

Question 111: If the SIP approach were adopted, is it likely that U.S. members of foreign markets would wish to transmit their orders to such markets through more than one SIP registered with the Commission? If so, should all but one of those SIPs be exempt from registration?

Question 112: Under the SIP approach, should foreign markets that allow their U.S. members to transmit their orders solely through a registered SIP have a safe harbor from registration as national securities exchanges?

Question 113: What type of activities should a registered SIP be permitted to conduct on behalf of a foreign market without the SIP or the foreign market registering as an exchange?

Question 114: What types of automated broker-dealer systems, both operational and contemplated, would be encompassed within the above description of access providers to foreign markets? How widespread are these activities?

Question 115: Would the above description of broker-dealer access providers adequately and clearly exclude traditional brokerage activities, particularly handling the execution of customer orders on foreign markets? If not, how should such activities be distinguished from traditional brokerage activities, particularly traditional cross-border activities? Should U.S. broker-dealers that provide investors with access to foreign markets be subject to any additional requirements?

Question 116: Should foreign broker-dealers that provide U.S. investors with automated access to foreign markets be required to register as broker-dealers on the basis of that activity?

Question 117: What types of conditions, if any, should the Commission place on access providers if it were to pursue that approach?

Question 118: If the Commission decides to regulate access providers to foreign markets, what criteria should the Commission use in determining whether an exchange is a *bona fide* foreign market? Should a market be required to have at least a majority of foreign members in order to be a *bona fide* foreign market? Should the Commission exclude exchanges that provide terminals in the United States?

Question 119: Should the Commission regulate as a U.S. exchange any market that, although organized and having its principal place of business outside of the United States, is under common control with or controlled by U.S. persons, or whose decisions regarding trading rules, practices, or procedures are made by U.S. persons?

Question 120: What factors should the Commission use in determining whether an exchange is operating a trading facility in the United States and is not a *bona fide* foreign market? If exchange-owned terminals are located in the United States, should this constitute operating a trading facility in the United States?

Question 121: What effect would a reinterpretation of the term ''exchange'' under section 3(a)(1) of the Exchange Act have on any Commission proposal to regulate SIP and broker-dealer access providers?

Question 122: If the Commission decides to regulate access providers to foreign markets, should the Commission require access providers to transmit orders only to foreign markets that are willing to share, and capable of sharing, information with the Commission in connection with investigations involving violations of U.S. securities laws? If so, what standard should the Commission use in determining whether a foreign market would provide meaningful assistance to the Commission? If commenters believe that SIP and/or broker-dealer access providers should be permitted to transmit orders to any foreign market, indicate how the Commission could ensure that it has the ability to enforce the applicable provisions of the federal securities laws.

Question 123: Should the Commission require access providers to transmit orders only to foreign markets that are located in countries that have entered into arrangements with the Commission to provide enforcement and information sharing assistance?

Question 124: If the Commission regulated access providers through the approach described above, should SIP access providers be limited to providing their services to sophisticated institutions or should they be allowed to provide any U.S. investor with the capability of directly trading on foreign markets as members? If so, should broker-dealer access providers be subject to similar requirements?

Question 125: If the Commission permits SIP access providers to offer their services only to broker-dealers and certain sophisticated institutions, how should this category of sophisticated institutions be defined?

Question 126: Should the Commission permit SIP and broker-dealer access providers to transmit orders to foreign markets for the securities of U.S. issuers or only for the securities of non-U.S. issuers?

Question 127: Should the Commission limit the ability of SIP and broker-dealer access providers to transmit orders to foreign markets for the securities of non-U.S. issuers if the ''principal market'' for those securities is located in the United States? If so, how should the Commission determine when the ''principal market'' of a non-U.S. security is located in the United States?

Question 128: If the Commission permits SIP and broker-dealer access providers to transmit orders to foreign markets only for securities of non-U.S. issuers, how should the Commission distinguish between U.S. and non-U.S. issuers?

Question 129: If the Commission decides to regulate access providers to foreign markets, should they be required to make and keep records? What records should registered SIP and broker-dealer access providers be required to maintain?

Question 130: Should access providers be required to file periodic reports? If so, what information should those contain?

Question 131: Should broker-dealer access providers be required to keep records of denials of access to their services? Should they be required to notify the Commission of such denials of access?

Question 132: What types of risks should be disclosed to users of SIP and broker-dealer access providers? For example, should SIP and broker-dealer access providers be required to disclose the listing and maintenance standards of foreign markets to which they transmit orders on behalf of U.S. persons? What

would be the costs associated with such a requirement?

Question 133: Should access providers be required to make disclosures to sophisticated institutions?

Question 134: What market information should SIP and broker-dealer access providers be required to provide to the users of their services?

Question 135: Should direct trading in foreign listed companies be limited to those that satisfy U.S. disclosure standards in order to better protect U.S. investors?

Question 136: Is it sufficient to merely disclose to investors that the information available about a foreign security may significantly differ from the information that would be available about U.S. securities? Do public policy concerns dictate that the Commission make distinctions based on whether investors receive adequate information?

Question 137: Are there circumstances under which unregistered foreign securities should be permitted to trade on foreign markets through an access provider? For example, should the Commission establish some *de minimis* threshold for a foreign security based on the dollar value of the U.S. float or trading volume in that security, or on the relative percentage of U.S. float or trading volume compared to that of the home or worldwide markets?

Question 138: Should the exemption from registration under Exchange Act Rule 12g3–2(b) be available if a significant portion of an issuer's float is traded in the United States?

Question 139: Given that broker-dealers currently trade unregistered securities for customers, should the Commission reconsider its approach to securities registration requirements in this context? Are there other viable alternatives that would ensure adequate disclosure to U.S. investors trading on foreign markets?

Question 140: Is trading in unregistered foreign securities through an access provider to a foreign market appropriate if access is limited to sophisticated investors? For example, should access providers be permitted to transmit orders for unregistered foreign securities to a foreign market on behalf of qualified institutional buyers as defined in Rule 144A of the Securities Act?

Question 141: Are there uniform procedures that the Commission should impose on foreign markets or on access providers to assure that securities are not sold to U.S. investors in circumstances that result in a public distribution of securities in the United States that are not registered under the Securities Act?

Question 142: What are the consequences to SEC reporting companies if unregistered foreign securities listed on foreign markets are available to be purchased or sold through access providers?

Question 143: Would any of the approaches described above provide an effective means of addressing the issues raised by foreign market activities in the United States, including providing key protections for U.S. investors? What would be the benefits of each approach? What would be the drawbacks of each approach?

Dated: May 23, 1997.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–14284 Filed 6–3–97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

[SPATS No. KS–017–FOR]

Kansas Regulatory Program and Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Kansas program and Abandoned Mine Land Reclamation Plan (hereinafter the ''Kansas program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to Kansas' regulations for its regulatory program and abandoned mine land reclamation plan pertaining to communications, petitions to initiate rulemaking, notice of citizen suits, preparation and submission of reports by the permittee, definitions, permit applications, administrative hearing procedures, civil penalties, permit review, permit revision, permit renewals, permit transfers, assignments, and sales, permit conditions, permit suspension or revocation, termination of jurisdiction, exemption for coal extraction incident to government-financed highway or other construction, exemption for coal extraction incidental to the extraction of other minerals, coal exploration, bonding procedures, performance standards, revegetation, interim performance standards, underground mining, small operator assistance program, lands unsuitable for surface mining, training, certification, and responsibilities of blasters and operators, employee financial interest, inspection and enforcement, eligible lands and water, reclamation project evaluation, consent to entry, liens, appraisals, contractor responsibility, exclusion of certain noncoal reclamation sites, and abandoned mine land reclamation plan reports. The amendment is intended to revise the Kansas program to be consistent with the corresponding Federal regulations.

This document sets forth the times and locations that the Kansas program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4:00 p.m., c.d.t., July 7, 1997. If requested, a public hearing on the proposed amendment will be held on June 30, 1997. Requests to speak at the hearing must be received by 4:00 p.m., c.d.t. on June 19, 1997.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Russell W. Frum, Mid-Continent Regional Coordinating Center, at the address listed below.

Copies of the Kansas program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Mid-Continent Regional Coordinating Center.

Russell W. Frum, Mid-Continent Regional Coordinating Center, Office of Surface Mining Reclamation and Enforcement, Alton Federal Building, 501 Belle Street, Alton, Illinois, 62002, Telephone: (618) 463–6460.

Kansas Department of Health and Environment, Surface Mining Section, 4033 Parkview Drive, Frontenac, Kansas 66763, Telephone (316) 231–8540.

FOR FURTHER INFORMATION CONTACT: Russell W. Frum, Mid-Continent

Regional Coordinating Center, Telephone: (618) 463–6460.

SUPPLEMENTARY INFORMATION:

I. Background on the Kansas Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Kansas program. Background information on the Kansas program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the January 21, 1981, **Federal Register** (46 FR 5892). Subsequent actions concerning the Kansas program can be found at 30 CFR 916.10, 916.12, 916.15, and 916.16.

II. Description of the Proposed Amendment

By letter dated May 7, 1997 (Administrative Record No. KS–615), Kansas submitted a proposed amendment to its program pursuant to SMCRA. Kansas submitted the proposed amendment in response to letters dated May 20, 1996, and January 6, 1997 (Administrative Record Nos. KS–608 and KS–612, respectively), that OSM sent to Kansas in accordance with 30 CFR 732.17(c), in response to a letter dated September 26, 1994 (Administrative Record No. AML–KS–169), that OSM sent to Kansas in accordance with 30 CFR 884.25(b), and at its own initiative. Kansas proposes to amend the Kansas Administrative Regulations (K.A.R.). The full text of the proposed program amendment submitted by Kansas is available for public inspection at the locations listed above under **ADDRESSES.** A brief discussion of the proposed amendment is presented below.

A. Kansas Regulatory Program

1. Regulations Proposed for Revocation or Deletion

Kansas proposes to revoke or delete the following sections of the K.A.R.: 47–1–1, title of rules; 47–1–4, sessions; 47–1–10, general notice requirement; 47–2–14, definition of complete and accurate application; 47–4–14, public hearings; 47–4–14a(b)(2), definition of person; and 47–4–14a (d)(4)(G), (d)(5)(B)(i), (d)(17)(C), formal hearings;

2. Regulations with Editorial Changes

Kansas proposes minor wording changes, paragraph notation changes, citation corrections, and other editorial changes in the following sections of the K.A.R.: 47–1–3, communication; 47–1–8, petitions to initiate rulemaking; 47–1–9, notice of citizen suits, 47–1–11, permittee preparation and submission of reports; 47–2–21, definition of employee; 47–2–53, definition of regulatory authority or state regulator authority; 47–2–53a, definition of regulatory program; 47–2–58, definition of significant, imminent, environmental harm to land, air or water resources; 47–2–64, definition of state act; 47–2–67, definition of surety bond; 47–2–74, definition of public road; 47–3–1, application for mining permit; 47–3–3a, permit application maps; 47–3–42, application for mining permit; 47–4–14a(a)(2), administrative hearing procedure; 47–4–14a(b), definition of party; 47–4–14a(c), rules of procedure; 47–4–14a(d), formal hearings; 47–4–15, administrative hearings—discovery; 47–4–16, interim orders for temporary relief; 47–4–17, administrative hearings—award of costs; 47–5–5a, civil penalties; 47–5–16, final assessment and payment of civil penalty; 47–6–1, permit review; 47–6–2, permit revision; 47–6–3, permit renewals; 47–6–4, permit transfers, assignments, and sales; 47–6–6, permit conditions; 47–6–7, permit suspension or revocation; 47–6–9, exemption for coal extraction incident to government-financed highway or other construction; 47–6–10, exemption for coal extraction incidental to the extraction of other minerals; 47–7–2, coal exploration; 47–8–9, bonding procedures; 47–8–11, use of forfeited bond funds; 47–9–1, performance standards; 47–9–2, revegetation; 47–9–4, interim performance standards; 47–10–1, underground mining; 47–11–8, small operator assistance program; 47–12–4, lands unsuitable for surface mining; 47–13–4, training, certification, and responsibilities of blasters and operators; 47–13–5, responsibilities of operators and blasters-in-charge; 47–13–6, training; 47–14–7, employee financial interests; 47–15–1a, inspection and enforcement; 47–15–3, lack of information—inability to comply; 47–15–4, injunctive relief; 47–15–7, state inspections; 47–15–8, citizen's requests for state inspections; 47–15–15, service of notices of violations and cessation orders; and 47–15–17, maintenance of permit areas. Substantive revisions included in these regulations are summarized below.

3. K.A.R. 47–2–75, Definitions

a. Kansas proposes to revise its adoption by reference of applicable Federal definitions contained in 30 CFR 700.5, 701.5, 705.5, 773.5, and 846.5 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

b. Kansas proposes to revise its definition of director at K.A.R. 47–2–75(a)(5) [was 47–2–75(a)(6)] by referencing additional sections of the Federal regulations for which the term ''director'' means the Director, Office of Surface Mining, Reclamation, and Enforcement. The additional referenced sections are 30 CFR 705.4(a), 705.11(c) and (d), 705.13, 705.15, 705.19(a), and 705.21.

c. At K.A.R. 47–2–75(e)(6), Kansas proposes to revise its adoption by reference of 30 CFR 846.5 by specifying that the reference to ''Section 703 of the act'' shall be replaced by ''K.S.A. 1995 Supp. 75–2973.''

4. K.A.R. 47–3–2(b), Application for Mining Permit

At K.A.R. 47–3–2(b), Kansas proposes to revise its adoption by reference of applicable Federal regulations concerning permit applications at 30 CFR 777.11, 777.13, 777.14, and 777.15 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

5. K.A.R. 47–3–42, Application for Mining Permit

a. At K.A.R. 47–3–42(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations concerning permit applications at 30 CFR Parts 773, 778, 779, 780, and 785 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

b. At K.A.R. 47–3–42(a)(2), in its adoption by reference of 30 CFR 778.14, Kansas proposes to specify that the term ''act'' shall mean ''the surface mining control and reclamation act of 1977 (Pub. L. 95–87)'' and amendments thereto.

c. At K.A.R. 47–3–42(a)(15), Kansas proposes to remove its adoption by reference of 30 CFR 779.22, land-use information.

d. At K.A.R. 47–3–42(a)(17), Kansas proposes to adopt by reference 30 CFR 780.4.

e. At K.A.R. 47–3–42(a)(43), Kansas proposes to add a clarifying statement to its adoption by reference of 30 CFR 773.15. The statement reads as follows:

> Only in paragraph 30 CFR 773.15(b) shall the term ''act'' mean ''surface mining control and reclamation act of 1977 (Pub. L. 95–87)'' and amendments thereto. All other references to the term ''act'' in 30 CFR 773.15 shall be replaced with ''state act.''

f. AT K.A.R. 47–3–42(a)(45), Kansas proposes to add a clarifying statement to its adoption by reference of 30 CFR 773.20. The statement reads as follows:

> except in subsection (c)(2) ''43 CFR 4.1370 through 4.1377, where OSM is the regulatory author, or under the State program equivalent, where a state is the regulatory authority'' shall be replaced by ''K.A.R. 47–4–14a''

g. At K.A.R. 47–3–42(a)(47), Kansas proposes to adopt 30 CFR 773.22 by reference.

h. At K.A.R. 47–3–42(a)(48), Kansas proposes to adopt 30 CFR 773.23 by reference.

i. At K.A.R. 47–3–42(a)(49), Kansas proposes to adopt 3 CFR 773.24 by reference with exceptions that replace certain Federal Terms and citations with the appropriate State terms and citations and by providing the State address where an individual may submit information on a challenge of the status of a State violation.

j. At K.A.R. 47–3–42(a)(50), Kansas proposes to adopt 30 CFR 773.25 by reference with exceptions that replace certain Federal terms and citations with the appropriate State terms and citations. Kansas is also proposing to replace 30 CFR 773.25(b) with K.A.R. 47–3–42(a)(50)(B) which authorizes the secretary of the Kansas Department of Health and Environment or his designee to make decisions concerning ownership or control relationships within Kansas' coal mining applications, issued permits, and state violations.

6. K.A.R. 47–4–14a, Administrative Hearing Procedures

a. At K.A.R. 47–4–14a(c)(2), Kansas proposes to change the information on where to file administrative hearing documents. All documents are to be filed with the administrative appeals section of the Kansas Department of Health and Environment, suite 400D, 109 SW 9th, Topeka, Kansas 66612–1215.

b. At K.A.R. 47–4–14a(d)(2)(D), concerning disqualification of a presiding officer, Kansas proposes to add a new provision that reads as follows:

> In the event that the presiding officer fails to grant a petition for disqualification, the petitioning party may file an affidavit of personal bias or disqualification with substantiating facts, and the matter of disqualification shall be determined by the secretary.

c. At K.A.R. 47–4–14a(d)(6)(E)(iv), Kansas proposes to add a provision that requires notice of a formal hearing to be posted at the surface mining section office and, where practicable, be published in a newspaper of general circulation in the area of the mine at least seven days prior to the hearing.

d. At K.A.R. 47–4–14a(d)(15), Kansas proposes to allow the presiding officer or secretary or secretary's designee to take action on a petition for stay either before or after the effective date of an initial or final order.

7. K.A.R. 47–4–15, Administrative Hearings—Discovery

At K.A.R. 47–4–15, Kansas proposes to add an introductory statement regarding discovery in administrative hearings: ''Discovery shall be permitted to the extent allowed by the presiding officer or as agreed to by the parties.''

8. K.A.R. 47–5–5a, Civil Penalties

a. At K.A.R. 47–5–5a(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations concerning civil penalties at 30 CFR 845.11, 845.12, 845.13, 845.14, 845.15, 845.16, 845.17, 845.18, 845.19, and Part 846 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

b. At K.A.R. 45–5–5a(a)(10), Kansas proposes exceptions to its adoption of 30 CFR Part 846 by replacing certain Federal terms and citations with the appropriate State terms and citations. Kansas also proposes to adopt by reference 30 CFR 870.15(e)(1)–(5), (f), and (g) as they relate to 30 CFR 846.18(d) with the exception of the sentence in paragraph (f) that specifies that ''[t]his penalty is in addition to the interest described in paragraph (c) of this section.''

c. At K.A.R. 47–5–5a(b)(13) through (20), Kansas proposes to add more State terms that will replace specified Federal terms wherever they appear in the text of the Federal regulations, concerning civil penalties, adopted by reference under K.A.R. 47–5–5a(a).

d. Kansas proposes to revise K.A.R. 47–5–5a(c)(5), concerning the burden of proof in civil penalty proceedings, by requiring that the department have the burden of going forward to establish a prima facie case as to the fact of the violation, the amount of the civil penalty, and the ultimate burden of persuasion as to the amount of the civil penalty and that the person who petitioned for review have the ultimate burden of persuasion as to the fact of the violation.

e. Kansas proposes to revise K.A.R. 47–5–5a(c)97)(C), concerning the initial order of the presiding officer, by requiring the presiding officer to order the department to remit the appropriate amount to the person who made the payment within 30 days of receipt of the order finding no violation or reducing the penalty paid.

f. Kansas proposes to revise K.A.R. 47–5–5a(c)(7)(D) by requiring that if the presiding officer increases the amount of the civil penalty above that of the proposed assessment, the presiding officer is to order payment of the appropriate amount within 15 days after an order increasing the civil penalty if mailed.

9. K.A.R. 47–6–3, Permit Renewals

At K.A.R. 47–6–3(a), Kansas proposes to revise its adoption by reference of 30 CFR 774.15, concerning permit renewals, from as they existed on July 1, 1990, to as they existed on July 1, 1995.

10. K.A.R. 47–6–4, Permit Transfers, Assignments, and Sales

At K.A.R. 47–6–4(b), Kansas proposes to revise its adoption by reference of 30 CFR 774.17, concerning transfer, assignments, or sale of permit rights, from as they existed on July 1, 1990, to as they existed on July 1, 1995.

11. K.A.R. 47–6–6, Permit Conditions

At K.A.R. 47–6–6(a), Kansas proposes to revise its adoption by reference of 30 CFR 773.17, concerning permit conditions, from as they existed on July 1, 1990, to as they existed on July 1, 1995.

12. K.A.R. 47–6–7, Permit Suspension or Revocation

Kansas proposes to revise K.A.R. 47–6–7(h)(1) by requiring a party to file a notice of appeal of an initial order in a suspension or revocation proceeding with the secretary within 15 days after receipt of the order.

13. K.A.R. 47–6–9, Exemption for Coal Extraction Incident to Government-Financed Highway or Other Construction

At K.A.R. 47–6–9(a), Kansas proposes to revise its adoption by reference of the Federal regulations at 30 CFR 707.4, 707.5, 707.11, and 707.12 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

14. K.A.R. 47–6–10, Exemption for Coal Extraction Incidental to the Extraction of Other Minerals

At K.A.R. 47–6–10(a), Kansas proposes to revise its adoption by reference of the Federal regulations at 30 CFR 702.1, 702.5, 702.10, 702.11, 702.12, 702.13, 702.14, 702.15, 702.16, 702.17, and 702.18 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

15. K.A.R. 47–7–2, Coal Exploration

At K.A.R. 47–7–2(a), Kansas proposes to revise its adoption by reference of the Federal regulations 30 CFR 772.11, 772.12, 772.13, 772.14, and 772.15 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

16. K.A.R. 47–8–9, Bonding Procedures

At K.A.R. 47–8–9(a), Kansas proposes to revise its adoption by reference of the Federal regulations 30 CFR 800.4, 800.5, 800.11, 800.12, 800.13, 800.14, 800.15, 800.16, 800.17, 800.20, 800.21, 800.30, 800.40, 800.50, and 800.60 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

17. K.A.R. 47–9–1, Performance Standards

a. At K.A.R. 47–9–1(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations 30 CFR 810 from as they existed on July 1, 1990, to as they existed on July 1, 1995. At K.A.R. 47–9–1(a)(3), Kansas proposes to add an exception to the adoption of 30 CFR 810.11: the reference to ''parts 815 through 828'' shall be replaced by their counterpart in K.A.R. 47–9–1. Kansas also proposes to add exceptions at new subsection (a)(5): the phrases ''every state program'' and ''the applicable regulatory program'' shall be replaced by ''the regulatory program.''

b. At K.A.R. 47–9–1(b), Kansas proposes to revise its adoption by reference of applicable Federal regulations 30 CFR Part 815 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

c. K.A.R. 47–9–1(c), Surface Coal Mining Performance Standards. (1) At K.A.R. 47–9–1(c), Kansas proposes to revise its adoption by reference of applicable Federal regulations 30 CFR 816 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

(2) Kansas proposes an exception to its adoption of 30 CFR 816.61 at subsection (c)(17): the term ''subchapter'' shall not be replaced by K.A.R. 47–9–1(c), and everything but the statement ''all blasting operations shall be conducted under the direction of a certified blaster'' shall be deleted from 30 CFR 816.61(c)(1).

(3) Kansas proposes to delete the existing language in subsection (c)(35) and to add new subsection (c)(35) to adopt 30 CFR 816.101, backfilling and grading time and distance requirements, by reference. The rest of the paragraphs in subsection (c) were renumbered to reflect this addition.

(4) Kansas proposes to add its adoption by reference of 30 CFR 816.102 to new subsection (c)(36) with an exception: subsections (k)(3)(i) and (ii) of 30 CFR 816.102 are deleted.

(5) At redesignated subsection (c)(43), Kansas proposes to remove previously approved exceptions to its adoption by reference of 30 CFR 816.116. These exceptions are deletion of editorial note ''3'' and specific language in 30 CFR 816.116(c)(2).

(6) Kansas also proposes to add additional requirements at subsection (c)(43) in its adoption by reference of 30 CFR 816.116(a) and (c)(4).

Subsection (a)(3) is added specifying that the data being used for bond release shall be submitted to the department annually. The data is to include information for the last augmented seeding, which shall start the extended liability period. The planting reports, including soil tests, are to be submitted by March 31, of the year following the year in which the soil tests were performed. The production and ground cover data are to be submitted within 30 days of the date that the production and ground cover were sampled. Ground cover shall include species identification. Raw field data may be submitted to fulfill this requirement. The tabulated results shall then be submitted by March 31 of the following year. All data shall be clearly identified as to the bond release management area that it represents.

Subsection (c)(4)(i) is revised to add language concerning normal husbandry practices: The normal husbandry practices used to repair gullies shall be approved in advance by the United States Department of the Interior, Office of Surface Mining Reclamation and Enforcement.

(7) In its adoption of 30 CFR 816.133, postmininig land use, at K.A.R. 47–9–1(c)(46), Kansas proposes to delete subsection (d).

(8) At K.A.R. 47–1–9(d)(3), Kansas proposes to delete 30 CFR 816.107, steep slope backfilling and grading, from its adoption by reference of 30 CFR 816.116.

e. K.A.R. 47–1–9(e), Underground Mining Performance Standards. (1) At K.A.R. 47–9–1(e), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 817 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

(2) Kansas proposes an exception to its adoption of 30 CFR 817.61 at K.A.R. 47–1–9(e)(17): the term ''subchapter'' shall not be replaced by K.A.R. 47–9–1(d), and everything but the statement ''all blasting operations shall be conducted under the direction of a certified blaster'' shall be deleted from 30 CFR 817.61(c)(1).

(3) Kansas also proposes to add additional requirements at K.A.R. 47–9–1(e)(39) in its adoption by reference of 30 CFR 817.116(a). Subsection (a)(3) is added specifying that the data being used for bond release shall be submitted to the department annually. The data is to include information for the last augmented seeding, which shall start the extended liability period. The planting reports, including soil tests, are to be submitted by March 31, of the year following the year in which the soil tests were performed. The production and ground cover data are to be submitted within 30 days of the date that the production and ground cover were sampled. Ground cover shall include species identification. Raw field data may be submitted to fulfill this requirement. The tabulated results shall then be submitted by March 31 of the following year. All data shall be clearly identified as to the bond release management area that it represents.

(4) In its adoption of 30 CFR 817.133, postmining land use, at K.A.R. 47–9–1(e)(44), Kansas proposes to delete subsection (d).

f. K.A.R. 47–9–1(f), Auger Mining Performance Standards. At K.A.R. 47–9–1(f), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 819 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

g. K.A.R. 47–9–1(g), Prime Farmland Special Performance Standards. At K.A.R. 47–9–1(g), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 823 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

h. K.A.R. 47–9–1(h), Coal Preparation Plants not Located within the Permit Area of a Mine Performance Standards. At K.A.R. 47–9–1(h), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 827 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

i. K.A.R. 47–9–1(i), In Situ Processing Special Performance Standards. At K.A.R. 47–9–1(i), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 828 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

j. At. K.A.R. 47–9–1(j), Kansas revised its list of terms that replaces terms in the Federal regulations adopted by reference under K.A.R. 47–9–1. At subsection (j)(8), any reference to ''Part 816'' is replaced by ''K.A.R. 47–9–1(c).'' At subsection (j)(9), any reference to ''Part 817'' is replaced by ''K.A.R. 47–9–1(d).''

18. K.A.R. 47–9–4, Interim Performance Standards

At K.A.R. 47–9–4(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Parts 710, 715, and 716 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

19. K.A.R. 47–10–1, Underground Mining

At K.A.R. 47–10–1(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Parts 783 and 784 from as they existed on July 1, 1990, to as they existed on July 1, 1995. Kansas further proposes to last the actual Federal regulation sections adopted rather than listing the sections not included in its adoption by reference of 30 CFR Parts 783 and 784.

20. K.A.R. 47–11–8, Small Operator Assistance Program

At K.A.R. 47–11–8(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 795 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

21. K.A.R. 47–12–4, Lands Unsuitable for Surface Mining

a. At K.A.R. 47–12–4(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Parts 761, 762, and 764 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

b. Kansas proposes to revise K.A.R. 47–12–4(a)(6), which adopts 30 CFR 762.12 by reference, by specifying that the term ''secretary'' shall mean the ''secretary of the United States Department of Interior.''

22. K.A.R. 47–13–4, Training, Certification, and Responsibilities of Blasters and Operators

a. At K.A.R. 47–13–4(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 850 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

b. Kansas proposes to remove existing K.A.R. 47–13–4(b)(2) and (3) and to renumber paragraphs (b)(4) through (6) as (b)(2) through (3).

23. K.A.R. 47–14–7, Employee Financial Interests

At K.A.R. 47–14–7(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Part 705 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

24. K.A.R. 47–15–1a, Inspection and Enforcement

a. At K.A.R. 47–15–1a(a), Kansas proposes to revise its adoption by reference of applicable Federal regulations at 30 CFR Parts 840, 842, and 843 from as they existed on July 1, 1990, to as they existed on July 1, 1995.

b. K.A.R. 47–15–1a(b), Kansas revised its list of terms that replaces terms in the Federal regulations adopted by reference under K.A.R. 47–15–1a by adding paragraphs (b)(20) and (b)(21). Paragraph (b)(20) specifies that the term ''Director'' shall be replaced by ''secretary,'' and paragraph (b)(21) specifies that the reference to ''30 CFR 843.15(e)'' shall be replaced by ''An informal public hearing shall be conducted in accordance with K.A.R. 47–4–14a.''

B. Kansas Abandoned Mine Land Reclamation Plan

1. Regulations with Editorial Changes

Kansas proposes minor working changes, paragraph notation changes, citation corrections, and other editorial changes in the following sections of the K.A.R.: 47–16–1, eligible lands and water; 47–16–2, reclamation project evaluation; 47–16–3, consent to entry; 47–16–4, entry for study or exploration; 47–16–5, entry and consent to reclaim; 47–16–6, liens; 47–16–7, appraisals; and 47–16–8, satisfaction of liens. Substantive revisions included in these regulations are summarized below.

2. K.A.R. 47–16–5, Entry and Consent to Reclaim

Kansas proposes to revise K.A.R. 47–16–5(b)(1) to read as follows:

(1) Before entry a written finding shall be made by the Secretary with reasons supporting the following conclusions: (A) an emergency exists constituting a danger to the public health, safety, or general welfare; and (B) no other person or agency will act expeditiously to restore, reclaim, abate, control, or prevent the adverse effects of coal mining practices.

3. K.A.R. 47–16–9, Contractor Responsibility

Kansas proposes to add a new section that requires each successful bidder for an abandoned mine land reclamation project contract to be eligible under 30 CFR 772.15(b)(1), as adopted by reference in K.A.R. 47–3–42(a)(44), at the time of contract award to receive permit or conditional permit to conduct surface coal mining operations

4. K.A.R. 47–16–10, Exclusion of Certain Noncoal Reclamation Sites

Kansas proposes to add a new section which excludes certain nonncoal sites from being reclaimed with money from the abandoned mine land funds and which specifies contractor eligibility requirements for reclamation of noncoal sites.

K.A.R. 47–16–10(a)(1) excludes the reclamation of sites and areas designated for remedial action pursuant to the Uranium Mill Tailings Radiation Control Act of 1978, K.A.R. 47–16–10(a)(2) excludes sites listed for remedial action pursuant to the Comprehensive Environmental Response Compensation and Liability Act of 1980.

K.A.R. 47–16–10(b)(1) requires that each successful bidder for an abandoned mine land reclamation project contract for noncoal reclamation to be eligible under 30 CFR 773.15(b)(1), as adopted by reference in K.A.R. 47–3–42(a)(44), at the time of contract award to receive a permit or conditional permit to conduct surface coal mining operations.

K.A.R. 47–16–10(b)(2) requires that bidder eligibility for each contract be confirmed by the Office of Surfaced Mining's automated applicant violator system.

5. K.A.R. 47–16–11, Reports

Kansas proposes a new section which specifies the reports that must be submitted to the Office of Surface Mining Reclamation and Enforcement on a semiannual and annual basis and upon project completion.

K.A.R. 47–16–11(a) requires Kansas to submit semiannually a financial status report, form SF–269, for the department's administrative grant and/or cooperative agreement; a performance report, form OSM–51, covering the performance aspect of the grant and/or cooperative agreement; an outlay report and request for reimbursement for construction programs, form SF–271, and a performance report, form OSM–51, for each activity or project on which some work as occurred.

K.A.R. 47–16–(b) requires Kansas to submit annually a financial status report, form SF–269, for the department's administrative grant and/or cooperate agreement; a final performance report, form OSM–51, covering the performance aspects of the grant and/or cooperative agreement; an annual outlay report and request for reimbursement for construction program, form SF–271; and a cumulative annual performance report, form OSM–51.

K.A.R. 47–16–11(c) requires Kansas to submit form OSM–76 upon project completion to report the accomplishments achieved through the project.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed

adequate, it will become part of the Kansas program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Mid-Continent Regional Coordinating Center will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to speak at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.d.t. on June 19, 1997. The location and time of the hearing will be arranged with those persons requesting the hearing. Any disabled individuals who has need for a special accommodation to attend accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT.** If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak, and who wish to do so will be heard following those who have been scheduled. The hearing will end after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

Public Meeting

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et. seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 916

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 23, 1997.

Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 97–14548 Filed 6–3–97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY–1387]

Surface Coal Mining and Reclamation Operations on Federal Lands Under the Permanent Program; State-Federal Cooperative Agreements; Kentucky

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is proposing to adopt a cooperative agreement between the Department of the Interior and the State of Kentucky for the regulation of surface coal mining and reclamation operations on Federal Lands in Kentucky under the permanent regulatory program. Such a cooperative agreement is provided for in the Surface Mining Control and Reclamation Act of 1977 (SMCRA). This notice of proposed rulemaking provides information on the proposed terms of the cooperative agreement.

DATES: Written comments must be received by 4:00 p.m., E.D.T., July 7, 1997. If requested, a public hearing on the proposed amendment will be held on June 30, 1997. Requests to speak at the hearing must be received by 4:00 p.m., E.D.T., on June 19, 1997.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to William

J. Kovacic, Director, at the address listed below.

Copies of the Kentucky program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may received one free copy of the proposed amendment by contacting OSM's Lexington Field Office.

William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503, Telephone: (606) 233–2896.

Department of Surface Mining Reclamation and Enforcement, 2 Hudson Hollow Complex, Frankfort, Kentucky 40601. Telephone: (502) 564–6940.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, Telephone: (606) 233–2896.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 18, 1982, **Fedeal Register** (47 FR 21404). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

II. Description of the Proposed Amendment

By letter dated May 2, 1997, (Administrative Record No. KY–1387) from the Commissioner of the Natural Resources and Environmental Protection Cabinet (NREPC), Kentucky submitted a proposed amendment to its program pursuant to SMCRA. The purpose of the proposed amendment is to give Kentucky, through a State-Federal Cooperative Agreement (Agreement), primacy in the administration of it's approved permanent regulatory program on Federal lands in the State.

Section 523(c) if SMCRA, 30 USC 1201 et seq., and the implementing regulations at 30 CFR Part 745, allow a State and the Secretary of the Interior to enter into a permanent program cooperative agreement if the State has an approved State program for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands. Permanent program cooperative agreements are authorized under section 523(c) which provides that, ''Any State with an approved State program may elect to enter into a cooperative agreement with the Secretary to provide for State regulation of surface coal mining and reclamation operations on Federal lands within the State, provided the Secretary determines in writing that such State has the necessary personnel and funding to implement such a cooperative agreement in accordance with the provision of this Act.''

Section 745.11(b) (1) through (8) of OSM's regulations require that certain information be submitted with a request for a permanent program cooperative agreement, if the information has not been previously submitted in the State program. Much of the information relating to the budget, staffing, and equipment necessary for assuring the duties of inspecting surface coal mining and reclamation operations on Federal lands have been previously submitted by Kentucky in the State program. In addition, the State of Kentucky submitted written certification of the Kentucky Attorney General to OSM that no State statutory, regulatory or other legal constraint exists which would limit the capability of NREPC to fully comply with the terms of the proposed cooperative agreement and section 523(c) of SMCRA, as implemented by 30 CFR Part 745.

The full text of the proposed agreement is included as part of this proposed rule making. OSM emphasizes that the proposed cooperative agreement may be subject to further change as a result of public comment and/or further discussion with the State of Kentucky.

The proposed agreement as submitted by Kentucky is comprised of sixteen articles. A brief summary of the articles appears below.

Article I: Introduction, Purpose and Responsible Agencies

This article sets forth the legal authority for the Agreement and states that the Agreement provides for State regulation of surface coal mining and reclamation operations on Federal lands in Kentucky. The article also designates the NREPC as the agency responsible for administering the Agreement on behalf of the Governor of Kentucky (Governor) and OSM as the agency responsible for administering the Agreement on behalf of the Secretary of the Department of the Interior (Secretary).

Article II: Effective Date

This article provides that on signature by the Secretary and the Governor, the Agreement would become effective 30 days after publication in the **Federal Register** as a final rule.

Article III: Definitions

This article provides that the terms and phrases used in the Agreement shall have the same meaning as those set forth in SMCRA, KRS 350 and the rules and regulations promulgated pursuant to those acts. The procedures to be followed in the event the definitions conflict are also specified.

Article IV: Applicability

This article states that the laws, regulations, terms and conditions of Kentucky's approved State program are applicable to Federal lands in Kentucky except as otherwise stated in the Agreement, SMCRA, 30 CFR 740.4 and 740.13, or other applicable Federal Laws, Executive Orders or regulations. This article also designates the proper authority for hearings of appealable actions.

Article V: General Requirements

This article affirms that NREPC has the authority under State law to carry out this agreement. It also establishes the procedures for funding of NREPC's responsibilities under the Agreement and the right to NREPC to terminate the agreement should OSM be unable to adequately fund the program. This article provides for exchanging of information and reporting between OSM and NREPC, and requires NREPC to have adequate personnel with sufficient equipment and facilities to carry out the requirements of the program. Finally, the article discusses the determination and disposition of funds generated from permit application fees and civil penalties.

Article VI: Review of Permit Application Package

Paragraphs A through C of Article VI generally describe the procedures that the State and OSM will follow in the review and analysis of permit application packages (PAP) for operations on Federal lands. The term ''permit application package'' is defined under 30 CFR 740.5. NREPC will assume primary responsibility for the review of PAP except in the case of leased Federal coal where OSM will prepare a mine plan decision document. OSM will obtain the Secretary's approval for the document.

The article further establishes guidelines for material to be submitted in the PAP and the procedures to be

used by OSM and NREPC in reviewing the PAP. Coordination between NREPC, OSM and other Federal Agencies in conducting the review is spelled out. Finally, the article provides guidelines for making a decision on the permit application and informing the applicable parties of the decision. The review procedures for permit revisions, renewable and the transfer, assignment or sale of permit rights is also discussed.

Article VII. Inspections

This article specifies that NREPC will conduct inspections of the operation on Federal lands and will prepare and file inspection reports documenting the inspection in accordance with the program. This article provides that NREPC will be point of contact and primary inspection authority in dealing with operators but also specifies that authorized Federal land management agencies will not be prevented from conducting necessary inspections. Procedures for handling citizen complaints of imminent danger to the public health and safety or of significant imminent environmental harm to land, air or water resources received by OSM are also discussed.

Article VIII: Enforcement

This article deals with the responsibility for issuance of enforcement actions resulting from violations on surface coal mining and reclamation sites on Federal lands. NREPC will have the lead in issuing enforcement actions except in cases where Federal laws and Executive orders reserve such rights to the Secretary. The article provides for the exchange of information concerning enforcement actions and also provides that personnel from NREPC and OSM will be mutually available to serve as witnesses in enforcement actions taken by either party.

Article IX: Bonds

This article specifies the procedures by which a permittee will secure a performance bond to cover the operator's responsibility under the Act and Program. Assignment of the bond in the event of termination of the Agreement and procedures to be followed for bond release and forfeiture are also discussed. Finally the article provides that OSM or the appropriate Federal Agency is responsible for the collection and maintenance of Federal lease bonds.

Article X. Designating Areas Unsuitable for All or Certain Types of Surface Coal Mining and Reclamation Operations and Activities, Valid Existing Rights (VER), and Compatibility Determinations.

The unsuitably petitions portion of the article reserves authority to designate Federal lands as unsuitable for mining to the Secretary. The article further specifies the procedures to be followed when a petition to designate land areas unsuitable for all or certain types of surface coal mining operations that could impact adjacent Federal or non-Federal lands pursuant to Section 522(c) of the Act is received. The VER and Compatibility Determinations portion of the article require OSM to make VER determinations on Federal lands where proposed operations are prohibited or limited by Section 522(e)(2)(1) of the Act or for determinations of compatibility pursuant to section 522(e)(2) of the Act.

Article XI: Termination of Cooperative Agreement

This article allows the Agreement to be terminated by the Governor or the Secretary under the provisions of 30 CFR 745.15.

Article XII: Reinstatement of Cooperative Agreement

This article provides that the Agreement, if terminated in whole or part, may be reinstated under the provisions of 30 CFR 745.14. This article also provides for the reservation of powers and authority to the Secretary as specified in 30 CFR 745.13.

Article XIII: Amendment of Cooperative Agreement

This article provides that the Agreement may be amended by mutual agreement of the Governor and the Secretary in accordance with 30 CFR 745.14.

Article XIV: Changes in State or Federal Standards

This article describes the procedures to be followed when new or revised performance or reclamation requirements or enforcement and administrative procedures are promulgated.

Article XV: Changes in Personnel and Organization

Under the terms of this article each party to the Agreement must notify the other of changes in personnel, organization and funding, or other changes that may affect the implementation of the Agreement.

Article XVI: Reservation of Rights

This article provides that the agreement will not be construed as waiving or preventing the assertion of any rights in this Agreement that the State or Secretary may have under laws other than the Act or their regulations, including but not limited to those listed in Appendix A.

The full text of the Agreement appears below:

Kentucky Cooperative Agreement

The Governor of the State of Kentucky (the Governor) and the Secretary of the Department of the Interior (the Secretary) enter into a Cooperative Agreement (Agreement) to read as follows:

Article I: Introduction, Purpose, and Responsible Agencies

A. Authority

This Agreement is authorized by Section 523(c) of the Surface Mining Control and Reclamation Act (Act), 30 U.S.C. 1273 (c), which allows a State with a permanent regulatory program approved by the Secretary under 30 U.S.C. 1253, to elect to enter into an Agreement for the regulation and control of coal exploration operations not subject to 43 CFR Group 3400 and surface coal mining and reclamation operations on Federal lands. This Agreement provides for State regulation consistent with the Act, the Federal lands program (30 CFR Chapter VII, subchapter D) and the Kentucky State Program (Program) for surface coal mining and reclamation operations on Federal lands.

B. Purposes

The purposes of this Agreement are to (a) foster Federal-State cooperation on the regulation of surface coal mining and reclamation operations and coal exploration operations not subject to 43 CFR Group 3400, (b) minimize intergovernmental duplication of effort and (c) provide for uniform and effective application of the Program on all lands in Kentucky in accordance with the Act and the Program.

C. Responsible Administrative Agencies

The Kentucky Natural Resources and Environmental Protection Cabinet (NREPC), acting through the Department for Surface Mining Reclamation and Enforcement (DSMRE), shall be responsible for administering this Agreement on behalf of the Governor. The Office of Surface Mining Reclamation and Enforcement (OSM) shall administer this Agreement on behalf of the Secretary.

Article II: Effective Date

After being signed by the Secretary and the Governor, this Agreement shall be effective 30 days after publication in the **Federal Register** as a final rule. This Agreement shall remain in effect until terminated as provided for in Article XI.

Article III: Definitions

The terms and phrases used in this Agreement, which are defined in the Act, 30 CFR Parts 700, 701 and 740 and defined in

the KRS 350 and the rules and regulations promulgated pursuant to that Act, shall have the same meanings as set forth in said definitions. Where there is a conflict between the above referenced State and Federal definitions, the definitions used in the approved State Program will apply except in the case of a term which defines the Secretary's continuing responsibilities under the Act or other laws.

Article IV: Applicability

In accordance with the Federal lands program, the laws, regulations, terms and provisions of the Program are applicable to Federal lands in Kentucky except as otherwise stated in this Agreement, The Act, 30 CFR 740.4 and 745.13 or other applicable Federal laws, Executive Orders or regulations.

Orders and decisions issued by the NREPC in accordance with the Program that are appealable shall be appealed to the reviewing authority in accordance with the Program. Orders and decisions issued by the Secretary or his authorized agents that are appealable shall be appealed to the Department of the Interior's Office of Hearings and Appeals.

Article V: General Requirements

The Governor and the Secretary affirm that they will comply with all provisions of this Agreement.

A. Authority of State Agency

NREPC has and shall continue to have the authority under State law to carry out this agreement.

B. Funding

Upon application by NREPC, and subject to appropriations, OSM will provide the State with funds to defray the costs associated with carrying out its responsibilities under this Agreement as provided in Section 705(c) of the Act and 30 CFR Part 735. Such funds will cover the full cost incurred by NREPC in carrying out those responsibilities. The amount of the grant will be determined using the procedures specified in the Federal Assistance Manual Chapter 3–10 and Appendix III.

For purposes of this agreement, actual costs of NREPC's administration of its approved program on Federal lands in accordance with this agreement shall be that percentage of NRECP's total program expenditures during any specific grant period that equals the percentage of Federal lands within all lands under permit in the state of Kentucky for that specific grant period.

If NREPC applies for a grant but sufficient funds have not been appropriated to OSM, OSM and NREPC will meet to decide upon appropriate measures that will insure that mining operations on Federal lands located in Kentucky are regulated in accordance with the Program. The NREPC also reserves the right to terminate this agreement should OSM be unable to adequately fund this program.

C. Reports and Records

NREPC will make annual reports to OSM containing information with respect to compliance with terms of this Agreement pursuant to 30 CFR 745.12(d). Upon request, NREPC and OSM will exchange information generated under this Agreement, except where prohibited by Federal or State law.

OSM will provide NREPC with a copy of any final evaluation reports prepared concerning State administration and enforcement of this Agreement. NREPC comments on the report will be attached before being sent to the Congress or other interested parties.

D. Personnel

NREPC shall have the personnel necessary to fully implement this Agreement in accordance with the provision of the Act, applicable regulations, the Federal lands program and the approved Program.

E. Equipment and Facilities

NREPC will assure itself access to equipment, laboratories and facilities to perform all inspections, investigations, studies, tests and analyses that are necessary to carry out the requirements of this Agreement.

F. Permit Application Fees and Civil Penalties

The amount of the fee accompanying an application for a permit for operations on Federal lands in Kentucky shall be determined in accordance with KRS 350.060 and Federal law. All permit fees and civil penalties collected from operations on Federal lands will be retained by the State. Permit fees shall be considered Program income. Civil penalties shall not be considered Program income. The financial status report submitted to OSM pursuant to 30 CFR 735.26 shall include the amount of fees and civil penalties collected and attributable to Federal lands during the prior State fiscal year.

Article VI: Review of Permit Application Package

A. Responsibilities

NREPC will assume primary responsibility for the analysis, review, and approval, disapproval, or conditional approval of the permit application component of the permit application package (PAP) required by 30 CFR 740.13 for surface coal mining and reclamation operations in Kentucky on Federal lands. NREPC will assume the responsibilities for review of permit applications to the extent authorized in 30 CFR 740.4(c)(1), (2), (3), (4), (6), and (7).

For proposals to conduct surface coal mining operations involving leased Federal coal, OSM is responsible for preparing a mining plan decision document in accordance with 30 CFR 746.13 and obtaining the Secretary's approval.

The Bureau of Land Management (BLM) is responsible for matters concerned exclusively with regulations under 43 CFR Group 3400.

The Secretary reserves the right to act independently of NREPC to carry out responsibilities under laws other than the Act or provisions of the Act not covered by the Program, and in instances of disagreement over the Act and the Federal lands program. The Secretary will make determinations under the Act that cannot be delegated to the State, some of which have been delegated to OSM.

Responsibilities and decisions which can be delegated to NREPC under other applicable Federal laws may be specified in working agreements between OSM and the State with the concurrence of any Federal agency involved and without amendment to this agreement.

B. Permit Application Package

NREPC shall require an applicant proposing to conduct surface coal mining and reclamation operations on Federal lands to submit a PAP with an appropriate number of copies to NREPC. NREPC will furnish OSM, the Federal land management agency, and any other agency with jurisdiction or responsibility over Federal lands affected by operations proposed in the PAP with an appropriate number of copies of the PAP. The PAP will be in the form required by NREPC and will include any supplemental information required by OSM, the Federal land management agency, and any other agency with jurisdiction or responsibility over Federal lands affected by operations proposed in the PAP.

At a minimum, the PAP will satisfy the requirements of 30 CFR 740.13 (b) and include the information necessary for NREPC to make a determination of compliance with the Program, and for OSM, the appropriate Federal land management agencies, and any other agencies with jurisdiction or responsibilities over Federal lands affected by operations proposed in the PAP to make determinations of compliance with applicable requirements of the Act, the Federal lands program, other Federal laws, Executive Orders, and regulations for which they are responsible.

C. Review Procedures

NREPC will be the primary point of contact for applicants regarding the review of the PAP for compliance with the Program and State laws and regulations. OSM will review the applicable portions of the PAP for compliance with the non-delegated responsibilities of the Act and for compliance with the requirements of other Federal laws, Executive Orders, and regulations.

OSM and NREPC will develop a work plan and schedule for PAP reviews that comply with the time limitations established by the state program, and each agency will designate a person as the federal lands liaison. The federal lands liaison will serve as the primary points of contact between OSM and NREPC throughout the review process. Not later than 45 calendar days after receipt of the PAP, unless a different schedule is agreed upon, OSM will furnish NREPC with its review comments on the PAP and specify any requirements for additional data.

OSM and NREPC will coordinate with each other during the review process as needed. NREPC will send to OSM copies of any correspondence with the applicant and any information received from the applicant regarding the PAP. OSM will send to NREPC copies of all OSM correspondence which may have a bearing on the PAP.

OSM will provide technical assistance to NREPC when requested, and will have access

to NREPC files concerning operations on Federal lands. NREPC will keep OSM informed of findings made during the review process which bear on the responsibilities of OSM or other Federal agencies.

D. Coordination Between NREPC, OSM, and Other Federal Agencies

NREPC will, to the extent authorized, consult with the Federal land management agency and BLM pursuant to 30 CFR 740.4 (c) (2) and (3), respectively. NREPC will also be responsible for obtaining the comments and determinations of other agencies with jurisdiction or responsibility over the Federal lands affected by the operations proposed in the PAP. NREPC will request all Federal agencies to furnish their findings or any request for additional information to NREPC within 45 calendar days of the date of receipt of the PAP. OSM will, upon request, assist NREPC in obtaining such information.

In accordance with 30 CFR 745.12(g)(2), where lands containing leased Federal coal are involved, NREPC will provide OSM, in the form specified by OSM in consultation with NREPC, with written findings indicating that each permit application is in compliance with the terms of the regulatory program and a technical analysis of each permit application to assist OSM in meeting its responsibilities under other applicable Federal laws and regulations.

Where leased Federal coal in involved, OSM will consult with and obtain the concurrences of BLM, the Federal land management agency, and any other agency with jurisdiction or responsibility over the Federal lands affected by the operations proposed in the PAP as required to make its recommendation for the Secretary's decision on the mining plan.

Where BLM contacts the applicant in carrying out its responsibilities under 43 CFR Group 3400, BLM will immediately inform NREPC of its actions and provide NREPC with a copy of documentation of all decisions within 5 calender days.

E. Permit Application Decision and Permit Issuance

NREPC will prepare a State decision package, including written findings and supporting documentation, indicating whether the PAP is in compliance with the Program. NREPC will make the decision on approval, disapproval, or conditional approval of the permit on Federal lands.

Any permit issued by NREPC will incorporate any lawful terms or conditions imposed by the Federal land management agency, including conditions relating to post-mining land use, and will be conditioned upon compliance with the requirements of the Federal land management agency.

NREPC may make a decision on approval, disapproval, or conditional approval of the permit on Federal lands in accordance with the Program prior to the necessary Secretarial decision on the mining plan when leased Federal coal is involved, provided that NREPC advises the operator in the permit that Secretarial approval of the mining plan must be obtained before the operator may conduct surface coal mining operations on the Federal lease. NREPC will reserve the right to amend or rescind any requirements of the permit to conform with any terms or conditions imposed by the Secretary in the approval of the mining plan.

After making its decision on the PAP, NREPC will send a notice to the applicant, OSM, the Federal land management agencies, and any other agency with jurisdiction or responsibility over Federal lands affected by the operations proposed in the PAP. A copy of the permit and written findings will be provided to OSM upon request.

F. Review Procedures for Permit Revisions; Renewals; and Transfer, Assignment, or Sale of Permit Rights

Any permit revision or renewal for a surface coal mining and reclamation operation on Federal lands will be reviewed and approved, or disapproved, by NREPC after consultation with OSM on whether such revision or renewal constitutes a mining plan modification pursuant to 30 CFR 746.18. OSM will inform NREPC within 10 calendar days of receiving a copy of a proposed permit revision or renewal, whether the permit revision or renewal constitutes a mining plan modification.

Transfer, assignment, or sale of permit rights on Federal lands shall be processed in accordance with the Program and 30 CFR 740.13 (e).

Article VII: Inspections

NREPC will conduct inspections of all surface coal mining and reclamation operations on Federal lands, in accordance with 30 CFR 740.4(c) (5) and the Program and prepare and file inspection reports in accordance with the Program. NREPC, subsequent to conducting any inspection pursuant to 30 CFR 740.4 (c) (5), and in a timely fashion which will not exceed 45 calendar days, will file with OSM's Lexington Field Office a legible copy of the completed State inspection report.

NREPC will be the point of contact and primary inspection authority in dealing with the operator concerning operations and compliance with the requirements covered by this Agreement, except as descried hereinafter. Nothing in this Agreement will prevent inspections by authorized Federal or State land management agencies for purposes other than those covered by this Agreement. The Department of the Interior acting through OSM, the Federal land management agency or any other agency with jurisdiction or responsibility over Federal lands to be affected under the proposed PAP, may conduct any inspections necessary to comply with obligations under 30 CFR Parts 842 and 843 and any laws other than the Act.

OSM will give NREPC reasonable notice of its intent to conduct an inspection under 30 CFR 842.11 in order to provide NREPC inspectors with an opportunity to accompany OSM inspectors. When OSM is responding to a citizen complaint of an imminent danger to the public health and safety, or of significant, imminent environmental harm to land, air or water resources pursuant to 30 CFR 842.11(b)(1)(ii)(c), it will contact NREPC and provide the opportunity for a joint Federal/State inspection. Inability of NREPC to make an immediate joint inspection will not be cause for OSM to delay a Federal inspection where a citizen has alleged, and OSM has just cause to believe, that an imminent danger to the public health and safety, or significant, imminent environmental harm to land, air or water resources exists. All citizen complaints which do not involve an imminent danger or significant, imminent environmental harm will be referred to NREPC for action.

Article VIII: Enforcement

NREPC will have primary enforcement authority under the Act concerning compliance with the requirements of this Agreement and the Program in accordance with 30 CFR 740.4(c)(5). Enforcement authority given to the Secretary under other Federal laws and Executive Orders including, but not limited to, those listed in Appendix A (attached) is reserved to the Secretary.

During any joint inspections by OSM and NREPC, NREPC will have primary responsibility for enforcement procedures including issuance of orders of cessation, notices of violation, and assessment of penalties.

NREPC will inform OSM prior to issuance of any decision to suspend or revoke a permit on Federal lands.

During any inspection made solely by OSM or any joint inspection where NREPC and OSM fail to agree regarding the propriety of any particular enforcement action, OSM may take any enforcement action necessary to comply with 30 CFR Parts 843, 845, and 846. Such enforcement action will be based on the standards in the Program, the Act, or both, and will be taken using the procedures and penalty system contained in 30 CFR Parts 843, 845, and 846.

NREPC and OSM will within 5 calendar days notify each other of all violations of applicable laws, regulations, orders, or approved mining permits subject to this Agreement, and of all actions taken with respect to such violations.

Personnel of NREPC and OSM will be mutually available to serve as witnesses in enforcement actions taken by either party.

This Agreement does not affect or limit the Secretary's authority to enforce violations of Federal laws other than the Act.

Article IX: Bonds

NREPC and the Secretary will require each permittee who conducts operations on Federal lands to submit a performance bond payable to the State of Kentucky for an amount adequate to cover the operator's responsibilities under the Act and Program. Such performance bond will be conditioned upon compliance with all requirements of the Act, the Program, State rules and regulations, and any other requirements imposed by the Department of the Interior. Such bond will state on its face that in the event the Federal Lands Cooperative Agreement between Kentucky and the U.S. Department of Interior is terminated, the portion of the bond covering the federal lands increment(s) shall be assigned to the United States. The bond shall also state that if subsequent to the forfeiture of the bond, the Cooperative Agreement is terminated, any unspent or uncommitted proceeds of the

portion of the bond covering the federal lands increment(s) shall be assigned to and forwarded to the United States. NREPC will advise OSM within 30 calendar days of any adjustments to the performance bond made pursuant to the Program.

Prior to releasing the permittee from any obligation under such bond for surface coal mining operations involving leased Federal coal, NREPC will obtain the concurrence of OSM. OSM concurrence will include coordination with the Federal land management agency and any other agency with jurisdiction or responsibility over Federal lands affected by the surface coal mining and reclamation operation.

Submission of a performance bond does not satisfy the requirements for a Federal lease bond required by 43 CFR Subpart 3474 or lessee protection bond required in addition to a performance bond, in certain circumstances, by Section 715 of the Act. Where Federal lease bonds or protections are required, OSM or the appropriate federal agency is responsible for the collection and maintenance of such bonds.

Article X: Designating Areas Unsuitable for All or Certain Types of Surface Coal Mining and Reclamation Operations and Activities, Valid Existing Rights (VER), and Compatibility Determinations

A. Unsuitability Petitions

1. Authority to designate Federal lands as unsuitable for mining pursuant to a petition is reserved to the Secretary.

2. When either NREPC or OSM receives a petition to designate land areas unsuitable for all or certain types of surface coal mining operations that could impact adjacent Federal or non-Federal lands pursuant to Section 522(c) of the Act, the agency receiving the petition will notify the other agency of receipt within 5 calendar days and of the anticipated schedule for reaching a decision, and request and fully consider data, information and recommendations of the other agency. OSM will coordinate with the Federal land management agency and any other agency with jurisdiction or responsibility over Federal lands within or adjacent to the petition area and will solicit comments from these agencies.

B. VER and Compatibility Determinations

The following actions will be taken when requests for determinations of VER pursuant to Section 522(e) (1) or (2) of the Act or for determinations of compatibility pursuant to section 522(e)(2) of the Act are received:

1. For Federal lands where proposed operations are prohibited or limited by Section 522(e) (1) or (2) of the Act and 30 CFR 761.11(a) or (b), OSM will make the VER determination.

2. OSM will process requests for determinations of compatibility under Section 522(e)(2) of the Act and 30 CFR 761.11(b) and 761.12(c).

Article XI: Termination of Cooperative Agreement

This Agreement may be terminated by the Governor or the Secretary under the provisions of 30 CFR 745.15.

Article XII: Reinstatement of Cooperative Agreement

If this Agreement has been terminated in whole or in part, it may be reinstated under the provisions of 30 CFR 745.16. The Secretary reserves the powers and authority specified in 30 CFR 745.13.

Article XIII: Amendment of Cooperative Agreement

This Agreement may be amended by mutual agreement of the Governor and the Secretary in accordance with 30 CFR 745.14.

Article XIV: Changes in State or Federal Standards

The Secretary or NREPC may, from time to time, promulgate new or revised performance or reclamation requirements or enforcement and administrative procedures. Each party will, if it determines it to be necessary to keep this Agreement in force, change or revise its regulations or request necessary legislative action.

Such changes will be made under the procedures of 30 CFR Part 732 for changes to the Program and under the procedures of Section 501 of the Act for changes to the Federal lands program.

NREPC and OSM will provide each other with copies of any changes to their respective laws, rules, regulations, policy statements, guidelines or standards pertaining to the enforcement and administration of this Agreement.

Article XV: Changes in Personnel and Organization

Each party to this Agreement will notify the other, when necessary, of any changes in personnel, organization and funding, or other changes that may affect the implementation of this Agreement to ensure coordination of responsibilities and facilitate cooperation.

Article XVI: Reservation of Rights

This Agreement will not be construed as waiving or preventing the assertion of any rights in this Agreement that the State or the Secretary may have under laws other than the Act or their regulations, including but not limited to those listed in Appendix A.

Approved:

_____

Governor of Kentucky Date

_____

Secretary of the Interior Date

Appendix A

1. The Federal Land Policy and Management Act, 43 U.S.C. 1701 *et seq.*, and implementing regulations.

2. The Mineral Leasing Act of 1920, 30 U.S.C. 181 *et seq.*, and implementing regulations, including 43 CFR Part 3480.

3. The National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*, and implementing regulations, including 40 CFR Part 1500.

4. The Endangered Species Act, 16 U.S.C. 1531 *et seq.*, and implementing regulations, including 50 CFR Part 402.

5. The Fish and Wildlife Coordination Act, as amended, 16 U.S.C. 661 *et seq.*, 48 Stat 401.

6. The Bald and Golden Eagle Protection Act of 1940, as amended, 16 U.S.C. 668–668d, and implementing regulations.

7. The Migratory Bird Treaty Act, as amended, 16 U.S.C. 701–718h *et seq.*

8. The National Historic Preservation Act of 1966, 16 U.S.C. 470 *et seq.*, and implementing regulations, including 36 CFR Part 800.

9. The Clean Air Act, 42 U.S.C. 7401 *et seq.*, and implementing regulations.

10. The Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*, and implementing regulations.

11. The Resource Conservation and Recovery Act of 1976, 42 U.S.C. 6901 *et seq.*, and implementing regulations.

12. The Reservoir Salvage Act of 1960, amended by the Preservation of Historical and Archaeological Data Act of 1976, 16 U.S.C. 469 *et seq.*

13. Executive Order 11593 (May 13, 1971), Cultural Resource Inventories on Federal Lands.

14. Executive Order 11988 (May 24, 1977), for flood plain protection.

15. Executive Order 11990 (May 24, 1977), for wetlands protection.

16. The Mineral Leasing Act for Acquired Lands, 30 U.S.C. 351 *et seq.*, and implementing regulations.

17. The Stock Raising Homestead Act of 1916, 43 U.S.C. 291 *et seq.*

18. The Archaeological Resources Protection Act of 1979, 16 U.S.C. 470aa *et seq.*, as amended.

19. The Constitution of the United States.

20. The Surface Mining Control and Reclamation Act of 1977, 30 U.S.C. 1201 *et seq.*

21. 30 CFR Chapter VII.

22. The Constitution of the State of Kentucky and State Law.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Kentucky program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rule making, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Lexington Field Office will not necessarily be considered in the final rule making or included in the Administrative Record.

Public Hearing

Persons wishing to speak at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., E.D.T. on June 19, 1997. The location and time of the

hearing will be arranged with those persons requested the hearing. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Public Meeting.

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 28, 1997.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 97–14549 Filed 6–3–97; 8:45 am]

BILLING CODE 4310–05–M

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Parts 1190 and 1191

Accessibility Guidelines for Outdoor Developed Areas

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of establishment of regulatory negotiation committee and first committee meeting.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) has decided to establish a regulatory negotiation committee to develop a proposed rule on accessibility guidelines for newly constructed and altered outdoor developed areas covered by the Americans with Disabilities Act and the Architectural Barriers Act. The regulatory negotiation committee will be comprised of organizations who represent the interests affected by the accessibility guidelines for outdoor developed areas. This notice also announces the times and location of the first meeting of the regulatory negotiation committee.

DATES: The first meeting of the regulatory negotiation committee is scheduled for June 26 and 27, 1997 beginning at 8:30 a.m. each day. The meeting will end at 5:00 p.m. on June 26, 1997 and at 4:00 p.m. on June 27, 1997.

ADDRESSES: The first meeting of the regulatory negotiation committee will be held at the offices of the Paralyzed Veterans of America, 801 18th Street, NW., Washington, D.C. 20006.

FOR FURTHER INFORMATION CONTACT: Peggy Greenwell, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., suite 1000, Washington, DC, 20004–1111. Telephone number (202) 272–5434 extension 34 (Voice); (202) 272–5449 (TTY). This document is available in alternate formats (cassette tape, braille, large print, or computer disk) upon request. This document is also available on the Board's Internet Site (http://www.access-board.gov/rules/outdoor.htm).

SUPPLEMENTARY INFORMATION: On April 18, 1997, the Architectural and Transportation Barriers Compliance Board (Access Board) published a notice of intent to establish a regulatory negotiation committee to develop a proposed rule on accessibility guidelines for newly constructed and altered outdoor developed areas covered by the Americans with Disabilities Act and the Architectural Barriers Act. 62 FR 19084 (April 18, 1997). The notice identified the interests that are likely to be significantly affected by the accessibility guidelines: State and local governments; individuals with disabilities; designers; conservation groups; trails groups; and private sector camping facilities. The notice proposed a list of 19 organizations to represent these interests on the regulatory negotiation committee. Comments were requested on the proposal to establish the regulatory negotiation committee and the proposed committee membership.

The comments supported the establishment of the regulatory negotiation committee. Six more organizations have been added to the regulatory negotiation committee in response to the comments. The following 25 organizations will comprise the regulatory negotiation committee:

American Association of Landscape Architects
American Camping Association
American Trails
Appalachian Trail Conference
Hawaii Commission on Persons with Disabilities
KOA (Kampgrounds of America), Inc.
National Association of State Park Directors
National Association of State Trail Administrators
National Center on Accessibility
National Council on Independent Living
National Parks and Conservation Association
National Recreation and Park Association
National Spinal Cord Injury Association
New York State Department of Environmental Conservation, Bureau of Public Lands
Paralyzed Veterans of America
Partners for Access to the Woods
Rails to Trails Conservancy
State of Washington, Interagency Committee for Outdoor Recreation
TASH (The Association of Severely Handicapped)
U.S. Architectural and Transportation Barriers Compliance Board
U.S. Army Corps of Engineers
U.S. Department of Agriculture, Forest Service
U.S. Department of the Interior, National Park Service
U.S. Department of Transportation, Federal Highway Administration
Whole Access

The first meeting of the regulatory negotiation committee will be held in Washington, DC on June 26 and 27, 1997. The times and location of the meeting are listed at the beginning of this notice. The meeting is open to the public. The meeting site is accessible to individuals with disabilities. Individuals with hearing impairments who require sign language interpreters should contact Peggy Greenwell by June 18, 1997 by calling (202) 272–5434 extension 34 (voice) or (202) 272–5449 (TTY).

Dated: May 29, 1997.

Patrick D. Cannon,

Chair, Architectural and Transportation Barriers Compliance Board.

[FR Doc. 97–14553 Filed 6–3–97; 8:45 am]

BILLING CODE 8150–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AI42

Claims Based on Aggravation of a Nonservice-Connected Disability

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations concerning secondary service connection for certain disabilities. This proposal is based on a recent decision by the United States Court of Veterans Appeals (CVA). The intended effect of this amendment is to conform VA regulations to the CVA decision, which clarified the circumstances under which veterans may be compensated for disabilities related to service-connected conditions.

DATES: Comments must be received by VA on or before August 4, 1997.

ADDRESSES: Mail or hand deliver written comments to: Director, Office of Regulations Management, Room 1154, 810 Vermont Ave., NW., Washington, DC 20420. Comments should indicate that they are submitted in response to ''RIN 2900-AI42.'' All written comments will be made available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Judith Veres, Consultant, Judicial Review Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420, (202) 273–7240.

SUPPLEMENTARY INFORMATION: Under the provisions of 38 U.S.C. 1110 and 1131, VA may establish service connection for disabilities resulting from disease or injury incurred or aggravated during a veteran's period of active military, naval, or air service. Once service connection is established for a veteran's disability, VA may authorize monetary compensation depending on the disability's level of severity. In addition, under 38 CFR 3.310, VA may establish service connection for a disability which is proximately due to or the result of a service-connected disease or injury.

In *Allen* v. *Brown,* 7 Vet. App. 439, 448 (1995), issued March 17, 1995, CVA held that, as a matter of law, when aggravation of a veteran's nonservice-connected condition is proximately due to or the result of a service-connected condition, the veteran is entitled to compensation for the degree of disability (but only that degree) over and above the degree of disability existing prior to aggravation. Prior to CVA's holding, VA paid compensation for a disability on a secondary basis only if the secondary condition was entirely caused by a service-connected disability. To conform § 3.310 to CVA's decision, VA is proposing to amend 38 CFR 3.310 to authorize compensation for the incremental increase in severity of a nonservice-connected disability which is proximately due to or the result of a service-connected condition.

In order to determine whether, and to what extent, a service-connected disease or injury has aggravated a non service-connected disability, VA must be able to determine the pre-aggravation severity of the disability in question. We, therefore, propose to stipulate that VA will not concede aggravation unless it has medical evidence, which pre-existed the aggravation, sufficient to establish the pre-aggravation severity of the condition. Since some conditions are inherently progressive and worsen naturally over time, we propose to specify that VA will not service-connect any increase in severity that is due to natural progression. These requirements would be consistent with the manner in which VA determines the degree of in-service aggravation of pre-existing disabilities, i.e., by comparing the severity of the condition when the veteran entered and left active military

service and excluding from consideration any increase in severity that is due to the natural progression of the condition. As with all other disabilities evaluated for VA purposes, the level of compensation would be determined under the provisions of VA's Schedule for Rating Disabilities.

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance program number is 64.109.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Approved: May 27, 1997.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 3 is proposed to be amended as set forth below:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A, continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Section 3.310 is amended by revising the section ledading; by redesignating paragraph (b) as paragraph (c); and by adding a new paragraph (b) to read as follows:

§ 3.310 Disabilities that are proximately due to, or aggravated by, service-connected disease or injury.

* * * * *

(b) *Aggravation of nonservice-connected disabilities.* Any increase in severity of a nonservice-connected disability that is proximately due to or the result of a service-connected disease or injury, rather than the normal progression of the disability, shall be service-connected. However, VA will not concede that a nonservice-connected disability was aggravated by a service-connected disease or injury in the absence of medical evidence extant before the aggravation sufficient to establish the pre-aggravation severity of the disability. The rating activity will determine the pre- and post-aggravation levels of severity under the Schedule for Rating Disabilities and determine the extent of aggravation by deducting the pre-aggravation level of severity, as well as any increase in severity due to the normal progression of the disability, from the current level.

(Authority: 38 U.S.C. 1110 and 1131)

* * * * *

[FR Doc. 97–14509 Filed 6–3–97; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60, 63, 260, 261, 264, 265, 266, 270, and 271

[FRL–5834–5]

Revised Technical Standards for Hazardous Waste Combustion Facilities; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability: extension of comment period.

SUMMARY: Since publication of the notice of data availability (62 FR 24212 (May 2, 1997)), EPA has received several requests to extend the comment period. Accordingly, the Agency is extending the comment period 15 days to June 17, 1997.

DATES: The comment period is extended to June 17, 1997.

ADDRESSES: Commenters must send an original and two copies of their comments referencing docket number F–97–CS4A–FFFFF to: RCRA Docket Information Center, Office of Solid Waste (5305G), U.S. Environmental Protection Agency Headquarters (EPA, HQ), 401 M Street, S.W., Washington, DC 20460. Deliveries of comments should be made to the Arlington, Virginia address listed below. Comments may be submitted electronically through the Internet to: rcra-docket@epamail.epa.gov. Comments in electronic format should also be identified by the docket number F–97–CS4A–FFFFF. All electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. For other information regarding submitting comments or viewing the comments received or supporting information, please refer to the proposed rule (61 FR 17358 (April 19, 1996)).

Commenters should not submit electronically any confidential business information (CBI). An original and two copies of the CBI must be submitted under separate cover to: RCRA CBI Document Control Officer, Office of Solid Waste (5305W), U.S. EPA, 401 M Street, S.W., Washington, DC 20460.

Public comments and supporting materials are available for viewing in the RCRA Information Center (RIC): Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, except for Federal holidays. To review docket materials, the public must make an appointment by calling 703–603–9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15 per page.

FOR FURTHER INFORMATION CONTACT: Larry Denyer, Office of Solid Waste (5302W), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 703–308–8770, e-mail address: denyer.larry@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On May 2, 1997, EPA published a notice of data availability. See 62 FR 24212. The Agency established a 30-day comment period and indicated that comments on the proposal would be accepted until June 2, 1997.

To date, EPA has received requests to extend the comment period from Ash Grove Cement Company, Cement Kiln Recycling Coalition, Chemical Manufacturers Association, Coalition for Responsible Waste Incineration, Holnam, Molten Metal Technology, Safety-Kleen, and Solite. Commenters felt the complexity of some of the issues in the NODA and the availability of certain data fields within the emissions database warranted an extension. Accordingly, the Agency is extending the comment period 15 days to June 17, 1997 to provide for a 45-day comment period.

Readers should again note that only comments about new information discussed in the May 2, 1997 notice will be considered by the Agency. Issues related solely to the April 19, 1996 proposed rule and other subsequent notices that are not directly affected by the documents or data referenced in today's Notice of Data Availability are not open for further comment.

Dated: May 22, 1997.

Elizabeth Cotsworth,

Acting Director, Office of Solid Waste.

[FR Doc. 97–14581 Filed 6–3–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300475; FRL–5600–6]

(S)-Hydroprene Biochemical Pest Control Agent; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA proposes to expand the tolerance for residues of hydroprene, [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11-trimethyl-2,4-dodecadienoate)], an insect growth regulator, on all food items in food-handling establishments to include perimeters and pantries, and warehouses to the list of permissible food storage sites and ultra low volume (ULV) fogging as a permissible treatment method under certain precautions and conditions. The Agency also proposes permitting the use of point source device treatments providing those devices do not come into direct contact with food preparation surfaces and are kept a minimum distance of 3 feet from exposed foods. The Agency is also proposing to restrict the tolerance expression to residues of [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11-trimethyl-2,4-dodecadienoate)], the *S*-racemer of hydroprene since the *R*-racemer is no longer being supported in reregistration. This regulation is proposed by the EPA at its own initiative.

DATES: Comments identified by the docket control number [OPP–300475] must be received on or before July 7, 1997.

ADDRESSES: Submit written comments by mail to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Public Docket, Room 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice.

Comments and data may also be submitted electronically by following the instructions under Unit IV of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Diana Horne, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W) Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location, telephone number and e-mail address: Room 5-W38, 5th Floor, CS#1, 2800 Crystal Drive, Arlington, VA 22202 (703) 308-8367; horne.diana@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA proposes to amend 40 CFR parts 180 and 185 by removing § 185.3625 and adding § 180.501, and by adding perimeters, pantries and warehouses to the list of permissible food storage sites and ultra low volume (ULV) fogging as a permissible treatment method under certain precautions and conditions. The Agency is also permitting the use of point source device treatments providing those devices do not come into direct contact with food preparation surfaces and must be kept a minimum distance of 3 feet from exposed foods. The Agency is also proposing to restrict the tolerance expression to residues of [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11-trimethyl-2,4-dodecadienoate)], the *S*-racemer of hydroprene. The *R*-racemer is being removed from the tolerance expression since Sandoz Agro Inc., the manufacturer, is supporting only the reregistration of (*S*)-hydroprene and no longer manufacturers the R/S hydroprene racemic mixture.

I. Background and Statutory Authority

In the **Federal Register** of August 12, 1992 (57 FR 36005), EPA promulgated a final rule which established a tolerance under sections 408 and 409 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a and 348, specifying a tolerance for (*R*)-hydroprene and (*S*)-hydroprene racemic mixture residues of the insect growth regulator in or on food commodities exposed during spot or crack and crevice treatment of food handling establishments at 0.2 ppm. This was in response to a pesticide tolerance petition (9H5573) filed by Zoecon Corporation.

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C, 136 at seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Section 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level. Section 408 governs EPA's establishment of exemptions from the requirement for a tolerance using the same safety standard as section 408(B)(2)(A) and incorporating the provisions of section 408(b)(2)(C) and (D). Section 408(e) gives EPA general authority to establish tolerances and exemptions from the requirement for a tolerance through notice and comment rulemaking procedures upon EPA's initiative.

New section 408(c)(2)(A)(i) allows EPA to establish an exemption from the

requirement of a tolerance only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption and to ''ensure that there is a reasonable certainty, that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue ... '' and specifies factors EPA is to consider in establishing an exemption. Section 408(c)(3)(B) provides for circumstances when no need exists for a practical method for detecting and measuring levels of pesticide chemical residue in or on food.

II. Risk Assessment and Statutory Findings

Consistent with section 408(b)(2)(A), EPA has reviewed the available scientific data and other relevant information in support of this action. The scientific data submitted in previous petitions and other relevant material have been evaluated including toxicological and residue chemistry data. EPA has assessed the toxicology data base for (*S*)-hydroprene and has sufficient data to assess its hazards and to make a determination on aggregate exposure.

A. Use Practices

1. *Use practices.* The biochemical pest control agent (*S*)-hydroprene is presently used on walls, floors, ceilings, attics, basements, or crawlspaces of apartment buildings, bakeries, bottling facilities, breweries, boiler rooms, cafeterias, candy plants, grocery stores, day care centers, hospitals, residential homes, office buildings, kitchens, laboratories, cereal processing facilities, manufacturing plants, mausoleums, meat and produce canneries, nursing homes, restaurants, schools, locker rooms, stores, taverns, warehouses, as well as various modes of transporation such as aircraft, buses, trucks, trailers, rail cars, and marine vessels. It is also applied in food handling establishments where food is held, prepared, processed or served including areas where food is received, prepared, packaged and stored, as well as enclosed food processing systems (mills, dairies, etc.) in spot and crack and crevices, and small food storage areas. This proposal would expand the permissible food storage sites to include warehouses, pantries and perimeters and also ultra low volume (ULV) fogging as a permissible treatment method.

2. *Application rates.* For general surface applications, one ounce of product is applied to 1,500 square feet surface area (0.0015 gram active ingredient/square foot) for surface spray/paint brush, spot and crack crevice preparations. The product may be applied every 4 months by spray/paint brush, hand pressurized or power operated sprayers, foggers, mechanical misting sprayers, aerosol generators, Ultra Low Volume (ULV) misters, or thermal foggers. For fogging, space spray/mist applications, 1 ounce product/12,000 cubic feet (0.2 gram active ingredient/1,000 cubic feet). Emissions from bait stations are at the rate of 0.001 gram active ingredient/square feet over a 3–month period.

B. Product Identity/Residue Chemistry

1. Plant metabolism. (*S*)-hydroprene is not applied to living plants or food and therefore plant metabolism studies have been waived. The currently regulated residues are the racemic components of hydroprene, namely [(*R*)-(Ethyl (2*E*,4*E*,)-3,7,11-trimethyl-2,4— dodecadienoate)], and [(*S*)-(Ethyl (2*E*,4*E*,)-3,7,11-trimethyl-2,4-dodecadienoate)] at 0.2 ppm. EPA proposes to keep the current tolerance limit of 0.2 ppm but to limit the regulated residue to [(*S*)-(Ethyl (2*E*,4*E*,7E)-3,7,11-trimethyl-2,4-dodecadienoate)]. The *R*-racemer is being removed from the tolerance expression since Sandoz Agro Inc., the manufacturer, is supporting only the reregistration of (*S*)-hydroprene and no longer manufacturers the R/S hydroprene racemer mixture.

2. *Analytical method.* The Agency has reviewed scientific data submitted by Zoecon Corporation and has determined that there is a practical analytical method for detecting and measuring levels of (*S*-)hydroprene in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. This method, Method No. 307, is an analytical method—Gas chromatography/Flame Ionization Detector and Mass Specific Detector/Selected Ion Monitoring (GC/FID and MD/SIM) with a limit of detection of 0.01 ppm for most foods and 0.02 ppm for butter. The method will be published in PAM II under Pesticide Reg. 40 CFR 185.3625. EPA has provided information on this method to the Food and Drug Administration. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resoruces and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5805.

3. *Magnitude of residues.* The Agency has also reviewed data for use of (*S*)-hydroprene as a diluted spray for partial area treatment of large food manufacturing/warehousing facilities. Residue studies of food commodities exposed under simulated warehouse pantry conditions for 24 hours indicate that the established tolerance of 0.2 ppm will not be exceeded as long as label directions are followed. Residue studies of food commodities exposed as a result of partial area treatments of large food handling/warehousing facilities indicated that food commodities exposed for up to 8 hours will not exceed the established tolerance of 0.2 ppm. Residues resulting from ULV fogging were also below the established tolerance of 0.2 ppm.

Also reviewed were exposure studies from the use of point source devices. Submitted residue studies indicated that bait and/or stations may be used in food handling establishments during food processing without exceeding the established tolerance of 0.2 ppm under the following conditions. The bait stations must not come into direct contact with food preparation surfaces and must be a minimum of 3 feet or more away from the exposed food.

C. Toxicological Profile

The toxicological findings include reviews/reassessments of a rat chronic toxicity study, rat carcinogenicity study, rat reproductive study, rat and rabbit developmental toxicity studies as well as an Agency assessment of the reference dose (RfD). The test material for all but one of the toxicology tests involved (*S*)-hydroprene which is known to be the more biologically active hydroprene racemer. An *R,S*-hydroprene racemic mixture was the test material in the rabbit developmental study.

1. *Acute toxicity.* Based on the available acute toxicity data, EPA has determined the (*S*)-hydroprene does not pose any acute dietary risks. The following mammalian toxicity studies have been conducted in support of the tolerance exemption for residues of technical (*S*)-hydroprene except for the

acute inhalation test and the skin sensitizing test.

Acute Toxicity Tests	Results	Rating
(*S*)-hydroprene technical unless otherwise stated.		
Acute Oral	LD_{50} > 5,000 mg/kg/day	Toxicity Category IV
Acute Dermal	LD_{50} > 5,000 mg/kg/day, abraded skin	Toxicity Category III
Acute Inhalation.	LC_{50} > 5.2 mg/L (actual) [65.7% formulation]	Toxicity Category III
Primary Dermal Irritation (Rat).	Mild irritation at 0 and 24 hours	Toxicity Category IV
Primary Eye Irritation (Rabbit).	Conjunctival irritation only after 24 hours	Toxicity Category IV
Dermal Sensitization (Guinea Pig).	Sensitizing agent [65.7% formulation]	Toxicity Category IV

2. *Genotoxicity.* There is no evidence for the Agency to believe that (*S*)-hydroprene, a biochemical, has genotoxic potential. Test results were negative for the following mutagenicity tests: unscheduled DNA synthesis in rat hepatocyte, micronucleus assay in mice, *in vivo* cytogenicity in rat bone marrow cells, and the Ames assay.

3. *Reproductive toxicity.* Originally, the Agency determined a parental toxicity no observed effect level (NOEL) of 300 ppm, lowest observed effect level (LOEL) at 1,500 ppm, a reproductive toxicity NOEL of 300 ppm and LOEL of 1,500 ppm (June 8, 1995 memo RfD/QA Peer Review Committee). The Agency has now determined that the parental toxicity NOEL is 1,500 ppm and the LOEL is 7,500 ppm for the rat reproductive toxicity study. The conclusion is based on a review of additional data indicating that: (a) Parental weight gain reductions of the low (300 ppm) and middle-dose (1,500 ppm) groups were sporadic and were not considered to be of biological significance; this is supported by the view of an FDA pathologist, (b) the mean parental body weight gains of the 7,500 ppm group males and females decreased more than 10% throughout the growth phase, when compared to the controls and appeared to be treatment-related, (c) body weight reductions of F1 generation males and females were inconsistent and did not exceed 10%; therefore body weight gains of F1 generation progeny could not be used to establish toxicological endpoints for setting the LOEL, (d) food efficiency of F1 generation and mean body weights of pups at birth were not affected by the treatment, (e) body weight gain reduction in pups of F1 and F2 were significantly reduced on days 14 and 21 at 7500 ppm when compared to controls, and (f) reduced conception rates in the F0 at the low- and high-dose levels were not treatment-related.

4. *Developmental Toxicity.* Following a reevaluation of the submitted data, the Agency has altered its earlier conclusion characterizing the post-implantation loss observed in the rabbit developmental toxicity study as developmental toxicity. As a result, the Agency is revising the developmental toxicity NOEL from 30 mg/kg/day to 90 mg/kg/day, the highest dose tested in rabbits. The observed developmental toxicity effects were maternal weight loss at the highest dose tested, 90 mg/kg/day. While the test material involved a mixture of R,*S*-hydroprene racemers, there were no adverse signs of development toxicity at the highest dosage levels.

5. *Subchronic toxicity.* A 3–month feeding study in rats resulted in a determination of lowest effect level (LEL) = 250 mg/kg/day and NOEL = 50 mg/kg/day. Vacuolated ovarian luteal cells were observed in females as were microscopic findings of homogeneous cytoplasm in male and in female hepatocytes. In a 28-day feeding study in rats, the LEL was 500 mg/kg/day and NOEL = 250 mg/kg/day. Observed was an increase in the kidney to brain weight ration and an increase in absolute kidney weight.

6. *Chronic toxicity.* In a previous review of the chronic toxicity phase of the rat study, the overall NOEL was considered to be 100 ppm (4.62 mg/kg/day in females), the lowest dose tested and was based on the observance of cytoplasmic vacuolization in the ovaries. However, the Agency now concludes that the cytoplasmic vacuolization observed in the ovaries is a result of cellular overload of inert endogenous products synthesized from hydroprene metabolites and thus constitutes no toxicological significance. This explanation is supported by an FDA pathologist (June 8, 1995 memo RfD/QA Peer Review Committee).

As a result of this finding (toxicological insignificance of the ovarian changes), the NOEL and LOEL are now 1,000 and 10,000 ppm, respectively, instead of 100 and 1,000 ppm. The NOEL and LOEL are based on reduced body weight gains in males and females, pancreatic arteritis in males, and increased incidence of syncytial macrophage aggregated in cervical lymph nodes and deep cholesterol clefts and cortical fatty vacuolization in the adrenals in females.

With respect to carcinogenicity, EPA used its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992). EPA has classified (*S*)-hydroprene as a Group ''D'' compound - not classifiable as to human carcinogenicity. In a previous review of the carcinogenicity phase of the rat study, the Agency noted that the incidence of thyroid follicular cell adenomas appeared to be increased in males of the highest dose group but never classified the compound with regard to its human carcinogenicity potential. The Agency, in a reconsideration of the findings, including the absence of a carcinogenicity study involving a second species, and the equivocal nature of the findings from the rat study, has now concluded that the data set presented is only suggestive of a carcinogenic response. *S*-hydroprene, therefore, should be classified as a ''Group D'' compound - not classifiable as to human carcinogenicity. The conclusion, as drawn from the rat study, is based on the following: (i) there was no increase in the incidence of carcinomas; the incidence of carcinomas in male groups were 6, 6, 2, 0 and 8%, respectively, in control group 1, control group 2, 100 ppm, 1,000 ppm and 10,000 ppm groups, (ii) there was no treatment-related increase in precancerous histopathological changes such as hyperplasia, (iii) the compound was not associated with a positive mutagenic response in several bioassay systems, (iv) the compound is not structurally related to any known carcinogen, and (v) the compound is a structural analog to methoprene, a pesticidal compound that has been adequately tested and did not demonstrate mutagenic or carcinogenic properties and has been found to be extensively metabolized via beta oxidation and, almost totally incorporated into components of the tricarboxylic acid cycle.

7. *Reference dose.* As a result of the recent findings, the Agency is revising the RfD from 0.05 mg/kg/day to 0.1 mg/kg/day based on the chronic toxicity in rats. Previously, in a February 2, 1994 meeting of the RfD/QA Peer Review Committee, the Agency tentatively based the RfD for this chemical on the two-generation reproduction study in rats with a NOEL of 15 mg/kg/day for parental and reproductive toxicity (June

8, 1995 memo RfD/QA Peer Review Committee). Parental and reproductive toxicity manifested as increased liver weight and increased incidence of cytoplasmic vacuolization of the ovaries in the F1 were observed at 75 mg/kg/day and higher dose levels. The rat chronic toxicity study was considered as a co-critical study with a NOEL of 4.62 mg/kg/day and a lowest effect level of 45.7 mg/kg/day. Similar effects were observed in this study. Although the chronic toxicity study in rats demonstrated a slightly lower NOEL than the reproductive toxicity study, the Agency considered the findings of the reproductive study to be more reliable. An uncertainty factor (UF) of 100 was used to account for inter-species extrapolation and intra-species variability. An additional UF of 3 was used to account for the lack of chronic toxicity data on a non-rodent species. On this basis, the RfD was calculated to be 0.05 mg/kg/day.

However, as a result of an April 20, 1995 reassessment meeting, the Agency has now determined that the RfD should be based on the chronic toxicity study in rats with a NOEL of 1,000 (36.2 and 45.7 mg/kg/day for males and females, respectively) (June 8, 1995 memo RfD/QA Peer Review Committee). Significantly decreased cumulative body weight gains in males (18%) and females (20.6%) during growth phase (0 to 80 weeks), syncytial macrophage aggregates in cervical lymph nodes, deep cholesterol clefts and cortical fatty vacuolization in the adrenals of females and pancreatic arteritis in males were observed at the next higher dose level of 10,000 ppm (377 and 485 mg/kg/day for males and females, respectively). A UF of 100 was used to account for inter-species extrapolation and intra-species variability. An additional UF of 3 was used to account for the lack of toxicity data on a non-rodent species.

On the basis of the forementioned studies, the RfD is calculated to be 0.1 mg/kg/day.

8. *Animal metabolism.* A rat metabolism study using a mixture of 2*E*/4*E* and 2Z/4*E* isomers was submitted. About 13% is retained in the carcasses of both males and female rats. Hydroprene concentration in the plasma peaked at 5 to 7 hours. Elimination was biphasic. The half-life of the second phase took place 2 to 10 days after dosing. In a 54 hour period, the highest residues were found after 6 hours, with highest levels found in the liver, fat and adrenal glands. The Agency has now classified (*S*)-hydroprene as a biochemical and therefore, metabolism data are normally not required by the Agency due to the non-toxic mode of action.

9. *Metabolite toxicology.* No metabolites have been identified for (*S*)-hydroprene. No metabolite toxicity studies are required for this pesticide which is presently classified as a biochemical.

D. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning all routes of exposures from the pesticide residue in the diet, including drinking water, and all other non-occupational exposures. The primary non dietary routes of exposures are exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*— a. *Food.* As indicated in earlier in this document, reviewed data indicate that (*S*)-hydroprene residue levels are below the tolerance level under worse-case scenarios.

b. *Drinking water.* Because the use pattern for (*S*)-hydroprene involves only indoor uses, EPA does not anticipate any exposure to result from residues of (*S*)-hydroprene in drinking water. Furthermore, the chemical is not readily water-soluble.

2. *Non-dietary exposure.* With regard to non-dietary exposure, the current registrations for (*S*)-hydroprene permits its use in cafeterias, supermarkets, as well as kitchens in households. For general surface treatments, the sprays must be allowed to dry before ventilation is turned back on. Under these conditions, the risk from non-dietary exposure to the general population is, thus, expected to be negligible.

E. Cumulative Exposure to Substances with Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically and structurally dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

F. Safety Determinations

1. *U.S. population.* In general, using conservative exposure assumptions described earlier, and, based on the completeness and reliability of the toxicity data, EPA has concluded that aggregate exposure to (*S*)-hydroprene will utilize 6.8 percent of the RfD for the U.S. population. It should be noted that there will be no exposure issues for (*S*)-hydroprene residues in drinking water since this biochemical pesticide is not used outdoors. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to *S*-hydroprene residues. There is no reason to believe that (*S*)-hydroprene possesses any immunotoxic or estrogenic properties at this time.

2. *Infants and children.* FFDCA section 408 provides that EPA shall

apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. EPA believes that reliable data support using the standard margin of exposure (usually 100X for combined inter- and intra-species variability) and not the additional tenfold margin of exposure when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin of exposure.

In assessing the potential for additional sensitivity of infants and children to residues of (*S*)-hydroprene, EPA considered data from a 2-generation reproduction study in the rat and developmental toxicity studies in the rat and rabbit.

Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. As detailed in a previous paragraph in the toxicological profile section of this document, with regard to the reproductive toxicity potential for (*S*)-hydroprene, the Agency has concluded that the observed parental weight gain reductions of the low (300 ppm) and middle-dose (1,500 ppm) groups were sporadic and were not considered to be of biological significance. At the highest dose tested, 7,500 ppm, there were no reproductive toxicity effects other than a less than severe reduction in body weight gain in pups of F1 and F2 on days 14 and 21.

The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. As discussed in the toxicology section, the Agency has set the developmental toxicity NOEL at 90 mg/kg/day, the highest dose tested in rabbits. There was no developmental effect on the pups observed at the highest dose tested in the study.

Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is more than adequate for this biochemical pesticide. The data from the reproductive and developmental toxicity tests do not suggest additional sensitivity for infants and children. Therefore, EPA concludes that an additional uncertainty factor is not warranted for (*S*)-hydroprene. EPA concludes that reliable data support the use of a 300-fold uncertainty factor as providing an adequate margin of safety for infants and children. Using the conservative exposure assumptions described above, EPA has determined that the percent of the RfD that will be utilized by aggregate exposure to residues of (*S*)-hydroprene ranges from 6.9 percent for nursing infants less than 1 year old to, 20.9 percent for non-nursing infants less than 1 year old to 13.4 percent for children 7 to 12 years old. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to (*S*)-hydroprene residues.

G. International Tolerances

There is no CODEX tolerance or any other international tolerance at this time.

H. Other Considerations

The Agency does not conduct acute dietary risk analyses for tolerances involving food handling establishments. It is the opinion of the Science Advisory Panel and the Agency that the calculations would result in a gross overestimation of acute dietary risk. In any case, there are no acute endpoints of concern for (*S*)-hydroprene.

The proposed tolerance amendment has been jointly reviewed per a Memorandum of Understanding between the California Environmental Protection Agency (CalEPA) and the Agency. CalEPA has also concluded that the proposed tolerance amendments present minimal toxicological concern.

I. Conclusion

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Based on the information and data considered, the Agency has determined that, in amending 40 CFR part 185, as proposed, there is reasonable certainty that no harm to the general population will result from aggregate exposure to the pesticide chemical residue.

IV. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300475] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in ''ADDRESSES''.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300475]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

V. Regulatory Assessment Requirements

This action proposes to establish a tolerance under section 408 ofthe FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). In addition, this proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require special OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact (46 FR 24950, May 4, 1981). In accordance

with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Food additive, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

Dated: May 22, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is proposed to be amended as follows:

PART 180—[AMENDED]

In part 180:

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

Authority: 21 U.S.C. 346a and 348.

b. Section 180.501 is added to read as follows:

§ 180.501 Hydroprene; tolerances for residues.

A tolerance of 0.2 part per million is established for residues of hydroprene [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11 trimethyl-2,4-dodecadienoate)], (CAS Reg. NO. 65733–18–8)# on all food items in food-handing establishments in accordance with the following prescribed conditions:

(a) Application shall be limited to spot, crack and crevice, perimeter and ultra low volume (ULV) fogging treatment in food storage or food-handling establishments, including warehouses, food service, manufacturing, and processing establishments such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries where food and food products are held, processed, and served: Provided that the food is removed or covered prior to such use, and food-processing surfaces are covered during treatment or thoroughly cleaned before using, or in the case of point-source device treatments, devices must not come into direct contact with food preparation surfaces and must be in a minimum distance of 3 feet from exposed foods.

(b) To assure safe use of the insect growth regulator, the label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

PART 185—[AMENDED]

In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.3625 [Removed]

b. Section 185.3625 is removed.

[FR Doc. 97–14298 Filed 6–3–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5830–9]

National Oil and Hazardous Substance Pollution Contingency Plan

National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Bayou Sorrel Superfund Site from the National Priorities List and request for comments.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 announces its intent to delete the Bayou Sorrel Superfund Site (Site) from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, constitutes Appendix B of 40 CFR Part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State of Louisiana, through the Louisiana Department of Environmental Quality (LDEQ), have determined that the Site poses no significant threat to public health, welfare, or the environment and, therefore, further remedial measures pursuant to CERCLA are not appropriate.

DATES: The EPA will accept comments concerning its proposal to delete this Site from the NPL until July 7, 1997.

ADDRESSES: Comments may be mailed to: Mr. Verne McFarland, Community Relations Coordinator (6SF–P), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6617.

Information Repositories: Comprehensive information on the Site is available through the public docket which is available for viewing at the Bayou Sorrel Superfund Site information repositories at the following locations:

U.S. EPA Region 6 Library (12th Floor), 445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6424 / 665–6427.

Louisiana Department of Environmental Quality, 290 Bluebonnet Road, Baton Rouge, Louisiana 70809, (504) 765–0487.

Police Jury of Iberville Parish, 10 Meriam, Plaquemine, LA 70765, (504) 687–5190.

Iberville Parish Library, 501 J. Gerald Berret Blvd., Plaquemine, LA 70765, (504) 687–2520.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen L. Tzhone, Remedial Project Manager (6SF–LP), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8409.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Intended Site Deletion

Appendices

A. Site Map
B. Deletion Docket Information

I. Introduction

The Environmental Protection Agency (EPA) Region 6 announces its intent to delete the Bayou Sorrel Superfund Site (Site) from the National Priorities List (NPL), Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), Code of Federal Regulations, Title 40 (40 CFR), Part 300, and request comments on the proposed deletion. The EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of those sites. As described in section 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions in the unlikely event that conditions at the site warrant such action.

The EPA will accept comments concerning its intent to delete for thirty (30) days after publication of this document in the **Federal Register** and a newspaper of record.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Bayou Sorrel Superfund Site and how the Site meets the deletion criteria.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that releases may be deleted from, or recategorized on the NPL where no further response is appropriate. In making a determination to delete a release from the NPL, EPA shall consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other parties have implemented all appropriate response actions required;

ii. All appropriate response under CERCLA has been implemented, and no further action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate

Even if a site is deleted from the NPL, where hazardous substances, pollutants, or contaminants remain at the site above levels that allow for unlimited use and unrestricted exposure, EPA's policy is that a subsequent review of the site will be conducted at least every five years after the initiation of the remedial action at the site to ensure that the site remains protective of public health and the environment. If new information becomes available which indicates a need for further action, EPA may initiate remedial actions. Whenever there is a significant release from a site deleted from the NPL, the site may be restored to the NPL without application of the Hazard Ranking System.

III. Deletion Procedures

The following procedures were used for the intended deletion of the Site:

(1) EPA Region 6 has recommended deletion and has prepared the relevant documents;

(2) The State of Louisiana concurred by letter dated January 30, 1997, with the deletion decision;

(3) A notice has been published in the local newspaper and has been distributed to appropriate federal, state, and local officials and other interested parties announcing the commencement of a 30-day public comment period on EPA's Notice of Intent to Delete; and

(4) All relevent documents have been made available for public review in the local Site information repositories.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. The NPL is designed primarily for informational purposes and to assist Agency management. As mentioned in Section II of this document, section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions.

For deletion of this Site, EPA's Regional Office will accept and evaluate public comments on EPA's Notice of Intent to Delete before making a final decision to delete. If necessary, the Agency will prepare a Responsiveness Summary to address any significant public comments received.

A deletion occurs when the Regional Administrator places a final notice in the **Federal Register**. Generally, the NPL will reflect deletions in the final update following the Notice. Public notices and copies of the Responsiveness Summary will be made available to local residents by the Regional office.

IV. Basis for Intended Site Deletion

The following information provides the Agency's rationale for the proposal to delete this Site from the NPL:

A. Site Location

The Site is located in section 40, 41, 42, 43 and in Township 10 South, Range 10 East, in Iberville Parish, Louisiana, approximately 20 miles southwest of Baton Rouge and six miles northwest of the town of Bayou Sorrel. The Site is ''T'' shaped and encompasses 265 acres of land. The west border of the Site is bound by a man-made drainage feature called ''Borrow River'' and approximately 100 yards west of Borrow River is the Atchafalaya Basin Protection Levee. The northern side of the Site is bound by the Upper Grand River and the eastern side is bound by the Pat Bayou. Undeveloped swamp land is adjacent to the Site on the south.

Access to the Site from the north is along the unpaved levee road 14 miles south of its intersection with Interstate 10 at Ramah, Louisiana. The same unpaved levee road provides access to the south of the Site from its origin six miles north of the town of Bayou Sorrel. The Upper Grand River also provides barge access to the Site.

B. Site History

Bayou Sorrel Superfund Site is a remediated and inactive site currently under an Operations and Maintenance (O&M) Plan agreed upon by the EPA and the potentially responsible parties. One million cubic feet of contaminated soil and sediments are entombed beneath two multi-layered, protective caps with 30 feet deep concrete barriers to halt any residual migration of pollution into groundwater and adjacent wetlands. The O&M Plan calls for 30 years of Site maintenance and monitoring to ensure the effectiveness of the cleanup activities.

The Site is known locally as the ''Grand River Pits,'' and was a petrochemical waste dump/landfill operated by the Environmental Purification Advancement Corporation (EPAC) from 1977 to 1978. Wastes were received by EPAC and dumped on approximately 50 acres of the total Site acreage. Disposed wastes included process wastes from pesticide and herbicide manufacturing, sulfide containing wastes from petrochemical manufacturing and petroleum exploration and production, and spent wash solutions from boiler cleaning. Incompatible chemicals were mixed haphazardly in four landfills, one drum burial area, four open ponds, and one landfarm.

In 1978, a truck driver died at the site when liquid waste dumped from his truck reacted with the disposed wastes to create lethal hydrogen sulfide gas. The 18th Judicial District Court ordered the Site closed and EPAC conducted closure activities from 1978 to 1979. Wastes were de-watered and transferred from three ponds to a fourth pond where solids were concentrated by evaporation and landfarming. The wastes were then combined with native soils and the ponds filled in and contoured.

After site closure, complaints about odors and surface water contamination in the swamps south of the Site were received by the State. To protest the continuing pollution from flooding and to stop trucks from dumping more waste into the ''Grand River Pits,'' area residents burned a bridge leading to the Site.

Based on the information obtained from the State, the Site was proposed to EPA's NPL on December 20, 1982, and finalized on September 8, 1983. This listing action provided the mechanism for EPA to use federal monies for cleanup actions at the Site. Consequently, the EPA conducted a Remedial Investigation to determine the nature and extent of wastes at the Site and a Feasibility Study to evaluate various cleanup alternatives. Following a public comment period, EPA signed the Record of Decision (ROD) for the Site in 1986. The cleanup remedy selected in the ROD was completed in 1990 and included the following remedial activities:

- Regrading the site to limit runoff of contaminants, control erosion, and divert storm water from the waste ponds;
- Covering two former disposal areas with topsoil/geomembrane/clay caps and installing a venting system to reduce the buildup of methane gas beneath the cap and a pore water

drainage system above the wastes and below the caps;

- Installing underground concrete barriers or ''slurry walls'' around the waste ponds to stop contaminant migration into ground water;
- Enclosing capped areas with security fences and building access roads to allow continued use of adjacent recreational land; and
- Installing a ground water monitoring system to monitor the effectiveness of the remedy.

C. Characterization of Risk

Continued monitoring of groundwater demonstrate that no significant risk to public health or the environment is posed by the hazardous materials remaining at the Site. Based on the successful remedial actions addressing the hazardous materials onsite, the monitoring results of O&M activities to date, and the public health consultation by the Agency for Toxic Substances and Disease Registry (ATSDR), EPA verifies the implemented Site remedy is protective of human health and the environment.

D. Community Involvement

Public participation activities have been satisfied as required in CERCLA section 113(k), 42 U.S.C. 9613(k), and section 117, 42 U.S.C. 9617. Documents in the deletion docket which EPA relied on for recommendation of the Site deletion from the NPL have been available to the public in the four information repositories.

E. Proposed Action

EPA, with concurrence of the State of Louisiana, has determined that all appropriate responses under CERCLA at the Bayou Sorrel Superfund Site have been completed, and that no further response actions, other than O&M and Five-Year reviews, are necessary. Therefore, EPA is proposing deletion of this Site from the NPL.

Dated: May 21, 1997.

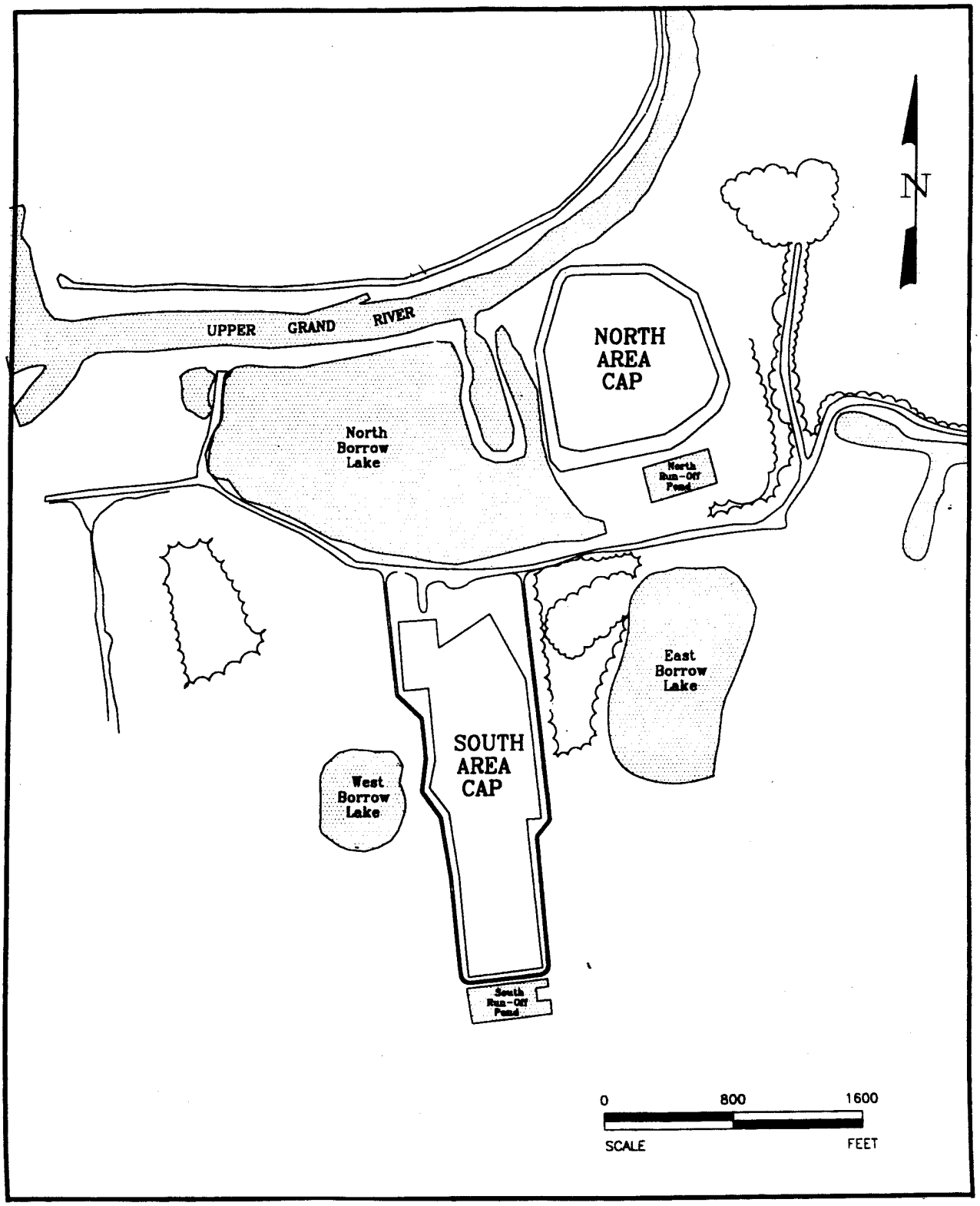
Myron O. Knudson,

Acting Regional Administrator, U.S. EPA Region 6.

BILLING CODE 6560–50–P

APPENDIX A

SITE MAP



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Appendix B—Bayou Sorrel Deletion Docket

- Remedial Investigation Report, Vol. I and II, CH2M Hill, November 27, 1985.
- Feasibility Study Report, CH2M Hill and SRW Associates, January 31, 1986.
- Endangerment Assessment, Life Systems, Inc., February 21, 1986.
- EPA Record of Decision, USEPA Region 6, November 14, 1986.
- Remedial Concept Design, ERM-Southwest, Inc., March 18, 1987
- Ground Water Statistics Plan, ERM-Southwest, Inc., April 28, 1987.
- Operation and Maintenance Plan, ERM-Southwest, Inc., December 14, 1988.
- Health Assessment, ATSDR, April 6, 1989.
- Quality Assurance Project Plan, ERM-Southwest, Inc., April 24, 1989.
- Sampling and Analysis Plan, ERM-Southwest, Inc., October 26, 1990.
- Remedial Action Report, ERM-Southwest, Inc., October 30, 1990.
- EPA Final Closeout Report, USEPA Region 6, May 26, 1992.
- EPA Five-Year Review, USEPA Region 6, September 30, 1993.
- Health Consultation, ATSDR, May 8, 1995.
- Regional Arsenic Groundwater Information, ERM-Southwest, Inc., December 6, 1995.
- Ground Water Statistics Report Post-Construction Year 6, Vol. I and II, ERM-Southwest, Inc., December 30, 1996.
- EPA Risk Assessment Concurrence on Deletion, USEPA Region 6, January 15, 1997.
- Louisiana State Concurrence on Deletion, LDEQ, January 30, 1997.
- Notice of Intent to Delete, USEPA Region 6, February 21, 1997.

[FR Doc. 97–14579 Filed 6–3–97; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF ENERGY

48 CFR Parts 932 and 970

RIN 1991–AB29

Acquisition Regulation: Contract Financing; Management and Operating Contracts

AGENCY: Department of Energy.

ACTION: Proposed rule.

SUMMARY: The Department of Energy (DOE) proposes to amend its Acquisition Regulation to incorporate coverage required by the Federal Acquisition Streamlining Act of 1994. These amendments will clarify the allowability of costs reimbursed under Department of Energy contracts and establishes the responsibilities of the remedy coordination official within the Department.

DATES: Written comments must be submitted no later than August 4, 1997.

ADDRESSES: Comments should be addressed to: Terrence D. Sheppard, Office of Policy (HR–51), Office of Procurement and Assistance Management, Department of Energy, 1000 Independence Avenue S.W., Washington, D.C. 20585.

FOR FURTHER INFORMATION CONTACT: Terrence D. Sheppard (202) 586–8193.

SUPPLEMENTARY INFORMATION:

I. Background
II. Section by Section Analysis
III. Public Comments
IV. Procedural Requirements
A. Review Under Executive Order 12866
B. Review Under Executive Order 12988
C. Review Under the Regulatory Flexibility Act
D. Review Under the Paperwork Reduction Act
E. Review Under the National Environmental Policy Act
F. Review Under Executive Order 12612

I. Background

This notice proposes to amend the Department of Energy Acquisition Regulation based on provisions in Sections 2051, 2151, and 2192 of the Federal Acquisition Streamlining Act of 1994 (the Act). These amendments establish: certification of cost submissions and assessment of penalties on unallowable costs; a remedy coordination official for payment requests suspected to be based on substantial evidence of fraud; parameters for resolution of questioned costs; guidance for application of cost principles; general prohibitions on severance payments to foreign nationals and compensation costs associated with a change in management control or ownership; clarification of employee morale, recreation, entertainment, executive branch lobbying, company furnished automobiles, and insurance costs which protect the contractor against defects in material or workmanship.

This rulemaking is intended to make only these specific changes. Additional rulemakings will address other aspects of the Act. On June 24, 1996, the Department of Energy published in the **Federal Register** (61 FR 32588) a notice of proposed rulemaking which also proposed changes to sections 970.3101–3, 970.5204–13, and 970.5204–14. Nothing in this proposed rulemaking conflicts with the proposed rulemaking of June 24, 1996.

II. Section by Section Analysis

1. The authority for Part 932 is restated.

2. Section 932.006–4, Procedures, is added which identifies the procedures the remedy coordination official within DOE shall follow.

3. The authority for Part 970 is restated.

4. Section 970.25 is added which provides the criteria under which the Head of the Contracting Activity (HCA) may waive the severance payment prohibitions at 970.3102–2(i)(2)(iv) and (v) and further directs the contracting officer to include a new solicitation provision 970.5204-XX addressing waiver of the restrictions which apply to foreign nationals' severance payments.

5. Section 970.3101–3 is amended by adding new paragraphs (b), (c), and (d). These new paragraphs establish requirements for the contracting officer to address the resolution of questioned costs; the documentation of questioned costs; and the attendance of the Department's auditor at negotiations, respectively.

6. Section 970.3101–7 is added to state the requirements for contractor certification of submissions for settlement of costs, penalties associated therewith, waiver provisions, and the prescribed contract clause.

7. Section 970.3102 is amended by designating the existing paragraph as (a) and adding a new paragraph (b) which provides guidance on applicability of the various cost principles.

8. Section 970.3102–2 is amended in paragraphs (i)(2) by adding a sentence at the end of the existing text to refer to new paragraphs (2)(iv) and (v); new paragraphs (2)(iv) and (v) are added which address severance payment for foreign nationals; new paragraph (vi) is added which refers the reader to 970.25 for the waiver criteria; and new paragraph (p) is added which makes unallowable those compensation costs associated with a change in management control or ownership.

9. Section 970.3102–5, Employee morale, health, welfare, food service, and dormitory costs, is amended in paragraph (a) to add wellness/fitness centers and delete the word ''recreation''; a new paragraph (b) is added which addresses the allowability of recreation costs; existing paragraphs (b), (c), (d), and (e) are relabeled as (c), (d), (e), and (f), respectively; and cross references are revised.

10. 970.3102–7, Legislative lobbying costs, is retitled as Political activity costs. The existing paragraph is rewritten and a paragraph has been added to also make unallowable the costs associated with executive branch lobbying.

11. 970.3102–17(b) is retitled as ''Government-owned, commercial rental, and company-furnished vehicles'' and a new paragraph (3) is added which reflects the addition of

coverage addressing the allowability of company-furnished automobiles.

12. 970.3103 is amended in paragraph (b) to reflect the new title of 970.3102–7.

13. Section 970.3272, Reduction or suspension of advance, partial, or progress payments, is added which prescribes the DOE policies and procedures to be followed upon finding substantial evidence of fraud.

14. Section 970.5204–13 is amended as follows: paragraph (d)(8)(iv) is revised by adding ''wellness/fitness centers'' at the end of the sentence; paragraph (e)(11) is revised by removing the coverage on recreation costs which is moved to a new paragraph (38); paragraph (e)(31) is revised to reflect the addition of executive branch lobbying costs as unallowable; new paragraph (e)(37) is added which adds gifts to the list of unallowables and states that employee achievement and recognition costs are not gifts; and paragraph (e)(38) is added to address the allowability of recreation costs.

15. Section 970.5204–14 is amended as follows: paragraph (d)(8)(iv) is revised by adding ''wellness/fitness centers'' at the end of the sentence; paragraph (e)(9) is revised by removing the coverage on recreation costs which is moved to a new paragraph (e)(36); paragraph (e)(29) is revised to make executive branch lobbying costs unallowable; new paragraph (e)(35) adds gifts to the list of unallowables and states that employee achievement and recognition costs are not gifts; and new paragraph (e)(36) is added to address the allowability of recreation costs.

16. Section 970.5204–16 is amended to state the requirement for contractor certification of submissions for settlement of costs; NOTES 3 and 4 are deleted; and the existing paragraph (e) is redesignated as (e)(i) for integrated management and operating contractors and a new (e)(ii) is created for nonintegrated contractors.

17. Section 970.5204–17 is amended by retitling as Political activity costs. A new paragraph (6) is added which makes unallowable the costs associated with attempts to influence executive branch actions.

18. A new solicitation provision and contract clause are added at 970.5204–XX. The solicitation provision states that the HCA has waived the restrictions on foreign nationals' severance payments. The alternate 1, contract clause, states that the HCA will consider waiving the restrictions on foreign nationals' severance payments.

19. A new clause 970.5204–YY, Reduction or suspension of advance, partial, or progress payments, is added which prescribes the DOE policies and procedures to be followed upon finding substantial evidence of fraud.

III. Public Comments

Interested persons are invited to participate by submitting data, views, or arguments with respect to the proposed Department of Energy Acquisition Regulation amendments set forth in this notice. Three copies of written comments should be submitted to the address indicated in the **ADDRESSES** section of this notice. All comments received will be available for public inspection in the DOE Reading Room, Room lE–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. All written comments received by the date indicated in the **DATES** section of this notice and all other relevant information in the record will be carefully assessed and fully considered prior to publication of the final rule. Any information considered to be confidential must be so identified and submitted in writing, one copy only. DOE reserves the right to determine the confidential status of the information and to treat it according to our determination (See 10 CFR 1004. 11).

The Department has concluded that this proposed rule does not involve a substantial issue of fact or law and that the proposed rule should not have substantial impact on the nation's economy or a large number of individuals or businesses. Therefore, pursuant to Public Law 95–91, the DOE Organization Act, and the Administrative Procedure Act (5 U.S.C. 553), the Department does not plan to hold a public hearing on this proposed rule.

IV. Procedural Requirements

A. Review Under Executive Order 12866

Today's regulatory action has been determined not to be a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' (58 FR 51735, October 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity: (2) write regulations to minimize litigation: and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction: (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftmenship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The Department of Energy has completed the required review and determined that, to the extent permitted by law, the regulations meet the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

This proposed rule was reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) which requires preparation of a regulatory flexibility analysis for any rule which is likely to have significant economic impact on a substantial number of small entities. DOE certifies that this rule will not have a significant economic impact on a substantial number of small entities, and, therefore, no regulatory flexibility analysis has been prepared.

D. Review Under the Paperwork Reduction Act

No new information or recordkeeping requirements are imposed by this rulemaking. Accordingly, no OMB clearance is required under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

E. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this rule falls into a class of actions which would not individually or cumulatively have significant impact on the human environment, as determined by DOE's regulations (10 CFR part 1021,

subpart D) implementing the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*). Specifically, this rule is categorically excluded from NEPA review because the proposed amendments to the DEAR do not change the environmental effect of the rule being amended (categorical exclusion A5). Therefore, this rule does not require an environmental impact statement or environmental assessment pursuant to NEPA.

F. Review Under Executive Order 12612

Executive Order 12612 (52 FR 41685, October 30, 1987) requires that regulations, rules, legislation, and any other policy actions be reviewed for any substantial direct effects on States, on the relationship between the National Government and the States, or in the distribution of power and responsibilities among the various levels of Government. If there are sufficient substantial direct effects, then the Executive Order requires the preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action. This proposed rule, when finalized, will revise certain policy and procedural requirements. States which contract with DOE will be subject to this rule. However, DOE has determined that this rule will not have a substantial direct effect on the institutional interests or traditional functions of the States.

List of Subjects in 48 CFR Parts 932 and 970

Government procurement.

Issued in Washington, D.C. on May 27, 1997.

Richard H. Hopf,

Deputy Assistant Secretary for Procurement and Assistance Management.

For the reasons set out in the preamble, Chapter 9 of Title 48 of the Code of Federal Regulations is proposed to be amended as set forth below.

1. The authority citation for Part 932 continues to read as follows:

Authority: 42 U.S.C. 7254; 40 U.S.C. 486(c).

PART 932—CONTRACT FINANCING

2. Section 932.006–4 is added before Subpart 932.1 to read as follows:

932.006–4 Procedures.

(a) The remedy coordination official shall follow the procedures identified in FAR 32.006–4.

(b) [Reserved]

3. The authority citation for Part 970 continues to read as follows:

Authority: Sec. 161 of the Atomic Energy Act of 1954 (42 U.S.C. 2201), sec 644 of the Department of Energy Organization Act, Public Law 95–91 (42 U.S.C. 7254).

PART 970—DOE MANAGEMENT AND OPERATING CONTRACTS

4. Subpart 970.25 is added to read as follows:

970.25 Foreign acquisition.

Subpart 970.2501—Severance payments for foreign nationals.

970.2501 Severance payments for foreign nationals.

(a) The Head of the Contracting Activity may waive the application of the provisions of 48 CFR 970.3102–2(i)(2) (iv) and (v) in accordance with 41 U.S.C. 256(e)(2) if:

(1) The application of the provisions would adversely affect the continuation of a program, project, or activity that provides significant support services for Department of Energy employees posted outside the United States;

(2) The contractor has taken, or plans to take, appropriate actions within its control to minimize the amount and number of incidents of payment of severance pay to employees under the contract who are foreign nationals; and

(3) The payment of severance pay under the contract is necessary to comply with a law that is generally applicable to a significant number of businesses in the country in which the foreign national receiving the payment performed services or is necessary to comply with a collective bargaining agreement.

(b) *Solicitation provision and contract clause.* The solicitation provision at 970.5204–XX, Waiver of Limitations on Severance Payments to Foreign Nationals, shall be included in solicitations and resulting contracts involving support services for Department of Energy operations outside of the United States expected to exceed $500,000, when, prior to the solicitation, the limitations on severance to foreign nationals has been waived. Use the Alternate 1 contract clause in solicitations and resulting contracts, when the Head of the Contracting Activity may waive the limitations on severance to foreign nationals after contract award.

5. Section 970.3101–3 is amended by adding paragraphs (b), (c), and (d) to read as follows:

970.3101–3 General basis for reimbursement of costs.

* * * * *

(b) A contracting officer shall not resolve any questioned costs until the contracting officer has obtained:

(1) Adequate documentation with respect to such costs; and

(2) The opinion of the Department of Energy's auditor on the allowability of such costs.

(c) The contracting officer shall ensure that the documentation supporting the final settlement addresses the amount of the questioned costs and the subsequent disposition of such questioned costs.

(d) The contracting officer shall ensure, to the maximum extent practicable, that the Department of Energy's auditor is afforded an opportunity to attend any negotiation or meeting with the contractor regarding a determination of allowability.

6. Section 970.3101–7 is added to read as follows:

970.3101–7 Cost submission, certification, penalties, and waivers.

(a) The contracting officer shall require that management and operating contractors provide a submission for settlement of costs incurred during the period stipulated on the submission and a certification that the costs included in the submission are allowable. The contracting officer shall assess a penalty if unallowable costs are included in the submission. Unallowable costs are either expressly unallowable or determined unallowable.

(1) An expressly unallowable cost is a particular item or type of cost which, under the express provisions of an applicable law, regulation, or contract, is specifically named and stated to be unallowable.

(2) A cost determined unallowable is one which, for that contractor

(i) Was subject to a contracting officer's final decision and not appealed;

(ii) The Department's Board of Contract Appeals or a court has previously ruled as unallowable; or

(iii) Was mutually agreed to be unallowable.

(b) If, during the review of the submission, the contracting officer determines that the submission contains an expressly unallowable cost or a cost determined to be unallowable prior to the submission, the contracting officer shall assess a penalty.

(c) If the contracting officer determines that a cost submitted by the contractor in its submission for settlement is

(1) Expressly unallowable, then the contracting officer shall assess a penalty in an amount equal to the disallowed cost allocated to the contract plus

interest on the paid portion of the disallowed cost. Interest shall be computed from the date of overpayment to the date of repayment using the interest rate specified by the Secretary of the Treasury pursuant to Pub. L. 92–41 (85 Stat. 97).

(2) Determined unallowable, then the contracting officer shall assess a penalty in an amount equal to two times the amount of the disallowed cost allocated to this contract.

(d) The contracting officer may waive the penalty provisions when

(1) The contractor withdraws the submission before the formal initiation of an audit of the submission and submits a revised submission;

(2) The amount of the unallowable costs allocated to covered contracts is $10,000 or less; or

(3) The contractor demonstrates to the contracting officer's satisfaction that:

(i) It has established appropriate policies, personnel training, and an internal control and review system that provides assurances that unallowable costs subject to penalties are precluded from the contractor's submission for settlement of costs; and

(ii) The unallowable costs subject to the penalty were inadvertently incorporated into the submission.

(e) The Head of the Contracting Activity may waive the certification when—

(1) It is determined that it would be in the best interest to waive such certification; and

(2) It states in writing the reasons for that determination and makes such determination available to the public.

7. Section 970.3102 is amended by removing the last sentence of the existing paragraph, designating the existing paragraph as (a) and adding a new paragraph (b) to read as follows.

970.3102 Application of cost principles.

* * * * *

(b) This section does not cover every element of cost. Failure to include any item of cost does not imply that it is either allowable or unallowable. The determination of allowability shall be based on the principles and standards in this subpart and the treatment of similar or related selected items. When more than one paragraph in this section is relevant to a contractor cost, the cost shall be apportioned among the applicable subsections, and the determination of allowability of each portion shall be based on the guidance contained in the applicable subsection. As an example, the cost of meals while in a travel status would normally be allowable if reasonable. However, the cost of alcoholic beverages associated with a meal would be unallowable. In no case shall costs made specifically unallowable under one cost principle be made allowable under another cost principle.

8. Section 970.3102–2 is amended by adding a sentence at the end of paragraph (i)(2) introductory text and adding new paragraphs (i)(2) (iv), (v), (vi), and (p) to read as follows:

970.3102–2 Compensation for personal services.

* * * * *

(i) * * *

(2) * * * In addition, paragraphs (i)(2)(iv) and (v) of this section apply if the severance cost is for foreign nationals employed outside the United States.

* * * * *

(iv) Notwithstanding the provision of paragraph (c) of this section, which references geographic area, under 41 U.S.C. 256(e)(1)(M), the costs of severance payments to foreign nationals employed under a service contract performed outside the United States are unallowable to the extent that such payments exceed amounts typically paid to employees providing similar services in the same industry in the United States.

(v) Further, under 41 U.S.C. 256(e)(1)(N), the costs of severance payments referred to in paragraph (i)(2)(iv) of this section are unallowable if the termination of employment is the result of the closing of, or curtailment of, activities at a United States facility in that country at the request of the government of that country.

(vi) The Head of the Contracting Activity may waive the application of the provisions of (i)(2)(iv) and (v) of this section under the conditions specified in 48 CFR 970.25.

* * * * *

(p) *Special compensation.* The following costs are unallowable:

(1) Special compensation to employees pursuant to agreements which permit payments in excess of the contractor's normal severance pay practices, if their employment terminates following a change in the management control over, or ownership of, the contractor or a substantial portion of its assets.

(2) Special compensation to employees pursuant to agreements which permit payments resulting from a change, whether actual or prospective, in the management control over, or ownership of, the contractor or a portion of its assets which is contingent upon the employee remaining with the contractor for a stated period of time.

9. Section 970.3102–5 is revised to read as follows:

970.3102–5 Employee morale, health, welfare, food service, and dormitory costs.

(a) Employee morale, health, and welfare activities are those services or benefits provided by the contractor to its employees to improve working conditions, employer-employee relations, employee morale, and employee performance. These activities include such items as house or employee publications, health or first-aid clinics, wellness/fitness centers, employee counseling services, awards for performance or awards made in recognition of employee achievements pursuant to an established contractor plan or policy, and, for the purpose of this section, food service and dormitory costs. However, these activities do not include, and should be differentiated from compensation for personal services as defined in 970.3102–2. Food and dormitory services include operating or furnishing facilities for cafeterias, dining rooms, canteens, lunch wagons, vending machines, living accommodations, or similar types of services for the contractor's employees at or near the contractor's facilities or site of the contract work.

(b) Costs of recreation, registration fees of employees participating in competitive fitness promotions, team activities, and sporting events are unallowable, except for the costs of employees' participation in company sponsored intramural sports teams or employee' organizations designed to improve company loyalty, team work, or physical fitness.

(c) Except as limited by paragraph (d) of this section, the aggregate of costs incurred on account of all activities mentioned in paragraph (a) of this section, less income generated by all such activities, is allowable to the extent that the net aggregate cost of all such activities, as well as the net cost of each individual activity, is reasonable and allocable to the contract work. Additionally, advance understandings with respect to the costs mentioned in paragraph (a) of this section are to be reached prior to the incurrence of these costs as required in 48 CFR 970.3101–6.

(d) Losses from the operation of food or dormitory services may be included as costs incurred under paragraph (c) of this section only if the contractor's objective is to operate such services at least on a break-even basis. Losses sustained because food services or lodging accommodations are furnished without charge or at prices or rates which obviously would not be

conducive to accomplishment of this objective are not allowable, except in those instances where the contractor can demonstrate that unusual circumstances exist, such that, even with efficient management, operation of the services on a break-even basis would require charging inordinately high prices, or prices or rates higher than those charged by commercial establishments offering the same services in the same geographical areas. Typical examples of such unusual circumstances are:

(1) Where the contractor must provide food or dormitory services at remote locations where adequate commercial facilities are not reasonably available, or

(2) Where it is necessary to operate a facility at a lower volume than the facility could economically support. Cost of food and dormitory services shall include an allocable share of indirect expenses pertaining to these activities.

(e) In those situations where the contractor has an arrangement authorizing an employee association to provide or operate a service such as vending machines in the contractor's plant, and retain the profits derived therefrom, such profits shall be treated in the same manner as if the contractor were providing the service, except as provided in paragraph (f) of this section.

(f) Contributions by the contractor to an employee organization, including funds set over from vending machines receipts or similar sources, may be included as cost incurred under paragraph (c) of this section, only to the extent that the contractor demonstrates that an equivalent amount of the costs incurred by the employee organization would be allowable, if incurred by the contractor directly.

10. Section 970.3102–7 is revised to read as follows:

970.3102–7 Political activity costs.

The following costs are unallowable, except for costs associated with providing information pursuant to 970.5204–17, unless approved by the contracting officer: Contractor costs incurred to influence either directly or indirectly—

(a) Legislative action on any matter pending before Congress, a State legislature, or a legislative body of a political subdivision of a State; or

(b) Federal, State, or local executive branch action on regulatory and contract matters, including costs incurred in regard to contract proposals.

11. Section 970.3102–17 Travel costs, is amended by revising the paragraph heading for (b) and by adding paragraph (b)(3) to read as follows:

970.3102–17 Travel costs.

* * * * *

(b) Government-owned, commercial rental, and company-furnished vehicles.* * *

(3) The costs of contractor-owned or -leased vehicles include the costs of lease, operation, maintenance, depreciation, insurance, and other similar costs. These costs are unallowable except as approved by the contracting officer. Except, no cost shall be allowed for the cost of company-furnished vehicles that are authorized for personal use by the employees.

* * * * *

12. Section 970.3103 is amended by revising paragraph (b) to read as follows:

970.3103 Contract clauses.

* * * * *

(b) The political activity cost prohibition clause at 48 CFR 970.5204–17 shall be included in all M&O contracts.

* * * * *

13. Section 970.3272 is added to subpart 970.32 to read as follows:

970.3272 Reduction or suspension of advance, partial, or progress payments.

(a) The procedures prescribed at FAR 32.006 shall be followed.

(b) The agency head has delegated their responsibilities under this section to the Senior Procurement Executive.

(c) The remedy coordination official is responsible for receiving, assessing, and making recommendations to the Senior Procurement Executive.

(d) The contracting officer shall insert the clause at 48 CFR 970.5204–XX, Reduction or suspension of contract payments, in management and operating contracts.

14. Section 970.5204–13, Allowable costs and fixed-fee (Management and Operating contracts), is amended by revising clause paragraphs (d)(8)(iv), (e)(11), (e)(31); and adding new paragraphs (e) (37) and (38) to read as follows:

970.5204–13 Allowable costs and fixed-fee (management and operating contracts).

* * * * *

(d) * * *

(8) * * *

(iv) Employee relations, welfare, morale, etc.; programs including incentive or suggestion awards; employee counseling services, health or first-aid clinics; house or employee publications; and wellness/fitness centers;

* * * * *

(e) * * *

(11) Entertainment, including costs of amusement, diversion, social activities; and directly associated costs such as tickets to shows or sports events, meals, lodging, rentals, transportation, and gratuities; costs of membership in any social, dining or country club or organization.

* * * * *

(31) Contractor costs incurred to influence either directly or indirectly—

(i) Legislative action on any matter pending before Congress, a State legislature, or a legislative body of a political subdivision of a State; or

(ii) Federal, State, or local executive branch action on regulatory and contract matters, including costs incurred in regard to contract proposals, as described in the ''Political Activity Cost Prohibition'' clause of this contract.

* * * * *

(37) Costs of gifts; however, gifts do not include awards for performance or awards made in recognition of employee achievements pursuant to an established contractor plan or policy.

(38) The costs of recreation, registration fees of employees participating in competitive fitness promotions, team activities, and sporting events except for the costs of employees' participation in company sponsored intramural sports teams or employee organizations designed to improve company loyalty, team work, or physical fitness.

15. Section 970.5204–14 is amended by revising clause paragraphs (d)(8)(iv), (e)(9), (e)(29); and adding new paragraphs (e)(35) and (e)(36) to read as follows:

970.5204–14 Allowable costs and fixed-fee (support contracts).

* * * * *

(d) * * *

(8) * * *

(iv) Employee relations, welfare, morale, etc.; programs including incentive or suggestion awards; employee counseling services, health or first-aid clinics; and house or employee publications; and wellness/fitness centers;

* * * * *

(e) * * *

(9) Entertainment, including costs of amusement, diversion, social activities; and directly associated costs such as tickets to shows or sports events, meals, lodging, rentals, transportation, and gratuities; costs of membership in any social, dining or country club or organization.

* * * * *

(29) Contractor costs incurred to influence either directly or indirectly—

(i) Legislative action on any matter pending before Congress, a State legislature, or a legislative body of a political subdivision of a State; or

(ii) Federal, State, or local executive branch action on regulatory and contract matters, including costs incurred in regard to contract proposals are not allowable contract costs and shall not be reimbursed by DOE.

* * * * *

(35) Costs of gifts; however, gifts do not include awards for performance or awards made in recognition of employee

achievements pursuant to an established contractor plan or policy.

(36) The costs of recreation, registration fees of employees participating in competitive fitness promotions, team activities, and sporting events except for the costs of employees' participation in company sponsored intramural sports teams or employee organizations designed to improve company loyalty, team work, or physical fitness.

16. Section 970.5204–16 is amended in the clause by removing **Notes 3** and **4** and revising paragraph (e) to read as follows:

970.5204–16 Payments and advances.

* * * * *

(e)(i) *Review and approval of costs incurred.* The contractor shall prepare and submit annually as of September 30, a voucher for the total of net expenditures accrued (i.e., net costs incurred) for the period covered by the voucher. The contractor shall certify the voucher subject to the penalty provisions for unallowable costs as stated in sections 306(b) and (h) of the Federal Property and Administrative Services of 1949 (41 U.S.C. 256), as amended. DOE, after audit and appropriate adjustment, will approve such voucher. This approval by DOE will constitute an acknowledgment by DOE that the net costs incurred are allowable under the contract and that they have been recorded in the accounts maintained by the contractor in accordance with DOE accounting policies, but will not relieve the contractor of responsibility for DOE's assets in its care, for appropriate subsequent adjustments, or for errors later becoming known to DOE.

(ii) Nonintegrated contractors shall prepare and submit a voucher for the total of net expenditures incurred for the period covered by the voucher. It is anticipated that this will be an annual submission unless otherwise agreed to by the contracting officer. The contractor shall certify the voucher subject to the penalty provisions for unallowable costs as stated in sections 306 (b) and (h) of the Federal Property and Administrative Services of 1949 (41 U.S.C. 256), as amended.

* * * * *

17. Section 970.5204–17 is amended by revising the section heading and clause heading and adding clause paragraph (a)(6) to read as follows:

970.5204–17 Political activity cost prohibition.

* * * * *

Political Activity Cost Prohibition (XXX 199X)

(a)* * *

(6) Contractor costs incurred to influence (directly or indirectly) Federal, State, or local executive branch action on regulatory and contract matters, including costs incurred in regard to contract proposals.

* * * * *

18. Section 970.5204–XX is added to read as follows:

970.5204–XX Waiver of limitations on severance payments to foreign nationals.

As prescribed in 48 CFR 970.25, insert the following solicitation provision, or its alternate 1, clause:

Waiver of Limitations on Severance Payments to Foreign Nationals (XXXX 199X)

Pursuant to Department of Energy Acquisition Regulation (DEAR) 48 CFR 970.25, the cost allowability limitations in (DEAR) 48 CFR 970.3102–2(i), (iv) and (v) are waived for this contract.

Alternate 1 (XXXX 199X). Substitute the following paragraph for the foregoing solicitation provision when the waiver of limitations to severance payments for foreign nationals has not been predetermined by the Department.

Pursuant to Department of Energy Acquisition Regulation (DEAR) 48 CFR 970.25, the Department will consider waiving the cost allowability limitations in (DEAR) 48 CFR 970.3102–2(i), (iv) and (v) for this contract.

19. Section 970.5204–YY is added to read as follows:

970.5204–YY Reduction or suspension of advance, partial, or progress payments upon finding of substantial evidence of fraud.

As prescribed in 48 CFR 970.3272, insert the following clause:

Reduction or Suspension of Advance, Partial, or Progress Payments (XXXX–199X)

(a) The contracting officer may reduce or suspend further advance, partial, or progress payments to the contractor upon a written determination by the Secretary that substantial evidence exists that the contractor's request for advance, partial, or progress payment is based on fraud.

(b) The contractor shall be afforded a reasonable opportunity to respond in writing.

[End of Clause]

[FR Doc. 97–14289 Filed 6–3–97; 8:45 am]

BILLING CODE 6450–01–P

Notices

Federal Register
Vol. 62, No. 107
Wednesday, June 4, 1997

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. DA–97–08]

Milk in the New England and Other Marketing Areas; Determination of Equivalent Cheese Price Series

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Determination of equivalent price series.

SUMMARY: It has been determined by the Secretary that the National Agricultural Statistics Service (NASS) U.S. average 40-pound block Cheddar cheese price is an equivalent cheese price alternative for use in computing the Basic Formula Price (BFP) which is used to establish milk prices in all Federal milk marketing orders. The Department has been using the simple average for the month of the National Cheese Exchange (NCE) 40-pound block Cheddar cheese price when computing the BFP. As a result of the closing of the NCE, a new cheese price series is needed to announce the BFP for May and future months. The NASS price will also be used to derive a protein price and/or milk quality adjustment in Federal milk orders that contain multiple component pricing plans.

EFFECTIVE DATE: June 5, 1997.

FOR FURTHER INFORMATION CONTACT: John F. Borovies, Chief, Order Formulation Branch, USDA/AMS/Dairy Division, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 720-7183, e-mail address john—f—borovies@usda.gov.

SUPPLEMENTARY INFORMATION: This action provides an equivalent cheese price series for calculation of the BFP which is used to derive milk prices in all Federal milk marketing orders (7 CFR Parts 1001, 1002, 1004, 1005, 1006, 1007, 1011, 1012, 1013, 1030, 1032, 1033, 1036, 1040, 1044, 1046, 1049, 1050, 1064, 1065, 1068, 1076, 1079, 1106, 1124, 1126, 1131, 1134, 1135, 1137, 1138, and 1139). The Department has been using the simple average for the month of the NCE 40-pound block Cheddar cheese price data to compute the BFP. However, a new cheese price series is needed by June 5, 1997, to announce the BFP for May and subsequent months, and derive a protein price and/or milk quality adjustment in 10 Federal orders which contain multiple component pricing plans (7 CFR Parts 1030, 1033, 1036, 1040, 1049, 1065, 1068, 1076, 1079, and 1124). Order provisions provide the Secretary authority to adopt an equivalent replacement if a price series needed to calculate the BFP is not available.

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable provisions of the orders, as amended, regulating the handling of milk in the aforesaid marketing areas, it is hereby found and determined that:

(1) Each Federal milk marketing order provides a BFP that is determined by the Department of Agriculture each month. The pricing formula is based on the prices paid to dairy farmers during the preceding month by unregulated manufacturing plants in Minnesota and Wisconsin, adjusted for changes in dairy product prices between the previous and current month. The NCE served as the source of prices for 40-pound block Cheddar cheese used to construct the BFP in all Federal milk orders.

(2) The price data was also used to calculate a protein price and/or milk quality adjustment in 10 Federal orders which contain multiple component pricing plans.

(3) Each order provides that if for any reason a price or pricing constituent required by the order for computing class prices or for other purposes is not available as prescribed in the order, the market administrator shall use a price or pricing constituent determined by the Secretary to be equivalent to the price or pricing constituent that is required.

(4) The NCE ceased operating after April 25, 1997. The BFP announcement on May 5 was based on April prices reported on the NCE; however, a new cheese price series is needed by June 5 to compute the BFP for May and future months.

(5) The new NASS price series will be announced weekly. It will include all transactions for bulk Cheddar cheese collected from plants located across the United States in which trades were placed during the previous week. Prices will be reported for the 40-pound block, 640-pound block, and 500-pound barrel. The 40-pound block Cheddar cheese price data will be used in the computation of the BFP.

(6) Accordingly, the new NASS U.S. average 40-pound block Cheddar cheese price is determined to be equivalent to the NCE price series for the purposes of computing the BFP used to establish milk prices under all Federal milk orders and deriving a protein price, and/or milk quality adjustment in Federal orders which contain multiple component pricing plans.

The authority citation for 7 CFR Parts 1001 through 1139 continues to read as follows:

Authority: 7 U.S.C. 601–674.

Dated: May 29, 1997.

Shirley R. Watkins,

Deputy Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 97–14477 Filed 6–3–97; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Newspapers Used for Publication of Legal Notice, Comment and Appeal of Decisions for Pacific Northwest Region, Oregon and Washington

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: On November 6, 1996, the Forest Service published a listing of the newspapers that would be used by all Ranger Districts, Forests, and the Regional Office of the Pacific Northwest Region to publish legal notice of all decisions subject to appeal under 36 CFR Parts 215 and 217 and to publish notice for public comment and notice of decisions subject to the provisions of 36 CFR Part 215. That notice was to inform interested members of the public which newspapers would be used to publish the legal notice for public comment and decision. This allows the public to receive constructive notice of decisions, to provide clear evidence of timely notice, and to achieve consistency in

administering the appeal process. There is no change to that listing of newspapers published in the November 6, **Federal Register** (61 FR 57383).

FOR FURTHER INFORMATION CONTACT: James Schuler, Regional Appeals Coordinator, Pacific Northwest Region, P.O. Box 3623, Portland, Oregon 97208–3623, phone: (503) 326–2322.

Dated: May 28, 1997.

Nancy Graybeal,

Deputy Regional Forester.

[FR Doc. 97–14526 Filed 6–3–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

California Spotted Owl Federal Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The California Spotted Owl Federal Advisory Committee will meet on July 7 and 8, 1997 in Sacramento, California. The Committee is comprised of nine members and a committee chair. The purpose of the meeting is for the Committee to hear presentations on the California Spotted Owl preliminary Revised Draft Environmental Impact Statement and the Sierra Nevada Ecosystem Project report. The meeting is open to public attendance, however, participation is limited to scheduled presentors and Committee members. Persons in attendance who wish to bring comments to the attention of the Committee may file written statements with the secretary for the Committee before or after the meeting.

DATES: The meeting will be held July 7 and 8, 1997. The meeting will begin at noon on July 7, and end at 4:00 p.m. on July 8.

ADDRESSES: The meeting will be held at State Office Building Number 9, 744 'P' Street, Sacramento, California.

FOR FURTHER INFORMATION CONTACT: Charles Philpot, Committee Chair, (503) 625–5758; or Jonathan Stephens, Forest Service, (202) 205–0948; or Katherine Clement, (415) 705–1834.

Dated: May 28, 1997.

Katherine Clement,

Assistant Regional Forester, Ecosystem Conservation.

[FR Doc. 97–14529 Filed 6–3–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Availability of Record of Decision for Upcountry Maui Watershed, Maui County, Hawaii

AGENCY: Natural Resources Conservation Service USDA.

ACTION: Notice of availability of record of decision.

SUMMARY: Kenneth M. Kaneshiro, Responsible Federal Official for projects administered under the provisions of Public Law 83–566 in the State of Hawaii, is hereby providing notification that a record of decision to proceed with the installation of the Upcountry Maui Watershed project, signed May 20, 1997, is available.

The record of decision documents the intent to implement Alternative 2—Agricultural Water Distribution System as set forth in the final Watershed Plan-Environmental Impact Statement (FEIS) for the Upcountry Maui Watershed, Maui County, Hawaii. The project will address the problems of inadequate and inconsistent irrigation water supply that prevent area farmers from full utilization of cropland and cause crop damage and losses during drought. The project will install a separate agricultural water system to supply untreated water for irrigation purposes to farmers in the Upper Kula area. The economic benefits derived by project implementation will exceed economic costs. The project meets the needs of the sponsoring local organizations.

The record of decision documents that the Upcountry Maui Watershed project uses all practicable means, consistent with other essential considerations of national policy, to meet the goals established in the National Environmental Policy Act. The FEIS has been prepared, reviewed, and accepted in accordance with the National Environmental Policy Act.

ADDRESSES: Single copies of this record of decision may be obtained from Kenneth M. Kaneshiro, State Conservationist, Natural Resources Conservation Service, 300 Ala Moana Blvd. Room 4316, P.O. Box 50004, Honolulu, Hawaii, 96850.

FOR FURTHER INFORMATION CONTACT: Michael Kolman, Assistant State Conservationist, Natural Resources Conservation Service, 300 Ala Moana Blvd. Room 4316, P.O. Box 50004, Honolulu, Hawaii, 96850, telephone (808) 541–2602.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904, Watershed Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials)

Dated: May 20, 1997.

Kenneth M. Kaneshiro,

State Conservationist.

[FR Doc. 97–14570 Filed 6–3–97; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Dunloup Creek Watershed, West Virginia

AGENCY: Natural Resources Conservation Service.

ACTION: Notice of reauthorization of federal funding.

SUMMARY: Pursuant to the Watershed Protection and Flood Prevention Act, Pub. L. 83–566, and the Soil Conservation Guidelines (7 CFR Part 622); U.S. Department of Agriculture gives notice of reauthorization of Federal funding for the Dunloup Creek Watershed Project, Fayette and Raleigh Counties, West Virginia. NRCS initiates planning assistance under the small watershed program. No comments were received during the 60 day comment period as noted in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Richard W. Sims, Acting State Conservationist, Natural Resources Conservation Service, 75 High Street, Room 301, Morgantown, West Virginia 26505, telephone: 304 291–4153; Fax: 304 291–4628.

Dated: May 29, 1997.

Richard W. Sims,

Acting State Conservationist.

(This activity is listed in the Catalog of Federal Domestic Assistance under NO. 10.904, Watershed Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials)

[FR Doc. 97–14551 Filed 6–3–97; 8:45 am]

BILLING CODE 3410–16–M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Michigan Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a community forum of the Michigan Advisory Committee to the Commission will convene at 9:00

a.m. to 5:00 p.m. on Thursday, June 26, 1997, at the Harley Hotel, 4041 Cascade Road, Grand Rapids, Michigan 49546. The purpose of the forum is to gather information regarding ''Race and Ethnic Intimidation in Grand Rapids.''

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Roland Hwang, 517–373–1476, or Constance Davis, Director of the Midwestern Regional Office, 312–353–8311 (TDD 312–353–8362). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 27, 1997.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 97–14572 Filed 6–3–97; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Minnesota Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Minnesota Advisory Committee to the Commission will convene a community forum at 9:00 a.m. to 5:00 p.m. on Thursday, June 19, 1997, at the Thunderbird Hotel and Convention Center, 2201 E. 78th Street, Bloomington, Minnesota 55425. The purpose of the forum is to ''Focus on Affirmative Action.''

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Alan Weinblatt, 612–292–8770, or Constance Davis, Director of the Midwestern Regional Office, 312–353–8311 (TDD 312–353–8362). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 27, 1997.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 97–14573 Filed 6–3–97; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the North Dakota Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the North Dakota Advisory Committee to the Commission will convene at 1:00 p.m. and adjourn at 4:00 p.m. on Tuesday, June 24, 1997, at the Country Suites, 3316 13th Avenue South, Fargo, North Dakota 58103. The purpose of the meeting is to brief the Committee on Commission and regional activities, discuss current civil rights issues in the State, and finalize plans for a second factfinding meeting in Fargo.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Betty L. Mills, 701–223–4643, or John Dulles, Director of the Rocky Mountain Regional Office, 303–866–1400 (TDD 303–866–1049). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 27, 1997.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 97–14574 Filed 6–3–97; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Day Clarification of Public Meeting of the West Virginia Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the West Virginia Advisory Committee to the Commission will convene on Thursday, June 12, 1997, not Wednesday, June 12, 1997. The original notice for the meeting was announced in the **Federal Register** on May 9, 1997, FR Doc 97–12199, Vol. 62, No. 90.

Persons desiring additional information should contact Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116).

Dated at Washington, DC, May 27, 1997.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 97–14575 Filed 6–3–97; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 890]

Grant of Authority for Subzone Status ZF Industries, Inc.; (Automotive Axles); Tuscaloosa County, Alabama

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, by an Act of Congress approved June 18, 1934, an Act ''To provide for the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' as amended (19 U.S.C. 81a-81u) (the FTZ Act), the Foreign-Trade Zones Board (the Board) is authorized to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved;

Whereas, an application from the City of Birmingham, Alabama, grantee of Foreign-Trade Zone 98, for authority to establish special-purpose subzone status for the automotive axle manufacturing plant of ZF Industries, Inc., in Tuscaloosa County, Alabama, was filed by the Board on April 16, 1996, and notice inviting public comment was given in the **Federal Register** (FTZ Docket 31–96, 61 FR 18375, 4–25–96); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, Therefore, the Board hereby grants authority for subzone status at the ZF Industries, Inc., plant in Tuscaloosa County, Alabama (Subzone 98B), at the location described in the application, subject to the FTZ Act and the Board's regulations, including § 400.28.

Signed at Washington, DC, this 23rd day of May 1997.

Jeffrey Bialos,

Acting Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 97–14480 Filed 6–3–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 42–97]

Foreign-Trade Zone 46—Cincinnati, Ohio, Area; Application for Expansion and Request for Manufacturing Authority, Cincinnati Milacron, Inc. (Horizontal Turning and Grinding Machinery and Related Consumable Products)

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Greater Cincinnati Foreign Trade Zone, Inc., grantee of FTZ 46, requesting authority to expand its zone at the Oakley Industrial Complex, and requesting, on behalf of Cincinnati Milacron, Inc., authority to manufacture horizontal turning and grinding machinery and metalworking consumable products under zone procedures within FTZ 46, Cincinnati, Ohio, area, within the Cincinnati Customs port of entry. 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 May 23, 1997.

FTZ 46 was approved on January 12, 1979 (Board Order 141, 44 FR 4003; 1/19/79) and relocated on December 19, 1994 (Board Order 720, 59 FR 66891; 12/28/94). The zone currently consists of 35 acres at 175 Progress Place in Springdale (Hamilton County), Ohio, some 17 miles north of downtown Cincinnati.

The applicant is now requesting authority to expand the zone by adding a site (122 acres–5 parcels) located at 4701 Marburg Avenue, Cincinnati, Ohio. The new site is owned by Cincinnati Milacron (CM), which will serve as operator of the site.

The application also requests authority on behalf of CM to manufacture horizontal turning and grinding machinery and metalworking consumable products under zone procedures at the Marburg Avenue facilities within the proposed expansion site of FTZ 46. The facilities (99 acres/2,450 employees) are used to produce computer-numerically-controlled horizontal turning and grinding (metal working) machines (horizontal machining centers/lathes, composites processing machines, flexible manufacturing cells, grinding machines; duty rates: 4.2, 4.4%) and consumable products used in metalworking (grinding wheels, soluble oil metal working fluids; duty rate: 1.5%). Components purchased from abroad (up to 29% of finished product value) include: lamps, oscilloscopes, chemical analysis instruments, wire and cables, electrical boards/panels, numerical process controllers, printed circuit assemblies, electrical apparatus, AC/DC motors, transformers, gears, flywheels, clutches, shaft couplings, pulleys, bearings (roller/ball), valves, parts of plastic/rubber forming machines, injection molding machines, parts of machine tools, parts of automatic data processing machines, spray guns, parts of centrifuges, filtering/purifying machines, heat exchange units, fans, pumps, linear acting engines, parts of nuclear reactors, fasteners, chain, wire ropes/cables, tubes/pipes and fittings, hoses, abrasive wheels, transfers, articles of plastic, oil seals, gaskets, conveyor/transmission belts, cements/mortars, and resins (1997 duty rates: free – 9.8%, 9.2¢/kg+2.4%). Foreign items used in the manufacture of metal working consumable products include grinding wheels, abrasives, diamond dressing, refractory ceramic goods, refractometers, cubic boron nitrate, silicon carbide, artificial corundum, glass frit, phenolic resins, epoxy resins, clay, furfuryl alcohol, and fiberglass reinforcements (1997 duty rates: free – 7.1%, .07¢/kg+2.8%). Some 15 percent of the finished machines are exported.

FTZ procedures would exempt CM from Customs duty payments on the foreign components used in export production. On its domestic sales, CM would be able to choose the duty rates that apply to finished turning and grinding machinery and metalworking consumable products for the foreign components noted above. CM would also defer duty payments on foreign-origin finished vertical turning and grinding machinery admitted to the proposed subzone. FTZ procedures would also exempt certain merchandise from state/local ad valorem inventory taxes. The application indicates that the savings from FTZ procedures would help improve CM's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is August 4, 1997. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to August 18, 1997).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce, Export Assistance Center, 36 East 7th St., Suite 2650, Cincinnati, OH 45202.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th Street & Pennsylvania Avenue, N.W., Washington, DC 20230.

Dated: May 23, 1997.

Dennis Puccinelli,

Acting Executive Secretary.

[FR Doc. 97–14479 Filed 6–3–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–815]

Certain Welded Stainless Steel Pipe From Taiwan, Initiation of Changed Circumstances Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of initiation of changed circumstances Antidumping Duty Administrative Review.

SUMMARY: In response to a request from Chang Mien Industries Co., Ltd. (Chang Mien), the Department of Commerce (the Department) is initiating a changed circumstances antidumping duty administrative review of the antidumping duty order on certain welded stainless steel pipe from Taiwan. See Notice of Amended Final Determination and Antidumping Duty Order; Certain Welded Stainless Steel Pipes From Taiwan, 59 FR 6619 (February 11, 1994); see also Amended Final Determination and Antidumping Duty Order; Certain Welded Stainless Steel Pipe From Taiwan, 57 FR 62300 (December 30, 1992). Chang Mien requested that the Department

determine that Chang Mien is the successor firm to Chang Tieh Industry Co., Ltd. (Chang Tieh), a respondent in the original less-than-fair-value (LTFV) investigation. The Department excluded Chang Tieh from the antidumping duty order on certain welded stainless steel pipe from Taiwan after calculating a margin of zero for Chang Tieh. See Notice of Amended Final Determination, 59 FR 6619. Chang Mien maintains that, as Chang Mien and Chang Tieh were related at the time of the LTFV investigation, Chang Mien was entitled to Chang Tieh's exclusion from the order *ab initio.* Chang Mien further states that, since publication of the order, Chang Mien has absorbed Chang Tieh, and asks that the Department issue a determination that Chang Mien is the successor firm to Chang Tieh and is, therefore, entitled to Chang Tieh's exclusion from the antidumping duty order. Chang Mien's request is filed pursuant to section 751(b) of the Tariff Act of 1930, as amended (the Tariff Act).

We are initiating an antidumping duty changed circumstances administrative review of the antidumping duty order on certain welded stainless steel pipe from Taiwan to determine whether or not Chang Mien is the successor firm to respondent Chang Tieh, and to determine whether Chang Mien is entitled to Chang Tieh's exclusion from the order.

EFFECTIVE DATE: June 4, 1997.

FOR FURTHER INFORMATION CONTACT: Robert M. James at (202) 482–5222, or John Kugelman at (202) 482–0649, AD/CVD Enforcement Office Eight, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230.

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department's regulations are to the current regulations, as amended by the interim regulations published in the **Federal Register** on May 11, 1995 (60 FR 25130).

SUPPLEMENTARY INFORMATION:

Background

On September 11, 1996, Chang Mien requested that the Department conduct a changed circumstances administrative review pursuant to section 751(b) of the Tariff Act to determine whether Chang Mien should properly be considered the successor firm to Chang Tieh and if, as such, Chang Mien should be excluded from the antidumping duty order. Chang Mien, on September 19, 1996, requested that the Department publish its preliminary results concurrently with this notice of initiation, pursuant to 19 CFR 353.22(f)(4). Citing the Department's September 17, 1996 notice of initiation and preliminary results of changed circumstances review in sugar and syrups from Canada, Chang Mien argues that the instant case is, like the sugar case, ''legally and factually straightforward'' and requested that the Department find that ''Chang Mien has provided *prima facie* evidence . . . that Chang Mien and its affiliated companies should be excluded from the instant [antidumping duty] order.'' Chang Mien's Letter to the Secretary, September 19, 1996 at 2; see also, Sugar and Syrups From Canada; Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review, 61 FR 48885 (September 17, 1996).

In a letter submitted on September 25, 1996, petitioners [1] objected to Chang Mien's request for an expedited review pursuant to section 751(b) of the Tariff Act. Petitioners assert that the factual and legal bases in the instant case are substantially different than in Sugars and Syrups from Canada, and that this case will require ''caution and close review'' prior to issuing any determination. See Petitioners' Letter of September 25, 1996 at 5.

The Department has examined Chang Mien's request for a changed circumstances administrative review and has determined that the facts before the Department in the instant case will require further investigation. The Department further concludes that it would be inappropriate to issue a preliminary determination prior to conducting this investigation. Therefore, the Department is not issuing preliminary results of its changed circumstances administrative review at this time. See Memorandum from Joseph A. Spetrini to Robert S. LaRussa, January 10, 1997, on file in Room B–099 of the Main Commerce Building.

Scope of the Review

The merchandise subject to this antidumping duty order is welded austenitic stainless steel pipe (WSSP) that meets the standards and specifications set forth by the American Society for Testing and Materials (ASTM) for the welded form of chromium-nickel pipe designated ASTM A–312. The merchandise covered by the scope of this order also includes austenitic welded stainless steel pipes made according to the standards of other nations which are comparable to ASTM A–312.

WSSP is produced by forming stainless steel flat-rolled products into a tubular configuration and welding along the seam. WSSP is a commodity product generally used as a conduit to transmit liquids or gases. Major applications include, but are not limited to, digester lines, blow lines, pharmaceutical lines, petrochemical stock lines, brewery process and transport lines, general food processing lines, automotive paint lines and paper process machines. Imports of WSSP are currently classifiable under the following Harmonized Tariff Schedule of the United States (HTS) subheadings: 7306.40.5005, 7306.40.5015, 7306.40.5040, 7306.40.5065 and 7306.40.5085. Although these subheadings include both pipes and tubes, the scope of this antidumping duty order is limited to welded austenitic stainless steel pipes. Although the HTS subheadings are provided for convenience and Customs purposes, the written description of the scope of this order is dispositive.

This changed circumstances administrative review covers Chang Mien, Chang Tieh, and any parties affiliated with Chang Mien or Chang Tieh.

Initiation of Changed Circumstances Antidumping Duty Administrative Review

Pursuant to section 751(b) of the Tariff Act, the Department will conduct a changed circumstances administrative review upon receipt of information concerning, or a request from an interested party for a review of, an antidumping duty order which shows changed circumstances sufficient to warrant a review of the order. See section 751(b)(1). Therefore, in accordance with section 751(b) and 19 CFR 353.22(f)(1)(i), we are initiating a changed circumstances administrative review based upon the factual information and argument contained in Chang Mien's September 11, 1996 request for this review.

The Department will publish in the **Federal Register** a notice of Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review, in accordance with 19 CFR 353.22(f)(1)(v), which will set forth the factual and legal conclusions upon which our preliminary results are based.

[1] Petitioners are: Avesta Sheffield, Inc., Bristol Metals, Inc., Damascus Tube Division, Damascus-Bishop Tube Co., Trent Tube Division, Crucible Materials Corp., and the United Steelworkers of America (AFL-CIO/CLC).

Not later than 270 days after publication of this Notice of Initiation, the Department will issue its final results of review, and will publish these results in the **Federal Register**. All written comments must be submitted in accordance with 19 CFR 353.31(e) and must be served on all interested parties on the Department's service list in accordance with 19 CFR 353.31(g).

This notice is in accordance with section 751(b)(1) of the Tariff Act and section 353.22(f)(1)(i) of the Department's regulations.

Dated: May 15, 1997.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 97–14482 Filed 6–3–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Export Trade Certificate of Review

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of initiation of process to revoke Export Trade Certificate of Review No. 95–00004.

SUMMARY: The Secretary of Commerce issued an export trade certificate of review to UPA, Inc. Because this certificate holder has failed to file an annual report as required by law, the Department is initiating proceedings to revoke the certificate. This notice summarizes the notification letter sent to UPA, Inc.

FOR FURTHER INFORMATION CONTACT: W. Dawn Busby, Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (''the Act'') (15 U.S.C. 4011–21) authorizes the Secretary of Commerce to issue export trade certificates of review. The regulations implementing Title III (''the Regulations'') are found at 15 CFR part 325. Pursuant to this authority, a certificate of review was issued on August 18, 1995 to UPA, Inc.

A certificate holder is required by law (Section 308 of the Act, 15 U.S.C. 4018) to submit to the Department of Commerce annual reports that update financial and other information relating to business activities covered by its certificate. The annual report is due within 45 days after the anniversary date of the issuance of the certificate of review (Sections 325.14(a) and (b) of the Regulations). Failure to submit a complete annual report may be the basis for revocation (Section 325.10(a) of the Regulations).

The Department of Commerce sent to UPA, Inc. on February 12, 1997, a letter containing annual report questions with a reminder that its annual report was due by October 2, 1996. Additional reminders were sent on April 11, 1997, and on May 2, 1997. The Department has received no response to any of these letters.

On May 27, 1997, and in accordance with Section 325.10 (c)(1) of the Regulations, a letter was sent by certified mail to notify UPA, Inc. that the Department was formally initiating the process to revoke its certificate. The letter stated that this action is being taken because of the certificate holder's failure to file an annual report.

In accordance with Section 325.10(c)(2) of the Regulations, each certificate holder has thirty days from the day after its receipt of the notification letter in which to respond. The certificate holder is deemed to have received this letter as of the date on which this notice is published in the **Federal Register**. For good cause shown, the Department of Commerce can, at its discretion, grant a thirty-day extension for a response.

If the certificate holder decides to respond, it must specifically address the Department's statement in the notification letter that it has failed to file an annual report. It should state in detail why the facts, conduct, or circumstances described in the notification letter are not true, or if they are, why they do not warrant revoking the certificate. If the certificate holder does not respond within the specified period, it will be considered an admission of the statements contained in the notification letter (Section 325.10(c)(2) of the Regulations).

If the answer demonstrates that the material facts are in dispute, the Department of Commerce and the Department of Justice shall, upon request, meet informally with the certificate holder. Either Department may require the certificate holder to provide the documents or information that are necessary to support its contentions (Section 325.10(c)(3) of the Regulations).

The Department shall publish a notice in the **Federal Register** of the revocation or modification or a decision not to revoke or modify (Section 325.10(c)(4) of the Regulations). If there is a determination to revoke a certificate, any person aggrieved by such final decision may appeal to an appropriate U.S. district court within 30 days from the date on which the Department's final determination is published in the **Federal Register** (Sections 325.10(c)(4) and 325.11 of the Regulations).

Dated: May 27, 1997.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

[FR Doc. 97–14521 Filed 6–3–97; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of scope rulings and anticircumvention inquiries.

SUMMARY: The Department of Commerce (the Department) hereby publishes a list of scope rulings and anticircumvention inquiries completed by Import Administration, between January 1, 1997, and March 31, 1997. In conjunction with this list, the Department is also publishing a list of pending requests for scope clarifications and anticircumvention inquiries. The Department intends to publish future lists within 30 days of the end of each quarter.

EFFECTIVE DATE: June 4, 1997.

FOR FURTHER INFORMATION CONTACT: Ronald M. Trentham, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482–4793.

Background

The Department's regulations (19 CFR 353.29(d)(8) and 355.29(d)(8)) provide that on a quarterly basis the Secretary will publish in the **Federal Register** a list of scope rulings completed within the last three months.

This notice lists scope rulings and anticircumvention inquiries completed by Import Administration, between January 1, 1997, and March 31, 1997, and pending scope clarification and anticircumvention inquiry requests. The Department intends to publish in July 1997 a notice of scope rulings and anticircumvention inquiries completed between April 1, 1997, and June 30, 1997, as well as pending scope clarification and anticircumvention inquiry requests.

The following lists provide the country, case reference number, requester(s), and a brief description of

either the ruling or product subject to the request.

I. Scope Rulings Completed Between January 1, 1997 and March 31, 1997

Brazil

A–351–817, C–351–818 *Certain Cut-to-Length Carbon Steel Plate*
Wirth Limited—Profile slab produced by Companhia Siderurgica de Tubarao (CST) is within the scope of the order. 4/2/97

Germany

A–428–801 *Antifriction Bearings*
Enkotec Company, Inc.—''Main bearings'' imported for incorporation into Enkotec Rotary Nail Machines are slewing rings and, therefore, are outside the scope of the order. 2/10/97

Singapore

A–559–801 *Antifriction Bearings*
Rockwell International Corporation—Automotive components known as cushion suspension units (or cushion assembly units or center bearing assemblies) are outside the scope of the order. 2/10/97

Japan

A–588–802 *3½'' Micro Disks*
TDK Corporation and TDK Electronics Corporation (collectively TDK)–TDK model PR–CLF2MA coated media web roll is within the scope of the order. 10/23/96. (Correction to Notice of Scope Rulings, 62 FR 9176, February 28, 1997)

A–588–804 *Antifriction Bearings*
Rockwell International Corporation—Automotive components known as cushion suspension units (or cushion assembly units or center bearing assemblies) are outside the scope of the order. 2/10/97

A–588–807 *Industrial Belts*
Honda Power Equipment Manufacturing Inc. (HPE)—Eight drive and blade belts produced by HPE are outside the scope of the order. 1/21/97
American Honda Motor Co., Inc. (AHM)—Twenty-two drive and blade belts produced by AHM are outside the scope of the order. 1/15/97

A–588–810 *Mechanical Transfer Presses*
Komatsu Ltd.,—Certain mechanical transfer press parts exported from Japan are outside the scope of the order. 10/1/96. (Correction to Notice of Scope Rulings, 62 FR 9176, February 28, 1997)

Russia

A–821–803 *Titanium Sponge*
Waldron Pacific, Inc.—Titanium tablets produced by electrolytic reduction are within the scope of the order. 3/6/97

II. Anticircumvention Rulings Completed Between January 1, 1996 and March 31, 1997

None.

III. Scope Inquiries Terminated Between January 1, 1997 and March 31, 1997

None.

IV. Anticircumvention Inquiries Terminated Between January 1, 1997 and March 31, 1997

None.

V. Pending Scope Clarification Requests as of March 31, 1997

Canada

A–122–823 *Certain Cut-to-Length Carbon Steel Plate*
Petitioners—Clarification to determine whether certain boron steels are within the scope of the order.

People's Republic of China

A–570–501 *Natural Bristle Paint Brushes and Brush Heads*
Kwick Clean and Green Ltd.—Clarification to determine whether a group of bristles held together at the base with glue, which are to be used as replaceable parts within the cavity of the paintbrush body, is within the scope of the order

A–570–504 *Petroleum Wax Candles*
Enesco Corporation—Clarification to determine whether a birthday candle (style #9500340) is within the scope of the order
Institutional Financing Services—Clarification to determine whether red/white candles packaged as peppermint candles are holiday novelty candles and, thus, outside the scope of the order
Sun-It Corporation—Clarification to determine whether taper candles containing oil of citronella are within the scope of the order
Ocean State Jobbers—Clarification to determine whether taper candles consisting of a blend of petroleum wax and beeswax are within the scope of the order
Fritz Companies, Inc.—Clarification to determine whether a taper with a design depicting a painted ''Christmas scene'' of holly ivy and berries, item # 416750, is within the scope of the order
Hallmark Cards, Inc.,—Clarification to determine whether the 399FMB5503 Formed Wax Peppermint Candy Candle is within the scope of the order
M.G. Maher & Co. Inc.—Clarification to determine whether a 12 inch spiral candle is within the scope of the order

A–570–808 *Chrome-Plated Lug Nuts*
Wheel Plus, Inc.—Clarification to determine whether imported zinc-plated lug nuts which are chrome-plated in the United States are within the scope of the order

A–570–822 *Helical Spring Lock Washers (HSLWs)*
Shakeproof Industrial Products Division of Illinois Tool Works (SIP)—Clarification to determine whether HSLWs which are imported to the United States in an uncut, coil form are within the scope of the order

A–570–827 *Certain Cased Pencils*
Nadel Trading Corporation—Clarification to determine whether a plastic, ''quasi-mechanical'' pencil (also known as the ''Bensia'' pencil) is within the scope of the order

A–570–836 *Glycine*
Consolidated Pharmaceutical Group, Inc.—Clarification to determine whether D(-) Phenylglycine Ethyl Dane Salt is within the scope of the order

South Korea

A–580–803 *Small Business Telephones from Korea*
TT Systems Corporation—Clarification to determine whether the ''Model 4300'' should be excluded from the scope of the order because it is a ''blocking'' system, whereas the order pertains to ''non-blocking'' systems

Taiwan

A–583–810 *Chrome-Plated Lug Nuts*
Wheel Plus, Inc.—Clarification to determine whether imported zinc-plated lug nuts which are then chrome-plated in the United States are within the scope of the order

A–583–820 *Helical Spring Lock Washers (HSLWs)*
Shakeproof Industrial Products Division of Illinois Tool Works (SIP)—Clarification to determine whether HSLWs imported into the United States in an uncut, coil form are within the scope of the order

Japan

A–588–804 *Antifriction Bearings (Other Than Tapered Roller Bearings), and Parts Thereof*
Koyo Seiko Co., Ltd.—Clarification to determine whether a cylindrical roller bearing, supposedly without a precision rating, for use as an axle

bearing in cars and trucks is within the scope of the order

A–588–813 *Light-Scattering Instruments and Parts Thereof*

Thermo Capillary Electrophoresis, Inc.—Clarification to determine whether diode array detectors and cell flow units are within the scope of the order

A–588–824 *Corrosion Resistant Carbon Steel Flat Products*

Drive Automotive Industries—Clarification to determine whether 2000 millimeter wide, made to order, corrosion resistant carbon steel coils are within the scope of the order

A–588–833 *Stainless Steel Bar*

Keystone Stainless Inc.—Clarification to determine whether ''Keystone 2000'', a specialty stainless steel bar product, should be excluded from the scope of the order because the manufacture of the product substantially differentiates it from any other product available

VI. Pending Anticircumvention Inquiries as of March 31, 1997

Mexico

A–201–805 *Certain Welded Non-Alloy Steel Pipe*

Allied Tube & Conduit Corp., Sawhill Tubular Division of Tex-Tube Co., Century Tube Corp., Laclede Steel Co., LTV Tubular Products Co., Sharon Tube Co., Western Tube & Conduit Co., Wheatland Tube Co., and CSI Tubular Products, Inc. (Petitioners)—Anticircumvention inquiry to determine whether imports of (i) pipe certified to the American Petroleum Institute (API) 5L line pipe specifications (API 5L or line pipe) and (ii) pipe certified to both the API 5L line pipe specifications and the less stringent American Society for Testing and Materials (ASTM) A–53 standard pipe specifications (dual certified pipe), falling within the physical dimensions outlined in the scope of the order, are circumventing the antidumping duty order

Korea

A–580–008 *Color Television Receivers from Korea*

International Brotherhood of Electrical Workers, the International Union of Electronic Electrical, Salaried, Machine & Furniture Workers, and the Industrial Union Department (the Unions)—Anticircumvention inquiry to determine whether Samsung Electronics Co., L.G. Electronics Inc., and Daewoo Electronics Co., are circumventing the order by shipping Korean-origin color picture tubes, printed circuit boards, color television kits, chassis, and other materials, parts and components to plants operated by related parties in Mexico where the parts are then assembled in CTVs and shipped to the United States. Additionally, an anticircumvention inquiry to determine whether Samsung by shipping Korean-origin color picture tubes and other CTV parts to a related party in Thailand for assembly into complete CTVs prior to exportation to the United States is circumventing the order

Interested parties are invited to comment on the accuracy of the list of pending scope clarification requests. Any comments should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

Dated: May 23, 1997.

Joseph A. Spetrini,

Deputy Assistant Secretary, Enforcement Group III.

[FR Doc. 97–14481 Filed 6–3–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Intent to Prepare a Draft Environmental Impact Statement on the Proposed Georgia Coastal Management Program

AGENCY: National Oceanic and Atmospheric Administration.

ACTION: Notice of intent to prepare a draft environmental impact statement as required under the National Environmental Policy Act 42 U.S.C. 4321, *et seq.* (NEPA).

SUMMARY: Notice is hereby given of the intent to prepare a Draft Environmental Impact Statement (DEIS) on the proposed approval of the Georgia Coastal Management Program (GCMP, or Program) under the provisions of Section 306 of the Federal Coastal Zone Management Act of 1972, as amended, 16 U.S.C. 1455, and distribute it in August 1997.

Federal approval of the GCMP would make the State eligible for program administration grant funds and require that Federal actions be consistent with the Program.

The Program is the culmination of several years of development and consists of numerous State policies on diverse management issues which are prescribed by statute and made enforceable under State law. The Program should improve the decision making process for determining appropriate coastal land and water uses in light of resource considerations. The Program should increase public awareness of coastal resources. Federal alternatives will include delaying or denying approval if certain requirements of the Coastal Zone Management Act have not been met. State alternatives include the possibility of modifying parts of the Program or withdrawal of the request for Federal approval.

In order to determine the scope and significance of issues to be addressed in the DEIS, the Office of Ocean and Coastal Resource Management (OCRM) hereby solicits comments on the proposed action, particularly with respect to the following issues:

(1) The adequacy of the scope and geographic coverage of the Program's laws and regulations to manage impacts on wetlands, beaches, and other vulnerable natural resources;

(2) The adequacy of the mechanisms for State agency coordination and consultation in order to effectively implement the GCMP; and

(3) The adequacy of the mechanisms for ensuring State agency consistency with the policies of the GCMP and resolving conflicts between agencies.

The manner in which the State proposes to address the above requirements was presented in the Public Review Draft of the Program Document of the GCMP, in November 1996, and a revised Program Document in January 1997. The State has considered all comments submitted in response to those documents in the preparation of the GCMP Draft Program Document to be released with the DEIS in August. Copies of the State document are available from OCRM.

DATES: Persons or organizations wishing to submit comments on these or other issues should do so by July 7, 1997. Any comments received after that time will be considered in the response to comments received on the DEIS.

ADDRESSES: Requests for the above described documents and all comments should be made to: Joshua Lott, Coastal Programs Division, Southeast Region, Office of Ocean and Coastal Resource Management, 1305 East-West Highway (N/ORM3), Silver Spring, Maryland 20910; tel. 301/713–3117, ext. 178, e-mail:jlott@coasts.nos.noaa.gov.

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

David L. Evans,

Acting Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 97–14473 Filed 6–3–97; 8:45 am]

BILLING CODE 3510–08–M

COMMODITY FUTURES TRADING COMMISSION

Public Information Collection Requirement

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of intent to renew information collection # 3038–0023, Regulations and forms relating to registration with the Commission.

SUMMARY: The Commodity Futures Trading Commission is planning to renew information collection 3038–0023, Regulations and Forms Relating to Registration with the Commission which is due to expire on August 31, 1997. The Commodity Exchange Act, as amended, requires the registration of all futures commission merchants, floor traders, floor brokers, associated persons, commodity trading advisors, commodity pool operators, introducing brokers, and leverage transaction merchants. In compliance with the Paperwork Reduction Act of 1995, the Commission solicits comments to: (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including the validity of the methodology and assumptions used; (2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of the information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

DATES: Comments must be received on or before August 4, 1997.

ADDRESS: Copies of the submission may be obtained from the CFTC Clearance Officer, 1155 21st Street NW, Washington, DC 20581, (202) 418–5160.

Title: Regulations and Forms Relating to Registration with the Commission.

Control number: 3038–0023.

Action: Extension.

Respondents: Commission Registrants.

Estimated Annual Burden: 27,467 hours.

Issued in Washington, D.C. on May 29, 1997.

Jean A. Webb,

Secretary to the Commission.

[FR Doc. 97–14594 Filed 6–3–97; 8:45 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of submission of information collection #3038–0018.

SUMMARY: The Commodity Futures Trading Commission has submitted information collection 3038–0018, Information Concerning Warehouses, to OMB for review and clearance under the Paperwork Reduction Act of 1995, (Pub. L. 104–13). The information collected pursuant to these rules is in the public interest and is necessary for market surveillance.

ADDRESSES: Persons wishing to comment on this information collection should do so within the next 30 days by contacting the Desk Officer, CFTC, Office of Management and Budget, Room 3228, NEOB, Washington, DC 20502, (202) 395–7340. Copies of the submission are available from the Agency Clearance Officer, (202) 418–5160.

Title: Information Concerning Warehouses.

Control Number: 3038–0018.

Action: Extension.

Respondents: Businesses (excluding small businesses).

Estimated Annual Burden: 30 total hours.

Respondents	Regulation (17 CFR)	Estimated number of respondents	Annual responses	Est. avg. hours per response
Businesses	1.42, 1.43	11	178	1.685

Issued in Washington, DC on May 29, 1997.

Jean A. Webb,

Secretary to the Commission.

[FR Doc. 97–14593 Filed 6–3–97; 8:45 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of submission of information collection #3038–0019.

SUMMARY: The Commodity Futures Trading Commission has submitted information collection 3038–0019, Stocks of Grain in Licensed Warehouses, to OMB for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The information collected pursuant to these rules is in the public interest and is necessary for market surveillance.

ADDRESSES: Persons wishing to comment on this information collection should contact the Desk Officer, CFTC, Office of Management and Budget, Room 3228, NEOB, Washington, DC 20502, (202) 395–7340. Copies of the submission are available from the Agency Clearance Officer, (202) 418–5160.

Title: Stocks of Grain in Licensed Warehouses.

Control Number: 3038–0019.

Action: Extension.

Respondents: Exchanges.

Estimated Annual Burden: 1,769 total hours.

Respondents	Regulation (17 CFR)	Estimated number of respondents	Annual responses	Est. avg. hours per response
Exchanges	1.44	3	1701	1.04

Issued in Washington, DC on May 29, 1997.

Jean A. Webb,

Secretary to the Commission.

[FR Doc. 97–14595 Filed 6–3–97; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0129]

Submission for OMB Review; Comment Request Entitled Cost Accounting Standards Administration

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance (9000–0129).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Cost Accounting Standards Administration. A request for public comments was published at 62 FR 14404, on March 27, 1997. No comments were received.

DATES: *Comment Due Date:* July 7, 1997.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, or obtaining a copy of the justification, should be submitted to: General Services Administration, FAR Secretariat (MVRS), 1800 F Street, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0129 in all correspondence.

FOR FURTHER INFORMATION CONTACT: Jeremy Olson, Federal Acquisition Policy Division, GSA (202) 501–3221.

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR 30.6 and 52.230–5 include pertinent rules and regulations related to the Cost Accounting Standards along with necessary administrative policies and procedures. These administrative policies require certain contractors to submit cost impact estimates and descriptions in cost accounting practices and also to provide information on CAS-covered subcontractors.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *.05* hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents, *644*; responses per respondent, *2.27*; total annual responses, *1,462*; preparation hours per response, *200.85*; and total response burden hours, *293,650*.

OBTAINING COPIES OF PROPOSALS: Requester may obtain copies of justifications from the General Services Administration, FAR Secretariat (MVRS), Room 4037, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–2164. Please cite OMB Control No. 9000–0129, Cost Accounting Standards Administration, in all correspondence.

Dated: May 30, 1997.

Sharon A. Kiser,

FAR Secretariat.

[FR Doc. 97–14561 Filed 6–3–97; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

Department of the Navy

Naval Research Advisory Committee; Open Meeting

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), notice is hereby given that the Naval Research Advisory Committee Panel on Ship-to-Warfighter Logistics for Small Unit Operations will meet on June 10–12, 1997. The meeting will be held at the Office of Naval Research, 800 North Quincy Street, Arlington, VA. The meeting will commence at 8:30 a.m. and terminate at 4:30 p.m. on June 10, 11 and 12, 1997. All sessions of the meeting will be open to the public.

The purpose of the meeting is to identify future science and technology opportunities, and assess technologies associated with Department of the Navy logistics initiatives in order to resupply forward-deployed Small Unit Operations with food, ammunition, water, fuel, batteries, medical supplies, etc., with minimum footprint and exposure time, and maintain communications for a period of seven days to several weeks.

FOR FURTHER INFORMATION CONCERNING THIS MEETING CONTACT: Ms. Diane Mason-Muir, Office of Naval Research, Naval Research Advisory Committee, 800 North Quincy Street, Arlington, VA 22217–5660, telephone number (703) 696–6769.

Dated: May 22, 1997.

Donald E. Koenig, Jr.,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 97–14584 Filed 6–3–97; 8:45 am]

BILLING CODE 3810–FF–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Published June 2, 1997, Docket No. 97–14387.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 1:30 p.m., June 10, 1997.

PLACE: The Defense Nuclear Facilities Safety Board, Public Hearing Room, 625 Indiana Avenue, NW, Suite 300, Washington, DC 20004.

STATUS: Open.

CHANGE IN THE MEETING: The meeting has been rescheduled to begin at 9:00 a.m. on June 10, 1997.

MATTERS TO BE CONSIDERED: Status of the Department of Energy's Implementation of Board Recommendation 94–1.

CONTACT PERSON FOR MORE INFORMATION: Richard A. Azzaro, Acting General Counsel, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW, Suite 700, Washington, DC 20004, (800) 788–4016. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The Board issued Recommendation 94–1 on May

26, 1994 to encourage the Department of Energy to act more quickly to place surplus nuclear materials in safe forms for interim storage. When production of nuclear weapons ceased in the early 1990's, large inventories of plutonium, uranium, spent nuclear fuel, and other hazardous materials were stored in temporary arrangements awaiting processing into weapons components or other disposition. The Board was concerned that such materials, some of which are in unstable chemical forms, may rupture or leak from their temporary containers, or may cause or contribute to a fire. The Board accordingly recommended that the Department initiate or accelerate programs to process and repackage such materials so that they could be safely stored. The Secretary of Energy accepted Recommendation 94–1 in full, and a mutually agreeable Implementation Plan was issued in February 1995 and accepted by the Board.

This Public Meeting is for the purpose of examining progress on Recommendation 94–1 activities. Department of Energy personnel will review the status of key current issues which endanger established milestones affecting programs to process uranium and plutonium into stable forms, package plutonium for interim storage, stabilize spent fuel, and maintain the facilities needed to perform these activities over the next several years. The largest Recommendation 94–1 programs are at the Savannah River Site, the Hanford Site, the Rocky Flats Environmental Technology Site, and Los Alamos National Laboratory, although most other defense nuclear sites are affected to some degree.

The Defense Nuclear Facilities Safety Board reserves its right to further schedule and otherwise regulate the course of this meeting, to recess, reconvene, postpone or adjourn the meeting, and otherwise exercise its authority under the Atomic Energy Act of 1954, as amended.

Dated: May 30, 1997.

John T. Conway,

Chairman.

[FR Doc. 97–14634 Filed 5–30–97; 8:45 am]

BILLING CODE 3670–01–M

DEPARTMENT OF ENERGY

Office of Strategic Petroleum Reserve; Opportunity for Public Comment

AGENCY: Department of Energy, Fossil Energy, Office of Strategic Petroleum Reserve.

ACTION: Extension of comment period for opportunity for public comment on Strategic Petroleum Reserve Policy.

SUMMARY: In preparation for the issuance of an Administration Statement of Policy concerning the capacity, size, use, and financing, among other issues, of the Strategic Petroleum Reserve, the Department of Energy, Office of Strategic Petroleum Reserve, on April 30, 1997, published a notice of opportunity for interested persons to submit written comments (62 FR 23437). The notice requested comments be submitted by June 16, 1997. Because of the extent of public interest in the policy review, and in order to provide for maximum participation by interested persons, the Office of Strategic Petroleum Reserve has decided to extend the filing date for comments.

DATES: Comments are due by July 14, 1997.

ADDRESSES: Mr. Richard D. Furiga, Deputy Assistant Secretary, Strategic Petroleum Reserve, FE–40, Room 3G–024, 1000 Independence Avenue, SW., Washington, DC 20805.

Comments may also be submitted by use of the Internet by linking to the DOE Fossil Energy web site at: http://www.fe.doe. gov/spr.html.

Issued in Washington, DC, on May 29, 1997.

Richard D. Furiga,

Deputy Assistant Secretary, Strategic Petroleum Reserve.

[FR Doc. 97–14547 Filed 6–3–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration, Department of Energy.

ACTION: Submission for OMB review; comment request.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The listing does not include collections of information contained in new or revised regulations which are to be submitted under section 3507(d)(1)(A) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) Collection number and title; (2) summary of the collection of information (includes sponsor (the DOE component)), current OMB document number (if applicable), type of request (new, revision, extension, or reinstatement); response obligation (mandatory, voluntary, or required to obtain or retain benefits); (3) a description of the need and proposed use of the information; (4) description of the likely respondents; and (5) estimate of total annual reporting burden (average hours per response × proposed frequency of response per year × estimated number of likely respondents.)

DATES: Comments must be filed on or before July 7, 1997. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Statistics and Methods Group at the address below.)

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Herbert Miller, Statistics and Methods Group (EI–70), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Miller may be telephoned at (202) 426-1103, FAX (202) 426–1081, or e-mail at hmiller@eia.doe.gov.

SUPPLEMENTARY INFORMATION:

The energy information collection submitted to OMB for review was:

1. NWPA–830R A/G, ''Standard Contract for Disposal of Spent Nuclear Fuel and/or High-Level Radioactive Waste''.

2. Office of Civilian Radioactive Waste Management; OMB No. 1901–0260; Extension of Currently Approved Collection; Mandatory.

3. The NWPA–830R A/G is designed to serve as the service document for entries into the DOE accounting records to transmit data from utilities concerning payment of their contribution to the Nuclear Waste Fund.

This form is used by electric utilities, vendors, and owners of nuclear fuel to purchase the services of DOE for disposal of their spent nuclear fuel and high-level waste.

4. Business or other for-profit.

5. 16,125 hours (37.94 hrs. × 3.4 responses per year × 125 respondents).

Statutory Authority: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13).

Issued in Washington, DC, May 27, 1997.

Jay H. Casselberry,

Agency Clearance Officer, Statistics and Methods Group, Energy Information Administration.

[FR Doc. 97–14546 Filed 6–3–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2977–000]

Commonwealth Edison Company; Notice of Filing

May 29, 1997.

Take notice that on May 15, 1997, Commonwealth Edison Company (ComEd), tendered for filing a new power Sales Schedule 10, Emergency Redispatch Service, under ComEd's Power Sales and Reassignment of Transmission Rights Tariff, PSRT–1.

ComEd requests an effective date of June 1, 1997, and has therefore requested that the commission waive the Commission's notice requirements. ComEd has served copies of the filing on the Illinois Commerce Commission, the Wisconsin Public Service Commission and all customers served under ComEd's PSRT–1 Tariff.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NW., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before June 10, 1997. 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.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14492 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP96–366–000 and FA94–15–002]

Florida Gas Transmission Company; Notice of Informal Settlement Conference

May 29, 1997.

Take notice that an informal settlement conference will be convened in this proceeding on Tuesday, June 3, 1997, at 1:00 p.m. and, if necessary, will continue on Wednesday, June 4, 1997, at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined in 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, please contact Sandra J. Delude at (202) 208–0583 or Kathleen M. Dias at (202) 208–0524.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14490 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–537–000]

Florida Gas Transmission Company; Notice of Application To Abandon

May 29, 1997.

Take notice that on May 21, 1997, Florida Gas Transmission Company (Applicant), 1400 Smith Street, Houston, Texas 77002, filed pursuant to Section 7(b) of the Natural Gas Act, for authority to abandon, a certificated transportation service with Southern Natural Gas Company (SNG). The service is Applicant's Rate Schedule X–23 in its FERC Gas Tariff, Original Volume No. 3. Applicant's proposal is more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that under this transportation service it transported 20,000 MMBtu/d on a best efforts basis from an interconnection between Applicant's facilities and Louisiana Resources Company in Vermilion Parish, Louisiana to an interconnection between Applicant and SNG in Washington Parish, Louisiana.

Any person desiring to be heard or make any protest with reference to said application should on or before June 19, 1997, file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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 the 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 application if no motion to intervene is filed within the time required, or if the Commission on its own review of the matter finds that permission and approval of the proposed abandonment are 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 Applicant to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14494 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP85–221–092]

Frontier Gas Storage Company; Notice of Sale Pursuant to Settlement Agreement

May 29, 1997.

Take notice that on May 22, 1997, Frontier Gas Storage Company (Frontier), c/o Reid & Priest, Market Square, 701 Pennsylvania Ave., N.W., Suite 800, Washington, D.C. 20004, in compliance with provisions of the Commission's February 13, 1985, Order in Docket No. CP82–487–000, *et al.*, submitted an executed Service Agreement under Rate Schedule LVS–1 providing for the possible sale of 1,000,000 MMBtu of Frontier's gas storage inventory on an ''in place'' basis to Western Gas Resources, Inc.

Under Subpart (b) of Ordering Paragraph (G) of the Commission's February 13, 1985, Order, Frontier is ''authorized to consummate the proposed sale in place unless the Commission issues an order within 20 days after expiration of such notice period either directing that the sale not take place and setting it for hearing or permitting the sale to go forward and establishing other procedures for resolving the matter. Deliveries of gas sold in place shall be made pursuant to a schedule to be set forth in an exhibit to the executed service agreement.''

Any person desiring to be heard or to make a protest with reference to said filing should, within 10 days of the publication of such notice in the **Federal Register** file with the Federal Energy Regulatory Commission (888 1st Street N.E., Washington, D.C. 20426) a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedures, 18 CFR 385.214 or 385.211. 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 proceding. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14496 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–544–000]

National Fuel Gas Supply Corporation; Notice of Request Under Blanket Authorization

May 29, 1997.

Take notice that on May 23, 1997, National Fuel Gas Supply Corporation (National), 10 Lafayette Square, Buffalo, New York 14203, filed in Docket No. CP97–544–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate a new residential sales tap under National's blanket certificate issued in Docket No. CP83–4–000 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.

National proposes to construct and operate a sales tap for delivery of approximately 150 Mcf annually of gas to National Fuel Gas Distribution Corporation (Distribution) at an estimated cost of $1,500, for which National will be reimbursed by Distribution. National further states that the proposed sales tap will be located on its Line G–M2 in Jefferson County, Pennsylvania.

Any person or the Commission's staff may, within 45 days after 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 Section 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 therefor, 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.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14488 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–541–000]

National Fuel Gas Supply Corporation; Notice of Application

May 29, 1997.

Take notice that on May 22, 1997, National Fuel Gas Supply Corporation (National Fuel), 10 Lafayette Square, Buffalo, New York 14203, filed in Docket No. CP97–541–000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon by sale, to Universal Resources Holdings, Inc. (Universal), Line R–1 which was installed under the budget authorization granted in Docket No. CP80–463,[1] all as more fully set forth in the application on file with the Commission and open to public inspection.

National Fuel proposes to abandon by sale to Universal a certificated gathering line designated as Line R–1, located in Warren County, Pennsylvania. Line R–1 consists of approximately 6,327 feet of 4-inch pipeline. National Fuel has agreed to sell the facilities to Universal for $1,550. National Fuel states that the proposed abandonment will not adversely affect its ability to provide transportation service to its customers.

Additionally, National Fuel requests a determination that subsequent to their transfer, Line R–1 and the appurtenant facilities will be nonjurisdictional gathering facilities whose operation by Universal will not be subject to the Commission's jurisdiction.

Any person desiring to be heard or to make any protest with reference to said application should on or before June 19, 1997, file with the Federal Energy Regulatory Commission, 888 First 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 385.214 or 385.211) 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

[1] 14 FERC ¶ 62,068 (1981).

the 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 application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are 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 National Fuel to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14493 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–529–000]

Natural Gas Pipeline Company of America; Notice of Application to Abandon Facilities

May 29, 1997.

Take notice that on May 19, 1997, Natural Gas Pipeline Company of America (Natural) filed an application pursuant to section 7(b) of the Natural Gas Act and Sections 157.7 and 157.18 of the Commission's Regulations, requesting permission and approval to abandon, by sale to Koch Gateway Pipeline Company (Koch), its interest in certain pipeline facilities with appurtenances, in offshore Louisiana, all as more fully set forth in this request which is on file with the Commission and open to public inspection.

Specifically, Natural requests permission and approval to abandon, by sale to Koch, Natural's fifty percent (50%) ownership interest in 2.3 miles of 16-inch pipeline lateral running from South Pass 78 to South Pass 77 in offshore Louisiana, which includes one dual 10-inch meter, a riser and appurtenances located South Pass Block 78 and a 16-inch subsea tap and appurtenances located in South Pass Block 77.

Any person desiring to be heard or to make any protest with reference to said request should on or before June 19, 1997, file with the Federal Energy Regulatory Commission, 888 First 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 385.214 and 385.211) 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 an 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 application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that the request should be granted. If a motion for leave to intervene is timely filed, or if the Commission on its 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 Natural to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14495 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. OA97–237–000, ER97–1079–000, and EC97–35–000]

New England Power Pool; Notice of Filing

May 29, 1997.

Take notice that on May 1, 1997, the New England Power Poor (NEPOOL) Executive Committee submitted a mitigation proposal in support of market rules for inclusion with the materials previously submitted on behalf of NEPOOL in the captioned dockets.

The NEPOOL Executive Committee states that copies of these materials were sent to the official service list in the captioned dockets, the New England Power Pool.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 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 June 10, 1997. 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.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14489 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ES97–34–000]

Valley Electric Association, Inc.; Notice of Application

May 29, 1997.

Take notice that on May 22, 1997, Valley Electric Association, Inc. (Valley) filed an application, under § 204 of the Federal Power Act, seeking authorization to issue debt under a line of credit issued by the National Rural Utilities Cooperative Finance Corporation (CFC) in the amount of $15 million. Funds drawn under the line of credit will be used for daily operational purposes and for the initial stages of a construction project. Valley also advised the Commission of borrowings that it had made without authorization under § 204 and requested that the Commission take no action with respect to such borrowings.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (128 CFR 385.211 and 385.214). All such motions or protests should be filed on or before June 10, 1997. Protests will be considered by the Commission 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 must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14491 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–545–000]

Texas Eastern Transmission Corporation; Notice of Request Under Blanket Authorization

May 29, 1997.

Take notice that on May 23, 1997, Texas Eastern Transmission Corporation (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056–5310, filed a request with the Commission in Docket No. CP97–545–000, pursuant to Sections 157.205, and 157.211 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to construct a delivery point in Monroe County, Kentucky, so that Texas Eastern may provide natural gas deliveries to Clay Gas Utility District (Clay), a municipal gas distributor and existing Texas Eastern customer authorized in blanket certificate issued in Docket No. CP82–535–000, all as more fully set forth in the request on file with the Commission and open to public inspection.

Texas Eastern proposes to construct and install a 2-inch tap valve and a 2-inch check valve on Texas Eastern's existing 36-inch Line No. 25 at approximate Mile Post 338.44 in Monroe County, Kentucky (Tap). In addition to the facilities described above, Clay will install a dual 2-inch turbine meter (Meter Station), approximately 10 feet of 2-inch pipeline which will extend from the Meter Station to the Tap, and electronic gas measurement equipment.

Texas Eastern states that Clay will reimburse Texas Eastern for 100% of the costs and expenses that Texas Eastern will incur for installing the facilities, which is estimated to be $76,000.00.

Any person or the Commission's staff may, within 45 days after the Commission has issued this notice, 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 Section 157.205 of the Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the allowed time, 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 NGA.

Lindwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–14487 Filed 6–3–97; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[OPP–34011; FRL 5715–8]

Notice of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request for amendment by registrants to delete uses in certain pesticide registrations.

DATES: Unless a request is withdrawn, the Agency will approve these use deletions and the deletions will become effective on December 1, 1997.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location for commercial courier, delivery, telephone number and e-mail: Room 216, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA (703) 305–5761; e-mail: hollins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of FIFRA, provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

II. Intent to Delete Uses

This notice announces receipt by the Agency of applications from registrants to delete uses in the 39 pesticide registrations listed in the following Table 1. These registrations are listed by registration number, product names, active ingredients and the specific uses deleted. Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant before December 1, 1997 to discuss withdrawal of the applications for amendment. This 180-day period will also permit interested members of the public to intercede with registrants prior to the Agency approval of the deletion.

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

EPA Reg No.	Product Name	Active Ingredient	Delete From Label
000228–00095	Riverdale 2,4-D L.V. 6 Ester	2,4-D 2-Ethylhexyl Ester	Ditchbanks and sugarcane
000228–00126	Riverdale Solution Emulsible	2,4-D 2-Ethylhexyl Ester	Ditchbanks and sugarcane
000228–00167	Riverdale 2D + 2DP Low Vol	2,4-D 2-Ethylhexyl Ester	Ditchbanks
000228–00139	Riverdale 2,4-D L.V. 4 Ester	2.4-D 2-Ethylhexyl Ester	Drainage ditchbanks
000228–00185	Riverdale Tri-Ester	2,4-D 2-Ethylhexyl Ester; Isooctyl 2- (2,4-dichlorophenoxy) propionate; Isooctyl 2-(2-methyl-4-chloro-phenoxy)propiionate	Ditchbanks
000228–00186	Riverdale 1D + 1DP Low Vol	2,4-D 2-Ethylhexyl Ester	Ditchbanks

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS—Continued

EPA Reg No.	Product Name	Active Ingredient	Delete From Label
000334–00245	Hysan 006 Weed Killer	2,4-D 2-Ethylhexyl Ester; Bromacil	Drainage ditchbanks
000432–00733	Cyper-Active 2.14 EC	Cypermethrin	Aircraft uses
000432–00758	Cypermethrin 40 WP	Cypermethrin	Aircraft uses
000432–00760	Saga WSB Insecticide	Tralomethrin	Aircraft uses
001381–00101	Class LV 6 Phenoxy Herbicide	2,4-D 2-Ethylhexyl Ester	Drainage ditchbanks
001381–00102	Class LV4 Phenoxy Herbicide	2,4-D 2-Ethylhexyl Ester	Drainage ditchbanks
001386–00060	Lo-V Ester Weed Killer	2,4-D 2-Ethylhexyl Ester	Drainage ditchbanks, rice, sugarcane, aquatic uses
002935–00499	Miller's 2,4-D LV Ester 6E	2,4-D 2-Ethylhexyl Ester	Ditchbanks
002935–00511	Lo-Vol 4D	2,4-D 2-Ethylhexyl Ester	Drainage ditchbanks
003125–00158	DI-Syston 68% Concentrate	Disulfoton	Rice, pineapples, spinach, sugar beets
003125–00183	DI-Syston Technical Insecticide	Disulfoton	Rice, pineapples, spinach, sugar beets
003125–00318	Bayleton 25% Wettable Powder Systemic Fungicide	Triadimefon	Cucurbits
003125–00320	Bayleton 50% Wettable Powder Fungicide in W.S.P.	Triadimefon	Wheat, grasses grown for seed, sugar beets, cucurbits
003125–00340	Bayleton 50% Wettable Powder Fungicide in W.S.P.	Triadimefon	Wheat, grasses grown for seed, subar beets, cucurbits
003876–00127	Slimicide C-41	Methylene-bis(thio-cyanate; Beta-Bromo- beta-nitrostyrene)	Once-through cooling
004816–00687	Turbocide Pest Control System with DDVP	Dichlorovinyl	Aircraft uses
004816–00688	Permanone Multi-Purpose 10% EC	Permethrin, mixed cis, trans	Aircraft uses
004816–00728	Tetraperm Crawling Insect Killer	Tetramethrin; Permethrin, mixed cis, trans	Aircraft uses
005481–00234	Low Vol 4-D Weed Killer	2,4-D 2-Ethylhexyl Ester	Ditchbanks
005481–00235	Low Vol 6-D Weed Killer	2,4-D 2-Ethylhexyl Ester	Ditchbanks
005905–00504	Barrage	2,4-D 2-Ethylhexyl Ester	Aquatic non-food uses
005905–00507	Weed Rhap Low Volatile Granular D	2,4-D 2-Ethylhexyl Ester	Aquatic non-food uses
005905–00508	Weed Rhap LV-6D	2,4-D 2-Ethylhexyl Ester	Sugarcane, drainage ditchbanks, aquatic nonfood uses
009779–00256	Riverside 2,4-D LV6	2,4-D 2-Ethylhexyl Ester	Drainage ditchbanks
009779–00257	Riverside 2,4-D LV4	2,4-D 2-Ethylhexyl Ester	Drainage ditchbanks
010182–00149	Captan Garden Spray	Captan	Soil & bench greenhouse treatment
019713–00337	Drexel LV 6 Weed Killer	2,4-D 2-Ethylhexyl Ester	Sugarcane, aquatic applications (for aquatic weeds in lakes, ponds, drainage ditches, marshes), drainage ditch banks
019713–00345	Drexel 4# Low Volatile Ester Herbicide	2,4-D 2-Ethylhexyl Ester	Sugarcane, drainage ditchbanks
033660–00036	VLN Trifluralin Technical	Trifluralin	Forage legumes
042750–00015	Albaugh 2,4-D LV4	2,4-D 2-Ethylhexyl Ester	Sugarcane, drainage ditchbanks, aquatic applications
042750–00020	Albaugh 2,4-D LV6	2,4-D 2-Ethylhexyl Ester	Sugarcane, drainage ditchbanks, aquatic applications
061272–00001	2,4-D Isooctyl Ester Technical	2,4-D 2-Ethylhexyl Ester	Sugarcane
061272–00007	2,4-D Isooctyl Ester Technical Grade	2,4-D 2-Ethylhexyl Ester	Sugarcane

The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2. — REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

Company No.	Company Name and Address
000228	Riverdale Chemical Co., 425 West 194th Street, Glenwood, IL 60425.
000334	Nysan Corporation, 3000 West 139th Street, Blue Island, IL 60406.
000432	AgrEvo Environmental Health, 95 Chestnut Ridge Road, Montvale, NJ 07645.
001381	Imperial, Inc., P.O. Box 536, Hampton, IA 50441.
001386	Universal Cooperatives, Inc., P.O. Box 460, Minneapolis, MN 55440.
002935	Wilbur-Ellis Company, 191 W. Shaw Ave., Suite 107, Fresno, CA 93704.
003125	Bayer Corporation, Agriculture Division, 8400 Hawthorn Road, Kansas City, MO 64120.
003876	Betz Laboratories, Inc., 4636 Somerton Road, Trevose, PA 19053.
004816	AgrEvo Environmental Health, 95 Chestnut Ridge Road, Montvale, NJ 07645.
005481	AMVAC Chemical Corp., c/o H.R. McLane, Inc., 7210 Red Road, Suite 206, Miami, FL 33143.
005905	Helena Chemical Co., 6075 Poplar Avenue, Suite 500, Memphis, TN 38119.
009779	Riverside/Terra Corp., 600 Fourth Street, P.O. Box 6000, Sioux City, IA 51102.
010182	Zeneca Ag Products, 1800 Concord Pike, Wilmington, DE 19897.
019713	Drexel Chemical Co., P.O. Box 13327, 1700 Channel Ave., Memphis, TN 38113.
033660	Industria Prodotti Chimici, S.P.A., c/o Lewis & Harrison Consultants, 122 C Street, N.W., Suite 740, Washington, DC 20001.
042750	Regulatory Consulting, 785 Country Club Drive, Senatobia, MS 38668.
061272	Registrations Plus, 425 West 194th Street, Glenwood, IL 60425.

III. Existing Stocks Provisions

The Agency has authorized registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: May 20, 1997.

Linda A. Travers,

Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 97–14299 Filed 6–3–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–41048; FRL–5718–3]

Fortieth Report of the TSCA Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The TSCA Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Fortieth Report to the Administrator of the EPA on April 28, 1997. In the Fortieth Report, which is included with this notice, the ITC revised the TSCA section 4(e) *Priority Testing List* by removing two isocyanates that were recommended in the 26th Report, one high production volume chemical, trichloromethane sulfenyl chloride that was recommended in the 36th Report and 2,4,6-tribromophenol that was recommended in the 39th Report. The ITC is also proposing procedures for chemical trade associations and producers, importers, processors, and users of future ITC-recommended chemicals to voluntarily provide data needed by U.S. Government organizations represented on the ITC and thereby reduce the need for the EPA to promulgate TSCA section 8 rules for these chemicals.

There are no designated or recommended with intent-to-designate chemicals or chemical groups in the Fortieth Report. EPA invites interested persons to submit written comments on the Report.

DATES: Written comments on the Fortieth ITC Report should be received by July 7, 1997.

ADDRESSES: Comments on the Fortieth Report should be submitted to both the ITC and the TSCA Docket. Send one copy of written comments to: John D. Walker, ITC Executive Director (7401), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Send six copies of written comments to: Document Control Office, Rm. ET–G–099, Office of Pollution Prevention and Toxics (7407), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. All submissions should bear the document control number OPPTS–41048.

Comments may also be submitted electronically by sending electronic mail (e-mail) to the ITC (walker.johnd@epamail.epa.gov) or the EPA (ncic@epamail.epa.gov). Electronic comments are preferred by the ITC. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of security encryption. Comments will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All comments in electronic form must be identified by the document control number OPPTS–41048. No TSCA ''Confidential Business Information'' (CBI) should be submitted through e-mail. Electronic comments on the Fortieth Report may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit IV of this document.

The public record supporting this action, including comments, is available for public inspection in the TSCA Non-Confidential Information Center (NCIC), Rm. NE B–607 at the address noted above from 12 noon to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director,

Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, 202–554–1404, TDD 202–554–0551.

SUPPLEMENTARY INFORMATION: EPA has received the TSCA Interagency Testing Committee's Fortieth Report to the Administrator.

I. Background

TSCA (Pub. L. 94–469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 260l *et seq.*) authorizes the Administrator of the EPA to promulgate regulations under section 4(a) requiring testing of chemicals and chemical groups in order to develop data relevant to determining the risks that such chemicals and chemical groups may present to health or the environment. Section 4(e) of TSCA established the Interagency Testing Committee (ITC) to recommend chemicals and chemical groups to the Administrator of the EPA for priority testing consideration. Section 4(e) directs the ITC to revise the TSCA section 4(e) *Priority Testing List* at least every 6 months.

II. The ITC Fortieth Report

The most recent revisions to the *Priority Testing List* are included in the ITC's Fortieth Report. The Report was received by the EPA Administrator on April 28, 1997, and is included in this notice. The Report removes two isocyanates that were recommended in the 26th Report (55 FR 23050, June 5, 1990), one high production volume chemical, trichloromethane sulfenyl chloride, that was recommended in the 36th Report (60 FR 42982, August 17, 1995)(FRL–4965–6), and 2,4,6-tribromophenol that was recommended in the 39th Report (62 FR 8578, February 25, 1997)(FRL–5580–9).

Trichloromethane sulfenyl chloride is being removed from the *Priority Testing List* because adequate subchronic toxicity data have been submitted to the ITC, monitoring data indicate that trichloromethane sulfenyl chloride is not likely to result in significant exposures to workers, and no additional U.S. Government data needs have been identified at this time.

The ITC is removing 2,4,6-tribromophenol from the *Priority Testing List* after reviewing data obtained from the Chemical Manufacturers Association's Brominated Flame Retardants Industry Panel Manager and representatives from a 2,4,6-tribromophenol manufacturer. These data demonstrated that:

1. 2,4,6-tribromophenol is used as a chemical intermediate to produce bis(tribomophenoxy)ethane, tetrabromobisphenol (a carbonate and epoxy oligomers), brominated epoxy resins and other flame retardants.

2. Greater than 99% of 2,4,6-tribromophenol produced as an end-product is shipped overseas to be used as an intermediate in the production of flame retardants.

3. Environmental and workplace monitoring indicate that 2,4,6-tribromophenol is not likely to result in substantial environmental releases or significant exposures to workers, consumers, or the general population.

Finally, the two isocyanates are being removed from the *Priority Testing List* because these chemicals are used as non-isolated intermediates and this use, combined with a low estimated vapor pressure (< 10–5 millimeter(mm) Mercury(Hg)@25° C) for both chemicals, is not likely to result in environmental releases or exposures to workers, consumers, or the general population.

The ITC is also proposing procedures for chemical trade associations and producers, importers, processors, and users of future ITC-recommended chemicals to voluntarily provide data needed by U.S. Government organizations represented on the ITC and thereby reduce the need for the EPA to promulgate TSCA section 8 reporting rules for these chemicals. The proposed procedures consist of:

1. Refining section 8 data needs.

2. Encouraging electronic data submissions.

3. Providing incentives for producers, importers, processors, and users of chemicals recommended by the ITC to voluntarily submit section 8 information in a form that is rapidly reviewed by the ITC and to establish partnerships with the ITC.

The ITC offers chemical trade associations, producers, importers, processors, and users that provide the ITC with easy-to-review (electronic) submissions and establish partnerships with the ITC the opportunity to potentially eliminate promulgation of TSCA section 8(a) preliminary assessment information reporting and section 8(d) health and safety data reporting rules.

III. Status of the Priority Testing List

The current TSCA section 4(e) *Priority Testing List* contains 11 chemical groups, four of which were designated by the ITC for testing.

IV. Public Record

EPA invites interested persons to submit detailed comments on the ITC's Fortieth Report.

A record has been established for this notice under document control number OPPTS–41048 including comments submitted electronically as described below. A public version of this record, including printed paper versions of electronic comments, which does not contain any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The public record is located in the TSCA Non-Confidential Information Center (NCIC), Rm. NE B–607, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to the ITC at:

walker.johnd@epamail.epa.gov and to the EPA at ncic@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of security encryption. Comments will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format.

The official record for the ITC's Fortieth Report, as well as the public version as described above, will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the EPA address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental protection, Chemicals, Hazardous substances.

Authority: 15 U.S.C. 2603.

Dated: May 28, 1997.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Administrator, U.S. Environmental Protection Agency

Summary

This is the 40th Report of the TSCA Interagency Testing Committee (ITC) to the Administrator of the U.S. Environmental Protection Agency (EPA). In this Report, the ITC is revising its TSCA section 4(e) *Priority Testing List* by removing two isocyanates that were recommended in the 26th Report (55 FR 23050, June 5, 1990), one High Production Volume Chemical, trichloromethane sulfenyl chloride that was recommended in the 36th Report (60 FR 42982, August 17, 1995)(FRL–

4965–6), and 2,4,6-tribromophenol that was recommended in the 39th Report (62 FR 8578, February 25, 1997)(FRL–5580–9). The ITC is also proposing procedures for chemical trade associations and manufacturers, importers, processors, and users of ITC-recommended chemicals to voluntarily provide data needed by the U.S. Government organizations represented on the ITC and thereby reduce the need for the EPA to promulgate TSCA section 8 rules for these chemicals. Comments on this Report should be submitted both to the ITC and the TSCA Public Docket. The revised TSCA section 4(e) *Priority Testing List* follows as Table 1.

TABLE 1.—THE TSCA SECTION 4(e) PRIORITY TESTING LIST (APRIL 1997)[1]

Report	Date	Chemical/Group	Action
26	May 1990	8 Isocyanates	Recommended with intent-to-designate
27	November 1990	62 Aldehydes	Recommended with intent-to-designate
28	May 1991	Chemicals with Low Confidence RfD	Designated
		Acetone	
		Thiophenol	
29	November 1991	10 Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers.	Recommended
30	May 1992	8 Siloxanes	Recommended
31	January 1993	24 Chemicals with insufficient dermal absorption rate data.	Designated
32	May 1993	32 Chemicals with insufficient dermal absorption rate data.	Designated
35	November 1994	24 Chemicals with insufficient dermal absorption rate data.	Designated
36	May 1995	9 High Production Volume Chemicals (HPVCs).	Recommended
37	November 1995	28 Alkylphenols and Ethoxylates	Recommended
39	November 1996	23 Nonylphenol Ethoxylates	Recommended

[1]The list of discrete chemicals currently on the *Priority Testing List* is available from the ITC.

I. Background

The TSCA Interagency Testing Committee (ITC) was established by section 4(e) of the Toxic Substances Control Act (TSCA) ''to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule for testing under section 4(a).... At least every six months..., the Committee shall make such revisions in the *Priority Testing List* as it determines to be necessary and to transmit them to the Administrator together with the Committee's reasons for the revisions'' (Pub. L. 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*). Since its creation in 1976, the ITC has submitted 39 semi-annual (May and November) Reports to the EPA Administrator transmitting the *Priority Testing List* and its revisions. These Reports have been published in the **Federal Register** and are also available from the ITC. The ITC meets monthly and produces its revisions of the List with the help of staff and technical contract support provided by EPA. ITC members and support personnel are listed at the end of this Report.

II. TSCA Section 8 Reporting

TSCA section 8 rules. Following receipt of the ITC's Report and the addition of chemicals to the *Priority Testing List*, the EPA's Office of Pollution Prevention and Toxics adds new chemicals from the List to TSCA section 8(a) and 8(d) rules that require manufacturers and importers of these chemicals to submit TSCA section 8(a) production and exposure data and manufacturers, importers and processors of the listed chemicals to submit TSCA section 8(d) health and safety studies within 60 days of the rules' effective date.

ITC's use of TSCA section 8 data. TSCA section 8(a) and 8(d) submissions are indexed in databases that are maintained by EPA. The ITC reviews the TSCA section 8(a) and 8(d) information and other available data on chemicals and chemical groups (e.g., TSCA section 4(a) and 4(d) studies, TSCA section 8(c) submissions, TSCA section 8(e) ''substantial risk'' notices, ''For Your Information'' (FYI) submissions to EPA, unpublished data submitted to U.S. Government organizations on the ITC and published papers) to determine if revisions to the *List* are necessary. Revisions can include changing a general recommendation to a specific designation for testing action by the EPA Administrator within 12 months, modifying the recommendation, or removing the recommended or designated chemical or chemical group from the *List*.

III. Procedures Promoting More Efficient Use of TSCA Section 8 Resources

A. Introduction

The ITC recognizes that substantive industry and government resources may be consumed to:

1. Promulgate TSCA section 8(a) and 8(d) rules.
2. Retrieve and submit data in response to these rules.
3. Index and review the submitted data.

The ITC is proposing procedures (described below) that promote more efficient use of these resources and that, in some cases, could eliminate the need to promulgate future TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) and section 8(d) Health and Safety Data rules.

B. Procedures

In future Reports to the EPA Administrator, the ITC will implement the following procedures to promote more efficient use of TSCA section 8(a) and 8(d) resources:

1. The ITC will recommend additional chemicals, add these chemicals to the TSCA section 4(e) *Priority Testing List*, and describe specific data necessary to meet the needs of U.S. Government organizations represented on the ITC. Studies for which data are not required under TSCA section 8(a) and 8(d) will be listed, if appropriate; e.g., studies on

mixtures and waste streams of certain chemicals.

2. In the Report describing additional chemical(s) added to the *Priority Testing List*, the ITC will:

a. Ask the EPA not to promulgate TSCA section 8(a) PAIR and TSCA section 8(d) Health and Safety Data rules.

b. Provide an opportunity for manufacturers, importers, processors, and users of chemicals recommended by the ITC to voluntarily provide FYI submissions. Two copies of FYI submissions should be mailed to the Document Processing Center (7407), Attn: FYI Coordinator, Information Management Division, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The cover letter should clearly identify the ITC as the recipient of the submission.

Specific requested information should be submitted (e.g., exposure and use information or toxicity studies) either by individual companies and/or by a consortium as follows:

i. Manufacuturers, importers, processors, or users of chemicals recommended by the ITC or a consortium representing all those manufacturers, importers, processors or users must submit an e-mail or letter of intent to the ITC Executive Director within 30 days of the date the ITC Report is published in the **Federal Register.**

ii. The e-mail or letter of intent must include a list of the types of data that will be voluntarily submitted and a timetable for the submission of the data.

iii. The timetable should reflect the time needed by the ITC to review the data before the next ITC Report is submitted to the EPA Administrator. The e-mail and mailing addresses of the ITC Executive Director are given at the end of this Report.

3. In a subsequent Report to the EPA Administrator, the ITC can ask the EPA to promulgate TSCA section 8(a) PAIR and TSCA section 8(d) Health and Safety Data rules for recommended chemical(s) if insufficient voluntary information is submitted to evaluate the recommended chemical(s). FYI studies should not be re-submitted as TSCA section 8 studies.

C. Supplemental Information

The ITC has had some success in obtaining voluntary exposure, use, and toxicity data from manufacturers, importers, processors, and users of chemicals that have been recommended and added to the *Priority Testing List* and establishing partnerships with chemical trade associations representing those manufacturers, importers, processors, and users. The ITC wants to pursue these voluntary approaches to data sharing and offers a few examples that have been successful in the past. In addition the ITC offers data to support its 30-day information request.

1. *Brominated flame retardants.* The voluntary submission from the Chemical Manufacturers Association's (CMA) Brominated Flame Retardants Industry Panel (BFRIP) Manager and a manufacturer of 2,4,6-tribromophenol provided production, importation, use, and exposure data in a form that was rapidly and easily reviewed by the ITC. In response to voluntarily providing these data in an easily-reviewed form, the ITC requested that the EPA not promulgate a PAIR for 2,4,6-tribromophenol and rapidly removed 2,4,6-tribromophenol from the *List* (see Unit V.A.1 of this ITC Report).

2. *Propylene glycol ethers.* The partnership with the CMA's Propylene Glycol Ethers Panel provided data needed by the Consumer Product Safety Commission (CPSC) that resulted in removal of all propylene glycol ethers from the *Priority Testing List* (60 FR 42982, August 17, 1995).

3. *Silicones.* The partnership with the Silicones Environmental Health and Safety Council (SEHSC) provided data needed by the Food and Drug Administration (FDA) and produced an electronic database of TSCA section 8(d) studies in a format compatible with the TSCA Test Submissions (TSCATS) database that resulted in removal of 43 of 56 siloxanes from the List (61 FR 4188, February 2, 1996).

Note: The ITC encourages manufacturers, importers, processors, or users of chemicals recommended by the ITC to develop TSCATS-compatible databases and to submit electronic information in a form that is rapidly and easily reviewed by the ITC, e.g. the TSCA Electronic Cover Sheet developed by the EPA and the CMA. TSCATS can be searched on the Right-to-Know web site (http:www.rtk.net), where in the future it will be possible to retrieve the TSCA Electronic Cover Sheet.

Thirty-day information requests. The ITC believes that 30 days from the date the ITC Report is published in the **Federal Register** is sufficient time for industry to submit an e-mail or letter of intent. The ITC sends its Reports to hundreds of chemical trade associations, chemical manufacturers, importers, processors, and users as well as numerous public health and environmental groups and chemical industry publications immediately after transmitting its Reports to the EPA Administrator. With this advanced notice of recommended chemicals, prior to **Federal Register** publication, the ITC recognizes that chemical trade associations, and manufacturers, importers, processors, and users of chemicals recommended by the ITC actually have 60- to 120-days notice of the number and type of chemicals that are recommended.

IV. ITC's Partnership Activities During This Reporting Period (November 1996 to April 1997)

Alkylphenols and ethoxylates. The ITC-CMA Alkylphenols and Ethoxylates Dialogue Group was established in March 1996 to facilitate the ITC's retrieval of information on uses, exposures, health effects, and ecological effects of alkyphenols and ethoxylates, and the CMA's understanding of data needed by the U.S. Department of the Interior (DOI), the FDA, the EPA, the National Institute of Environmental Health Sciences (NIEHS), and the U.S. Department of Agriculture (USDA). This dialogue group met to discuss ongoing mammalian toxicology studies.

Isocyanates. The ITC-CMA Diisocyanates Dialogue Group was established in November 1996 to facilitate the ITC's retrieval of information on uses, exposures, and health effects of diisocyanates and the CMA's understanding of data needed by the CPSC, the Department of Defense (DOD), the EPA, the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA). This dialogue group met to discuss production and commercial uses of diisocyanates.

Siloxanes. The ITC-SEHSC Dialogue Group was established in March 1993 to facilitate the ITC's retrieval of information on uses, exposures, and health effects of siloxanes, and the SEHSC's understanding of data needed by the FDA. This dialogue group met to discuss ongoing health effects and exposure studies.

V. Revisions to the TSCA Section 4(e) Priority Testing List

Revisions to the TSCA section 4(e) *Priority Testing List* are summarized in Table 2.

TABLE 2.— REVISIONS TO THE TSCA SECTION 4(e) PRIORITY TESTING LIST

CAS No.	Chemical name	Action	Date
118–79–6	2,4,6-Tribromophenol	Removed	4/97
	High Production Volume Chemicals.		
594–42–3	Trichloromethane sulfenyl chloride	Removed	4/97
	Isocyanates.		
4035–89–6	*Tris*(isocyanatohexyl)biuret	Removed	4/97
5873–54–1	1-Isocyanato-2-((4-isocyanatophenyl)methyl)benzene	Removed	4/97

A. Chemicals Removed From the Priority Testing List

1. *2,4,6-Tribromophenol*—a. *Rationale for removal.* The ITC is removing 2,4,6-tribromophenol from the *Priority Testing List* after reviewing data obtained from the CMA's BFRIP Manager and representatives from a 2,4,6-tribromophenol manufacturer. These data demonstrated that:

i. 2,4,6-tribromophenol is used as a chemical intermediate to produce bis(tribomophenoxy)ethane, tetrabromobisphenol A carbonate and epoxy oligomers, brominated epoxy resins, and other flame retardants.

ii. Greater than 99% of 2,4,6-tribromophenol produced as an end-product is shipped overseas to be used as an intermediate in the production of flame retardants.

iii. Environmental and workplace monitoring indicate that 2,4,6-tribromophenol is not likely to result in substantial environmental releases or significant exposures to workers, consumers, or the general population.

b. *Supporting information.* 2,4,6-Tribromophenol was recommended in the ITC's 39th Report because the NIEHS needed chronic toxicology and 2-year carcinogenesis study data (62 FR 8578, February 25, 1997). 2,4,6-Tribromophenol was recommended and not designated because the ITC wanted to promote a dialogue between 2,4,6-tribromophenol manufacturers and the NIEHS to explain the need for chronic toxicity and 2-year carcinogenesis study data.

Representatives of the ITC and NIEHS met with the CMA's BFRIP Manager and representatives from a 2,4,6-tribromophenol manufacturer to discuss data needs. The ITC and NIEHS representatives provided the CMA with a copy of the 39th Report that summarized existing health and safety data for 2,4,6-tribromophenol. The manufacturer's representatives provided the ITC with a list of studies that were previously submitted under TSCA section 8(d) and a list of producers, applications, commercial activities, and sales statistics.

2. *High Production Volume Chemicals (HPVCs)/trichloromethane sulfenyl chloride*—a. *Rationale for removal.* Trichloromethane sulfenyl chloride (CAS No. 594–42–3) is being removed from the *Priority Testing List* because adequate subchronic toxicity data have been submitted to the ITC, monitoring data indicate that trichloromethane sulfenyl chloride is not likely to result in significant exposures to workers, and no additional U.S. Government data needs have been identified at this time.

b. *Supporting information.* Trichloromethane sulfenyl chloride was a member of a group of 35 HPVCs that were recommended for 90-day subchronic toxicity testing in the ITC's 27th Report (56 FR 99534, March 6, 1991). The Substructure-based Computerized Chemical Selection Expert System (SuCCSES) was used to select these HPVCs during the ITC's sixth scoring exercise. SuCCSES is used to identify chemicals with shared substructures and associated health or ecological effects and similar TSCA production or importation volumes (Ref. 3, Walker, 1995). These HPVCs had annual production volumes exceeding one million pounds, but no 90-day subchronic toxicity data to identify potential health effects concerns. In its 36th Report (60 FR 42982, August 17, 1995), the ITC solicited specific use and exposure information on 12 HPVCs to facilitate its ability to decide whether these chemicals should be removed from the *Priority Testing List* or designated for testing.

As noted in the 37th Report (61 FR 4188, February 2, 1996)(FRL–4991–6), Zeneca, Inc. offered on September 19, 1995, to submit use and exposure information. Zeneca, Inc. provided use and exposure information to the ITC on August 14, 1996 (Ref. 4, Zeneca, 1996). Zeneca reported that of the 7.5 million pounds trichloromethane sulfenyl chloride produced per year, about 7 million pounds are completely consumed in an on-site enclosed process to produce a fungicide. Zeneca also reported that about 0.4 million pounds are shipped to a customer and completely consumed in an on-site enclosed process to produce a fungicide and that about 0.1 million pounds are shipped to a customer and completely consumed in the production of other substances. During manufacturing and use, about 5 workers per site handle trichloromethane sulfenyl chloride. Exposures to workers were less than 25% of the 1971 OSHA Permissable Exposure Level (PEL) of 0.1 parts per million (ppm) (0.8 milligram (mg)/meter (m)^3). The OSHA PEL was promulgated to protect workers against significant risks of eye and respiratory tract irritation, nausea, and pulmonary edema.

ICI Americas (now Zeneca) submitted a 1952 study; 2 dogs, 7 guinea pigs, and 7 rats were exposed to a nominal concentration of 1 ppm trichloromethane sulfenyl chloride for 3 months, 8 hours a day, 5 days a week (Ref. 1, ICI Americas, 1952). Exposures to dogs caused lacrimation, rhinorrhea, nausea, retching, coughing, and sneezing. At the termination of exposure, one dog was sacrificed (the other was held for observations, but no reports were provided) and the gross and microscopic pathology were indicative of bronchopneumonia. Exposures to guinea pigs caused lacrimation, rhinorrhea, and increased respiration; 6 guinea pigs died of pneumonia after 3 weeks. The rats survived, but microscopic examinations of lung tissue revealed thin ruptured alveolar walls, indicative of highly-irritating chemicals that can penetrate the lung.

ICI Americas (now Zeneca) submitted a 1987 study; groups of 18 male and 18 female Sprague-Dawley CD rats were exposed to trichloromethane sulfenyl chloride vapor for 6 hours per day, 5 days per week for between 70 and 72 exposure days (Ref. 2, ICI Americas, 1987). Cumulative concentrations were within 90% of the target concentrations of 0 (control), 0.1, 0.6, and 4 mg/m^3. Treatment-related decreases, relative to control values, were noted in body weights in females at the 4 mg/m^3 exposure level. Increased incidences of salivation (4 mg/m^3 exposure level for males) and sneezing (0.6 and 4 mg/m^3 exposure level for females; 4 mg/m^3 exposure level for males) were noted during the study. At the time of necropsy, mucus was found in the

tracheas of 2 of 18 female and 4 of 18 male rats at the 4 mg/m^3 exposure level. Microscopic observations of acute inflammation and hypertrophy and/or hyperplasia of the respiratory nasal epithelium were noted in both sexes at the 4 mg/m^3 exposure level. These microscopic alterations were apparently caused by the toxic and irritating properties of trichloromethane sulfenyl chloride. In conclusion, subchronic trichloromethane sulfenyl chloride exposures in Sprague-Dawley rats produced treatment-related nasal passage and lung alterations in the 0.6 and 4 mg/m^3 exposure levels. The no-observable-effect level (NOEL) in Sprague-Dawley rats was 0.1 mg/m^3.

3. *Isocyanates*—a. *Rationale for removal.* Two isocyanates are being removed from the *Priority Testing List* because these chemicals are used as non-isolated intermediates and this use, combined with a low estimated vapor pressure (< 10^5 millimeter (mm) mercury (Hg) @25° C) for both chemicals, is not likely to result in environmental releases or exposures to workers, consumers, or the general population.

b. *Supporting information.* In its 26th Report, the ITC recommended a group of 43 isocyanates for physical and chemical property testing in response to a nomination from the EPA to support its TSCA New Chemicals Program (55 FR 23050, June 5, 1990). The ITC removed 28 of these isocyanates from the *Priority Testing List* in its 35th Report (59 FR 67596, December 29, 1994) and 5 more isocyanates in its 37th Report (61 FR 4188, February 2, 1996)(FRL–4923–2).

In its 37th Report, the ITC also solicited consumer use and exposure data, information on the presence of diisocyanates in commercially available products and information on exposures that result from their use. In response to this solicitation, the ITC established a dialogue with the CMA's Diisocyanates Panel and obtained information on commercial uses. As a result, the ITC is removing 2 isocyanates from the *Priority Testing List*: tris(isocyanatohexyl)biuret (CAS No. 4035–89–6) and isocyanato-2-((4-isocyanatophenyl)methyl)benzene (CAS No. 5873–54–1). There are 8 isocyanates remaining on the List (Table 3).

TABLE 3.—ISOCYANATES REMAINING ON THE PRIORITY TESTING LIST

CAS No.	Chemical name
91–08–7	2,6-Toluene diisocyanate (2,6-TDI)

TABLE 3.—ISOCYANATES REMAINING ON THE PRIORITY TESTING LIST

CAS No.	Chemical name
101–68–8	4,4'-Diphenylmethane diisocyanate (MDI)
329–01–1	(α,α,α-Trifluoro-*m*-tolyl)isocyanate
584–84–9	2,4-Toluene diisocyanate (2,4-TDI)
4098–71–9 ...	Isophorone diisocyanate
5124–30–1 ...	1,1'-Methylenebis(4-isocyanatocyclohexane)
26447–40–5	1,1'-Methylenebis(isocyanatobenzene)
26471–62–5	Toluene diisocyanate (80% 2,4-TDI; 20% 2,6-TDI)

VI. References

(1) ICI Americas. Subchronic inhalation study with dogs, guinea pigs and rats (1952). DCN 88–920007341 and Fiche No. OTS0538474.[1]

(2) ICI Americas. Subchronic inhalation study with rats (1987). DCN 88–920007422 and Fiche No. OTS054675.[2]

(3) Walker, J.D. *Estimation Methods Used by the TSCA Interagency Testing Committee to Prioritize Chemicals for Testing: Exposure and Biological Effects Scoring and Structure Activity Relationships.* Toxicology Modeling 1:123–141 (1995).

(4) Zeneca. August 14, 1996 letter from Ms. Terry L. Wells, Product Regulatory Specialist, Zeneca Specialities, Wilmington, Delaware to Dr. John D. Walker, Executive Director, ITC, OPPT/EPA, Washington, DC (1996).

VII. TSCA Interagency Testing Committee

Statutory Organizations and Their Representatives

Council on Environmental Quality
Brad Campbell, Member
Douglas Sanders, Alternate

Department of Commerce
Edward White, Member

Environmental Protection Agency
David R. Williams, Member
Lois Dicker, Alternate

National Cancer Institute
Victor Fung, Member, Chair
Harry Seifried, Alternate

National Institute of Environmental Health Sciences
William Eastin, Member, Vice Chair
H.B. Matthews, Alternate

National Institute for Occupational Safety and Health
Henryka Nagy, Member
David A. Dankovic, Alternate

National Science Foundation
Linda Duguay, Member

Occupational Safety and Health Administration
Lyn Penniman, Member
Christine Whittaker, Alternate

Liaison Organizations and Their Representatives

Agency for Toxic Substances and Disease Registry
William Cibulas, Member

Consumer Product Safety Commission
Val Schaeffer, Member
Lakshmi C. Mishra, Alternate

Department of Agriculture
Clifford P. Rice, Alternate

Department of Defense
David A. Macys, Member

Department of the Interior
Barnett A. Rattner, Member

Food and Drug Administration
Edwin J. Matthews, Member
Raju Kammula, Alternate

National Library of Medicine
Vera Hudson, Member

National Toxicology Program
NIEHS, FDA, and NIOSH Members

Counsel
Mary Ellen Levine, Office of General Counsel, EPA

Technical Support Contractor
Syracuse Research Corporation

ITC Staff
John D. Walker, Executive Director
Norma S.L. Williams, Executive Assistant

TSCA Interagency Testing Committee, U.S. EPA/OPPT (MC/7401) 401 M St., SW., Washington, DC 20460, Phone: 202–260–1825, Fax: 202–260–7895, E-mail: walker.johnd@epamail.epa.gov.

[FR Doc. 97–14578 Filed 6–3–97; 8:45 am]
BILLING CODE 6560–50–F

[1]Studies are available at the EPA's TSCA Non-Confidential Information Center from noon until 4 p.m., Monday through Friday. The center is located in Rm. B-607 of EPA's NE Mall, 401 M St., SW., Washington, DC. Studies on microfiche are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, and the Chemical Information Systems, Inc., 7215 York Road, Baltimore, MD 21212. Studies can be retrieved by using either the document control number (DCN) or fiche number (Fiche No.).

[2]Ibid.

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–59359; FRL–5720–9]

Certain Chemicals; 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–97–5. The test marketing conditions are described below.

DATES: This notice becomes effective May 22, 1997. Written comments will be received until June 19, 1997.

ADDRESSES: Written comments, identified by the docket control number [OPPT–59359] and the specific TME number should be sent to: TSCA Nonconfidential Information Center (NCIC), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. NEB–607 (7407), 401 M St., SW., Washington, DC, 20460, (202) 554–1404, TDD (202) 554–0551.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@epamail.epa.gov. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by [OPPT–59359]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: Shirley D. Howard, New Chemicals Branch, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–611, 401 M St. SW., Washington, DC 20460, (202) 260–3780. e-mail: howard.sd@epamail.epa.gov.

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 human 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–97–5. 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 human 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 this notice must be met.

A notice of receipt of this application was not published in advance of approval. Therefore, an opportunity to submit comments is being offered at this time. EPA may modify or revoke the test marketing exemption if comments are received which cast significant doubt on its finding that this test marketing activity will not present an unreasonable risk of injury.

The following additional restrictions apply to TME–97–5. 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–97–5

Date of Receipt: April 8, 1997. The extended comment period will close June 19, 1997.

Applicant: Reichhold Chemicals Inc.

Chemical: (G) Polyurethane Adhesive.

Use: (G) Hot melted adhesive.

Production Volume: Confidential.

Number of Customers: Confidential.

Test Marketing Period: Confidential. Commencing on first day of commercial manufacture.

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 human 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 human health or the environment.

List of Subjects

Environmental protection, test marketing exemptions.

Dated: May 22, 1997.

Flora Chow,

Chief, New Chemicals Notice Management Branch, Office of Pollution Prevention and Toxics.

[FR Doc. 97–14577 Filed 6–3–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2200]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceedings

May 30, 1997.

Petitions for reconsideration have been filed in the Commission's rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of this document is available for viewing and copying in Room 239, 1919 M Street, NW., Washington, DC or may be purchased from the Commission's copy contractor, ITS, Inc. (202) 857–3800. Oppositions to this petition must be filed by June 19, 1997. See Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of Sections 2.106 of the Commission's Rules to Allocate Spectrum at 2 GHz for Use by the Mobile-Satellite Service. (ET Docket No. 95–18, RM–7927).

Number of Petitions Filed: 2.

Subject: Amendment to The Amateur Service Rules including Amendments for Examination Credit, Eligibility for a Club Station License, Recognition of The Volunteer Examiner Session Manager, a Special Event Call Sign System, and Self-Assigned Indicator in the Station Identification. (WT Docket No. 95–57, RMs–8301, 8418 and 8462).

Number of Petitions Filed: 1.

Subject: Toll Free Service Access Codes (CC Docket No. 95–155).

Number of Petitions Filed: 7.

Subject: Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies governing Them and Examination of Exclusivity and Frequency Assignments Policies of the Private Land Mobile Services. (PR Docket No. 92–235).

Number of Petitions Filed: 13.

Subject: Administration of the North American Numbering Plan Carrier Identifications Codes (CICs). (CC Docket No. 92–237).

Number of Petitions Filed: 3.

Federal Communications Commission.

LaVera F. Marshall,

Acting Secretary.

[FR Doc. 97–14472 Filed 6–3–97; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

[Docket No. 97–09]

Topocean Consolidation Service Ltd., Topocean Consolidation Service (Los Angeles) Inc. and Topocean Consolidation Service (New York) Inc. Possible Violations of Sections 8, 23(a) and 10(a)(1) of the Shipping Act of 1984; Order of Investigation and Hearing

Topocean Consolidation Service Ltd. (''Topocean Taiwan'') is a tariffed and bonded non-vessel-operating common carrier (''NVOCC'') located at 11F–1, 316, Sec. 5 Nan-King East Road, Taipei, Taiwan. Topocean Taiwan holds itself out as a NVOCC pursuant to its Automated Tariff Filing and Information System (''ATFI'') tariff, FMC No. 012067–002, effective June 12, 1996. According to Rule 24 of its tariff, Topocean Taiwan's resident agent in the United States for service of process is Topocean Consolidation Service (Los Angeles) Inc. located at 3780 W. Century Blvd., Inglewood, CA 90303. Between October 20, 1993 and September 15, 1995, Topocean Taiwan maintained an ATFI tariff (FMC No. 012067–001) which was canceled by the Federal Maritime Commission (''Commission'') in September 1995 for Topocean Taiwan's failure to maintain a NVOCC bond. In conjunction with filing its current tariff, Topocean Taiwan furnished a NVOCC bond, No. 18017, effective May 2, 1996 and issued by American Contractors Indemnity Company in Los Angeles, CA.

Topocean Consolidation Service (Los Angeles) Inc. (''Topocean LA'') is a tariffed and bonded NVOCC located at 3780 W. Century Blvd., Inglewood, CA. Topocean LA holds itself out as a NVOCC pursuant to its ATFI tariff, FMC No. 014097–001, effective June 12, 1996. Topocean LA maintains a NVOCC bond, No. 15885, issued by American Contractors Indemnity Company, located in Los Angeles, CA. Topocean LA is a United States destination agent for shipments from Topocean Taiwan.

Topocean Consolidation Service (New York) Inc. (''Topocean NY'') is a destination agent in the New York area for shipments from Taiwan and Hong Kong. Topocean NY is located at 145–17 155th St., Jamaica, NY 11434. It does not maintain with the Commission a NVOCC bond and tariff nor is it a licensed ocean freight forwarder. Topocean NY is a United States destination agent for shipments from Topocean Taiwan.

Topocean Taiwan appears to have operated as a NVOCC on numerous shipments between September 16, 1995 and June 11, 1996. A NVOCC is a common carrier that holds itself out to the public as a provider of ocean transportation for compensation and acts as a shipper in its relationship with an ocean common carrier for the transportation of cargo of other persons. Topocean Taiwan's ocean shipments originated in Taiwan and were discharged at United States ports. Each shipment generally reflects that a Topocean Taiwan ''house'', or NVOCC, bill of lading was issued in which Topocean Taiwan held itself out as a provider of ocean transportation. The NVOCC bill of lading would be tendered by the ultimate consignee to one of Topocean Taiwan's destination agents [1] upon arrival of the cargo at its United States destination. In each of these instances, Topocean Taiwan was listed as shipper on the ocean carrier's bill of lading. Thus, Topocean Taiwan, by providing and holding out to the public to provide transportation by water of cargo for compensation and by contracting as a shipper in relation to a common carrier for the transportation of cargo of other persons, appears to have operated as a NVOCC for these shipments.

According to the records of the Commission's Bureau of Tariffs, Certification and Licensing (''BTCL''), Topocean Taiwan did not have an effective tariff during this time period. Section 8 of the Shipping Act of 1984 (''1984 Act''), 46 USC app. 1707, provides that no common carrier may provide service in the United States foreign trade unless the carrier first has filed a tariff with the Commission showing all of its rates, charges and practices. Section 8 also states that no new rates may become effective earlier than 30 days after filing at the Commission. The Commission's regulations implementing this statutory provision, at 46 CFR 514.9(b)(9)(i)(A), explain that ''[n]ew tariffs * * * shall * * * be filed to become effective not earlier than 30 days after the date of filing.'' [2] Therefore, it would appear that Topocean Taiwan may have acted as a NVOCC for shipments which occurred between September 16, 1995, and June 11, 1996, without an effective tariff in violation of section 8 of the 1984 Act.

Section 23(a) of the 1984 Act, 46 U.S.C. app. 1721(a), requires every NVOCC to furnish to the Commission ''a bond, proof of insurance, or other such surety, as the Commission may require.'' Between September 16, 1995 and May 2, 1996, Topocean did not furnish a bond, proof of insurance or other such surety to the Commission as required by section 23(a). Therefore, Topocean Taiwan appears to have acted as a NVOCC for shipments which occurred between September 16, 1995 and May 2, 1996, without a bond, proof of insurance or other such surety in violation of section 23(a) of the 1984 Act.

It appears that Topocean LA and Topocean NY, in concert with Topocean Taiwan, knowingly and willfully obtained or attempted to obtain ocean transportation for cargo at less than the applicable rates in violation of section 10(a)(1) of the 1984 Act, 46 U.S.C. 1709(a)(1), by means of misdescription of commodities for numerous shipments transported by ocean common carriers between September 1, 1995 and April 30, 1997. Section 10(a)(1) of the 1984 Act prohibits any person knowingly and willfully, directly or indirectly, by means of false billing, false classification, false weighing, false report of weight, false measurement, or by any other unjust or unfair device or means, to obtain or attempt to obtain ocean transportation for property at less than the rates or charges that would otherwise be applicable.

It appears that the misdescribed shipments originated in Taiwan or Hong Kong and were discharged at or via United States ports. In each of these instances, Topocean Taiwan usually was listed as shipper on the ocean carrier's bill of lading, and the destination agents, Topocean LA and Topocean NY, acted as the consignee or notify party. Each shipment generally reflects that a Topocean Taiwan ''house'', or NVOCC, bill of lading, which correctly describes the commodity shipped, was issued for tender by the ultimate consignee to Topocean LA or Topocean NY upon

[1] Topocean Taiwan has at least three United States destination agents: Topocean LA, Topocean NY and Apex Maritime Co., Inc. (located near San Francisco, CA).

[2] The Commission's regulations at 46 CFR 514.1(e)(1), provide that ''[o]perating without an effective tariff on file with the Commission * * * is unlawful.''

arrival of the cargo at destination. The commodity descriptions on the NVOCC bills of lading do not match the commodity descriptions set forth on the ocean common carriers' bills of lading. According to the ocean common carriers' tariffs and service contracts, the commodities described on the ocean common carriers' bills of lading appear to have lower rates than the commodities described on the NVOCC 's bills of lading.

It further appears that the ocean common carriers rated the commodities in accordance with the inaccurate descriptions, while Topocean LA and Topocean NY accepted delivery of the cargo and paid ocean freight to the ocean common carriers on the basis of the lower rates attributable to the inaccurate commodity descriptions. Contemporaneous with the payment of freight, Topocean LA and Topocean NY issued arrival notices to the U.S. importers, which correctly described the commodity based on actual contents shipped. The resulting profit on these shipments would be divided equally between the United States destination agent (Topocean LA or Topocean NY) and Topocean Taiwan. Thus, Topocean NY and Topocean LA appear to have increased their profits on these shipments because of the misdescriptions. Therefore, it seems that Topocean LA and Topocean NY knowingly and willfully obtained or attempted to obtain ocean transportation for property at less than the applicable rates in violation of section 10(a)(1) of the 1984 Act.

Between September 1, 1995 and April 30, 1997, it appears that Topocean LA, in concert with Topocean Taiwan, knowingly and willfully obtained or attempted to obtain ocean transportation for property at less than the applicable rates in violation of section 10(a)(1) of the 1984 Act by means of false cargo measurements. In each instance, the ocean common carrier substituted a larger container for the container presumably requested by Topocean Taiwan. In accordance with the ocean common carrier's ''equipment substitution'' rule, the ocean freight for the requested container would be charged if the cargo's measurement did not exceed that which could be loaded into the requested container. The shipment record indicates that the substituted container was loaded beyond the cubic capacity of the requested container, but the ocean common carrier's bill of lading shows a cargo measurement which is less than that which could have been loaded into the requested container. As a result, Topocean LA paid the ocean freight for the requested containers rather than the higher ocean freight for the substituted containers.

The shipment records demonstrate that Topocean LA was cognizant that the shipments had been misdeclared as to the cubic measurement and were loaded at higher measurements only possible through the provision of a larger container. However, Topocean LA apparently paid the ocean freight according to the inaccurate measurement shown on the ocean common carrier's bill of lading. Therefore, it appears that Topocean LA knowingly and willfully obtained or attempted to obtain ocean transportation for property at less than the applicable rates between September 1, 1995 and April 30, 1997 in violation of section 10(a)(1).

On June 12, 1996, Topocean Taiwan became a tariffed and bonded NVOCC. At that time, Topocean Taiwan's shipments could be accepted by ocean common carriers,[3] and this cargo could be rated in accordance with ocean common carriers' applicable tariffs or service contracts. Based upon the facts set forth above, it appears that between June 12, 1996 and April 30, 1997, Topocean Taiwan may have obtained or attempted to obtain ocean transportation for property at less than the applicable rates by means of false cargo measurements or misdescriptions of cargo in violation of section 10(a)(1) of the 1984 Act.

Under section 13 of the 1984 Act, 46 USC app. 1712, a person is subject to a civil penalty of not more than $25,000 for each knowing and willful violation of the 1984 Act. In addition, section 23 of the 1984 Act, 46 U.S.C. app. 1721, provides that a common carrier's tariff may be suspended for violations of sections 10 (a)(1) of the 1984 Act.

Now therefore, it is Ordered, That pursuant to sections 3, 8, 10, 11, 13, 14 and 23 of the 1984 Act, 46 U.S.C. app. 1702, 1707, 1709, 1710, 1712, 1713 and 1721, and 46 CFR Part 514, an investigation is instituted to determine:

(1) Whether Topocean Consolidation Service Ltd. violated section 8 of the 1984 Act by operating as a common carrier without an effective tariff on file at the Commission between September 16, 1995 and June 11, 1996;

(2) Whether Topocean Consolidation Service Ltd. violated section 10(a)(1) of the 1984 Act between June 12, 1996 and April 30, 1997, by directly or indirectly obtaining ocean transportation for property at less than the rates and charges otherwise applicable by means of misdescriptions of commodities or false cargo measurements;

(3) Whether Topocean Consolidation Service Ltd. violated section 23(a) of the 1984 Act, by providing non-vessel-operating common carrier services without an effective bond filed at the Commission between September 16, 1995 and May 2, 1996;

(4) Whether Topocean Consolidation Service (Los Angeles) Inc. and/or Topocean Consolidation Service (New York) Inc. violated section 10 (a)(1) of the 1984 Act between September 1, 1995 and April 30, 1997, by directly or indirectly obtaining transportation at less than the rates and charges otherwise applicable by means of misdescription of commodities;

(5) Whether Topocean Consolidation Service (Los Angeles) Inc. violated section 10(a)(1) of the 1984 Act between September 1, 1995 and April 30, 1997, by directly or indirectly obtaining or attempting to obtain ocean transportation at less than the rates and charges otherwise applicable by means of false cargo measurements;

(6) Whether, in the event violations of section 8, 10 (a)(1) and 23(a) of the 1984 Act are found, civil penalties should be assessed against Topocean Consolidation Service Ltd., Topocean Consolidation Service (Los Angeles) Inc., and Topocean Consolidation Service (New York) Inc. and, if so, the amount of penalties to be assessed;

(7) Whether, in the event violations of section 10 (a)(1) of the 1984 Act are found, the tariffs of Topocean Consolidation Service Ltd. and Topocean Consolidation Service (Los Angeles) Inc. should be suspended or canceled; and

(8) Whether, in the event violations of the 1984 Act are found, an appropriate cease and desist order should be issued against Topocean Consolidation Service Ltd., Topocean Consolidation Service (Los Angeles) Inc. and Topocean Consolidation Service (New York) Inc.

It is further Ordered, That a public hearing be held in this proceeding and that this matter be assigned for hearing before an Administrative Law Judge of the Commission's Office of Administrative Law Judges at a date and place to be hereafter determined by the Administrative Law Judge in compliance with Rule 61 of the Commission's Rules of Practice and Procedure, 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Administrative Law Judge only after consideration has been given by the parties and the Presiding

[3] Section 10(b)(14) of the 1984 Act, 46 U.S.C. app. 1709(b)(14), prohibits ocean common carriers from knowingly and willfully accepting cargo from or transporting cargo for the account of an untariffed and unbonded NVOCC.

Administrative Law Judge to the use of alternative forms of dispute resolution, and upon a proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matters in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record;

It is further Ordered, That Topocean Consolidation Service Ltd., Topocean Consolidation Service (Los Angeles) Inc. and Topocean Consolidation Service (New York) Inc. are designated as Respondents in this proceeding;

It is further Ordered, That the Commission's Bureau of Enforcement is designated a party to this proceeding;

It is further Ordered, That notice of this Order be published in the **Federal Register**, and a copy be served on parties of record;

It is further Ordered, That other persons having an interest in participating in this proceeding may file petitions for leave to intervene in accordance with Rule 72 of the Commission's Rules of Practice and Procedure, 46 CFR 502.72;

It is further Ordered, That all further notices, orders, and/or decisions issued by or on behalf of the Commission in this proceeding, including notice of the time and place of hearing or prehearing conference, shall be served on parties of record;

It is further Ordered, That all documents submitted by any party of record in this proceeding shall be directed to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, in accordance with Rule 118 of the Commission's Rules of Practice and Procedure, 46 CFR 502.118, and shall be served on parties of record; and

It is further Ordered, That in accordance with Rule 61 of the Commission's Rules of Practice and Procedure, the initial decision of the Administrative Law Judge shall be issued by May 29, 1998 and the final decision of the Commission shall be issued by September 28, 1998.

Joseph C. Polking,

Secretary.

[FR Doc. 97–14470 Filed 6–3–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 18, 1997.

A. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Willard M. Johnson, as managing general partner of the WMJ/RMJ Family Limited Partnership II, Houston, Texas; to acquire 17.7 percent of the voting shares of Jamestown Union Bancshares, Inc., Jamestown, Tennessee, and thereby indirectly acquire Union Bank, Jameston, Tennessee.

B. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. John B. Bedene, Bruce Fowler Bedene, Becky Suzanne Bualle, and Barry William Bedene, as co-trustees of the Trust Estate established by the Will of John H. Bedene, Deceased, all of Arma, Kansas; to acquire 51 percent of the voting shares of Bedene Insurance Agency, Inc., Arma, Kansas, and thereby indirectly acquire The First State Bank, Arma, Kansas.

C. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Alvin L. Fields, Honey Grove, Texas; to acquire an additional 40.97 percent, for a total of 50 percent; and Ronald L. Wilburn, San Antonio, Texas, to acquire a total of 50 percent, of the voting shares of Quadco Bancshares, Inc., Ladonia, Texas, and thereby indirectly acquire Farmers and Merchants State Bank, Ladonia, Texas.

Board of Governors of the Federal Reserve System, May 29, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–14475 Filed 6–3–97; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 27, 1997.

A. Federal Reserve Bank of New York (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. MSB Mutual Holding Company, and MSB Financial Corp., both of Wall Township, New Jersey; to become bank holding companies by acquiring 100 percent of the voting shares of Manasquan Savings Bank, Wall Township, New Jersey.

B. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. ECSB Holding Company, Inc., Fort Walton Beach, Florida; to merge with American National Financial Corporation, Panama City, Florida, and thereby indirectly acquire First National Bank Northwest Florida, Panama City, Florida.

C. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. Simmons First National Corporation, Pine Bluff, Arkansas; to acquire 100 percent of the voting shares of First Bank of Arkansas, Russellville, Arkansas, and thereby indirectly acquire First Bank of Arkansas, Searcy, Arkansas.

D. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480-2171:

1. State Bank of Hawley Employee Stock Ownership Plan and Trust, Hawley, Minnesota; to acquire 32.8 percent of the voting shares of Bankshares of Hawley, Inc., Hawley, Minnesota, and thereby indirectly acquire State Bank of Hawley, Hawley, Minnesota.

E. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Moody Bancshares, Inc., Galveston, Texas, and Moody Bank Holding Company, Reno, Nevada; each to acquire an additional 0.38 percent, for a total of 25.4 percent, of the voting shares of The Moody National Bank of Galveston, Galveston, Texas.

2. New Woodson Bancshares, Inc., Graham, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of Woodson Bancshares, Inc., Woodson, Texas, and thereby indirectly acquire First State Bancorp, Inc., Carson City, Nevada, and First State Bank, Graham, Texas.

Board of Governors of the Federal Reserve System, May 29, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–14476 Filed 6–3–97; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Advisory Committee Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following advisory committee scheduled to meet during the month of June 1997:

Name: Health Services Research Dissemination Study Section.

Date and Time: June 19, 1997, 7:30 a.m.

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Delaware Room, Bethesda, Maryland 20815.

Open June 19, 1997, 7:30 a.m. to 7:45 a.m.

Closed for remainder of meeting.

Purpose: The Study Section is charged with the review of and making recommendations on grant applications for Federal support of conferences, workshops, meetings, or projects related to dissemination and utilization of research findings.

Agenda: The open session of the meeting on June 19, from 7:30 a.m. to 7:45 a.m. will be devoted to a business meeting covering administrative matters. During the closed session, the panel will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, Agency for Health Care Policy and Research, has made a formal determination that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members, minutes of the meeting, or other relevant information should contact Carmen Johnson, Office of Scientific Affairs, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594–1449 x1613.

Agenda items for all meetings are subject to change as priorities dictate.

Dated: May 21, 1997.

John Eisenberg,

Administrator.

[FR Doc. 97–14545 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 DAY–11–97]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

1. Continuing Medical Education (CME) Activity Registration Form—(0923–0013)—Extension—The Agency for Toxic Substances and Disease Registry (ATSDR) is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, The Superfund Amendments and Reauthorization Act (SARA), to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances into the environment. As stated in CERCLA, the Administrator of ATSDR is charged to ''assemble, develop as necessary, and distribute to the states, and upon request to medical colleges, physicians, and other health professionals, appropriate educational materials (including short courses) on this topic''.

The development and use of activity registration forms for documenting participation in these activities at these meetings is an integral part of this process. This attendance documentation process is required by the Accreditation Council for Continuing Medical Education (ACCME), the body that authorizes agencies and institutions to award nationally recognized continuing medical education (CME) credit. As a condition of relicensure, physicians in 40 states are required to participate in CME courses. Individual physicians in these states are required to submit the number of hours of CME credit to state boards of professional registration at the time of relicensure. Failure by the physician to provide this information in a timely fashion will result in suspension of professional licensure.

This request is for a 3-year extension of the current OMB approval of uniform CME activity registration forms—one machine entry form and the other manually entered—to serve as the initial step in the development of an attendance documentation system. The total annual burden hours are 83.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)	Total burden (in hrs.)
Manual Entry Registration Form	500	1	0.083	41.5
Scantron Registration Form	500	1	0.083	41.5

Dated: May 29, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–14531 Filed 6–3–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Community-Based Primary Prevention Programs to Prevent Intimate Partner Violence for a Safe America, Program Announcement 727: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreements for Community-Based Primary Prevention Programs to Prevent Intimate Partner Violence for a Safe America, Program Announcement 727.

Time and Date: 8:30 a.m.–5 p.m., June 24–25, 1997.

Place: Ramada Plaza Hotel, 4001 Presidential Parkway, Atlanta, Georgia 30341.

Status: Closed.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 727.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Contact Person for More Information: James S. Belloni, Associate Director, State and Community Activities, National Center for Injury Prevention and Control, CDC, M/S K02, 4770 Buford Highway, NE, Atlanta, Georgia 30341–3724, telephone 770/488–4538.

Dated: May 28, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–14524 Filed 6–3–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Determination of Optimal Frequency and Minimum Power Requirements for a New Radio-Frequency-Controlled Electrical Injury Protection System study protocol peer review.

Time and Date: 8:30–11:30 a.m., June 24, 1997.

Location: Suncrest Facility, Large Conference Room, NIOSH, CDC, 3040 University Avenue, Morgantown, West Virginia 26505.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: Participants will provide NIOSH with their individual advice and comments regarding technical and scientific aspects of the NIOSH protocol Determination of Optimal Frequency and Minimum Power Requirements for a New Radio-Frequency-Controlled Electrical Injury Protection System. Peer review panelists will review the study protocol and provide individual advice on the conduct of the study. Viewpoints and suggestions from industry, labor, academia, other governmental agencies, and the public are invited.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Shengke Zeng, NIOSH, CDC, M/S 119, 1095 Willowdale Road, Morgantown, West Virginia 26505, telephone (304) 285–5971.

Dated: May 29, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–14523 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0180]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the preapproved or emergency shipment of a blood product for manufacturing prior to completion of hepatitis B surface antigen (HBsAg) testing and shipment of a blood product for manufacturing when the donor is known to be reactive for HBsAg.

DATES: Submit written comments on the collection of information by August 4, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600

Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Shipment of a Blood Product Prior to Completion of Testing for Hepatitis B Surface Antigen (HbsAg)—21 CFR 610.40(b); and Shipment of Blood Products Known Reactive for HbsAg—21 CFR 610.40(d)—(OMB Control Number 0910–0168)—Reinstatement

Under Sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 264), FDA prescribes standards designed to ensure the safety, purity, potency, and effectiveness of biological products including blood and blood components and to prevent the transmission of communicable diseases. To accomplish this, FDA requires, among other things, that each unit of Whole Blood or Source Plasma be tested by a licensed serologic test for HbsAg. Section 610.40(b)(4) (21 CFR 610.40(b)(4)) permits preapproved or emergency shipments of blood products for further manufacturing before the test for HBsAg is completed. To obtain approval for such shipments, the collection facility must submit a description of the control procedures to be used by the collection facility and manufacturer. Proper control procedures are essential to ensure the safe shipment, handling, quarantine of untested or incompletely tested blood products, communication of test results, and appropriate use or disposal of the blood products based on the test results. Section 610.40(d)(1) and (d)(2) requires that a collection facility notify FDA of each shipment of HBsAg reactive source blood, plasma, or serum for manufacturing into hepatitis B vaccine and licensed or unlicensed in vitro diagnostic biological products, including clinical chemistry control reagents. The reporting requirements inform FDA of the shipment of potentially infectious biological products that may be capable of transmitting disease. The respondents for this information collection are the blood collection facilities that are shipping hepatitis B reactive products. FDA's monitoring of such activity is essential in the event that any deviations occur that may require immediate corrective action to protect public safety. The labeling helps ensure that product is safely and appropriately handled and used by the collection facility, shipper, and manufacturer.

Only a few firms are actually engaged in shipping hepatitis B reactive products and making the reports required by § 610.40. Further, there are very few to no emergency shipments per year related to further manufacturing and the only product currently shipped prior to completion of hepatitis B testing is a licensed product, Source Leukocytes. Shipments of Source Leukocytes are preapproved under the product license applications and do not require notification for each shipment. Currently, there have been no respondents reporting emergency or preapproved shipments (§ 610.40(b)). However, FDA is currently listing one report per year for emergency or preapproved shipments to account for the possibility of future emergency shipments.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.40(b)[1]	1	1	1	0.5	0.5
610.40(d)[2]	6	8.5	51	0.5	25.5

There are no capital costs or operating and maintenance costs associated with this information collection.

[1] This notice involves a brief letter and an enclosure. The letter identifies who is making the shipment, to whom the product was shipped, the nature of the emergency, the kind and quantity shipped, and the date of shipment. The enclosure is a copy of the shippers written standard operating procedures for handling, labeling storage, and shipment of contaminated (contagious) product. The burden for development and maintenance of standard operating procedures is approved under OMB No. 0910–0116. Preparation of the notice and duplication of standard operating procedure documents is estimated at one half hour per notice.

[2] The notice of reactive product shipment is limited to information on: the identity of the kind and amount of source material shipped; the name and address of the consignee; the date of shipment; and the manner in which the source material is labeled.

FDA has calculated no additional burden in this information collection package for the labeling requirements in § 610.40(d) because the information and statements on the label necessary for public disclosure and safety are provided by FDA in these regulations. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: May 28, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–14601 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0202]

Draft Guidance on Equivalence Criteria for Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing for public comment the criteria that the agency intends to use in evaluating whether the regulatory systems used by foreign countries to ensure the safety of foods exported to the United States for human consumption are equivalent to the regulatory system of the United States. Based on its evaluation, FDA will decide whether to institute the proceedings necessary to enter into an equivalence agreement with the foreign country.

DATES: Submit written comments by August 4, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Center for Food Safety and Applied Nutrition (HFS–415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3152.

SUPPLEMENTARY INFORMATION:

I. The SPS Agreement

Under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (the SPS Agreement), each member nation of the WTO, including the United States, is obligated to accept as equivalent a food regulatory system of another country if it provides the same level of health protection as is provided to consumers by its own system.

Equivalent regulatory systems need not be identical. Under the concept of equivalence, the ''sanitary or phytosanitary measures'' used by an exporting country may differ from the measures applied domestically by an importing country so long as these measures ''achieve the importing Member's appropriate level of sanitary or phytosanitary protection.'' According to the SPS Agreement, ''sanitary or phytosanitary measures'' include all relevant laws, decrees, and regulations; as well as procedures relating to end-product criteria, processes and production methods, testing, and inspection. Essentially, SPS measures include virtually any measure to protect human health arising from risks in food.

Under the SPS Agreement, the burden of demonstrating that equivalence exists rests with the exporting country. The importing country has the right to decide for itself whether the regulatory system of the exporting country is equivalent to its own or is inadequate to achieve ''the importing Member's appropriate level of sanitary or phytosanitary protection,'' or that inadequate evidence has been provided to demonstrate equivalence. The SPS Agreement specifies that exporting countries allow ''reasonable access'' to the importing country to inspect or carry out other procedures for evaluating equivalence. If the exporting country can demonstrate equivalence, the importing country ''shall accept'' the exporting country's system as equivalent.

Additionally, each member country is obligated to ''enter into consultations'' with a requesting country ''with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.'' Although the SPS Agreement does not require that every finding of equivalence of a measure or system of measures between countries should result in a bilateral or multilateral agreement, the SPS Agreement does require that members consult, if requested, with that potential goal.

A number of exporting nations have requested that the United States enter into consultations with them for the purpose of developing equivalence agreements for seafood. One reason for these requests is that FDA regulations for seafood (part 123 (21 CFR part 123)) mandate responsibilities for importers that are deemed to be met whenever an equivalence agreement exists that covers the seafood products being imported into the United States. These regulations become effective December 18, 1997 (60 FR 65096 to 65202, December 18, 1995).

Equivalence for other types of products is being discussed with exporting countries at their request. Similarly, the United States is seeking equivalence determinations from certain countries to which it exports food products.

It would be useful, therefore, for FDA to articulate how it intends to carry out equivalence determinations. FDA has decided that the best way to do so is by developing and publishing criteria that the agency intends to apply in determining whether equivalence exists between the U.S. food regulatory system and that of an international trading partner whose regulatory system is not essentially identical to the U.S. system.

FDA intends these criteria as guidelines that represent the agency's current thinking on equivalence for the SPS Agreement. The guidelines do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

II. Potential for Public Health and Other Benefits From Equivalence

FDA takes the view that equivalence in food safety measures between the United States and its international trading partners can be beneficial and should be fostered for its own sake. As countries achieve equivalence with the U.S. advanced regulatory system, consumers in this country will have greater assurance that imported foods are as safe and wholesome as domestically produced foods.

The situation with food imports into the United States provides an excellent example of the desirability of achieving equivalence between the United States and its trading partners. Food is imported into the United States from around the world and the number of formal customs entries every year is about 1.5 million.

For the most part, FDA's inspections of food processing facilities in other countries can occur only on a limited basis. Foreign inspections are extremely costly and usually are not undertaken without an invitation from the foreign country. FDA does make a consistent effort to inspect the foreign processors of some types of products, such as infant formula, but the number of such processors—and thus the number of such inspections—is relatively low.

FDA's traditional surveillance system for food imports has largely consisted of reviewing customs entries, engaging in field examinations and collecting samples for laboratory analysis, and placing products with a history of problems on detention without physical examination. While FDA performs either an electronic screening or a documentary review of virtually all customs entries with the help of automated systems, the agency can physically examine only a very small percentage of these entries. Huge sums of money would be needed to enable

FDA to increase its physical examination and sampling program.

Where equivalence has been determined to exist, however, the work of the foreign regulatory authority should serve to help ensure the safety of imports for U.S. consumers. Since the foreign inspection system will have been found to be equivalent to FDA's inspection system, FDA will be able to rely on the results of the foreign inspection system.

The possibility of equivalence agreements between and among international trading partners, with rights and benefits that accrue to the parties involved, provides an incentive for countries to improve their regulatory systems and the public health of their food exports as a means of achieving equivalence with more advanced regulatory systems. As equivalence is achieved, and agreements are reached recognizing the achievement of equivalence, trade is likely to flow more freely because of the reduced need by importing countries to engage in resource-intensive sampling and examination of products being offered for entry from countries with equivalent systems. For the United States, equivalence agreements will also mean that FDA will be able to target the limited resources it has for imports toward products from countries that have not been determined to be equivalent. Thus, FDA will be able to use its resources more efficiently and effectively. U.S. industry can also benefit from these agreements because in those cases where the U.S. system is found to be equivalent to that of its trading partners, acceptance of U.S. products by those countries is assured. The purposes and types of equivalence agreements are described later in this notice.

Finally, where equivalence exists and is acknowledged in an agreement, there will be no need under many circumstances for importing nations to continue to require certificates from the competent regulatory authority of the exporting country to accompany each shipment. (FDA does not generally require that imported products be accompanied by certificates; however, there is an increasing trend for foreign countries to require such certificates.) Where there is recognition that the exporting country's system provides an appropriate level of sanitary or phytosanitary protection, the issuance of certificates for specific products would represent a needless expenditure of public health resources with no obvious advantage to consumers or to industry. Adequate assurances may be achieved by providing lists of food processors that are in good standing with the regulatory authority of the exporting country or similar information.

III. Problem Solving Agreements vs. Equivalence Agreements

FDA has experience developing and entering into bilateral agreements with trading partners for the purpose of providing assurance that food from those countries will be safe for U.S. consumers. However, these agreements have focused on assuring compliance with U.S. requirements by the foreign regulatory authority for foods that present high risks or that have had persistent compliance problems, rather than on whether the regulatory systems were equivalent. Such agreements involve the application of virtually identical measures by the exporting and importing country to the subject commodity or compliance with specific end-product criteria to address a food safety problem.

For example, FDA has several longstanding Memoranda of Understanding (MOU's) with nations that export raw molluscan shellfish to the United States. Under these MOU's, each country has agreed to abide by the same detailed standards for regulating the growing and harvesting of raw molluscan shellfish that U.S. States have agreed to follow. These countries have entered into such MOU's in order to have access to the U.S. market. Under a Federal-State cooperative arrangement for raw molluscan shellfish, the National Shellfish Sanitation Program (NSSP), FDA lists the processors who have been found to be in compliance by States and countries that have a shellfish program that meets the NSSP standards. States decide what shipments of shellfish they will act against based on whether the processor of the shellfish is included on FDA's list. Recently, some of the countries with MOU's have expressed an interest in converting their MOU's from compliance-type agreements to equivalence agreements to permit some variations from the details of the U.S. program.

FDA has also periodically entered into MOU's or other less formal agreements with countries that have a significant volume of trade with the United States in certain products but have developed chronic, safety-related problems with these products. In these cases, the agreement is intended to correct these problems. Examples include agreements aimed at the control of excessive levels of lead and cadmium leaching from ceramicware for food use, the control of pesticide residues in certain types of fruits, and the control of pathogenic microorganisms in soft ripened cheese and certain dried milk products.

Traditionally, FDA has assigned a higher priority to agreements targeted toward solving specific problems than it has to recognizing foreign food control systems as providing the same level of protection as those in the United States. This policy of favoring problem solving agreements over others is set forth in FDA's Compliance Policy Guide (CPG) section 100.900, Attachment A, which contains the agency's criteria for how it will prioritize international MOU's.

In December 1995, FDA entered into a compliance-based Cooperative Arrangement with the New Zealand Ministries of Agriculture and Health for the purpose of ensuring the safety of fish and fishery products traded between the two countries. Significantly, it was not a problem solving agreement. Rather, it recognized that the strong regulatory systems in the United States and New Zealand enhanced the likelihood that products from each country would comply with the regulatory requirements of the other. The participants agreed to take this recognition into account in determining the frequency of border checks for fish and fishery products traded between the United States and New Zealand. While this arrangement was not intended to be an equivalence agreement, it does reflect the principle that the employment of comparable, high-standard regulatory systems by international trading partners can enable each nation to enhance the public health protection of its consumers and shift inspectional resources to other, more risky, products.

Although FDA continues to see merit in narrowly focused, problem solving MOU's, the agency also sees value in pursuing equivalence agreements. Therefore, FDA is considering revising CPG section 100.900, Attachment A, ''Food and Drug Administration Criteria for Memoranda of Understanding'' to add recognition of equivalence as a basis for entering into agreements with foreign governments. Should the agency choose to do so, it will issue a separate notice to that effect, with an opportunity for public comment.

IV. Possible Forms that Equivalence Agreements Could Take

There are several possible forms that equivalence agreements could take, depending upon the relevant circumstances.

A. ''One-Way'' Agreements vs. ''Two-Way'' Agreements

Equivalence agreements can involve simultaneous determinations by two countries that their regulatory systems are equivalent to one another (''two-way'' agreements). This is the favored type of agreement from FDA's standpoint. A determination that a trading partner's regulatory system is equivalent to the U.S. system means that imports from that country have been produced under circumstances that provide U.S. consumers with the same level of protection as domestic products. A determination by the trading partner that the U.S. system is equivalent to its system helps ensure that exports from the United States will flow freely to the country in question. It will be FDA's policy to negotiate ''two-way'' agreements whenever practicable.

FDA may, however, enter into ''one-way'' agreements as appropriate. A ''one-way'' agreement would involve a finding by only one country that the regulatory system of a foreign government was equivalent to its own. A ''one-way'' agreement would be appropriate where there existed, essentially, a one way flow of trade in the commodities that were subject to the agreement. A ''one-way'' agreement might also be entered into as a temporary measure when one country was prepared to find a trading partner's system equivalent to its own, but the other country was not yet able to make a similar determination. Instead of delaying the agreement until a ''two-way'' agreement could be completed, the two countries could decide to agree in ''one-way'' stages.

B. All Products or Processors vs. Some Products or Processors

FDA may negotiate equivalence agreements that encompass some or all foods being exported to the United States from a foreign country, but will generally focus on agreements that cover one or two food categories with a high trade volume. As indicated earlier, FDA expects that many of the initial food-related equivalence evaluations will involve fish and fishery products. (The U.S. imports about 55 percent of the seafood it consumes.) Such evaluations will not consider whether the regulatory system of the foreign country is equivalent for other products.

Even within the category of products being considered for an agreement (e.g., fish and fishery products), equivalence may exist for some of those products but not for others. In those cases, FDA would enter into equivalence agreements that cover only those products. An agreement of this nature would not preclude trade in the remaining products, but such trade would be outside the scope of the agreement and thus likely subject to more intense scrutiny at ports of entry. The two most predictable situations in which a limited equivalence determination is likely are: (1) Where the regulatory system of the foreign country is designed to achieve, or is only capable of achieving, equivalence for some products but not for others; and (2) where U.S. standards for certain products are more stringent than those of the foreign country so as to rule out equivalence for those products.

The same principle should hold true for processors as well as for products. Some countries have a mix of modern, relatively advanced processing operations and other operations that are much less so, and a regulatory structure capable of achieving equivalence only with regard to the advanced processors. Other countries differentiate between food processors that are licensed to export, and processors that are not so licensed. In any case, it is important to remember that the agreement is between the United States and the government of the foreign country and not with individual processors or other private entities.

C. ''Piggy Back'' (''Triangular'') Agreements

FDA is interested in exploring the concept of ''piggy back'' equivalence agreements (also referred to as ''triangular'' agreements). Under this concept, two countries that have established an equivalence agreement would agree that additional agreements between either of the countries and a third country would be recognized by both countries. Thus, if FDA had both an equivalence agreement with Country ''A'' and a ''piggy back'' arrangement with Country ''A,'' and Country ''A'' had an equivalence agreement with Country ''B,'' FDA would recognize that Country ''B'' is equivalent to the United States in part on the basis of Country ''A's'' finding.

For such a system to work, a basis must exist for FDA to have found on its own that Country ''B's'' system was equivalent to the U.S. system. Among other things, FDA would have to have a high level of confidence in Country ''A's'' ability to make an equivalence determination, based on a detailed knowledge of Country ''A's'' verification and audit capabilities. This knowledge and confidence could be acquired through a mutual undertaking of audit responsibilities and a sharing of the results of audits. There would always have to be some form of confirmation by FDA that equivalence exists along with an adequate administrative record to support a finding of equivalence.

If such an arrangement could be established, it would provide enhanced incentives for countries to achieve equivalence with the most advanced regulatory systems because a finding of equivalence with one advanced country could hasten equivalence with other advanced countries. Obviously, a ''piggy back'' system would also permit a significant public health gains and resource savings for countries in negotiating equivalence agreements.

Some experience with equivalence agreements will be needed before FDA could enter into ''piggy back'' agreements. The agency invites public comment on this issue.

V. The Equivalence Agreement Process

FDA contemplates a process that will involve a paper review, an on-site verification review, and public notice and comment in making a determination that a foreign country's regulatory system is equivalent. The paper review would compare the U.S. system of laws, regulations, standards, regulatory practices and procedures, and all other relevant matters with those of the foreign country based on information provided by the foreign government. The review, which would be carried out by FDA in the United States, is expected to consist in part of a side-by-side comparison of the elements of the U.S. system and the elements of the foreign system to determine what similarities and differences exist between the two systems and to provide the basis for an assessment of the significance of the differences. This paper review will cover both the foreign country's requirements for industry and its inspection system.

If the paper review shows that the two systems may be equivalent, the results of this paper review will form the basis for one or more on-site visits to verify the results of the paper review and to obtain whatever additional information may be necessary. The purpose of an on-site visit would not be to inspect the processors in that country, although it is expected to include visits to some processors, but rather to verify that the foreign regulatory system, including its plant inspection system, is functioning as indicated in the paper review. The on-site visit is an audit of the system, not an audit of foreign processors.

FDA would then make a preliminary determination of whether equivalence exists and would publish this preliminary determination in a notice

for public comment in the **Federal Register**. FDA is under an obligation to do so in accordance with Pub. L. 103–465, the implementing legislation for U.S. participation in WTO agreements. This law states:

If the Commissioner [of Food and Drugs] proposes to issue a determination of the equivalency of a sanitary or phytosanitary measure of a foreign country to a sanitary or phytosanitary measure of the Food and Drug Administration that is not required to be promulgated as a rule under the Federal Food, Drug, and Cosmetic Act or other statute administered by the Food and Drug Administration, the Commissioner shall publish a notice in the **Federal Register** that identifies the basis for the determination that the measure provides at least the same level of sanitary or phytosanitary protection as the comparable Federal sanitary or phytosanitary measure. The Commissioner shall provide opportunity for interested persons to comment on the notice. The Commissioner shall not issue a final determination on the issue of equivalency without taking into account the comments received.

FDA is committed to this public process and intends that **Federal Register** notices published in accordance with this requirement will provide the public with a full explanation of why FDA has tentatively concluded that equivalence exists in a given situation. This explanation should cover, at a minimum, both the results of the paper review and a summary of the on-site visit. The final determination will take into account the comments received.

VI. Fundamental Principles

In determining whether equivalence exists and in entering into any agreements on equivalence, FDA intends to be guided by several basic principles. These include the following:

A. Transparency of Process and Reasoning

As indicated above, the factual basis for a determination of equivalence must be publicly available and clearly understood. To the extent that FDA is looking to foreign regulatory authorities to help to ensure the safety of food for U.S. consumers, the public has a right to review and understand the basis for FDA's action. Consumer confidence in food depends in large measure on the confidence it has in the regulatory safeguards that exist for that food.

B. No Loosening of Standards

U.S. standards will not be relaxed to facilitate a finding of equivalence. For example, products that contain unapproved additives or that contain poisonous or deleterious substances in amounts sufficient to render them adulterated under Federal law will be adulterated even if an equivalence agreement exists. Unless the foreign country can provide reasonable assurance that its products will meet these standards (i.e., will not be adulterated), equivalence will not be possible, at least for those products.

C. Fundamental Fairness and Consistency

Processing requirements that are essential for the production of safe food are germane to both domestic products and products that are imported into the United States, although, as discussed later, equivalence may permit appropriate latitude regarding the details.

D. Adequate Verification

If FDA has entered into an equivalence agreement, the agency must engage in adequate ongoing verification, including appropriate checking of imports, to ensure that equivalence continues to exist. FDA cannot rely solely on foreign regulatory authorities to ensure that equivalence is maintained. Presumably this principle will hold true for the foreign regulatory authority as well.

VII. What Is Equivalence?

A. United States Levels of Protection

As stated in section I of this document, according to the SPS Agreement, equivalence is achieved when an exporting country's measures meet an importing country's ''appropriate level of sanitary or phytosanitary protection,'' even though those measures are not the same as those of the importing country. A level of protection can be viewed in terms of the limitation on risk that a society requires relative to a particular hazard or hazards.

In the United States, the appropriate levels of sanitary or phytosanitary protection for the foods regulated by FDA are governed by the very broad, qualitative provisions of the Federal Food, Drug, and Cosmetic Act (the act), and the regulations issued under it, which state the circumstances in which a product will be deemed to present an unacceptable risk to U.S. consumers, i.e., will be deemed to be ''adulterated.'' For example, a food additive will be deemed to adulterate a food unless it is approved for use in that food (section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(c))) based on a showing that there is a ''reasonable certainty'' that no harm will result from its becoming a component of the food (section 409(a) of the act (21 U.S.C. 348(a)) and § 170.3(i) (21 CFR 170.3(i))). Food is also adulterated if it is contaminated with an added poisonous or deleterious substance ''which may render it injurious to health'' (section 402(a)(1) of the act). The act has several other adulteration provisions, including provisions that apply in specific situations, such as in the preparation of infant formula and the use of color additives. Sometimes, as with food additives, the act (a food additive must be ''safe'' under section 409) and the regulations (definition of ''safe'' in § 170.3(i)) must be read together.

These governing provisions express levels of protection in terms of overarching public health standards. However, in considering a particular risk or types of risks, these broadly stated standards need further elaboration to provide understanding of how they apply. For example, a determination of whether there is a reasonable certainty of no harm from the use of a food additive is dependant on an operational definition of that standard that facilitates its application to a specific food use of a substance. Operational definitions can be found in various places, ranging from the explanatory materials that are developed in rulemaking (i.e., preambles) to the codified text of a rule (see §§ 170.3, 170.20, and 170.22 (21 CFR 170.20 and 170.22)), to guidance materials, and even to judicial decisions.

For example, the operational definition for ''reasonable certainty of no harm'' from the use of a food additive involves determining the exposure to that additive that will not produce adverse effects in humans. This level is obtained through the application of an appropriate, scientifically based, safety factor (e.g., 100-fold, as provided in § 170.22) to the lowest no-effect level observed in a toxicological study in animals. As can be seen from this example, the level of protection afforded by the law of the United States is the protection that emerges when a broad, statutory public health standard is applied, through an operational definition, to a particular risk.

Operational definitions serve as a bridge between the underlying standard and the measures that are developed to achieve the desired level of protection. In the above example, the primary measure that the United States uses to achieve its level of protection for food additives is an approved level of the additive that is permissible in a particular food.

Quantification is not the only way to provide a level of protection, and in many situations quantification is not practical. An excellent example of a

level of protection that is qualitative rather than quantitative is that provided by the food safety processing system known as Hazard Analysis Critical Control Point (HACCP), which FDA has mandated for the processing of seafood. The statutory standard from which this protection derives states that food should not be prepared, packed, or held under conditions ''whereby it may have been rendered injurious to health'' (section 402(a)(4) of the act). Concerns about the conditions under which seafood is processed led FDA to conclude that to give this standard meaning in the circumstances under which seafood is processed, it would be necessary to impose a prevention-oriented system of food safety controls which would operate to define the statutory standard by ensuring that hazards are identified in advance and then prevented or reduced to an acceptable level through the application of several specific principles (see the preamble to FDA's seafood regulations (60 FR 65096). The primary measure by which this level of protection is achieved is a regulation that requires that food processors establish and operate under such a system (21 CFR part 123).

B. Measures for Achieving U.S. Levels of Protection

As the previous examples demonstrate, the United States provides protections both through outcome (whether the food contains an unapproved substance or an undesirable substance in sufficient quantity to adulterate it) and method of production (i.e., whether the conditions under which a food is prepared, packed, or held are conducive to producing a safe product). It is important to recognize that food is adulterated under U.S. law unless there is adherence to all applicable protections. A food might be free of contaminants, and thus be consistent with the protections extended by law in that respect, but still be adulterated under section 402(A)(4) of the act because it was processed under insanitary conditions whereby it may have become contaminated.

Thus, the U.S. regulatory system for food addresses both outcome and processing. As a practical matter, therefore, FDA would expect that another country's SPS measures must also address both outcome and processing if those measures are to provide assurance that food offered for export to the United States meets the U.S. level of protection.

1. Outcome

In establishing and enforcing tolerances, or maximum residue levels (MRL's), for food contaminants or residues of pesticides or veterinary drugs in foods as risk management measures, the United States ensures that its levels of protection are met. MRL's are based on assessments of the risks to human health and specifically to the health of U.S. consumers. These assessments take into account factors such as toxicity, expected residue levels based on labeled use of the product, and expected dietary exposures based on the U.S. diet.

As these factors suggest, the U.S. MRL's are based in part on domestic circumstances. It is not clear how a less stringent MRL could, alone, address these factors in a way that achieves the same level of protection for U.S. consumers as the U.S. MRL. Further, food containing contaminants or residues in excess of U.S. MRL's are deemed to be adulterated under U.S. law. Therefore, as a practical matter, as part of evaluating whether a foreign regulatory system can be judged equivalent, the agency would expect adequate assurances that U.S. MRL's will not be exceeded in those foods being exported to the United States.

It may be possible for a country with a less stringent MRL, or no MRL, to achieve equivalence, however, if it can demonstrate that the products that it exports to the U.S. will not contain contaminants in excess of the U.S. MRL. If, for example, the United States has established level ''L'' for a particular contaminant in a food, an exporting country could demonstrate that the food that it exports to the United States will not contain the contaminant because conditions do not exist there whereby the food would be exposed to the contaminant or contain levels in excess of the U.S. MRL.

An exporting country could also seek to present scientific evidence to demonstrate that the United States could meet its own level of protection with a less stringent MRL. While importing countries may occasionally revise older MRL's on the basis of such demonstrations, FDA expects that these revisions will occur only in limited situations if the importing country already bases its SPS measures on science, as does the United States.

In addition to tolerances, or MRL's, which are considered binding under U.S. law, FDA has provided ''action levels'' for contaminants as nonbinding guidance for FDA, industry, and the public about the level at which the contaminants in question may pose a health risk, based on available science. In providing nonbinding regulatory guidance, FDA may choose to take regulatory action when it finds that an action level has been exceeded or decide to exercise discretion based on the circumstances and risks posed by the particular case. Nevertheless, the manner in which the action level is applied to domestic products and to imports should be the same, and action levels should be taken into account when determining equivalence.

2. Conditions of Production

How a product is prepared, packed, or held can be of great importance to the safety of the product. As with the issuance of tolerances or MRL's, FDA periodically issues regulations on how certain foods must be processed to ensure that the foods are safe, and that U.S. levels of protection are met. The agency engages in inspections of processing establishments to determine whether these processing requirements are being carried out.

Attention to processing helps ensure that food is safe by preventing potential food safety problems and by ensuring that processors are aware of problems that may develop, and that they address those problems when they do occur. Sanitary and phytosanitary measures are credible to the extent that they decrease the likelihood that problems will occur, or increase the likelihood that problems will be discovered and corrected quickly, even when the regulatory inspector is not present.

End-product testing, which measures outcome, cannot generally be relied upon exclusively to provide an adequate level of protection because it only tests for a specific risk or group of risks on a particular day. The results of end-product sampling may or may not be representative of the actual, continuing risk, depending upon product uniformity, the amount of sampling, and other factors. Processing controls coupled with adequate verification by a regulatory authority provide an essential assurance that food will not present unacceptable risks. Processing controls can assure that the level of protection is met in many circumstances where end-product testing alone realistically cannot.

FDA, therefore, has issued several regulations that focus on how food is to be processed. The overall purpose of these regulations is to require that processing methods and equipment be appropriate to control potential risks. The regulations take into account available scientific evidence on food safety hazards and controls, relevant processes and production methods, and relevant economic factors, including costs and benefits. One of these regulations establishes basic sanitation principles and good manufacturing practices for all foods (''Current Good

Manufacturing Practice in Manufacturing, Packing, or Holding Food,'' (part 110 (21 CFR part 110)). Others require a specific processing regimen to control a particular problem or problems in certain types of foods. These regulations are key elements in FDA's regulatory system.

For purposes of equivalence, therefore, FDA will be looking for SPS measures established by an exporting country that fully address the objectives and purposes of applicable FDA regulations. FDA's examination may occur on a provision-by-provision basis, or on some other basis, as the agency deems necessary. To the extent possible, for example, differences in requirements affecting the actual physical dimensions or components of equipment (e.g., hand washing equipment for employees) will generally be less important than whether the broader public health purposes or objectives to which the equipment relates (i.e., personnel hygiene) are being adequately addressed. In any event, FDA will be prepared to articulate the objectives or purposes of its regulatory provisions during consultations on equivalence with foreign governments.

3. Labeling and Other Special Considerations

FDA notes that the SPS Agreement includes labeling within its definition of sanitary or phytosanitary measures. Not all labeling falls within this definition, however. Regarding labeling that does meet the definition, it is not clear to FDA how labeling that fails to meet U.S. requirements could be equivalent to these requirements. Therefore, the agency is not offering criteria at this time on how such labeling could be found to be equivalent and invites comment on whether differing SPS labeling requirements can be equivalent, and how determinations of equivalence should be made.

Similar difficulties may be presented by particular types of foods (e.g., infant formula and medical foods), which are subject to special statutory requirements (see section 412 of the act (21 U.S.C. 350a)). Therefore, FDA also requests comment about how it should handle equivalence determinations for those types of products.

4. Elements of the U.S. Regulatory System

As indicated previously, SPS measures include laws, decrees, regulations, and related matters. Clearly, the operations and functions of a country's regulatory system, which implements laws and issues decrees and regulations, constitute SPS measures. It is thus necessary to identify the elements of the U.S. regulatory system and the purposes that these elements serve in order that foreign regulatory systems can be compared against these measures and purposes.

For foods regulated by FDA, there are essentially two layers of regulatory authority: Federal or national authority, represented primarily by FDA, with regulatory jurisdiction over food in interstate commerce, as broadly defined in relevant case law, and individual State and local regulatory systems, with regulatory jurisdiction over food within their boundaries. The State systems are germane for purposes of ''two way'' equivalence primarily because States engage in regulatory inspections of food processors in addition to those conducted by FDA. Inspections, as discussed below, are a key element of the U.S. regulatory system.

The elements of the U.S. regulatory system may be thought of as falling into two broad categories. The first is infrastructure, which includes applicable law and the government bodies charged with implementing the law. The second category is implementation, or performance, which relates to how the infrastructure actually operates to prevent and control food-related risks. It is worth pointing out that, under the U.S. system, private food producers are responsible for producing safe food, while government is essentially responsible for verifying that producers are meeting their obligations and for taking remedial action when they fail to do so.

a. *Infrastructure*.

1. *Law*. The United States has national law that includes the following purposes:

- To prohibit the introduction of adulterated or misbranded food into commerce;
- To broadly establish what constitutes adulteration and misbranding;
- To authorize national regulatory agencies with the power to establish standards for foods (including how it is prepared, packed, and held), to conduct mandatory inspections of food processors, to issue processing requirements for food, and to take enforcement action to prevent adulterated or misbranded food from entering commerce and to remove it from any stage of interstate commerce if found.

In order for equivalence to be achieved, a foreign country needs to have laws applicable to food to be exported to the United States that achieve essentially the same objectives and will meet U.S. levels of protection. In addition, as discussed below, the foreign country must have the authority to implement the law in an appropriate way and must be, in fact, doing so.

2. *Regulatory authority*. The United States has national regulatory agencies that implement Federal food safety law applicable to all food in interstate commerce in the United States, including food to be exported. Essential characteristics of these agencies include, but are not limited to, the following:

- A regulatory infrastructure capable of, and engaged in, identifying existing and potential public health problems associated with food and capable of establishing appropriate regulatory policy with regard to such problems, including, but not limited to, the establishment of scientifically-based regulatory standards, processing requirements, and guidelines. This capability includes the ability, either within the agency or through contact with other agencies, to determine the causes of illness from foods that may be consumed domestically or shipped for export.
- An inspection infrastructure capable of, through appropriate training and experience, and engaged in conducting mandatory inspections of commercial entities that prepare, pack, and handle food to determine whether these entities are meeting their responsibility to produce food that is not adulterated. Inspections should include both observation and the taking of product samples for laboratory or organoleptic examination.
- A laboratory infrastructure that is capable of, and engaged in, analyzing samples to determine the presence and quantity of adulterants that are reasonably likely to affect food, including but not limited to pathogens, chemicals, toxins, and parasites. The methodologies used should have, in most cases, been approved or validated by recognized entities that are competent to evaluate such methods. The competency of the laboratories to use these methods has been appropriately evaluated and maintained through extensive quality assurance programs.
- An enforcement infrastructure that is capable of, and engaged in, reviewing the findings from inspections and making rapid determinations as to whether regulatory action is necessary to resolve existing or potential public health problems. Where regulatory action is necessary, the enforcement infrastructure has available to it a range of actions designed to remove violative product from distribution and prevent a recurrence of the problem.
- An internal monitoring infrastructure to preserve the integrity and credibility of the agency's food

protection system. The infrastructure must be able to issue and enforce rules and procedures to promote ethical behavior, and to protect against conflict of interest, among its employees.

In order to be equivalent to the United States, a foreign country should have a regulatory infrastructure with jurisdiction over food to be exported to the United States that, at a minimum, possesses these characteristics. It is not necessary that these characteristics reside solely within a single government agency. They may be performed by multiple agencies at a national level or, under a Federal-type system, by a combination of national and local government agencies, as long as there is adequate assurance that the functions are being carried out adequately and in a reasonably consistent and coordinated manner.

Also, FDA does not rule out the possibility that nongovernment entities might be able to perform some regulatory functions under strictly controlled circumstances. When any function is performed by a nongovernment entity, such as a private inspection organization, there must be sufficient government oversight of the private organization to ensure that the relevant regulatory functions are being carried out adequately and in a manner that preserves the integrity and credibility of the functions. Ultimate regulatory responsibility must continue to rest with the government. In determining whether equivalence exists under such circumstances, FDA would expect the foreign government to be engaged in rigorous oversight over the nongovernment entity.

b. *Implementation.*

Equivalent implementation is achieved when the foreign regulatory infrastructure is carrying out its functions in a manner that provides a reasonable assurance that the products being offered for import into the United States meet our country's levels of protection and thus are not adulterated under U.S. law. While FDA will examine each function separately, the decision as to whether equivalence exists will be based on a consideration of whether the foreign country's system as a whole in some way provides the assurances that are provided by the U.S. system. As indicated previously, the whole system must be able to provide assurances beyond those that would be provided solely through end-product testing.

This examination may also take into account relevant conditions in the foreign country. For example, in considering whether inspections occur with sufficient frequency, FDA may consider sanitary and other conditions in that country, and particularly in processing plants, that bear on how much on-site presence and intervention by regulatory authorities is necessary to provide adequate assurance that adulterated products are not being exported. Furthermore, the degree to which industry uses appropriate processing controls can influence the methods and procedures by which government verifies compliance.

When considering the performance of the country's regulatory infrastructure, FDA intends to take into account experience already acquired with that country, including historical data from FDA monitoring of its products that are exported to the United States.

APPENDIX

Equivalence for Seafood

Because FDA has already received requests for consultations on seafood from a number of countries, the agency is including in this Appendix specific guidance on determining equivalence with its seafood HACCP regulations and with other features of its regulatory program for seafood. FDA may choose to issue specific additional guidance for other types of food at a later date.

A. HACCP and the Prerequisites

FDA's seafood HACCP regulations declare that fish and fishery products in interstate commerce are adulterated if they are not processed in accordance with the principles of HACCP and prerequisite requirements for sanitation provided for therein (§ 123.6(g)), regardless of whether the products may be otherwise adulterated. As with other regulations, the FDA seafood HACCP regulations have the force and effect of law. The regulations apply to imports into the United States as well as to products produced domestically.

In the absence of a determination of equivalence, imports must be processed in compliance with the regulations. In any consultations relating to equivalence, an exporting nation will be given the opportunity to demonstrate that its own measures for the seafood that is being exported from it to the United States are adequate to ensure that the objectives and purposes of each provision of the U.S. regulations will be met.

The seafood HACCP regulations require that fish and fishery products be processed under a system of preventive controls to ensure the safety of the food for human consumption. As part of this system, commercial processors must demonstrate the following: (1) A knowledge of safety hazards to which their products are subject; and (2) the ability to identify and apply controls that eliminate or minimize the likelihood of the occurrence of those hazards in the products. HACCP is essentially the opposite of end-product testing, which attempts to detect problems after they have occurred. As a scientifically-based processing control system, HACCP is able to achieve the level of protection deemed appropriate for the risks posed by seafood. End-product testing or other types of process controls that do not involve systematic, daily monitoring in conjunction with hazard analysis, cannot achieve this level of protection.

The preventive controls of HACCP are applied through the application of seven internationally recognized principles, all of which are required of seafood processors in the FDA regulations. These are:

(1) Conduct a hazard analysis.

(2) Identify the critical control points (CCP) in the process. A CCP is a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can, as a result, be prevented, eliminated, or reduced to acceptable levels.

(3) Establish critical limits for preventive measures associated with each identified CCP. A critical limit is the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

(4) Establish CCP monitoring requirements.

(5) Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

(6) Establish effective recordkeeping procedures that document the HACCP system.

(7) Establish procedures for verification that the HACCP system is working correctly.

These principles have been recognized in a Codex Alimentarious Code of Practice for Food Hygiene guide. Countries seeking a determination of equivalence regarding seafood should have measures involving a system of preventive controls that honors these seven principles. There is latitude regarding how countries mandate and operate such a system. For example, FDA regulations contemplate a mix of processor and government activities to fulfill the seventh principle, verification. Hypothetically, however, a country electing to have its regulatory agency conduct all verification activities would be given the opportunity to

demonstrate that its verification procedures meet the purposes and objectives of the U.S. requirement. It is worth noting that the purposes and objectives of each provision of the seafood HACCP regulations are addressed in the preambles to the regulations when issued as a proposal (59 FR 4142, January 28, 1994) and as a final rule (December 18, 1995).

FDA's seafood HACCP requirements do not replace or supersede the Good Manufacturing Practices regulations for all foods in part 110 (see section VII.B.2 of this document). These provisions provide basic good manufacturing practices for all foods. Countries seeking a determination of equivalence must always demonstrate SPS measures that meet the objectives and purposes of part 110, regardless of the types of food that are to be the subject of the equivalence determination.

In addition to the seven principles cited above, FDA's seafood HACCP regulations require processors to engage in a sanitation program as a prerequisite to HACCP (§ 123.11). The importance of good sanitation as a prerequisite to HACCP is internationally recognized, as exemplified by the discussions on this subject at the most recent meeting of the Codex Alimentarious Committee on Fish and Fishery Products. The FDA prerequisite program requires processors to monitor and keep records of how, on a daily basis, they are meeting the conditions and practices specified in part 110 relating to eight fundamental areas of sanitation. Countries seeking equivalence should have in place measures that meet the purposes and objectives of the U.S. prerequisite requirements for sanitation.

B. FDA's Seafood HACCP Guidelines

FDA's seafood HACCP regulations provide the basic ground rules and principles for establishing HACCP systems. For example, processors must conduct a hazard analysis to determine what hazards must be controlled through the seven principles of HACCP. The regulations themselves contain little detailed guidance, however, regarding what the result of that hazard analysis should be in a given situation.

It would not be sufficient for a seafood processor to implement a HACCP system that failed to properly identify all specific hazards that should be identified during the hazard analysis process or that failed to establish appropriate controls for those hazards. Therefore, to provide guidance on what FDA would consider adequate in implementing the regulations, FDA has issued guidelines entitled the ''Fish and Fishery Products Hazards and Controls Guide.''

A country seeking a determination of equivalence for seafood should be able to demonstrate that hazards identified by its system, and the controls applied to those hazards, are appropriate to the purposes and objectives of the seven principles of HACCP. When making the determination for seafood, FDA will use the ''Fish and Fishery Products Hazards and Controls Guide'' in evaluating the exporting country's measures relating to the identification of hazards and the implementation of controls for those hazards.

As with a domestic processor, the exporting country has the opportunity to demonstrate that hazards are being adequately addressed through controls other than those described in the guidelines. Moreover, during consultations with that country, FDA would be willing to consider arguments that it is mistaken in its judgment regarding hazards and controls (just as FDA is willing to listen to arguments of this nature from domestic processors). In any event, there must ultimately be agreement between the two countries on the outcome of hazard analysis as well as on appropriateness of the other elements of the program (e.g., the adequacy of controls for the identified hazards).

At the outset, FDA plans to conduct its reviews on a product-by-product basis, until such time as the agency has sufficient confidence that it is no longer necessary to demonstrate adequate hazard analysis and controls for each product to be exported from a particular country.

C. Raw Molluscan Shellfish

The safety of molluscan shellfish for human consumption raw or partially cooked involves special considerations that must be taken into account when determining equivalence. Because they are sedentary, filter-feeding animals, molluscan shellfish can accumulate pathogens and other types of contaminants that are harmful to humans. For example, the positive relationship between harvesting areas contaminated by sewage pollution and shellfish-borne enteric disease is well established. Consequently, the condition of the water from which they are harvested is critical to the safety of molluscan shellfish, especially those that are intended to be consumed raw or partially cooked.

The U.S. program to ensure the safety of raw molluscan shellfish centers around a classification system for opening and closing molluscan shellfish harvesting waters. This aspect of the program is run by the governments of U.S. States that possess shellfish harvesting waters. FDA audits and evaluates these State programs. The procedures and standards for classifying waters, and for conducting other aspects of the program, are in a document known as the Manual of Operations of the National Shellfish Sanitation Program. From FDA's perspective, the Manual of Operations has the status of a guideline. Each State in the program, however, has agreed to strictly adhere to it. Moreover, each State in the program has agreed to reject shellfish that have not been grown, harvested, or otherwise processed in accordance with the Manual of Operations.

Several countries have entered into MOU's with FDA for the export of raw molluscan shellfish to the United States. (See FDA, International Cooperative Agreements (November 1996); available from National Technical Information Service.) Under these MOU's, the exporting countries have agreed to comply with the Manual of Operations, as if each were a U.S. State. Some of these countries have expressed an interest in renegotiating these agreements as equivalence agreements rather than compliance agreements.

The Manual of Operations is comprehensive and highly detailed. Where differences exist between an exporting country's program and details in the Manual of Operations, judgments must be made about the significance of the differences. Equivalence determinations should focus on matters of significance. A country seeking a determination of equivalence with the United States for raw molluscan shellfish needs to demonstrate that its program meets the purposes and objectives of the Manual of Operations wherever a significant difference exists between its program and the provisions of the Manual.

Dated: May 27, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–14600 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0190]

Cranial Electrotherapy Stimulators; Submission of Safety and Effectiveness Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order requiring manufacturers of cranial electrotherapy stimulators (CES) to submit to FDA a summary of, and citation to, all information known or otherwise available to them respecting the device, including adverse safety and effectiveness information concerning the device that has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA is requesting this information in order to determine whether the classification of the device should be revised, or whether a regulation requiring the submission of a premarket approval application (PMA) for the device should be issued. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to revoke the requirement that manufacturers of CES devices submit a PMA or notice of completion of a product development protocol (PDP) for the device.

DATES: Summaries and citations must be submitted by August 14, 1998.

ADDRESSES: Submit summaries and citations to the Documents Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Doreen M. Melling, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This notice refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date, as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However, submission of a PMA, or a notice of completion of a PDP is not required until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Also, such a device is exempt from the investigational device exemption (IDE) regulations of 21 CFR part 812 until the date stipulated by FDA in the final rule requiring the submission of a PMA for that device. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions the agency deems necessary to provide such assurance. Thus, the SMDA modified the definition of class II devices to permit reliance on special controls, rather than performance standards alone, to provide reasonable assurance of safety and effectiveness.

The SMDA also added new section 515(i) of the act. This section requires FDA to order manufacturers of preamendments class III devices for which no final regulation has been issued requiring the submission of PMA's to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, or distributors to maintain records and to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or that a malfunction of the device is likely to cause death or serious injury on recurrence. Section 515 (i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III; and, for devices remaining in class III, to establish a schedule for the issuance of a rule requiring the submission of PMA's for the device.

In the **Federal Register** of August 24, 1995 (60 FR 43967), FDA issued a final rule to require the submission of a PMA or a notice of completion of a PDP for the CES device. FDA had not issued an order under section 515(i) of the act for the CES device before issuing this final rule. FDA has since become aware of additional information relevant to the possible reclassification of the device from class III to class II or class I. As a result, in the **Federal Register** of January 28, 1997 (62 FR 4023), FDA proposed to revoke the rule requiring the submission of a PMA or notice of completion of a PDP. At that time, FDA said that it believed that it is more appropriate to invoke the procedures under section 515(i) of the act for the CES device. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule based on the proposal (62 FR 4023).

In this document, FDA is requiring manufacturers of CES devices to submit a summary of, and citation to, all safety and effectiveness information known or otherwise available to them respecting such devices, including adverse information concerning the devices which has not been submitted under section 519 of the act.

II. Statutory Authority and Enforcement

In addition to the provisions of section 515(i) of the act described in section I of this document, this order is issued under section 519 of the act, as implemented by § 860.7(g)(2) (21 CFR 860.7(g)(2)). This regulation authorizes FDA to require reports or other information bearing on the classification of a device. Section 519 of the act also requires the reporting of any death or serious injury caused by a device or by its malfunction.

Failure to furnish the information required by this order results in the device being misbranded under section 502(t) of the act (21 U.S.C. 352(t)) and is a prohibited act under sections 301(a) and (q) of the act (21 U.S.C. 331(a) and (q)). The agency will use its enforcement powers to deter noncompliance. Violations of section 301 of the act may be subject to seizure or injunction under sections 304(a) and 302(a) of the act (21 U.S.C. 334(a) and 332(a) respectively). In addition, violations under section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)), and criminal prosecution under section 303(a) of the act.

III. Order

The agency is hereby issuing this order under sections 515(i) and 519 of the act and § 860.7(g)(1) of the regulations. Under the order, the required information shall be submitted by August 14, 1998, so that FDA may begin promptly the process established by section 515(i) of the act to either revise or sustain the current classification of these devices.

IV. Required Contents of Submissions

By the date listed in section III of this document, all manufacturers currently marketing CES devices shall provide a summary of, and citation to, any information known or otherwise available to them respecting the devices, including adverse safety and effectiveness data which has not been submitted under section 519 of the act. FDA suggests that it may be in the best interest of submitters to summarize the information submitted under section 519 of the act to facilitate FDA's decision making, even though such information is not required.

The information should be submitted in one of the two following formats depending on whether the applicant is aware of any information which would support the reclassification of the device into class I (general controls) or class II (special controls). Information which would support the reclassification of the device must consist of adequate, valid scientific evidence showing that general controls alone (class I), or general controls and special controls (class II) will provide a reasonable assurance of the safety and effectiveness of the device.

For manufacturers who do not believe that existing information would support the reclassification of their device into class I or class II, the information provided should be submitted in the following format:

1. *Indications for use*. A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.

2. *Device description*. An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.

3. *Other device labeling*. Other device labeling that includes contraindications, warnings and precautions and/or promotional materials.

4. *Risks*. A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.

5. *Alternative practices and procedures*. A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

6. *Summary of preclinical and clinical data*. The summary of preclinical and clinical data should include the conclusions drawn from the studies which support the safety and effectiveness of the device as well as special controls, if any, which address the adverse effects of the device on health. The summary should include a brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography*. A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who believe that existing information would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition which should include the information described below in addition to the information required under 21 CFR 860.123.

1. *Identification*. A brief narrative identification of the device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.

2. *Risks to health*. An identification of the risks to health should summarize all adverse safety and effectiveness information, which have not been submitted under section 519 of the act particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.

3. *Recommendation*. A statement whether the manufacturer believes the device should be reclassified into class I or class II.

4. *Summary of reasons for recommendation*. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.

5. *Summary of valid scientific evidence on which the recommendation is based*. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is a reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, particularly controlled studies, studies and objective trials without matched controls, well documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. (See § 860.7(c)(2)).

According to § 860.7(d)(1), there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, in accordance to § 860.7(e)(1), there is reasonable assurance that a device is

effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions.

Magnetic resonance imaging devices, Docket Nos. 87P–0214/CP1 through CP13, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P–0083, were both reclassified from class III to class II following the submission of reclassification petitions. Both petitions are available upon submission of a Freedom of Information request to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857.

V. Submission of Required Information

The summary of and citation to, any information required by the act must be submitted by August 14, 1998, to the Document Mail Center (address above).

Dated: May 28, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–14599 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0189]

Recovery of Investigational New Drugs From Clinical Investigators; Revised Compliance Policy Guide; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised compliance policy guide (CPG) 7132c.05 entitled, ''Recovery of Investigational New Drugs from Clinical Investigators.'' Revised CPG 7132c.05 deletes obsolete drug citations in the Code of Federal Regulations. These references were superseded under the investigational new drug rewrite (IND Rewrite). Revised CPG 7132c.05 clarifies the terminology used to classify the recovery of investigational new drugs from clinical investigators consistent with existing regulations. In addition, consistent with the current CPG, this policy continues to apply to new animal drugs being studied under investigational new animal drug applications.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of revised CPG 7132c.05 ''Recovery of Investigational New Drugs from Clinical Investigators '' (CPG 7132c.05) to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit written comments on revised CPG 7132c.05 to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: JoAnne C. Marrone, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–1242.

SUPPLEMENTARY INFORMATION:

I. Background

FDA extensively revised its regulations governing the submission and review of IND's on March 19, 1987. These new regulations, called the IND Rewrite, were part of FDA's ongoing efforts to improve and streamline the new drug approval process. There are several provisions in the regulations that refer to the return of unused supplies to the sponsor of the IND. This revised CPG is intended to clarify the terminology to be used when it is necessary to recover investigational drugs from clinical investigators, consistent with the regulations.

This guidance document represents the agency's current thinking on the recovery of investigational drugs from clinical investigators. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Request for Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of revised CPG 7132c.05 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the revised CPG (Chapter 4, Sec. 444.100) is also available via Internet using the World Wide Web (www) (connect to the ORA home page at http://www.fda.gov/ora/compliance_ ref/cpg).

Dated: May 27, 1997.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 97–14471 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2540 and HCFA-R–48]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility (SNF) and Skilled Nursing Facility Health Care Complex Cost Report, and supporting regulations 42 CFR 413.13, 413.20, 413.24 and 413.157; *Form No.:* HCFA–2540; *Use:* The Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report is the cost report to be used by freestanding SNFs to submit annual information to achieve a settlement of

costs for health care services rendered to Medicare beneficiaries. The 2540 now includes the reporting requirements to submit data electronically. *Frequency:* Annually; *Affected Public:* Business or other for profit, Not for profit institutions, and State, local, or tribal government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 1,372,000.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Conditions of Participation, and supporting regulations 42 CFR 482.12, 482.22, 482.27, 482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62 and 482.66; *Document No.:* HCFA-R–48; *Use:* Hospitals seeking to participate in the Medicare and Medicaid programs must meet the Conditions of Participation (COP) for Hospitals, 42 CFR Part 482. The information collection requirements contained in this package are needed to implement the Medicare and Medicaid COP for hospitals. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 1,500; *Total Annual Responses:* 1,500; *Total Annual Hours Requested:* 53,522.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's web site address at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Date: May 27, 1997.

Edwin J. Glatzel

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–14500 Filed 6–2–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[ORD–100–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: April 1997

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

ACTION: Notice.

SUMMARY: No new proposals for Medicaid demonstration project were submitted to the Department of Health and Human Services during the month of April under the authority of section 1115 of the Social Security Act. One proposal was withdrawn and no proposals were approved or disapproved during that time period. (This notice can be accessed on the Internet at http://www.hcfa.gov/ord/sect1115.htm.)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: *Mail correspondence to:* Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson, (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the **Federal Register** (59 FR 49249) that specified: (1) The principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the **Federal Register** with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, Disapproved, and Withdrawn Proposals for the Month of April 1997

A. Comprehensive Health Reform Programs

1. New Proposals

No new proposals were received during the month of April.

2. Pending Proposals

Pending proposals for the month of March 1997 found in the **Federal Register** of May 12, 1997 (62 FR 25957) remain unchanged, except for the deletion of the Community Care of Kansas, which was withdrawn on April 23, 1997, and the addition of the New Jersey Managed Charity Care Demonstration, which was received in March.

3. Approved Conceptual Proposals (Award of Waivers Pending)

No conceptual proposals were approved during the month of April.

4. Approved Proposals

No proposals were approved during the month of April.

5. Disapproved Proposals

No proposals were disapproved during the month of April.

6. Withdrawn Proposals

The following comprehensive health reform proposal was withdrawn voluntarily by the State during the month of April.

Demonstration Title/State: Community Care of Kansas—Kansas.

Description: Kansas proposed to implement a ''managed cooperation demonstration project'' in four predominantly rural counties, and to assess the success of a non-competitive

managed care model in rural areas. The demonstration would have enrolled persons currently eligible in the Aid to Families with Dependent Children (AFDC) and AFDC-related eligibility categories, and expand Medicaid eligibility to children ages 5 and under with family incomes up to 200 percent of the Federal poverty level.

Date Received: March 23, 1995.

Date Withdrawn: April 23, 1997.

B. Other Section 1115 Demonstration Proposals

1. New, Pending, Approved, Disapproved, and Withdrawn Proposals

No proposals were received, approved, disapproved, or withdrawn during the month of April.

Pending proposals for the month of March 1997 found in the **Federal Register** of May 12, 1997 (62 FR 25957) remain unchanged.

III. Requests for Copies of a Proposal

Requests for copies of a specific Medicaid proposal should be made to the State contact listed for the specific proposal. If further help or information is needed, inquiries should be directed to HCFA at the address above.

(Catalog of Federal Domestic Assistance Program, No. 93.779; Health Financing Research, Demonstrations, and Experiments)

Dated: May 22, 1997.

Barbara Cooper,

Acting Director, Office of Research and Demonstrations.

[FR Doc. 97–14537 Filed 6–3–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Phase I Trials of Anti-Cancer Agents.

Date: July 21–23, 1997.

Time: July 21—7:00 p.m. to 10:00 p.m., July 22–23—8:00 a.m. to 5:00 p.m.

Place: Embassy Suites Chevy Chase Pavilion, 4300 Military Road, N.W., Washington, D.C. 20015.

Contact Person: Ray Bramhall, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH Executive Plaza North, Room 643, 6130 Executive Boulevard, MSC 7410, Bethesda, MD 20892–7410, Telephone: 301/496–3428.

Purpose/Agenda: To evaluate and review grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14513 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Center for Research Resources Special Emphasis Panel (SEP) meeting:

Name of SEP: Comparative Medicine.

Date: June 2, 1997.

Time: 9:30 a.m.

Place: One Washington Circle Hotel, Board Room, One Washington Circle, Washington, DC 20037.

Contact Person: Dr. Bela J. Gulyas, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, (301) 435–0811.

Purpose/Agenda: To evaluate and review grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applicants and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program No. 93.306, Laboratory Animal Science and Primate Research)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14510 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Molecular Biology and Genetics of Sleep and Sleep Disorders.

Date: June 19–20, 1997.

Time: 8:00 p.m.

Place: Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland 20814.

Contact Person: Anthony M. Coelho, Jr., Ph.D., Two Rockledge Center, Room 7182, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0288.

Purpose/Agenda: To review and evaluate grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to this meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health).

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14518 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of the following National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel (SEP) meetings:

Name of SEP: Rheumatoid SCORS Review.
Date: June 25–27, 1997.
Time: June 25—5:00 p.m.–10:00 p.m., June 26—8:30 a.m.–5:00 p.m., June 27—8:30a.m.–adjournment.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.
Contact Person: Melvin H. Gottlieb, Ph.D., Scientific Review Administrator, Natcher Building, 45 Center Drive, Rm 5AS25N, Bethesda, Maryland 20892–6500, Telephone: 301–594–4952.
Purpose/Agenda: To evaluate and review research grant applications.

Name of SEP: Scleroderma SCORS Review.
Date: July 13–15, 1997.
Time: July 13—5:00 p.m.–10:00 p.m., July 14—8:30 a.m.–5:00 p.m., July 15—8:30 a.m.–adjournment.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.
Contact Person: Melvin H. Gottlieb, Ph.D., Scientific Review Administrator, Natcher Building, 45 Center Drive, Rm 5AS25N, Bethesda, Maryland 20892–6500, Telephone: 301–594–4952.
Purpose/Agenda: To evaluate and review research grant applications.

Name of SEP: Osteoporosis SCORS Review.
Date: July 22–24, 1997.
Time: July 22—5:00 p.m.–10:00 p.m., July 23—8:30 a.m.–5:00 p.m., July 24—8:30 a.m.–adjournment.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.
Contact Person: Tommy L. Broadwater, Ph.D., Chief, Grants Review Branch, Scientific Review Administrator, Natcher Building, 45 Center Drive, Rm 5AS25U, Bethesda, Maryland 20892–6500, Telephone: 301–594–4952.
Purpose/Agenda: To evaluate and review research grant applications.

These meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The discussion of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with these applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. [93.846, Project Grants in Arthritis, Musculoskeletal and Skin Diseases Research], National Institutes of Health, HHS)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14511 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the National Institute of General Medical Sciences meeting:

Committee Name: Biomedical Research & Research Training Committee (BRRT) Subcommittee-A.
Date: June 10, 1997.
Time: 08:00 a.m. until conclusion.
Place: Georgetown Holiday Inn, 2101 Wisconsin Avenue, N.W., Washington, DC 20007.
Contract Person: Carol Latker, Ph.D., Office of Scientific Review, Scientific Review Administrator, NIGMS, 45 Center Drive, Room 1AS–13k, Bethesda, MD 20892–6200, 301–594–2848.
Purpose: To review training grant applications.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6). Title 5 U.S.C. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences; 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research, 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS])

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14512 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: AIDS Applications and AITRC Conflicts.
Date: June 26–27, 1997.
Time: 8:30 a.m.
Place: The OMNI Shoreham Hotel, 2500 Calvert Street, N.W., Wisconsin Ave., Washington, D.C. 20008, (202) 234–0700.
Contact Person: Dr. Paula Strickland, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C02, Bethesda, MD 20892, (301) 402–0643.
Purpose/Agenda: To evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14514 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel meeting:

Name of SEP: Helicobacter Pylori.
Date: July 16–17, 1997.
Time: 8:00 am.
Place: Crowne Plaza Hotel, 1001 14th Street, N.W., Washington, D.C. 20005
Contact Person: Roberta Haber, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6as-25N, National Institutes of Health, Bethesda, Maryland 20892–6600, Phone: (301) 594–8898.
Purpose/Agenda: To review and evaluate grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as

patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14515 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Date: July 1, 1997.

Time: 11 a.m. to adjournment.

Place: 6120 Executive Blvd., Rockville MD 20892 (telephone conference call).

Contact Person: Richard S. Fisher, Ph.D., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, Bethesda MD 20892–7180, 301–496–8693.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code. The applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14516 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following advisory committee meeting of the National Institute of General Medical Sciences Special Emphasis Panel:

Committee Name: NIGMS Special Emphasis Panel—Initiative for Minority Student Development.

Date: June 22–24, 1997.

Time: 8:30 a.m.–11:00 a.m.–June 22; 8:30 a.m.–5:00 p.m.–June 23.

Place: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Contact Person: Michael A. Sesma, Ph.D., Scientific Review Administrator, NIGMS, Office of Scientific Review, 45 Center Drive, Room 1AS–19, Bethesda, MD 20892–6200, 301–594–2048.

Purpose: To review and evaluate program project grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences; 93.589, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS].)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14517 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Child Health and Human Development Special Emphasis Panel (SEP) meeting:

Name of SEP: Mechanism to Limit CNS Bilirubin Influx: P-glycoprotein (Teleconference).

Date: June 24, 1997.

Time: 1:00 p.m. (EST)–adjournment.

Place: 6100 Executive Boulevard, 6100 Building, Room 5E03, Rockville, Maryland 20852.

Contact Person: Hameed Khan, Ph.D., Scientific Review Administrator, NICHD, 6100 Executive Boulevard, 6100 Building, Room 5E01, Rockville, Maryland 20852, Telephone: 301–496–1485.

Purpose/Agenda: To evaluate and review a grant application.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. This discussions of this application could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.864, Population Research and No. 93.865, Research for Mothers and Children, National Institutes of Health.)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14520 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Clinical Sciences.

Date: June 26, 1997.

Time: 12:00 p.m.

Place: NIH, Rockledge 2, Room 4134, Telephone Conference.

Contact Person: Dr. Clark Lum, Scientific Review Administrator, 6701 Rockledge Drive, Room 4134, Bethesda, Maryland 20892, (301) 435–1195.

Name of SEP: Multidisciplinary Sciences.

Date: July 9–11, 1997.

Time: 7:00 p.m.

Place: Radisson Hotel, Salt Lake City Airport, Salt Lake City, Utah.

Contact Person: Dr. Lee Rosen, Scientific Review Administrator, 6701 Rockledge Drive, Room 5116, Bethesda, Maryland 20892, (301) 435–1171.

Name of SEP: Multidisciplinary Sciences.

Date: July 14, 1997.

Time: 8:00 a.m.

Place: Holiday Inn, Bethesda, Maryland.

Contact Person: Dr. Nadarajen A. Vydelingum, Scientific Review Administrator, 6701 Rockledge Drive, Room 5210, Bethesda, Maryland 20892, (301) 435–1176.

Name of SEP: Clinical Sciences.

Date: July 14, 1997.

Time: 8:00 a.m.

Place: Holiday Inn, Chevy Chase, Maryland.

Contact Person: Ms. Josephine Pelham, Scientific Review Administrator, 6701 Rockledge Drive, Room 4106, Bethesda, Maryland 20892, (301) 435–1786.

Name of SEP: Biological and Physiological Sciences.

Date: July 17–18, 1997.

Time: 3:00 p.m.

Place: Doubletree Hotel, Rockville, Maryland.

Contact Person: Dr. Syed Quadri, Scientific Review Administrator, 6701 Rockledge Drive, Room 4132, Bethesda, Maryland 20892, (301) 435–1211.

Purpose/Agenda: To review Small Business Innovation Research.

Name of SEP: Chemistry and Related Sciences.

Date: June 30–July 1, 1997.

Time: 8:00 a.m.

Place: Bristol Wyndham Hotel, Washington, DC.

Contact Person: Dr. Richard Panniers, Scientific Review Administrator, 6701 Rockledge Drive, Room 5106, Bethesda, Maryland 20892, (301) 435–1166.

Name of SEP: Biological and Physiological Sciences.

Date: July 28–29, 1997.

Time: 8:30 a.m.

Place: Holiday Inn, Silver Spring, Maryland.

Contact Person: Dr. Robert Su, Scientific Review Administrator, 6701 Rockledge Drive, Room 5144, Bethesda, Maryland 20892 (301) 435–1025.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93,893, National Institutes of Health, HHS)

Dated: May 28, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–14519 Filed 6–3–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS)

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: **http://www.health.org**.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratory, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7875, (formerly: Bayshore Clinical Laboratory)

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931/334–263–5745

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866/800–433–2750

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787/800–242–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5784

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917

CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–549–8263 / 800–833–3984 (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093 (formerly: Cox Medical Centers)

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P. O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045/847–688–4171

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941–418–1700/800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912–244–4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800–898–0180/206–386–2672 (formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310
ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601–236–2609
General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267
Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800–725–3784/915–563–3300 (formerly: Harrison & Associates Forensic Laboratories)
Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051
LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913–888–3927/800–728–4064 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.)
Laboratory Corporation of America, 888 Willow St., Reno, NV 89502, 702–334–3400 (formerly: Sierra Nevada Laboratories, Inc.)
Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)
Laboratory Specialists, Inc., 113 Jarrell Dr., Belle Chasse, LA 70037, 504–392–7961
Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734
MedExpress/National Laboratory Center, 4022 Willow Lake Blvd., Memphis, TN 38118, 901–795–1515/800–526–6339
Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43614, 419–381–5213
Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302–655–5227
MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800–832–3244/612–636–7466
Methodist Hospital of Indiana, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Blvd., Indianapolis, IN 46202, 317–929–3587
Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800–752–1835/309–671–5199
MetroLab-Legacy Laboratory Services, 235 N. Graham St., Portland, OR 97227, 503–413–4512, 800–237–7808(x4512)
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612–725–2088
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 805–322–4250
Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800–322–3361
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134
Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509–926–2400 / 800–541–7891
PharmChem Laboratories, Inc., 1505-A O'Brien Dr., Menlo Park, CA 94025, 415–328–6200 / 800–446–5177
PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817–595–0294 (formerly: Harris Medical Laboratory)
Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–338–4070 / 800–821–3627
Poisonlab, Inc., 7272 Clairemont Mesa Blvd., San Diego, CA 92111, 619–279–2600 / 800–882–7272
Premier Analytical Laboratories, 15201 I–10 East, Suite 125, Channelview, TX 77530, 713–457–3784 / 800–888–4063 (formerly: Drug Labs of Texas)
Presbyterian Laboratory Services, 1851 East Third Street, Charlotte, NC 28204, 800–473–6640
Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800–526–0947 / 972–916–3376 (formerly: Damon Clinical Laboratories, Damon/MetPath, CORNING Clinical Laboratories)
Quest Diagnostics Incorporated, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220–3610, 800–574–2474 / 412–920–7733 (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories, CORNING Clinical Laboratories)
Quest Diagnostics Incorporated, 4444 Giddings Road, Auburn Hills, MI 48326, 810–373–9120 (formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath, CORNING Clinical Laboratories)
Quest Diagnostics Incorporated, 1355 Mittel Blvd., Wood Dale, IL 60191, 630–595–3888 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratories Inc.)
Quest Diagnostics Incorporated, 2320 Schuetz Rd., St. Louis, MO 63146, 800–288–7293 / 314–991–1311 (formerly: Metropolitan Reference Laboratories, Inc., CORNING Clinical Laboratories, South Central Division)
Quest Diagnostics Incorporated, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5590 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratory)
Quest Diagnostics Incorporated, National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410–536–1485 (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science, CORNING National Center for Forensic Science)
Quest Diagnostics Incorporated, 7470 Mission Valley Rd., San Diego, CA 92108–4406, 800–446–4728 / 619–686–3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute, CORNING Clinical Laboratories)
Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130
Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76504, 800–749–3788
S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505–727–8800 / 800–999-LABS
SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91405, 818–989–2520 / 800–877–2520
SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 34748, 352–787–9006 (formerly: Doctors & Physicians Laboratory)
SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 847–447–4379/800–447–4379 (formerly: International Toxicology Laboratories)
SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800–523–0289 / 610–631–4600 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301 (formerly: SmithKline Bio-Science Laboratories)
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219–234–4176
Southwest Laboratories, 2727 W. Baseline Rd., Suite 6, Tempe, AZ 85283, 602–438–8507
St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee St., Oklahoma City, OK 73102, 405–272–7052
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260
TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818–226–4373/800–966–2211 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)
UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800–492–0800/818–996–7300 (formerly: MetWest-BPL Toxicology Laboratory)
UTMB Pathology-Toxicology Laboratory, University of Texas Medical Branch, Clinical Chemistry Division, 301 University Boulevard, Room 5.158, Old John Sealy, Galveston, Texas 77555–0551, 409–772–3197

The Standards Council of Canada (SCC) Laboratory Accreditation Program for Substances of Abuse (LAPSA) has been given deemed status by the Department of Transportation. The SCC has accredited the following Canadian laboratory for the conduct of forensic urine drug testing required by Department of Transportation regulations: NOVAMANN (Ontario) Inc., 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905–890–2555.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 97–14612 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel I in June.

A summary of the meeting and a roster of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: (301) 443–4783.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meeting will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, this meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: June 10, 1997.

Place: Sheraton City Centre Hotel and Towers, 1143 New Hampshire Avenue, N.W., Monticello Conference Room, Washington, DC 20037.

Closed: June 10, 1997, 3:00 p.m.–Adjournment.

Panel: Cooperative Agreements on Criminal Justice Diversion Interventions for Individuals with Co-Occurring Mental Illness and Substance Abuse Disorders.

Contact: Walter Sloboda, Room 11C–22, Parklawn Building, Telephone: (301) 594–2197 and FAX: (301) 443–3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: May 28, 1997.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 97–14485 Filed 6–3–97; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meetings

Pursuant to Pub. L. 92–463, notice is hereby given of the following meetings of the SAMHSA Special Emphasis Panel I in June.

A summary of the meetings and a roster of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: (301) 443–4783.

Substantive program information may be obtained from the individuals named as Contact for the meetings listed below.

The meetings will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: June 4, 1997.

Place: Sheraton City Centre Hotel & Towers, 1143 New Hampshire Avenue, NW, City Centre II Room, Washington, DC 20037.

Closed: June 4, 1997, 1 p.m.–adjournment.

Panel: Center for Mental Health Services Minority Fellowship Program.

Contact: Stanley Kusnetz, M.S. Ed., Room 17–89, Parklawn Building, Telephone: 301–443–3042 and FAX: 301–443–3437.

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: June 16–20, 1997.

Place: Sheraton City Centre Hotel & Towers, 1143 New Hampshire Avenue, NW, City Centre I Room, Washington, DC 20037.

Closed: June 16–19, 1997, 8 a.m.–5 p.m.; June 20, 1997, 9 a.m.–adjournment.

Panel: Center for Substance Abuse Prevention Starting Early, Starting Smart Program.

Contact: Allen Smith, Ph.D., Room 17–89, Parklawn Building, Telephone: 301–443–2595 and FAX: 301–443–3437.

This notice is being published less than 15 days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: May 29, 1997.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 97–14543 Filed 6–3–97; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of Draft Conservation Agreement for the Topeka Shiner in the Mill Creek Watershed District in Kansas for Review and Comment

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The Fish and Wildlife Service (Service) announces the availability for public review of a Draft Conservation Agreement for the Topeka shiner (*Notropis topeka*) in the Mill Creek Watershed District in Kansas. This species is designated a candidate species, indicating that the Service has on file substantial information on biological vulnerability and threats to support a proposal to list it as an endangered or threatened species. The Conservation Agreement was developed jointly by the Service, the Kansas Department of Wildlife and Parks, and the Mill Creek Joint Watershed District No. 85. The agreement focuses on reducing and eliminating some of the more significant threats to the species resulting from flood control measures proposed for implementation within the basin, maintaining core populations of the species necessary for long-term viability, while still allowing the District to achieve an effective level of flood control to meet its needs. The Service solicits review and comment from the public on this draft document.

DATES: Comments on the Draft Conservation Agreement must be received on or before July 7, 1997 to be considered by the Service during preparation of the final Conservation Agreement and prior to the Service's determination whether it will be a signatory party to the agreement.

ADDRESSES: Persons wishing to review the Draft Conservation Agreement may obtain a copy by contacting the Field Supervisor, U.S. Fish and Wildlife Service, 315 Houston, Suite E, Manhattan, Kansas 66502. Written comments and materials regarding the Draft Conservation Agreement also should be directed to the same address. Comments and materials received will

be available on request for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. William H. Gill, Field Supervisor (see **ADDRESSES** section), telephone (913) 539–3474, extension 14.

SUPPLEMENTARY INFORMATION:

Background

The Topeka shiner is a minnow native to small plains streams in Iowa, Kansas, Minnesota, Missouri, Nebraska, and South Dakota. It occurs in pools of small streams with good water quality and clarity. Plowing of the prairie sod for farming and development to other land uses has resulted in significant reductions in water quality in most plains streams, with concurrent reductions in the number of stream reaches suitable for the species. A status review completed for the Topeka shiner by the Service in 1993 concluded that the range and distribution of the species had declined significantly, and that past and current threats were such that the species warranted listing under the Endangered Species Act. In addition to water quality impacts, one of the current threats facing the species is the construction of dams on streams where it occurs. Due to a combination of factors, possibly including increased predation and blockage of upstream and downstream emigration, the Topeka shiner has been known to disappear from streams on which dams are constructed. The Mill Creek Watershed Joint District No. 85 approached the Service and the Kansas Department of Wildlife and Parks in an attempt to coordinate their proposed tributary dam construction in such a way to minimize impacts on the species and ensure its maintenance in the basin into the future.

The Conservation Agreement which resulted from that initial contact outlines specific steps which will be taken by all three entities in an effort to meet the dual goals of species conservation and flood protection. At the heart of the agreement is the designation of all streams in the Mill Creek basin based on their degree of importance to the species. Class 1 streams are those characterized by recent collections of apparently stable, self-sustaining populations of Topeka shiners, with few or no existing watershed dams already in place. Class 2 streams are characterized by recent collections of smaller or less stable numbers of Topeka shiners, with some watershed dam control already in place. Class 3 streams are characterized by an absence of Topeka shiners in recent sampling efforts, or the species present in very low numbers associated with more widespread current and ongoing watershed control measures.

The parties agree that no watershed dam construction shall be done beyond any which may currently exist in Class 1 streams. In Class 2 streams, dam construction may not exceed 20 percent control of total runoff surface area for that stream. In Class 3 streams, dam construction may proceed up to as much as 40 percent control of the runoff of the individual stream. It is further agreed that no watershed dam will be constructed within one stream mile of any currently known Topeka shiner population. This agreement would result in the elimination or significant modification of 19 dams originally proposed for construction by the District. Additional aspects of the agreement would be the formation of a management and recovery plan for that portion of the Topeka shiner's range within the District's boundaries, implementation of land treatment measures designed to improve habitat conditions for the species, and continued monitoring of occupied streams.

Public Comments Solicited

The Service will use information received in its determination as to whether it should be a signatory party to the agreement. Comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning the draft document are hereby solicited. All comments and materials received will be considered prior to the approval of any final document.

Author: The primary author of this notice is Dan Mulhern (see **ADDRESSES** section), telephone (913) 539–3473, extension 16.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

Dated: May 29, 1997.

Terry T. Terrell,

Deputy Regional Director, Denver, Colorado.

[FR Doc. 97–14528 Filed 6–3–97; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Proposed Information Collections to be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposals for the two collections of information described below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collections of information may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the proposal should be made within 60 days directly to the Bureau clearance officer, U.S. Geological Survey, 807 National Center, 12201 Sunrise Valley Drive, Reston, Virginia, 20192, telephone (703) 648–7313.

Specific public comments are requested as to:

1. Whether the collection of information is necessary for the proper performance of the functions on the bureaus, including whether the information will have practical utility;
2. The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used:
3. The quality, utility, and clarity of the information to be collected; and
4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Collection No. 1

Title: General Public Knowledge of Natural Resource Policy in southeastern Colorado and northern New Mexico.

OMB Approval Number: New Collection.

Abstract: Understanding institutional processes is an important component of ecosystem management. The authorities, policies, and practices of local, state and federal agencies and how those policies are perceived by the public greatly affects the way people interact with ecosystems. Yet, for most ecosystems there is no comprehensive understanding of the numbers, functions or effects of these factors. This is particularly true of southern Colorado and northern New Mexico which is undergoing rapid and extensive change. A survey will be administered to a stratified random sample of citizens living in: Archuleta, La Plata,

Montezuma, Delores counties in Colorado and San Miguel county in New Mexico. Natural resource land managers and county government officials in these five counties need to understand citizen knowledge of forest management policies—particularly regarding recreation management—in order to develop adequate management practices. The intended effect is to better inform managers and assist with development of citizen involvement programs.

Bureau Form Number: None.

Frequency: One time.

Description of Respondents: Individuals or households.

Estimated completion time: 12 minutes per respondent (approximate).

Number of respondents: 320 (400 mail-surveys).

Burden hours: 64 hours. (The burden hour estimates are based on 12 minutes to complete each questionnaire and an 80% return rate).

Collection No. 2

Title: General Public Knowledge of Natural Resource Policy in S.E. Utah.

OMB Approval Number: New Collection.

Abstract: Understanding institutional processes is an important component of ecosystem management. The authorities, policies, and practices of local, state and federal agencies and how those policies are perceived by the public greatly affects the way people interact with ecosystems. Yet, for most ecosystems there is no comprehensive understanding of the numbers, functions or effects of these factors. This is particularly true of southeastern Utah which is undergoing rapid and extensive change. A survey will be administered to a stratified random sample of citizens living in Grand, Wayne, Carbon, Emery and San Juan counties in southeastern, Utah. Natural resource land managers and county government officials in these five counties need to understand citizen knowledge of natural resource policies—particularly regarding recreation management—in order to develop adequate management practices. The intended effect is to better inform managers and assist with development of citizen involvement programs.

Bureau Form Number: None.

Frequency: One time.

Description of Respondents: Individuals or households.

Estimated completion time: 12 minutes per respondent (approximate).

Number of respondents: 320 (400 mail-surveys).

Burden hours: 64 hours. (The burden hour estimates are based on 12 minutes to complete each questionnaire and an 80% return rate).

Dated: May 23, 1997.

Dennis B. Fenn,

Chief Biologist.

[FR Doc. 97–14501 Filed 6–3–97; 8:45 am]

BILLING CODE 4310–31–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–962–1020–00]

Notice of Availability for the Montana/Dakotas Standards for Rangeland Health and Guidelines for Livestock Grazing Management Final Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The final environmental impact statement (EIS) describes the environmental impacts of adopting regional standards for rangeland health and guidelines for livestock grazing management (standards and guidelines) on BLM-administered lands in Montana, North Dakota, and South Dakota. The proposed standards and guidelines would be incorporated into 10 BLM land use plans that cover about 8.4 million acres of BLM-administered land in Montana and the Dakotas. This action is proposed in accordance with revised regulations for livestock grazing on BLM-administered lands (43 CFR 4100). The proposed standards and guidelines were developed in coordination with four Resource Advisory Councils and other public input.

FOR FURTHER INFORMATION CONTACT: Sandy Brooks, Project Manager, BLM Montana State Office, P.O. Box 36800, Billings, Montana 59107–6800, or 406–255–2929.

SUPPLEMENTARY INFORMATION: The Preferred Alternative described in the final EIS is the Proposed Action (Alternative Two) analyzed in the draft and supplement to the draft EIS, with changes set forth in the final EIS. Modifications to the Preferred Alternative were based on public comment, Resource Advisory Council (RAC) input, and internal agency review. The modifications included in the Preferred Alternative neither change the scope of the final EIS nor alter the analysis of the environmental impacts. The final EIS incorporates by reference the draft EIS and the supplement to the draft EIS, except as noted.

Three alternatives were considered in detail in the final EIS for standards and guidelines. The no action alternative (continuation of current management direction) provides a baseline for comparison with other alternatives. The preferred alternative (which was the proposed action in the draft) analyzes the impacts of incorporating regional standards and guidelines into affected land use plans. The third alternative analyzes the impacts of implementing the fallback standards and guidelines defined in BLM's grazing regulations. Several alternatives were considered, but dismissed from detailed analysis. These included a no grazing alternative; designating areas of critical environmental concern (ACECs) and research natural areas (RNAs); reintroduction of bison on public rangelands to achieve standards and guidelines; and developing guidelines for uses other than livestock grazing.

Dated: May 28, 1997.

Thomas P. Lonnie,

Deputy State Director, Division of Resources.

[FR Doc. 97–14483 Filed 6–3–97; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–300–1990–00]

Intent To Prepare an Environmental Impact Statement for the Revision of the Surface Management Regulations—43 CFR 3809 for Operations Under the Mining Law of 1872, as Amended

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent and scoping, extension of comment period.

SUMMARY: The Bureau of Land Management (BLM) is extending to June 23, 1997, the comment period for its notice of intent to prepare an Environmental Impact Statement (EIS) on the revision of its surface management regulations. BLM published the notice of intent on April 4, 1997. The extension is in response to several requests from interested parties for additional time to prepare and submit information.

DATES: In order to be considered for preparation of the draft EIS, scoping comments are most useful if received on or before June 23, 1997.

ADDRESSES: Mail or hand-deliver written comments to Paul McNutt, 3809/EIS Team Leader, Bureau of Land Management, Nevada State Office, P.O. Box 12000, Reno, NV 89520–0006. See the **SUPPLEMENTARY INFORMATION** section

for the electronic access and filing address. Comments will be available for public review at 850 Harvard Way, Reno, Nevada, from 8:00 a.m. to 4:00 p.m. Pacific time, Monday through Friday, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Paul McNutt, (702) 785-6400 or via e-mail: pmcnutt@nv.blm.gov. An alternate contact is Scott Haight, (406) 538–7461 or via e-mail: shaight@mt1353.ldo.mt.blm.gov. Individuals who use a telecommunications device for the deaf may call the Federal Information Relay Service at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m. Eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing Address

Commenters may transmit comments electronically via the Internet to: 3809EIS@wo.blm.gov. Please submit comments as an ASCII file and avoid the use of special characters or encryption. Please include your name and address in your message. If you do not receive a confirmation from the system that we have received your Internet message, contact Mr. McNutt directly at (702) 785–6400.

On April 4, 1997, BLM announced its intent to prepare an environmental impact statement for the proposed revision of its surface management regulations. In the notice, BLM invited comments and suggestions on the scope of the rulemaking and analysis and informed the public that BLM will hold public meetings in seven cities during May 1997 to facilitate the public comment process. The notice gave interested parties 60 days, until June 3, 1997, to submit comments. See 62 FR 16177–16178 for information about the areas of concern with the existing surface management regulations and public comment procedures. On April 29, 1997, BLM amended the notice of intent to add public meetings in San Francisco, California. See 62 FR 23264.

BLM has received several requests to extend the public comment period to allow interested parties additional time to prepare and submit written comments. After careful consideration of these requests, we are extending the comment period until June 23, 1997.

Dated: May 28, 1997.

Bob Armstrong,

Assistant Secretary for Land and Minerals Management.

[FR Doc. 97–14508 Filed 6–3–97; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–930–1430–01; CACA 7021 et al.]

Public Land Order No. 7262; Modification and Revocation of 19 Secretarial Orders, 3 Public Land Orders, and 2 Bureau of Land Management Orders, which withdrew lands for the Bureau of Reclamation; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order modifies 10 Secretarial orders, 2 Public Land Orders, and 1 Bureau of Land Management Order to establish a 25-year term as to 133,310.80 acres of lands withdrawn for the Bureau of Reclamation. These lands have been and will remain closed to surface entry and mining, but have been and will remain open to mineral leasing. This order also revokes 18 Secretarial Orders, 1 Public Land Order, and 1 Bureau of Land Management Order insofar as they affect 482,797.32 acres of lands withdrawn for the Bureau of Reclamation. All of the lands are located in the California Desert Conservation Area as defined by Section 601 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1781(c) (1988). Of the 482,797.32 acres being revoked, 468,051.40 acres will be opened to surface entry and mining unless closed by overlapping withdrawals or temporary segregations of record. The remaining 14,745.92 acres have been and will remain closed to surface entry and mining because those lands are included in necessary, overlapping withdrawals for the Bureau of Reclamation that are being modified by this order. The lands being opened to mining by this order are located in the California Desert Conservation Area and will be administered in accordance with the Guidelines for Mineral Exploration and Development contained in the Bureau of Land Management's California Desert Conservation Area Plan, as amended, and 43 CFR 3802 and 3809.

EFFECTIVE DATE: July 7, 1997.

FOR FURTHER INFORMATION CONTACT: Duane Marti, BLM California State Office (CA–931.4), 2135 Butano Drive, Sacramento, California 95825; 916–979–2858.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. The following 10 Secretarial orders, 2 Public Land Orders, and 1 Bureau of Land Management Order are hereby modified to expire 25 years from the effective date of this order, unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1988), the Secretary determines that the withdrawals shall be extended insofar as they affect the lands described in a public notice published in the **Federal Register** on March 3, 1992 (57 FR 7599), as corrected by three correction notices published on May 4, 1992 (57 FR 19135 and 57 FR 19163) and May 26, 1993 (58 FR 30181):

(a) Secretarial Order dated October 24, 1944 (CACA 7074);

(b) Secretarial Order dated October 16, 1931 (CACA 7101);

(c) Secretarial Order dated February 19, 1929 (CACA 7103);

(d) Secretarial Order dated January 31, 1903 (CACA 7231);

(e) Secretarial Order dated April 2, 1909 (CACA 7232);

(f) Secretarial Order dated February 28, 1918 (CACA 7234);

(g) Secretarial Order dated March 15, 1919 (CACA 7235);

(h) Secretarial Order dated October 19, 1920 (CACA 7236);

(i) Secretarial Order dated July 26, 1929 (CACA 7238);

(j) Secretarial Order dated June 4, 1930 (CACA 7239);

(k) Public Land Order 3262 dated October 29, 1963 (CARI 01051);

(l) Public Land Order 4690 dated September 15, 1969 (CARI 07752);

(m) Bureau of Land Management Order dated July 23, 1947 (CACA 7073).

The areas described within the above Secretarial orders, public land orders, and the Bureau of Land Management order aggregate 133,310.80 acres in Imperial, Riverside, and San Bernardino Counties, California.

The lands referenced above continue to be withdrawn from settlement, sale, location, or entry under the general land laws, including the mining laws, to protect the Bureau of Reclamation's Colorado River Storage Project, All American Canal Project, Senator Wash Pump Storage Project, and Yuma Reclamation Project. These lands have been and will remain open to leasing under the mineral leasing laws.

2. The following 18 Secretarial Orders, 1 Public Land Order, and 1 Bureau of Land Management Order are hereby revoked insofar as they affect the lands located in the California Desert Conservation Area, as defined by Section 601 of the Federal Land Policy and Management Act of 1976, 43 U.S.C.

1781(c) (1988), but not described in the **Federal Register** public notice or correction notices described in paragraph 1 above:

(a) Secretarial Order dated June 4, 1931 (CACA 7021);

(b) Secretarial Order dated March 26, 1931 (CACA 7056);

(c) Secretarial Order dated September 8, 1903 (CACA 7060);

(d) Secretarial Order dated July 1, 1904 (CACA 7063);

(e) Secretarial Order dated August 19, 1932 (CACA 7069);

(f) Secretarial Order dated October 16, 1931 (CACA 7101);

(g) Secretarial Order dated July 2, 1902 (CACA 7102);

(h) Secretarial Order dated February 19, 1929 (CACA 7103);

(i) Secretarial Order dated January 31, 1903 (CACA 7231);

(j) Secretarial Order dated April 2, 1909 (CACA 7232);

(k) Secretarial Order dated February 16, 1918 (CACA 7233);

(l) Secretarial Order dated February 28, 1918 (CACA 7234);

(m) Secretarial Order dated March 15, 1919 (CACA 7235);

(n) Secretarial Order dated October 19, 1920 (CACA 7236);

(o) Secretarial Order dated December 13, 1920 (CACA 7237);

(p) Secretarial Order dated July 26, 1929 (CACA 7238);

(q) Secretarial Order dated June 4, 1930 (CACA 7239);

(r) Secretarial Order dated September 10, 1940 (CACA 7240);

(s) Public Land Order 3330 dated February 10, 1964 (CARI 02052);

(t) Bureau of Land Management Order dated April 5, 1956 (CACA 7241).

The areas described within the above Secretarial orders, public land order, and Bureau of Land Management order aggregate 482,797.32 acres in Imperial, Riverside, and San Bernardino Counties, California.

3. At 10 a.m. on July 7, 1997, the lands referenced in paragraph 2 will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 10 a.m. on July 7, 1997, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

4. At 10 a.m. on July 7, 1997, the lands referenced in paragraph 2 will be opened to location and entry under the United States mining laws, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of any of the lands referenced in paragraph 2 of this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1988), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: May 28, 1997.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 97–14486 Filed 6–3–97; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request

AGENCY: Minerals Management Service (MoMS), Interior.

ACTION: Notice of extension of a currently approved collection.

SUMMARY: The Department of the Interior has submitted to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act of 1995 (Act) the collection of information discussed below. The Act requires that OMB provide interested Federal agencies and the public an opportunity to comment on information collection requests. The Act also provides that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Submit written comments by July 7, 1997.

ADDRESSES: Submit comments and suggestions directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior (1010–0078), 725 17th Street, NW, Washington, DC 20503.

Send a copy of your comments to the Minerals Management Service, Rules Processing Team, Mail Stop 4700, 381 Elden Street, Herndon, Virginia 20170–4817.

FOR FURTHER INFORMATION CONTACT:

Alexis London, Engineering and Operations Division, Minerals Management Service, telephone (703) 787–1600. You may obtain copies of the supporting statement and collection of information by contacting MMS's Information Collection Clearance Officer at (202) 208–7744.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR 250, Subpart O, Training of Lessee and Contractor Employees Engaged in Oil and Gas and Sulphur Operations in the OCS.

OMB Number: 1010–0078.

Abstract: Respondents provide information and maintain records on the training of certain employees working in the Outer Continental Shelf (OCS). Training organizations submit training programs for initial accreditation and subsequent renewal; request exceptions to training requirements; submit course schedules and letters with course rosters; and maintain records of training programs and trainees. Lessees may request approval of alternative training programs, and they must provide training drills to new employees and record the results. The MMS uses the information to ensure that certain workers in the OCS are properly trained in the use of equipment and procedures in drilling, well-completion, well-workover, and well-servicing well control operations and production safety system operations. The information is necessary to verify personnel training compliance with the requirements. Responses to this collection of information are mandatory. The information collected is required in the final rule published in the **Federal Register** on February 5, 1997 (62 FR 5320, as corrected in 62 FR 7298 on February 18, 1997), amending 30 CFR part 250, subpart O. The rule became effective on March 5, 1997.

Description of Respondents: Federal OCS oil and gas and sulfur lessee and training organizations.

Estimated Number of Respondents: 185.

Frequency: The reporting and recordkeeping requirements and number of responses vary for each section and are mostly on occasion or annual (see chart below).

BURDEN BREAKDOWN

Citation 30 CFR 250 subpart O	Reporting requirement	Frequency	Number	Burden (hours)	Annual burden hours
217 See footnote 1	Request exceptions (departures) to training requirements.	On occasion	30 exceptions	.25	[3] 8
221	Request approval of alternative training program.	On occasion	2.4 alternative programs.	200	480
224	Apply to MMS for renewal of training program accreditation.	On occasion	16 renewal accreditations.	53	848
225	Apply to MMS for approval of new training program accreditation.	On occasion	5 new programs	100	500
226 (c), (d), (j), (k)	Supply trainees with various documents, manuals, course updates, and certificates of training.	No burden—supplying these documents would be usual and customary practice for a training situation.			0
226(h)	Furnish MMS personnel a copy of training program and plan during on-site review.	No burden—these documents would be readily available.			0
226(i)	Submit course schedule to MMS	Annual; on occasion	61 schedules	14.5	[3] 885
226(l) See footnote 2	Send MMS letter and course roster at the completion of each course.	On occasion	3,000 letters/rosters	.08	240
Total Reporting			3,114 (rounded) responses.		2,961

Footnotes:

[1] The revised subpart O rule eliminates the refresher training requirement and the 60-day ''window'' time element, including the window for basic training. Under the old regulations, MMS received approximately 150 requests each year for exceptions, most of which were for departures to the ''window.'' We anticipate that there will be very few requests for exceptions to the training requirement now that there is no ''window'' and only basic training is mandated.

[2] In 1996 training organizations submitted 4,498 rosters to MMS. The revised subpart O eliminates the requirement for refresher training and changes the timing for basic training. This will result in an estimated 30–40% reduction in mandatory training depending upon the training category with a corresponding reduction in reporting.

[3] Rounded.

Estimated Annual Burden on Respondents: Reporting burden of 2,961 hours.

Form Number: N/A.

Comments: In compliance with the Paperwork Reduction Act of 1995, Section 3506(c)(2)(A), each agency shall provide notice and otherwise consult with members of the public and affected agencies concerning this collection of information in order to solicit comment to (a) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility, (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, (c) enhance the quality, utility, and clarity of the information to be collected, and (d) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Comments should be made directly to the addresses listed under the addresses section of this notice. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days; therefore, public comments should be submitted to OMB within 30 days in order to assure their maximum consideration.

Bureau Clearance Officer: Jo Ann Lauterbach (202) 208–7744.

Dated: May 23, 1997.

E. P. Danenberger,

Chief, Engineering and Operations Division.

[FR Doc. 97–14474 Filed 6–3–97; 8:45 am]

BILLING CODE 4310–MR–M

DEPARTMENT OF JUSTICE

Office of Justice Programs

Office of Juvenile Justice and Delinquency Prevention

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Notice of information collection under review; Juvenile residential facility census.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the **Federal Register** and allowed 60 days for public comment.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 7, 1997. This process is conducted in accordance with 5 CFR Part 1320.10. Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC, 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW, Washington, DC, 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534. Written comments and suggestions from the public and affected agencies should address one or more of the following points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of information collection: new collection.

(2) The title of the form/collection: Juvenile Residential Facility Census.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection. Form: None. Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract. Primary: Public and Private Residential Facilities for Juveniles. Other: None. This collection will gather information necessary to routinely monitor the types of facilities into which the juvenile justice system places young persons and the services available in these facilities.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 3,500 respondents with an average 7 hours per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 24,500 biennial burden hours.

Public comment on this proposed information collection is strongly encouraged.

Dated: May 29, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–14535 Filed 6–3–97; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF JUSTICE

Office of Justice Programs

Office of Juvenile Justice and Delinquency Prevention

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review; Census of juveniles in residential placement.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the **Federal Register** and allowed 60 days for public comment.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 7, 1997. This process is conducted in accordance with 5 CFR, Part 1320.10. Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC, 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW, Washington, DC, 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534. Written comments and suggestions from the public and affected agencies should address one or more of the following points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of information collection: new collection.

(2) The title of the form/collection: Census of Juveniles in Residential Placement.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection. Form: CJ–14, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract. Primary: Public and private juvenile detention, correctional, shelter, facilities. Other. None.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 3,500 respondents and average 4 hours to respond.

(6) An estimate of the total public burden (in hours) associated with the collection: 11,142 biennial burden hours.

Public comment on this proposed information collection is strongly encouraged.

Dated: May 29, 1997.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 97–14536 Filed 6–3–97; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D–10398, et al.]

Proposed Exemptions; Robert A. Benz & Co., P.A., Certified Public Accountants Employees Profit Sharing Plan (the Plan)

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

Unless otherwise stated in the Notice of Proposed Exemption, all interested persons are invited to submit written comments, and with respect to exemptions involving the fiduciary prohibitions of section 406(b) of the Act, requests for hearing within 45 days from the date of publication of this Federal Register Notice. Comments and request for a hearing should state: (1) the name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be

adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5507, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Robert A. Benz & Co., P. A., Certified Public Accountants Employees Profit Sharing Plan (The Plan) Located in Pensacola, Florida

[Application No. D–10398]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 12847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a) and 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to both (1) the proposed cash sale (the Sale) of certain real property (the Property) to the Plan by Robert A. Benz & Co., P.A., Certified Public Accountants (the Employer), a party in interest with respect to the Plan, and (2) the proposed lease-back (the Lease) of the Property by the Plan to the Employer; provided:

(A) The terms and conditions of the transactions are at least as favorable to the Plan as those obtainable from unrelated parties;

(B) The Plan is represented at all times and for all purposes with respect to the Sale and the Lease by a qualified, independent fiduciary;

(C) The Sale is a one-time transaction for a lump sum cash payment;

(D) The purchase price is the fair market value of the Property as determined on the date of the Sale by a qualified, independent appraiser;

(E) The monthly rents paid to the Plan will be adjusted every year after the first 12 months of the Lease by an amount to reflect the greater of either a 3 percent per year increase or the most recent percentage increase in the U. S. Department of Labor Consumer Price Index;

(F) In addition, the rents initially paid under the Lease are no less than the fair market rental value of the Property as determined by a qualified, independent appraiser, and thereafter are adjusted every third year to be no less than the fair market rental value as then determined by the independent appraiser;

(G) The Lease is a triple-net lease under which the Employer as the lessee is obligated for all expenses incurred by the Property, including all taxes and assessments, maintenance, insurance, utilities, and any other expense;

(H) The qualified, independent fiduciary of the Plan monitors and enforces compliance with the terms and conditions of the Lease and the exemption herein proposed;

(I) At all times the qualified, independent fiduciary for the Plan determines that the Lease is in the best interests of the Plan and its participants and beneficiaries, and at all times determines that there are adequate protections of the rights of the participants and beneficiaries of the Plan, and takes all the necessary steps to protect those rights;

(J) In the event the Plan sells the Property and the proceeds received from the sale plus the net rentals received for the Property are less than the Plan's cost of acquiring, holding, and maintaining the Property plus a 5 per cent per annum compounded rate of return on the cost to the Plan in acquiring, holding, and maintaining the Property, the Employer, or its successors, shall pay in cash the difference to the Plan within 45 days of the sale;

(K) No commissions, expenses, or costs shall be incurred by the Plan from the Sale or the Lease; and

(L) At all times during the Sale and Lease, the fair market value of the Property represents less than 25 percent of the total assets of the Plan.

Summary of Facts and Representations

1. The Plan is a defined contribution plan that is a profit sharing plan as described in section 401(a) of the Code, and is exempt from taxation pursuant to section 501 of the Code. The Plan has seven participants and beneficiaries and total assets of $2,300,000, as of December 31, 1996. The fiduciary of the Plan is Mr. Robert A. Benz, who is a certified public accountant and also is the president and director as well as 90.79 percent stockholder of the Employer. The Employer is being purchased under a long-term contract from Mr. Benz by other Certified Public Accountants who are presently employed by the Employer. The Employer has been in existence over thirty years as a public accounting firm, and now is a registered professional association under the statutes of Florida.

The independent fiduciary for the Plan in connection with the proposed transactions is Mr. J. Thomas Fife (the Independent Fiduciary), a resident of Pensacola, Florida, and a Vice President-Investments, for Paine Webber, Incorporated in its Pensacola, Florida office. When accepting his appointment with a written agreement, the Independent Fiduciary was given discretionary authority by the Plan with respect to the acquisition and the leasing of the Property and the management, control, and disposition of

the Property. The Independent Fiduciary represents that after a review the terms of the Plan and its portfolio and the terms and conditions of the proposed Sale and the Lease of the Property he is able to render a favorable opinion with respect to the proposed transactions. In addition, the Independent Fiduciary represents that his qualifications, background, and experience qualify him to act as the independent fiduciary for the Plan in connection with the proposed Sale and Lease. The Independent Fiduciary also represents that he has no interest in the Employer or the Plan, and no interest or relationship with any employee, shareholder, or director of the Employer. The Independent Fiduciary has also acknowledged that he has knowledge and experience with the responsibilities, duties, and liabilities of an independent fiduciary under the Act; and that he has a net-worth in excess of the appraised fair market value of the Property.

2. The Property, which the Employer proposes to sell to the Plan and lease-back, is located at 1823 North 9th Avenue, Pensacola, Florida, and consists of a tract of land, zoned commercial, with improvements, totaling approximately 14,404 square feet in area. The improvements on the Property consists of a one-story concrete office building of approximately 4,463 square feet and adjoining asphalt parking facilities. It is encumbered by a real estate mortgage with current balance of $214,951.60, which is to be paid off at the closing of the Sale, so that the Plan is to acquire the title to the Property free and clear of the mortgage. The Property is used solely by the Employer in its business of providing accounting services to the public.

Mr. Richard H. Sherrill of Sherrill Appraisal Company located in Pensacola, Florida, an independent MAI appraiser (the Independent Appraiser) determined, as of November 11, 1996, that the Property has fair market value of $395,000. As of January 27, 1997, the Independent Fiduciary determined the fair market rental value of the Property is $34,500 for the first year of the Lease, based upon a ten year lease providing for a triple net rental terms whereby the lessee pays all expenses. In addition, there is a provision for annual rent increases.

3. The applicant represents that the Sale of the Property to the Plan by the Employer is for cash in an amount equal to the fair market value as determined by an independent appraiser, which amount is less than 17.5 percent of the total assets of the Plan.

The applicant represents the Sale is contingent upon the simultaneous execution of the Lease by the Plan and the Employer. The Lease is a triple-net lease under which the Employer, as the lessee, will pay all expenses incurred by the Property during the term of the Lease including taxes, insurance, maintenance, repairs, utilities, and any other expense. The term of Lease is for a duration of ten years. If the lessee has performed all the covenants contained in the Lease, the lessee has an option to extend the Lease for an additional two years under the same terms and conditions as the original Lease. Beginning in the first year of the Lease, the annual rental is $34,500, and will be adjusted every year thereafter to be the greater of either an increase of 3 percent in the rent or an increase equal to the most recent percentage increase of the Consumer Price Index as determined by the U.S. Department of Labor. Also, the applicant represents that on every third year of the Lease, the rent will be adjusted so as to be no less than the fair market rental value of the Property as then determined by an independent appraiser selected by the Independent Fiduciary, and in no event will the amount of the rent be lowered.

In addition, the applicant represents that it will indemnify and hold the Plan harmless from any liability arising from the Plan purchasing and holding the Property, including, but not limited to, hazardous material found on the Property, violation of zoning, land use regulations or restrictions, and violation of federal, state, or local environmental regulations or laws.

The applicant also represents that if the Independent Fiduciary decides to sell the Property and the proceeds from the sale plus net rentals received for the Property are less than the Plan's cost of acquiring, holding, and maintaining the Property plus a 5 per cent per annum compounded rate of return, the Employer, or its successors, shall pay the difference in cash to the Plan within 45 days of the date of the sale.

The applicant also represents that in order to ensure that the best interests of the Plan are served and to protect the rights of all the Plan participants and beneficiaries, the Independent Fiduciary has the ultimate authority to make distribution of the Property. At the time of distribution of benefits to Mr. Benz, the Independent Fiduciary will determine whether or not the interests of the Plan and its participants and beneficiaries are protected and better served by distributing the Property in kind to Mr. Benz as part of his vested benefits in the Plan, or whether or not the Plan will retain or dispose of the Property in some other manner.

4. In summary, the applicant represents that the proposed transactions satisfies the criteria for an exemption under section 408(a) of the Act because (a) the proposed transactions have been reviewed and approved by the Independent Fiduciary of the Plan; (b) the fair market value and the fair market rental value of the Property have been determined by an Independent Appraiser; (c) the Plan will pay no more than the fair market value for the Property and will receive the fair market rental value from the Lease; (d) in the event the Plan sells the Property and the proceeds received from the sale plus the net rentals received for the Property are less than the Plan's cost of acquiring, holding, and maintaining the Property plus a 5 per cent per annum compounded rate of return on the cost to the Plan of acquiring, holding, and maintaining the Property, the Employer, or its successors, shall pay in cash the difference to the Plan within 45 days of the sale; (e) the Independent Fiduciary will monitor and enforce the terms and conditions of the Sale and the Lease on behalf of the Plan; (f) the Independent Fiduciary will have exclusive authority with respect to the management, control, and disposition of the Property; and (g) the Independent Fiduciary has determined that the proposed Sale and Lease are in the best interests and protective of the rights of the Plan and its participants and beneficiaries.

FOR FURTHER INFORMATION CONTACT: Mr. C.E. Beaver of the Department, telephone (202) 219–8881. (This not a toll-free number.)

Gart Brothers Sporting Goods Company 401(k) Plan (the Plan) Located in Denver, Colorado

[Application No. D–10403]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale (the Sale) by the Plan of a 5 per cent interest (the Interest) in the Hampden Enterprises Limited Partnership (the Partnership) to the Gart Bros. Sporting Goods Company, the

sponsor of the Plan (the Employer) and a party in interest with respect to the Plan; provided (1) the terms and conditions of the transaction are at least as favorable to the Plan as those obtainable from unrelated parties, (2) the Sale is a one-time transaction for cash, (3) the Plan pays no commissions nor incurs any other expenses in connection with the proposed transaction, (4) the Plan receives as consideration from the Sale the greater of either (a) the total funds expended by the Plan in acquiring and holding the Interest, less any return of capital realized from its investment in the Interest, or (b) the fair market value of the Interest as determined on the date of the Sale by an independent appraiser, and (5) if the Employer ever receives more from the Interest than it pays the Plan when acquiring the Interest, the Employer will pay the Plan the excess.

Summary of Facts and Representations

1. The Plan, effective April 1, 1995, and a successor by amendment to a profit sharing plan that had been established on November 1, 1970, is a defined contribution plan which features (a) employer-matching funding and salary deferral contributions by Plan participants, and (b) self-directed investments by Plan participants of their respective Plan accounts. The Plan is intended to be qualified pursuant to the requirements of sections 401(a) and 401(k) of the Code. The total assets of the Plan are $3,251,355, as of September 30, 1996, and the total participants in the Plan are approximately 747, as of January 17, 1997. The fiduciary of the Plan is the Advisory Committee (the Fiduciary) appointed by the Employer to administer the Plan and to direct the trustee of the Plan with respect to the investments of Plan assets by the participants. Currently, the Fiduciary consists of three employees all of whom are minority shareholders and two are officers of the Employer. The trustee of the Plan is Wells Fargo Bank (Colorado), N.A. (The Trustee) whose principal offices are located in San Franciso, California.

2. The Employer, a Colorado corporation, is a wholly owned subsidiary of Gart Sports Company, a Delaware corporation, which is privately held by 78 shareholders. The Employer was originally founded by the Gart family in 1928 as a family-operated, retail sporting goods store located in Denver, Colorado. From 1971 to the present, the Employer, through several changes in ownership, has expanded its retail stores in size and location throughout six states in the Rocky Mountain Region to include more than 60 stores and more than 1,700 employees.

3. The applicant represents that on November 16, 1987, the Plan, with an investment of $206,000 acquired the Interest in the Partnership, which had been established on March 20, 1970, from an unrelated person, The Denver Sympathy Fountain, a Colorado non-profit corporation.[1] As of March 17, 1997, this investment in the Partnership was determined to have a fair market value of $123,830 by Hale Companies, Inc., a real estate firm, located in Parker, Colorado. Hale Companies, Inc. represents that it is not related to the Plan, the Plan sponsor, or to the Fiduciary of the Plan.

The applicant represents, that because the value of real estate plummeted in Denver, Colorado during the late 1980s and early 1990s, the Partnership, on November 30, 1994, sold an asset, which consisted of real property, and distributed $70,500 to the Plan. During March 1995 the Partnership sold another parcel of real property to Mainstreet Quincy, LLC (Mainstreet LLC), a Colorado limited liability company, for a total sum of $5,010,000. At the closing of the sale of the second parcel of real property, Mainstreet LLC tendered as payment to the Partnership the sum of $760,000 in cash (of which $33,000 was distributed to the Plan on March 22, 1995) and two promissory notes. The first note is in the amount of $1,175,000, and promises to pay one-half of the earned annual 6 percent interest on every March 15th and September 15th, plus annual payments of $293,000 every March 15th on the outstanding principal until the obligation becomes due and payable in full on March 15, 2000. The second note is in the amount of $3,075,000, and earns 6 per cent interest with no interest or principal payable until the note matures on March 15, 2000. The applicant represents that the two promissory notes and a reserve account of approximately $11,000 are the only assets currently possessed by the Partnership.

4. On March 31, 1994, the Fiduciary communicated to the Partnership its desire to sell the Interest to other limited partners in the Partnership and received no response to its communication. During 1996 the Fiduciary again attempted with no success to sell the Interest to the other limited partners of the Partnership; and also, to a secondary market-maker of limited partnership interests. Also during 1996, an attempt was made by the Plan without success to sell its interest in the Partnership to Mainstreet LLC.

The applicant represents that on March 15, 1997, Mainstream LLC defaulted on the interest payment due on its first promissory note. On April 1, 1997, the applicant received confirmation from the U.S. Bankruptcy Court in Denver, Colorado that on December 30, 1996, Mainstream LLC, d/b/a Main Street Homes had filed for reorganization under Chapter 11 of the Bankruptcy Act and was assigned Case No. 96–26283CEM.

5. The applicant requests an administrative exemption from the prohibited transaction provisions of the Act to enable the Plan to sell the Interest it holds to the Employer, so that not only will the participants of the Plan be able to self-direct all the assets in their individual accounts, but they will be able to unburden the Plan of its investment in the Partnership. Also, the applicant represents that by selling the Interest to the Employer the Plan will avoid selling the Interest at a discounted price on the secondary market, and will avoid any commissions or other expenses in connection with the transaction.

The applicant represents that the Employer will pay to the Plan as consideration for the Sale of the Interest to the Employer the greater of either (a) the total funds expended by the Plan in acquiring and holding the Interest, less any return of capital from its investment in the Interest, or (b) the fair market value of the Interest as determined on the date of the Sale by an independent appraiser. The Trustee represents in a letter dated April 4, 1997, that it will ensure that the Plan will receive the consideration from the Sale as required by the proposed exemption of the Department.

6. In summary, the applicant represents that the proposed transaction will satisfy the criteria of section 408(a) of the Act because (a) the terms and conditions of the transaction are at least as favorable to the Plan as those obtainable from unrelated parties; (b) the Sale of the Interest involves a one-time transaction for cash; (c) the Plan will not incur the payment of any commissions nor any other expenses; (d) the transaction will enable the participants of the Plan to direct the investments of all the assets in their individual accounts in the Plan; (e) the Trustee will ensure that the consideration paid by the Employer is (i) the greater of either the funds expended by the Plan from acquiring

[1] The applicant represents that the individuals who were the members of the Advisory Committee and Plan Fiduciaries at the time the Plan acquired the Interest are no longer Fiduciaries of the Plan or employed by the Employer.

and holding the Interest, less any return of capital from the Interest, or (ii) the fair market value of the Interest as determined by an independent, qualified appraiser; and (f) if the Employer ever receives more from the Interest than it pays the Plan when acquiring the Interest, the Employer will pay the Plan the excess.

FOR FURTHER INFORMATION CONTACT: Mr. C.E. Beaver of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

First Savings Bank, F.S.B. Profit Sharing and Employee Stock Ownership Plan (the Plan) Located in Clovis, New Mexico

[Application No. D–10409]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 C.F.R. Part 2570, Subpart B (55 F.R. 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of sections 406(a), 406 (b)(1) and (b)(2), and 407 of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply, effective December 26, 1996 to (1) the acquisition by the Plan of certain stock rights (the Rights) pursuant to a stock rights offering (the Offering) by Access Anytime Bancorp, Inc. (the Parent), which is the parent corporation of First Savings Bank, F.S.B. (the Employer), the sponsor of the Plan; (2) the holding of the Rights by the Plan during the subscription period of the Offering; and (3) the exercise of certain of the Rights by the Plan; provided that the following conditions are satisfied:

(A) The Plan's acquisition and holding of the Rights occurred in connection with the Offering made available to all shareholders of common stock of the Parent;

(B) All holders of the common stock of the Employer were treated in the same manner with respect to the Offering, including the Plan;

(C) All decisions regarding the holding and potential exercise of the Rights by the Plan were made in accordance with Plan provisions for individually-directed investment of participant accounts by the individual Plan participant whose account in the Plan received Rights in the Offering; and

(D) With respect to any participants' accounts in the Plan for which no valid instructions were timely filed regarding the Rights during the Offering, such Rights expired unexercised in the same manner as unexercised Rights issued to all other holders of the common stock of the Parent, since the Rights were not transferable and could not be sold.

EFFECTIVE DATE: This exemption, if granted, will be effective as of December 26, 1996.

Summary of Facts and Representations

1. The Employer is a federal savings bank that conducts full service banking operations from its main office in Clovis, New Mexico, two branch locations in Clovis and Portales, New Mexico and a loan production office in Rio Rancho, New Mexico. Access Anytime Bancorp, Inc. (the Parent) is a Delaware public corporation [2] which was organized to become a holding company for the Employer. Pursuant to a merger agreement (the Merger) between the Employer and the Parent, and upon approval of the holders of the common stock of the Employer (the Employer Stock) on October 18, 1996, all outstanding shares of Employer Stock were converted into and exchanged for an equal number of shares of common stock of the Parent (Parent Stock). The Employer continues its banking operations as a wholly-owned subsidiary of the Parent.

2. The Employer maintains the Plan as a defined contribution plan combining a profit sharing component (the PSP) with an employee stock ownership component (the ESOP) for the benefit of employees of the Employer and each of the employers which are members of a controlled group with the Employer. As of October 31, 1996, the Plan had approximately 54 participants and total assets of $319,659. The trustee of the Plan is Roddy Pearce (the Trustee), who is an officer of the Employer. The Plan provides for individual participant accounts (the Accounts) in both the ESOP and the PSP, and participant-directed investment of the PSP Accounts. The Trustee acts as custodian of Plan assets, holding legal title to the assets and executing investment directions in accordance with the participants' directions. A committee appointed by the Employer's board of directors (the Committee) reviews all investment direction forms filed by Plan participants to check for possible errors, such as the failure of a participant to enter a signature or to specify clear instructions. The Plan assets in the ESOP are invested primarily in Parent Stock under the direction of the Trustee, and the assets in the PSP are invested pursuant to participant directions among nine different investment options. As of October 31, 1996, the ESOP component of 35 Accounts in the Plan held a total of 9,798 shares of Parent Stock comprising approximately 18 percent of total Plan assets.

3. Following the Merger and the conversion of Employer Stock to Parent Stock, the Parent commenced on December 26, 1996 (the Opening Date) an offering (the Offering) of new shares of Parent Stock to all holders of record (the Shareholders) of Parent Stock as of December 20, 1996 (the Record Date) pursuant to nontransferable subscription rights (the Rights) [3] issued to all of the Shareholders, including the Plan. One Right was issued for each share of Parent Stock held by the Shareholders, and each Right conferred upon its holder an entitlement to purchase one new share of Parent Stock at a stated subscription price of $5.25 per share (the Subscription Price) during the Offering, prior to close of business on the date of the Offering's expiration (the Expiration Date). The original Expiration Date was January 31, 1997, but the directors of the Parent extended the Offering to April 8, 1997. Under the terms of the Offering, each Right was non-transferable and was required to expire if not exercised prior to the close of the Expiration Date. As of the Opening Date, 732,198 shares of Parent stock were issued and outstanding, held by 450 Shareholders, including the Plan Accounts' investments in 9,798 shares, which constituted about 1.33 percent of all issued and outstanding Parent Stock. The Employer and the Parent are requesting an exemption for the Plan's acquisition and holding of 9,798 Rights pursuant to the Offering and, to the extent the Rights were exercised, for the exercise of the Rights, under the terms and conditions described herein.

4. In anticipation of the Offering, the Plan and its related trust agreement were amended with respect to all Plan participants with an Account invested in the Parent Stock (Invested Participants). Prior to this amendment and restatement of the Plan, participants had no authority to direct any investments of the ESOP portion of their Accounts. With the amendment, the Plan document enabled Invested Participants to determine the disposition of all Rights allocated to their Accounts. Pursuant to these

[2] The common stock of Access Anytime Bancorp, Inc. is publicly traded on the National Association of Securities Dealers Automated Quotation Small-Cap Market System under the symbol, ''AABC''.

[3] The Department notes that the Rights do not constitute ''qualifying employer securities'' within the meaning of section 407(d)(5) of the Act.

amended Plan provisions, each Invested Participant was permitted to direct the Trustee to exercise any or all of the Rights attributable to his or her Account. The Employer represents that the amendment and restatement of the Plan to provide pass-through elections to Plan participants was intended to place the Invested Participants in a like position with other Shareholders for purposes of the Offering. Since all shares of Parent Stock held by the Plan were allocated to participant Accounts, all decisions with respect to the Rights acquired by the Plan were made by individual Invested Participants. In order to exercise the Rights, the Invested Participants were required to file valid instructions with the Trustee no later than the close of the Expiration Date and to liquidate a sufficient portion of the non-Parent Stock assets in their Accounts to cover the Subscription Price. Those Rights with respect to which the Invested Participant failed to file with the Trustee valid exercise instructions before close of business on the Expiration Date expired in the same manner as the Rights held by non-Plan Shareholders. The Employer represents that 5,000 Rights were exercised by Invested Participants, that the remaining 4,798 Rights expired on the Expiration Date, and that no expenses were incurred by the Invested Participants or the Plan in connection with the Offering.

5. The Employer represents that upon commencement of the Offering, all Invested Participants were notified of the Offering and the procedure for filing instructions with the Trustee with respect to the Rights. The Employer states that all instructions timely filed by the Invested Participants were properly executed. The Employer represents that the Plan was necessarily involved in the Offering because the Parent accorded equal treatment to all Shareholders with respect to issuance of the Rights, and that the Plan was entitled to all rights and benefits available to other Shareholders. The Employer maintains that all actions by the Trustee with respect to the Offering were taken pursuant to express instructions of Invested Participants except when an Invested Participant failed to file timely, valid instructions, in which case the Rights were allowed to expire unexercised, since the Rights were non-transferable and could not be sold. The Employer represents that the Plan procedures requiring Invested Participants to file written instructions with the Trustee in order to exercise the Rights, and the expiration of the Rights upon the failure to do so, were fully disclosed in the advance notice to Invested Participants.

6. In summary, the applicant represents that the transactions satisfied the criteria of section 408(a) of the Act for the following reasons: (A) The Plan's acquisition of the Rights resulted from an independent act of the Parent; (B) With respect to all aspect of the Offering, all Shareholders were treated in the same manner, including the Plan; (C) All decisions with respect to the Plan's acquisition, holding and control of the Rights were made by the individual Invested Participants whose Accounts held Parent Stock, except for those Invested Participants who failed to file timely and valid instructions, in which case the Rights expired unexercised; and (D) The acquisition and holding of Rights affected 35 of the Plan's 54 participants whose accounts held only about 1.33 percent of the Parent Stock issued and outstanding as of the Record Date of the Offering.

FOR FURTHER INFORMATION CONTACT: Ronald Willett of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

BP America Inc. Retirement Trust (the BP Trust), Located in Cleveland, Ohio; IBM Retirement Plan Trust (the IBM Trust), Located in Armonk, New York; United States Steel Corporation Plan (the US Steel Plan), Located in Pittsburgh, Pennsylvania; and Retirement Plan of Marathon Oil Company (the Marathon Plan), Located in Findlay, Ohio; (collectively, the Plans)

[Application Nos. D–10441 through D–10444]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (D) of the Code, shall not apply to (1) the proposed granting to The Industrial Bank of Japan, Limited, New York Branch (IBJ), as the representative of lenders (the Lenders) participating in a credit facility (the Facility), of security interests in limited partnership interests in The Westbrook Real Estate Fund II, L.P. (the Partnership) owned by the Plans with respect to which some of the Lenders are parties in interest; and (2) the proposed agreements by the Plans to honor capital calls made by IBJ in lieu of the Partnership's general partner; provided that (a) the proposed grants and agreements are on terms no less favorable to the Plans than those which the Plans could obtain in arm's-length transactions with unrelated parties; (b) the decisions on behalf of each Plan to invest in the Partnership and to execute such grants and agreements in favor of IBJ are made by a fiduciary which is not included among, and is independent of, the Lenders and IBJ; and (c) with respect to plans that may invest in the Partnership in the future, such plans will have assets of not less than $100 million and not more than 5% of the assets of such plans will be invested in the Partnership.

Summary of Facts and Representations

1. The Partnership is a Delaware limited partnership the general partner of which is Westbrook Real Estate Partners Management II, L.L.C. (the General Partner), a Delaware limited liability company. The Partnership has an eight-year term from the initial closing date, expiring on February 24, 2005, and will be self-liquidating. The Partnership has been organized to make investments, including leveraged equity investments, in undervalued or inappropriately capitalized real estate assets and portfolios, and corporate real estate. Proceeds from the sale or refinancing of properties generally will not be reinvested, but will be distributed to the limited partners, so that the Partnership will be self-liquidating.

2. After execution of the Partnership Agreement (the Agreement), the General Partner sought capital commitments through private placement and has obtained, as a result, irrevocable, unconditional capital commitments in excess of at least $410,000,000 from approximately 17 current and prospective purchasers of limited partnership units (the Limited Partners). The Agreement requires Limited Partners to make capital contributions upon receipt of notice from the General Partner. Under the Agreement, the General Partner may make a call for cash contributions, also known as a ''drawdown'', up to the total amount of the Limited Partner's capital commitment upon 15 business days' notice, with some limitations. The Partners' capital commitments are structured as irrevocable, unconditional and binding commitments to contribute equity when capital calls are made by the General Partner. The obligation of each Limited Partner to contribute the full amount of its capital commitment is secured by a security interest granted to

the Partnership in the Limited Partner's partnership interest.

3. In the ordinary course of its business operations, it is contemplated that the Partnership will incur indebtedness in connection with many of its investments. This on-going need for credit will be provided by the Facility, a two-year, eleven month arrangement for revolving credit with restricted availability levels, which will enable the Partnership to consummate investments quickly without the delay of separate arrangements for interim or permanent financing for each investment. The Facility is funded by the Lenders, represented by IBJ and NationsBank, N.A. (NationsBank) which will also be participating lenders. IBJ and NationsBank will serve as administrative agents for the Facility. The Facility will be a non-recourse obligation of the Partnership which matures in the year 2000 and which is secured by a security interest in the Limited Partners' capital commitments, the General Partner's right to make drawdowns and the Partnership's lien and security interest in each Limited Partner's partnership interest. As additional security, the Facility will require each Limited Partner to execute an agreement (the Security Agreement) granting to IBJ, for the benefit of each Lender, a security interest and lien in the Limited Partner's partnership interest, and covenanting with IBJ, for the benefit of the Lenders, that such Limited Partner will unconditionally honor any drawdown made by IBJ in accordance with the Agreement in lieu of the General Partner to the full extent of the Limited Partner's unfunded capital commitment.

4. The trusts which hold assets of the Plans (the Trusts) own limited partnership interests as Limited Partners in the Partnership. Some of the Lenders may be parties in interest with respect to some of the Plans in the Trusts by virtue of such Lenders' (or their affiliates') provisions of fiduciary services to such Plans with respect to Trust assets other than the Partnership interests. IBJ is requesting an exemption to permit the Trusts to enter into the Security Agreements under the terms and conditions described herein. The Plans and the other Limited Partners with the largest interests in the Partnership and the extent of their respective capital commitments to the Partnership are described as follows:

(a) The BP Trust holds the assets of the following Plans: BP America Master Hourly Plan for Represented Employees, a defined benefit plan with 16,165 participants as of December 31, 1995, and BP America Retirement Accumulation Plan, a defined benefit plan with 25,636 participants as of that date. The BP Trust also holds assets from some smaller Plans (together with two above-described Plans, the BP Plans). The approximate fair market value of the total assets of the BP Plans held in the BP Trust is $1.6 billion. The fiduciary of the BP Plans generally responsible for investment decisions is S.W. Percy, Chief Executive Officer, BP America, Inc. Mr. Percy is also the fiduciary responsible for reviewing and authorizing the investment in the Partnership to which the exemption proposed herein relates. The BP Trust has undertaken a total capital commitment of $10,000,000 in the Partnership.

(b) The IBM Trust holds the assets of the IBM Retirement Plan (the IBM Plan), a defined benefit pension plan with 289,934 participants as of December 31, 1995, and assets with a total value of approximately 31 billion dollars as of that date. The fiduciary of the IBM Plan generally responsible for investment decisions is the IBM Investment Committee, which is the fiduciary responsible for reviewing and authorizing the IBM Plan's investment in the Partnership. The IBM Trust has undertaken a total capital commitment of $75,000,000 in the Partnership.

(c) The USS Special Investments Group Trust holds assets of the US Steel Plan, a defined benefit pension plan with 139,082 participants as of December 31, 1995, and with assets of approximately 8.5 billion dollars as of that date. The fiduciary responsible for reviewing and authorizing the investment in the Partnership by the US Steel Plan is United States Steel and Carnegie Pension Fund, Trustee, which is the fiduciary of the US Steel Plan generally responsible for investment decisions. This Trust has undertaken a total capital commitment of $20,000,000 in the Partnership.

(d) The MRO Special Investments Group Trust holds assets of the Marathon Plan and the Petroleum Marketing Retirement Plan (the PMR Plan). The Marathon Plan is a defined benefit plan with 10,519 participants and approximately $881 million in total assets as of December 31, 1995. The PMR Plan is a defined benefit plan with 6,608 participants and approximately $15.9 million in total assets as of December 31, 1995. The fiduciary of the Marathon Plan and the PMR Plan generally responsible for investment decisions is United States Steel and Carnegie Pension Fund, Trustee, which is also the fiduciary responsible for reviewing and authorizing the investment in the Partnership to which the exemption proposed herein relates. This Trust has undertaken a total capital commitment of $5,000,000 in the Partnership.

(e) The applicant represents that it is possible that one or more other Plans may become Limited Partners at some time in the future, and requests relief for any such Plan under the exemption proposed herein, provided the Plan meets the standards and conditions set forth herein. The applicant further represents that any such Plan will have assets of at least $100 million, and that no more than 5% of the assets of such Plan will be invested in the Partnership.

(f) Limited Partners which are not ERISA-covered plans include:

(i) Arkansas Teacher Retirement System, which has undertaken a total capital commitment of $50,000,000.

(ii) Allstate Insurance Company, which has undertaken a total capital commitment of $20,000,000.

(iii) Atlantic Equity Corporation, which has undertaken a total capital commitment of $20,000,000.

(iv) The Trustees of Columbia University, which has undertaken a total capital commitment of $20,000,000.

(v) The Trustees of Dartmouth College, which has undertaken a total capital commitment of $10,000,000.

(vi) New York State Common Retirement Fund, which has undertaken a total capital commitment of $25,000,000.

(vii) Commonwealth of Pennsylvania State Employees' Retirement System, which has undertaken a total capital commitment of $56,000,000.

(viii) J.H. Pew Freedom Trust, which has undertaken a total capital commitment of $4,200,000.

(ix) J.N. Pew, Jr. Trust, which has undertaken a capital commitment of $2,100,000.

(x) Mabel Pew Myrin Trust, which has undertaken a total capital commitment of $2,700,000.

(xi) Pew Memorial Trust, which has undertaken a total capital commitment of $21,000,000.

(xii) State of Wisconsin Investment Board, which has undertaken a total capital commitment of $75,000,000.

(xiii) The General Partner, which has undertaken a total capital commitment of $4,151,515.

5. IBJ represents that the Partnership will obtain an opinion of counsel that the Partnership will constitute an ''operating company'' under the Department's plan asset regulations [29 CFR 2510.3–101(c)] if the Partnership is operated in accordance with the Agreement and the offering memorandum (the Offering) distributed

in connection with the private placement of the limited partnership interests.[4]

6. IBJ represents that the Security Agreement constitutes a form of credit security which is customary among financing arrangements for real estate limited partnerships, wherein the financing institutions do not obtain security interests in the real property assets of the partnership. IBJ also represents that the obligatory execution of the Security Agreement by the Limited Partners for the benefit of the Lenders was fully disclosed in the Offering as a requisite condition of investment in the Partnership during the private placement of the limited partnership interests. IBJ represents that with respect to the Partnership and its activities, the only direct relationship between any of the Limited Partners and any of the Lenders is the execution of the Security Agreements. All other aspects of the transaction, including the negotiation of all terms of the Credit Facility, are exclusively between the Lenders and the Partnership. IBJ represents that the proposed executions of the Security Agreements will not affect the abilities of the Trusts to withdraw from investment and participation in the Partnership. The only Plan assets to be affected by the proposed transaction are each Plan's limited partnership interests in the Partnership and the related Plan obligations as Limited Partners to respond to drawdowns up to the total amount of each Plan's capital commitment to the Partnership.

7. IBJ represents that neither it nor any Lender acts or has acted in any fiduciary capacity with respect to any Trust's investment in the Partnership and that IBJ is independent of and unrelated to those fiduciaries (the Trust Fiduciaries) responsible for authorizing and overseeing the Trusts' investments in the Partnership. Each Trust Fiduciary represents independently that its authorization of Trust investment in the Partnership was free of any influence, authority or control by the Lenders. The Trust Fiduciaries represent that the Trust's investments in and capital commitments to the Partnership were made with the knowledge that each Limited Partner would be required subsequently to grant a security interest in the Partnership to the Lenders and to honor drawdowns made on behalf of the Lenders without recourse to any defenses against the General Partner. Each Trust Fiduciary individually represents that it is independent of and unrelated to IBJ and the Lenders and that the investment by the Trust for which that Trust Fiduciary is responsible continues to constitute a favorable investment for the Plans participating in that Trust and that the execution of the Security Agreement is in the best interests and protective of the participants and beneficiaries of such Plans.

8. In summary, the applicants represent that the proposed transactions satisfy the criteria of section 408(a) of the Act for the following reasons: (1) The Plans' investments in the Partnership were authorized and are overseen by the Trust Fiduciaries, which are independent of the Lenders; (2) None of the Lenders have any influence, authority or control with respect to the Plans' investments in the Partnership or the Plans' executions of the Security Agreements; and (3) The Trust Fiduciaries invested in the Partnership on behalf of the Plans with the knowledge that the Security Agreements are required of all Limited Partners investing in the Partnership.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete and accurately describe all material terms of the transaction which is the subject of the exemption. In the case of continuing exemption transactions, if any of the material facts or representations described in the application change after the exemption is granted, the exemption will cease to apply as of the date of such change. In the event of any such change, application for a new exemption may be made to the Department.

Signed at Washington, DC, this 30th day of May, 1997.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 97–14559 Filed 6–3–97; 8:45 am]

BILLING CODE 4510–29–P

[4] The Department expresses no opinion herein as to whether the Partnership will constitute an operating company under the regulations at 29 CFR 2510.3–101.

NATIONAL BANKRUPTCY REVIEW COMMISSION

Meeting

AGENCY: National Bankruptcy Review Commission.

ACTION: Notice of Public Meeting.

Time and Date: Thursday, June 19, 1997; 10 a.m. to 5:30 p.m. and Friday, June 20 1997; 8:30 a.m. to 5 p.m.

Place: Theodore Levin United States Courthouse, 231 West Lafayette Boulevard—Room 115, Detroit, Michigan. It is recommended that the public use the entrance located at Fort Street. The handicap entrance is also located on Fort Street.

Status: The meeting will be open to the public.

Notice: At its public meeting, the Commission will consider general administrative matters and substantive agenda items including small business, single asset and partnership bankruptcies; sections 105 and 362(b) of the Bankruptcy Code; and the use of alternative dispute resolution, mediators

and examiners in Chapter 11 cases. Other substantive matters include: Chapter 11, consumer bankruptcy, government, jurisdiction and procedure, mass torts and future claims, service to the estate and ethics, and preferences. Two open forum sessions for public participation are tentatively scheduled for June 19, 1997 from 4:30 p.m. to 5:30 p.m. and June 20, 1997 from 8:30 a.m. to 9:30 a.m. The dates and times for the open forum sessions are subject to change. The public meeting on June 19, 1997 will be preceded by a meeting of the Service to the Estate and Ethics Working Group, which is also open to the public. The Working Group session will begin on June 19, 1997 at 8 a.m. and will be held at Theodore Levin United States Courthouse—Room 115.

SUPPLEMENTARY INFORMATION: Any individual or organization who wants to make an oral presentation to the National Bankruptcy Review Commission concerning the Commission's statutory responsibilities may do so at the open forum sessions. Persons who would like to make an oral presentation to the Commission at the open forum sessions should register in advance by contacting the National Bankruptcy Review Commission at (202) 273–1813 no later than 5 p.m. est on June 18, 1997 or register in person at the National Bankruptcy Review Commission registration desk at the meeting site. Open forum registrants are asked to provide name, organization (if applicable), address and phone number. If the volume of requests to speak at the open forum sessions exceeds the time available to accommodate all such requests, the speakers will be chosen on the basis of order of registration.

Oral presentations will be limited to five minutes per speaker. Persons speaking at the open forum sessions are requested, but not required, to supply twenty (20) copies of their written statements prior to their presentations to the National Bankruptcy Review Commission, Thurgood Marshall Federal Judiciary Building, One Columbus Circle, N.E., Suite 5–130, Washington, DC 20544. Written submissions are not subject to any limitations.

FOR FURTHER INFORMATION CONTACT: Susan Jensen-Conklin or Carmelita Pratt at the National Bankruptcy Review Commission, Thurgood Marshall Federal Judiciary Building, One Columbus Circle, NE, Suite 5–130, Washington, DC 20544; Telephone Number: (202) 273–1813.

Susan Jensen-Conklin,

General Counsel.

[FR Doc. 97–14598 Filed 6–3–97; 8:45 am]

BILLING CODE 6820–36–P

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Civil and Mechanical Systems; Notice of Meetings

This notice is being published in accord with the Federal Advisory Committee Act (Pub. L. 92–463, as amended). During the period June 17 through June 20, 1997, the Special Emphasis Panel will be holding panel meetings to review and evaluate research proposals. The dates, contact person, and types of proposals are as follows:

Special Emphasis Panel in Civil and Mechanical Systems (1205)

1. *Date:* June 17, 1997.
Contact: Dr. Priscilla Nelson, Program Director, Geomechanical, Geotechnical, & Geoenvironmental Program. Telephone: (703) 306–1361.
Type of Proposal: To Review and Evaluate Unsolicited Proposals as part of the selection process for awards.
2. *Date:* June 18, 1997.
Contact: Dr. Priscilla Nelson, Program Director, Geomechanical, Geotechnical, & Geoenvironmental Program. Telephone: (703) 306–1361.
Type of Proposal: To Review and Evaluate Unsolicited Proposals as part of the selection process for awards.
3. *Date:* June 19, 1997.
Contact: Dr. K. Chong, Program Director, Geomechanical and Structural Cluster. Telephone: (703) 306–1361.
Type of Proposal: To Review and Evaluate Unsolicited Proposals as part of the selection process for awards.
4. *Date:* June 19–20, 1997.
Contact: Dr. K. Chong, Program Director, Geomechanical and Structural Cluster. Telephone: (703) 306–1361.
Type of Proposal: To Review and Evaluate Unsolicited Proposals as part of the selection process for awards.
Times: 8:30 a.m. to 5:00 p.m. each day.
Place: National Science Foundation, 4201 Wilson Blvd., Arlington, VA.
Type of Meetings: Closed.
Purpose of Meetings: To provide advice and recommendations concerning proposals submitted to NSF for financial support.
Agenda: To review and evaluate unsolicited proposals as part of the selection process for awards.
Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: May 29, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–14557 Filed 6–3–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Elementary, Secondary and Informal Education; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name and Committee Code: Special emphasis Panel in Elementary, Secondary and Informal Education (#59).
Date and time: Monday–Tuesday, June 23–24, 1997, 8:00 a.m.–5:00 p.m.
Place: St. James Hotel, 950 24th St., NW., Washington, DC 20037.
Type of Meeting: Closed.
Contact Person: Dr. Gerhard Salinger, Program Director, Division of Elementary, Secondary and Informal Education, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1614.
Purpose of Meeting: To provide advice and recommendations concerning proposals for the Advance Technological Education Program submitted to NSF for financial support.
Agenda: To review and evaluate proposals as part of the selection process for awards.
Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: May 29, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–14556 Filed 6–3–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Geosciences; Notice of Meetings

This notice is being published in accord with the Federal Advisory

Committee Act (Pub. L. 92–463, as amended). During the period June 1 through September 1, 1997, the Special Emphasis Panel will be holding panel meetings to review and evaluate research proposals. The dates, contact persons, and types of proposals are:

Special Emphasis Panel in Geosciences (1756)

1. *Date:* June 23–24, 1997.
Contact: Dr. Richard Behnke, (703) 306–1519, Section Head, Division of Atmospheric Sciences, Room 775.
Type of Proposal: Space Weather Research Program.
2. *Date:* August 21–22, 1997.
Contacts: Dr. Sunanda Basu, (703) 306–1529, Program Director, Dr. Robert Robinson, (703) 306–1531, Program Director, Division of Atmospheric Sciences, Room 775
Type of Proposal: Coupling, Energetics and Dynamics of Atmospheric Regions (Cedar).
Times: 8:30 a.m. to 5:00 p.m. each day.
Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA.
Type of Meeting: Closed.
Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.
Agenda: To review and evaluate proposals submitted to the Directorate as part of the selection process for awards.
Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 USC 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: May 29, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–14555 Filed 6–3–97; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–334]

Duquesne Light Company; Notice of Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (Commission) has issued Amendment No. 204 to Facility Operating License No. DPR–66 issued to Duquesne Light Company, et al., (the licensee) which revised the Technical Specifications for operation of the Beaver Valley Power Station, Unit No. 1, located in Shippingport, Pennsylvania. The amendment is effective as of the date of issuance, to be implemented within 60 days.

The amendment modified Technical Specification (TS) 5.3.1.2.a to increase the maximum allowable U–235 enrichment of new fuel assemblies in the new fuel storage racks to 5.0 weight percent with a tolerance of +0.05 weight percent, and modified TS 5.3.1.2.c to increase the maximum allowable K_{eff} to less than or equal to 0.98 for moderation by aqueous foam.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License and Opportunity for a Hearing in connection with this action was published in the **Federal Register** on March 25, 1997 (62 FR 14166). No request for a hearing or petition for leave to intervene was filed following this notice.

The Commission has prepared an Environmental Assessment related to the action and has determined not to prepare an environmental impact statement. Based upon the environmental assessment, the Commission has concluded that the issuance of the amendment will not have a significant effect on the quality of the human environment (62 FR 27791).

For further details with respect to the action see (1) the application for amendment dated February 27, 1997, (2) Amendment No. 204 to License No. DPR–66, (3) the Commission's related Safety Evaluation, and (4) the Commission's Environmental Assessment. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room located at the B.F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, PA 15001.

Dated at Rockville, Maryland, this 28th day of May 1997.

For the Nuclear Regulatory Commission.

Donald S. Brinkman,

Senior Project Manager, Project Directorate I–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97–14532 Filed 6–3–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–220]

Niagara Mohawk Power Corporation; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–63 issued to Niagara Mohawk Power Corporation (NMPC) for operation of the Nine Mile Point Nuclear Station Unit No. 1 (NMP1) located in Lycoming, New York.

The proposed amendment would make an administrative change to the NMP1 Technical Specifications (TSs). The administrative change is to add a supervisory position to the list of personnel who may be required to hold a senior reactor operator license.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 1, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The addition of the position of GSO [General Supervisor Operations] and the requirement for either the GSO or the

Manager Operations to have an SRO, [Senior Reactor Operator] license is a restructuring of the Operations department. The proposed changes are administrative changes that provide additional Operations management oversight capabilities. The resulting organization meets the requirements of ANSI [American National Standards Institute] N18.1–1971 and SRP [Standard Review Plan] 13.1.1–13.1–3. No physical modification of the plant is involved and no changes to the methods in which plant systems are operated are required.

None of the precursors of previously evaluated accidents are affected, and no new failure modes are introduced. Therefore, this change will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The operation of Nine Mile Point Unit 1, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The addition of the position of GSO and the requirement for either the GSO or the Manager Operations to have an SRO license is a restructuring of the Operations department. The proposed changes are administrative changes that provide additional Operations management oversight capabilities. The resulting organization meets the requirements of ANSI N18.1–1971 and SRP 13.1.1–13.1.3. No physical modification of the plant is involved and no changes to the methods in which plant systems are operated are required. As such, the change does not introduce any new failure modes or conditions that may create a new or different accident. Therefore, this change does not in itself create the possibility of a new or different kind of accident from any accident previously evaluated.

The operation of Nine Mile Point Unit 1, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

The addition of the position of GSO and the requirement for either the GSO or the Manager Operations to have an SRO license is a restructuring of the Operations department. The proposed changes are administrative changes that provide additional Operations management oversight capabilities. The resulting organization meets the requirements of ANSI N18.1–1971 and SRP 13.1.1–13.1.3. No physical modification of the plant is involved and no changes to the methods in which plant systems are operated are required. As such, this change does not in itself adversely affect any physical barrier to the release of radiation to plant personnel or to the public. Therefore, the change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, agrees that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By July 7, 1997, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with

the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one 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 a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 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) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Alexander W. Dromerick, Acting Director: 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 20555–0001, and to Mark J. Wetterhahn, Esquire, Winston and Strawn, 1400 L Street, NW., Washington, DC 20005–3502, 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 May 16, 1997, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Dated at Rockville, Maryland, this 30th day of May 1997.

For the Nuclear Regulatory Commission.

Alexander W. Dromerick,

Acting Director, Project Directorate I–1, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97–14534 Filed 6–3–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–346]

Toledo Edison Company, Centerior Service Company and the Cleveland Electric Illuminating Company; Davis-Besse Nuclear Power 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 certain requirements of its regulations to Facility Operating License No. NPF–3, issued to the Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company (the licensees), for operation of the Davis-Besse Nuclear Power Station (DBNPS), located in Ottawa County, Ohio.

Environmental Assessment

Identification of the Proposed Action

The proposed action would exempt the licensees from certain requirements of 10 CFR 73.55, ''Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors Against Radiological Sabotage.'' The requested exemption would allow the implementation of a hand geometry biometric system of site access control in conjunction with photograph identification badges and would allow the badges to be taken offsite. The proposed action is in accordance with the licensees' application for exemption dated January 20, 1997, which superseded the previous application dated June 28, 1996, as supplemented by letter dated October 4, 1996. A previous environmental assessment addressing the June 28, 1996, submittal, as supplemented October 4, 1996, was published on August 14, 1996 (61 FR 42273).

The Need for the Proposed Action

Pursuant to 10 CFR 73.55(a), the licensees are required to establish and maintain an onsite physical protection system and security organization.

In 10 CFR 73.55(d), ''Access Requirements,'' it is specified in part that ''The licensee shall control all points of personnel and vehicle access into a protected area.'' In 10 CFR 73.55(d)(5), it is specified in part that ''A numbered picture badge identification system shall be used for all individuals who are authorized access to protected areas without escort.'' It is further specified that an individual not employed by the licensee (for example, contractors) may be authorized access to protected areas without an escort provided the individual ''receives a picture badge upon entrance into the protected area which must be returned upon exit from the protected area * * *.''

Currently, unescorted access for both employee and contractor personnel into the DBNPS is controlled through the use of picture badges. Positive identification of personnel who are authorized and request access into the protected area is established by security personnel making a visual comparison of the individual requesting access and that individual's picture badge. The picture badges are issued, stored, and retrieved at the entrance/exit location to the protected area. In accordance with 10 CFR 73.55(d)(5), contractor personnel are not allowed to take their picture badges offsite. In addition, in accordance with the plant's physical security plan, the licensees' employees are also not allowed to take their picture badges offsite. The licensees propose to implement an alternative unescorted access control system that would eliminate the need to issue and retrieve picture badges at the entrance/exit location to the protected area. The proposal would also allow contractors who have unescorted access to keep their picture badges in their possession

when departing the DBNPS site. In addition, the site security plans will be revised to allow implementation of the hand geometry system and to allow employees and contractors with unescorted access to keep their picture badges in their possession when leaving the DBNPS site.

An exemption from certain requirements of 10 CFR 73.55(d)(5) is needed to authorize implementation of the licensees' proposal.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action. In addition to their picture badges, all individuals with authorized unescorted access will have the physical characteristics of their hand (hand geometry) registered with their picture badge number in a computerized access control system. Therefore, all authorized individuals must have not only their picture badges to gain access into the protected area, but must also have their hand geometry confirmed.

All other access processes, including search function capability and access revocation, will remain the same. A security officer responsible for access control will continue to be positioned within a bullet-resistant structure. The proposed system is only for individuals with authorized unescorted access and will not be used for individuals requiring escorts.

The underlying purpose for requiring that individuals not employed by the licensees must receive and return their picture badges at the entrance/exit is to provide reasonable assurance that the access badges could not be compromised or stolen with a resulting risk that an unauthorized individual could potentially enter the protected area. Although the proposed exemption will allow individuals to take their picture badges offsite, the proposed measures require that not only the picture badge be provided for access to the protected area, but also that verification of the hand geometry registered with the badge be performed as discussed above. Thus, the proposed system provides an identity verification process that is at least equivalent to the existing process.

Accordingly, the Commission concludes that the proposed exemption to allow individuals not employed by the licensees to take their picture badges offsite will not result in an increase in the risk that an unauthorized individual could potentially enter the protected area. Consequently, the Commission concludes that granting the exemption will not increase the probability or consequences of any accident, will make no changes in the types of any effluents that may be released offsite, and will not significantly increase the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does involve features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect non-radiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed action, the staff considered denial of the proposed action. Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the DBNPS.

Agencies and Persons Consulted

In accordance with its stated policy, on April 1, 1997, the staff consulted with the Ohio State official, Carol O'Claire of the Ohio Emergency Management Agency, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensees' letter dated January 20, 1997, which is available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the University of Toledo, William Carlson Library, Government Documents Collection, 2801 West Bancroft Avenue, Toledo, Ohio 43606.

Dated at Rockville, Maryland, this 29th day of May 1997.

For the Nuclear Regulatory Commission.

Jon B. Hopkins,

Acting Director, Project Directorate III–3, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 97–14533 Filed 6–3–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of June 2, 9, 16, and 23, 1997.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of June 2

Wednesday, June 4

11:30 a.m.—Affirmation Session (Public Meeting) (if needed)

Week of June 9—Tenative

Wednesday, June 11

9:00 a.m.—Briefing by the Executive Branch (Closed—Ex. 1)

Thursday, June 12

1:30 p.m.—Briefing on Status of License Renewal (Public Meeting), (Contact: P.T. Kuo, 301–415–3147)

3:00 p.m.—Briefing on Steam Generator Issues (Public Meeting), (Contact: Brian Sheron, 301–415–2722)

4:30 p.m.—Affirmation Session (Public Meeting) (if needed)

Friday, June 13

9:00 a.m.—Briefing on Medical Regulation Issues (Public Meeting), (Contact: Catherine Haney, 301–415–6852)

Week of June 16—Tentative

Thursday, June 19

11:30 a.m.—Affirmation Session (Public Meeting) (if needed)

Week of June 23—Tenative

Wednesday, June 25

10:00 a.m.—Briefing on Operating Reactors and Fuel Facilities (Public Meeting), (Contact: William Dean, 301–415–1726)

11:30 a.m.—Affirmation Session

(Public Meeting) (if needed)

2:00 p.m.—Briefing on Salem (Public Meeting), (Contact: John Zwolinski, 301–415–1453)

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Bill Hill (301) 415–1661.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrc.gov/SECY/smj/schedule.htm.

This notice is distributed by mail to several hundred subscribers: if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary. Attn: Operations Branch, Washington, D.C. 20555 (301–415–1661).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to wmh@nrc.gov or dkw@nrc.gov.

* * * * *

Dated: May 30, 1997.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 97–14679 Filed 6–2–97; 10:21 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Biweekly Notice

Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law 97-415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Public Law 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from May 12, 1997, through May 22, 1997. The last biweekly notice was published on May 21, 1997 (62 FR 27792).

Notice Of Consideration Of Issuance Of Amendments To Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, And Opportunity For A Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By July 7, 1997, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room for the particular facility involved. 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 a 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 interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first

prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one 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 a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC, by the above date. Where petitions are filed during the last 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) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to **(Project Director)**: 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 20555-0001, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of 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 which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

Consumers Power Company, Docket No. 50-155, Big Rock Point Plant, Charlevoix County, Michigan

Date of amendment request: April 22, 1997 (supersedes October 15, 1996, request)

Description of amendment request: The proposed amendment would revise the Big Rock Point Technical Specifications to correct several administrative and editorial inconsistencies.

Basis for proposed no significant hazards consideration determination: 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. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes are clarifications within the Technical Specifications, and do not alter the technical content of the technical specifications. Plant operation or configuration is not affected. The postulated doses received by the general public and plant personnel as a direct result of accidents previously described, are not affected. Plant operation or configuration is not affected. Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes are either clarifications to correct inconsistencies within the Technical Specifications, or corrections of typographical errors. The proposed changes do not alter the facility in any way, therefore the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The proposed change[s] [do] not affect any margin of safety as defined by the Plant Technical Specifications.

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.

Local Public Document Room location: North Central Michigan College, 1515 Howard Street, Petoskey, Michigan 49770

Attorney for licensee: Judd L. Bacon, Esquire, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201

NRC Project Director: John N. Hannon

Consumers Power Company, Docket No. 50-155, Big Rock Point Plant, Charlevoix County, Michigan

Date of amendment request: April 30, 1997

Description of amendment request: The proposed amendment would alter the company name in the Facility Operating License DPR-6 and Technical Specifications for the Big Rock Point Plant. Specifically, the proposed amendment would revise the company name from ''Consumers Power Company'' to ''Consumers Energy Company.''

Basis for proposed no significant hazards consideration determination: 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. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes alter the company name in the Facility Operating License and Technical Specifications to reflect the change from ''Consumers Power Company'' to ''Consumers Energy Company''. The company will continue to own all of the same assets, will continue to serve the same customers, and will continue to honor all existing obligations and commitments.

Since the proposed changes do not alter the technical content of any Facility Operating License or Technical Specifications requirements, they do not alter the design, function, or operation of any plant structure, system, or component.

Therefore, the changes will not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes alter the company name in the Facility Operating License and Technical Specifications to reflect the change from ''Consumers Power Company'' to ''Consumers Energy Company''. The company will continue to own all of the same assets, will continue to serve the same customers, and will continue to honor all existing obligations and commitments.

Since the proposed changes do not alter the technical content of any Facility Operating License or Technical Specifications requirements, they do not alter the design, function, or operation of any plant structure, system, or component.

Therefore, the changes will not create the possibility of a new or different kind of accident from any previously evaluated.

3. Involve a significant reduction in a margin of safety.

Since the proposed changes do not alter the technical content of any Facility Operating License or Technical Specifications requirements, they do not alter the design, function, or operation of any plant structure, system, or component.

Therefore, the changes will not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: North Central Michigan College, 1515 Howard Street, Petoskey, Michigan 49770

Attorney for licensee: Judd L. Bacon, Esquire, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201

NRC Project Director: John N. Hannon

Duke Power Company, Docket No. 50-413, Catawba Nuclear Station, Unit 1, York County, South Carolina

Date of amendment request: May 8, 1997

Description of amendment request: The proposed amendment would add a phrase to the footnote to Section 3.4.1.2 of the Technical Specifications that would permit all reactor coolant pumps (RCPs) to be deenergized for up to 4 hours during Mode 3 on a one-time basis. Currently, the RCPs are permitted to be deenergized for up to 1 hour during Mode 3. The proposed change would allow the licensee to perform a natural circulation test using the new steam generators (installed in late 1996).

Basis for proposed no significant hazards consideration determination: 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 activity does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed natural circulation test would be performed in Mode 3 with the reactor subcritical. This transient is bounded by the transient analyzed in UFSAR [Updated Final Safety Analysis Report] Section 15.2.6, Loss of Non-Emergency AC Power to the Station Auxiliaries. For this ANS [American Nuclear Society] Condition II event, the reactor is assumed to be operating at 102% power, the turbine driven auxiliary feedwater pump is assumed unavailable and each steam generator is assumed to have 18% of the steam generator tubes plugged. By contrast, the planned natural circulation test would be performed with the reactor subcritical, less than 0.1% of the tubes plugged in each steam generator, and all support systems such as auxiliary feedwater, operable for the test. Therefore, the proposed natural circulation test would not involve a significant increase in the probability or consequences of an accident previously evaluated.

2) The activity does not create the possibility of a new or different type of accident from any accident previously evaluated.

The proposed change does not involve a physical alteration of the unit (i.e., no new or different equipment will be installed), nor will the function of equipment be changed. The change will allow for a one time performance of a natural circulation test in Mode 3 which will provide useful data on the natural circulation capabilities of the new Babcock and Wilcox International (BWI) steam generators that were recently installed at Catawba Unit 1. The test data will be utilized to validate analysis and simulator models. Plant operators will also receive valuable experience from performance of the test. The test will be conducted using written and approved procedures. An Emergency procedure (EP/1/A/5000/ECA-0.1) is also available to the Operators for this test. This test is bounded by the Loss of Non-Emergency AC Power to the Station Auxiliaries event in Section 15.2.6 of the Catawba UFSAR. For these reasons, the planned natural circulation test will not create the possibility of a new or different type of accident from any previously evaluated.

3) The activity does not involve a significant reduction in the margin of safety.

Margin of safety is associated with confidence in the ability of the fission product barriers (the fuel and fuel cladding, the Reactor Coolant System pressure boundary, and the containment) to limit the level of radiation doses to the public. As demonstrated by the bounding UFSAR analysis in Section 15.2.6, none of the fission product barriers are adversely impacted by the proposed one-time change. The proposed change does not alter the manner in which safety limits, limiting safety system setpoints, or limiting conditions for operation are determined. For these reasons, the activity does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the proposed amendments involve no significant hazards consideration.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242

NRC Project Director: Herbert N. Berkow

Florida Power and Light Company, Docket Nos. 50-250 and 50-251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of amendment request: February 24, 1997, as supplemented on April 24, 1997.

Description of amendment request: The licensee proposed changes to Technical Specification Section 6.9.1.7, Core Operating Limits Report, to reflect use of the Westinghouse Best Estimate Large Break Loss-of-Coolant Accident (LOCA) methodology for large break LOCA analysis, including supporting documents.

Basis for proposed no significant hazards consideration determination: 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:

Question 1 Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

The plant conditions assumed in the analysis are bounded by the design conditions for all equipment in the plant. Therefore, there will be no increase in the probability of a Loss of Coolant Accident

(LOCA). The consequences of a LOCA are not being increased. That is, it is shown that the emergency core cooling system is designed so that its calculated cooling performance conforms to the criteria contained in 10 CFR 50.46 paragraph (b). No other accident is potentially affected by this change. Therefore, neither the BiWeekly probability nor the consequences of an accident previously evaluated is increased due to the proposed change.

Question 2 Does the proposed license amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

No new modes of plant operation are being introduced. The parameters assumed in the analysis are within the design limits of existing plant equipment. All plant systems will perform as designed in response to a potential accident. Therefore, the proposed license amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated.

Question 3 Does the proposed amendment involve a significant reduction in the margin of safety?

The analysis in support of the proposed license amendment realistically models the expected response of the Turkey Point Units 3 & 4 nuclear core during a postulated LOCA. Uncertainties have been accounted for as required by 10 CFR 50.46. A sufficient number of loss of coolant accidents with different break sizes, different break locations and other variations in properties have been calculated to provide assurance that the most severe postulated loss of coolant accidents were analyzed. It has been shown by the analysis that there is a high level of probability the criteria contained in 10 CFR 50.46 paragraph (b) would not be exceeded. Therefore, the proposed amendment does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Florida International University, University Park, Miami, Florida 33199

Attorney for licensee: M.S. Ross, Attorney, Florida Power & Light, P.O. Box 14000, Juno Beach, Florida 33408-0420

NRC Project Director: Frederick J. Hebdon

Florida Power Corporation, et al., Docket No. 50-302, Crystal River Nuclear Generating Plant, Unit No. 3, Citrus County, Florida

Date of amendment request: February 17, 1997 as revised May 1, 1997.

Description of amendment request: The proposed amendment would change the Crystal River Unit 3 (CR-3) Technical Specifications (TS) to implement 10 CFR Part 50, Appendix J, ''Primary Reactor Containment Leakage Testing for Water-Cooled Reactors,'' Option B. This option allows to change from prescriptive testing requirements to performance-based testing requirements based on the leakage rate testing history of the containment and components. The proposed TS changes include revision to TS 3.6.1, 3.6.3, and addition of ''Containment Leakage Rate Testing Program'' to TS 5.0. The licensee did not propose any deviations from methods approved by the Commission and endorsed in the applicable regulatory guide. This notice supersedes the previous notice dated February 28, 1997 (62 FR 9214)

Basis for proposed no significant hazards consideration determination: 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:

Criterion 1

Does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The TS amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to the TS are to implement Option B of 10 CFR 50, Appendix J, at CR-3. The proposed changes will result in increased intervals between containment leakage tests based on the leakage rate testing history. The proposed changes do not involve a change to the plant design or operation and does not change the testing methodology.

NUREG-1493, ''Performance-Based Containment Leak-Test Program,'' provides the technical basis of 10 CFR 50, Appendix J, Option B. NUREG-1493 contains a detailed evaluation of the expected leakage from containment and the associated consequences. The increased risk due to increasing the intervals between containment leakage tests was also evaluated. The NUREG used a statistical approach to determine that the increase in the expected dose to the public due to decreasing the testing frequency is extremely low. NUREG-1493 also concluded that a small increase is justifiable in comparison to the benefits from decreasing the testing frequency. The primary benefit is in the reduction in occupational radiation exposure.

Criterion 2

Does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The TS amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed TS amendment incorporates the performance-based testing approach authorized by 10 CFR 50 Appendix, J, Option B. Decreasing the testing frequency allowed by this change does not involve a change to plant design or operation. Safety related equipment and safety functions are not altered as a result of this change. Decreasing the testing frequency does not affect testing methodology. As a result, the proposed change does not affect any of the parameters or conditions that could contribute to the initiation of any accidents.

Criterion 3

Does not involve a significant reduction in the margin of safety.

This TS amendment does not involve a significant reduction in the margin of safety.

The proposed TS amendment does not change the methodology of the containment leakage rate testing program or program acceptance criteria. The proposed TS change does affect the frequency of containment leakage rate testing. With an increased interval between tests, a small possibility exists that an increase in leakage could go undetected for a longer period of time. Based on the operational experience at CR-3, it has been demonstrated that the leak-tightness of the containment building has consistently been significantly below the allowable leakage limit. Adequate controls are in place to ensure that required maintenance and modifications are performed.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Coastal Region Library, 8619 W. Crystal Street, Crystal River, Florida 32629

Attorney for licensee: R. Alexander Glenn, Corporate Counsel, Florida Power Corporation, MAC - A5A, P. O. Box 14042, St. Petersburg, Florida 33733-4042

NRC Project Director: Frederick J. Hebdon

Florida Power Corporation, et al., Docket No. 50-302, Crystal River Nuclear Generating Plant, Unit No. 3, Citrus County, Florida

Date of amendment request: March 27, 1997, as supplemented April 3, and May 1, 1997.

Description of amendment request: The proposed amendment would revise the technical specifications (TS) for the Crystal River Nuclear Plant Unit 3 (CR3) relating to the Once Through Steam Generator's (OTSG's) tube inspection acceptance criteria. Specifically, the licensee proposed to:

(1) revise TS 3.4.12 (d) to specify 150 gallons per day limit on primary-to-secondary leakage through either OTSG;

(2) add TS 5.6.2.10.2 e. to define inspection requirements and disposition criteria for applicable tubes in the ''B'' OTSG first span;

(3) revise TS 5.6.2.10.4.a.7 to define ''pit-like Intergranular attack indications≥

(4) revise TS 5.6.2.10 and 5.7.2 to delete requirements that were specific to the interim tube plugging criteria applicable until Refuel 11.

Basis for proposed no significant hazards consideration determination: 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. Will operation of the facility in accordance with this proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

FPC Response:

No. The CR-3 components addressed by this proposed change are the Once Through Steam Generators (OTSGs), identified by plant tagging procedures as RCSG-1A and RCSG-1B. The OTSGs are straight tube, straight shell heat exchangers which allow for heat removal and the subsequent production of steam as a result of heat transfer from the primary side reactor coolant to the secondary side feedwater. Proposed changes are; retaining reduced primary-to-secondary leak rates approved previously for one cycle only, returning inspection result reporting requirements to those previously implemented, and establishing new inspection requirements for the ''B'' OTSG. Sunset clauses are being removed from pages containing requirements effective for one refueling outage and subsequent operating cycle only.

Based on review of Chapter 14 of the CR-3 Final Safety Analysis Report (FSAR), FPC performed analyses to assess the consequences of a steam generator tube rupture event, including the complete severing of a steam generator tube. The analyses concluded that CR-3 was sufficiently designed to ensure that, in the event of a steam generator tube rupture, the radiological doses would not exceed the allowable limits prescribed by 10 CFR 100, and would not result in additional tube failures and further degradation of the reactor coolant pressure boundary.

Retaining the present primary-to-secondary leakage limit (LCO 3.4.12, RCS Operational Leakage) that was previously approved for the current operating cycle will continue to provide assurance that should a significant leak occur, it would be detected and the plant will be shut down in a timely manner to reduce the likelihood of a potential tube rupture. This value of primary-to-secondary leakage applicable to both OTSGs is conservative relative to existing safety analyses and would result in lower doses than currently calculated and found acceptable. Removing reporting requirements specific to use of alternate flaw sizing criteria approved for Refueling Outage 10 only, and returning to previous reporting requirements applicable to both OTSGs, has no effect on operating plant safety. These requirements are administrative only and do not affect steam generator inspection or disposition of inspection results.

The proposed change to the ''B'' OTSG inspection criteria establishes that future inspections will include 100% inspection of the first span of specific tubes which are known to have indications of degradation. The degradation of these tubes is attributed to a common non-random mechanism.

The results of inspections of these tubes will be dispositioned using the same criteria as all other OTSG tubes for determination of the need for plugging or sleeving. Therefore, the proposed change will not increase the probability or consequence of an accident previously evaluated as all tubes degraded beyond acceptable limits will be subject to consistent corrective actions.

2. Will operation of the facility in accordance with this proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

FPC Response:

No. The purpose of OTSG tube inspection is to identify tubes that may have a higher potential for failure due to degradation that results in a reduced ability to withstand operating conditions. Neither the type of inspection of OTSG tubes nor the process for performing inspections will be changed by this amendment. Consistent criteria will be applied to disposition inspection results and consistent corrective actions will be taken for tubes that exceed this criteria. Retaining the lower leakage limit is conservative relative to existing analyses. Changes to revise requirements for reporting inspection results, and remove ''sunset'' clauses addressing the applicability of License Amendment 154 until Refueling Outage 11 only, do not alter the design or operation of the OTSGs. Therefore, no new or different kind of accident will be created as a result of these changes.

3. Will operation of the facility in accordance with this proposed change involve a significant reduction in margin of safety?

FPC Response:

No. The analyses that have been performed on the effects of OTSG tube failures, as reported in the CR-3 FSAR, have demonstrated that internal and offsite consequences are within allowable limits. This change will not alter the acceptance criteria for inspection results. Since this change will assure that a group of tubes with existing first span pit-like inter-granular attack indications are inspected each inspection period, the likelihood of detecting active degradation, as well as the probability of repairing degraded tubes prior to the degradation resulting in a through-wall opening or tube rupture, is increased. Retaining the currently accepted primary-to-secondary leakage limit continues to provide assurance that should a significant leak occur, it would be detected and the plant will be shut down in a timely manner to reduce the likelihood of a potential tube rupture, thereby maintaining or improving the existing margin of safety. Changes to revise requirements for reporting inspection results, and remove ''sunset'' clauses addressing the applicability of License Amendment 154 until Refueling Outage 11 only, do not alter the design or operation of the OTSGs. Therefore, these changes will not involve a reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Coastal Region Library, 8619 W. Crystal Street, Crystal River, Florida 32629

Attorney for licensee: R. Alexander Glenn, Corporate Counsel, Florida Power Corporation, MAC-A5A, P.O. Box 14042, St. Petersburg, Florida 33733-4042

NRC Project Director: Frederick J. Hebdon

GPU Nuclear Corporation, et al., Docket No. 50-289, Three Mile Island Nuclear Station, Unit No. 1, Dauphin County, Pennsylvania

Date of amendment request: May 8, 1997

Description of amendment request: The proposed amendment incorporates additional analytical methods, GPU Nuclear Topical Reports, TR-078, TR-087, TR-091, and TR-092P, previously approved by the NRC, to Technical Specifications (TS) Section 6.9.5.2. These Topical Reports will be utilized by GPU Nuclear to perform core reload design analysis for the Three Mile Island, Unit 1 (TMI-1) Facility. TS 6.9.5.2 is also being editorially revised to relocate the existing note that the current revision level shall be specified in the Core Operating Limits Report (COLR) such that it applies to the additional Topical Reports, as well as BAW-10179 P-A.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration (SHC), which is presented below:

GPU Nuclear has determined that this Technical Specification Change Request poses no significant hazards as defined by 10 CFR 50.92.

1. Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability of occurrence or the consequences of an accident previously evaluated. The proposed change to reference the analytical methodologies specified in GPU Nuclear Topical Reports TR-078, TR-087, TR-091,and TR-092 use[d] in TMI-1 core reload design analysis is considered administrative since these Topical Reports

have been reviewed and approved by the NRC for use at TMI-1.

Therefore, the proposed change does not involve a significant increase in the probability of occurrence or the consequences of an accident previously evaluated.

2. Operation of the facility in accordance with the proposed amendment would not create the possibility of a new or different kind of accident from any previously evaluated. The proposed change to reference NRC-approved GPU Nuclear Topical Reports TR-078, TR-087, TR-091, and TR-092P will continue to ensure that approved methods and criteria are used to establish core operating limits.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Operation of the facility in accordance with the proposed amendment would not involve a significant reduction in a margin of safety. The proposed change to reference NRC-approved GPU Nuclear Topical Reports TR-078, TR-087, TR-091, and TR-092P maintains existing margins of safety since approved methods and criteria are still used to establish core operating limits.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Law/Government Publications Section, State Library of Pennsylvania, (REGIONAL DEPOSITORY) Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, PA 17105.

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Patrick D. Milano, Acting

Northeast Nuclear Energy Company, et al., Docket No. 50-336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of amendment request: May 8, 1997

Description of amendment request: The proposed amendment would modify the minimum accuracy stated in Technical Specification (TS) Table 3.3-8, ≥Meteorological Monitoring Instrumentation,'' for the instruments used to measure wind speed and air temperature - delta T. TS Bases Section 3/4.3.3.4 would also be modified to reflect the proposed changes to TS Table 3.3-8.

Regulatory Guide 1.23 (Safety Guide 23), ''Onsite Meteorological Programs,'' dated March 17, 1972, provides recommended instrument accuracies for meteorological instrumentation. The proposed minimum instrument accuracies for the air temperature - delta T and the wind speed (only when the wind speed is greater than 5 miles per hour) do not meet the recommended accuracies of Regulatory Guide 1.23. However, margin is included to account for uncertainties.

Basis for proposed no significant hazards consideration determination: 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. Involve a significant increase in the probability or consequence of an accident previously evaluated.

The proposed changes modify the accuracy requirements for the instruments which are used to measure wind speed and air temperature - delta T. The data obtained from the meteorological instrumentation would be used to: a) estimate the public dose following routine or accidental releases of airborne radioactivity, b) make decisions regarding actions to protect the public in the event of an accident involving a release of airborne radioactivity, and c) establish radiological dispersion parameters to determine radiological doses in design basis accident calculations.

The proposed minimum instrument accuracy requirements are more than sufficient to meet the purposes denoted above. The meteorological parameters measurement uncertainties insignificantly affect the results when compared to the accuracies of the source term estimates, meteorological dispersion models, dose models, and meteorological forecasting. Therefore, there is no impact on the consequences (offsite doses) associated with previously evaluated accidents.

The proposed changes do not alter the way any structure, system, or component functions, do not alter the manner in which the plant is operated, and do not have any impact on the protective boundaries and safety limits for the protective boundaries. Therefore, the proposed changes do not impact the probability of any previously evaluated accidents.

Thus, the license amendment request does not impact the probability of an accident previously evaluated nor does it involve a significant increase in the consequence of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes modify the accuracy requirements for the instruments which are used to measure wind speed and air temperature - delta T. The data provided by these instruments assist in responding to a design basis accident which may involve a release of airborne radioactivity. The instruments are used for post accident monitoring and serve a passive role; they cannot initiate or mitigate any accident.

The proposed changes do not alter the way any structure, system, or component functions and do not alter the manner in which the plant is operated. They do not introduce any new failure modes.

Thus, the license amendment request does not create the possibility of a new or different kind of accident from any previously analyzed.

3. Involve a significant reduction in a margin of safety.

As discussed above, the proposed changes modify the accuracy requirements for the instruments which are used to measure wind speed and air temperature - delta T which could impact the radiological dispersion coefficient used to determine radiological doses in design basis accident calculations. However, the differences in the instrument accuracies and the Regulatory Guide 1.23 requirements have been determined not to significantly affect the dispersion coefficients. Thus, there is no significant impact on offsite doses associated with previously analyzed accidents. Therefore, there is no significant reduction in the margin of safety for the design basis accident analysis.

Thus, the license amendment request does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Learning Resources Center, Three Rivers Community-Technical College, 574 New London Turnpike, Norwich, CT 06360, and the Waterford Library, ATTN: Vince Juliano, 49 Rope Ferry Road, Waterford, CT 06385

Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, CT 06141-0270

NRC Deputy Director: Phillip F. McKee

Northeast Nuclear Energy Company (NNECO), et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: April 14, 1997

Description of amendment request: Technical Specification 3.4.9.3.a requires two relief valves be operable to protect the reactor coolant system from overpressurization when any reactor coolant system cold leg is less than 350—F. The proposed amendment revises the setpoint of the residual heat removal suction relief valves.

Basis for proposed no significant hazards consideration determination: 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:

NNECO has reviewed the proposed change in accordance with 10CFR 50.92 and has concluded that the change does not involve a significant hazards consideration (SHC). The bases for this conclusion is that the three criteria of 10CFR 50.92(c) are not satisfied. The proposed change does not involve a SHC because the changes would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change to Technical Specification 3.4.9.3 to decrease the setpoint of the residual heat removal suction relief valves from 450 psig [plus or minus] 3% to 440 psig [plus or minus] 3% ([greater than or equal to] 426.8 psig and [less than or equal to] 453.2 psig) is consistent with the design capabilities and system requirements of the relief valves and the relief valves are not credited in previously evaluated accidents.

Therefore, the proposed change does not involve a significant increase in the probability or consequence of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change to Technical Specification 3.4.9.3 to decrease the setpoint of the residual heat removal suction relief valves from 450 psig [plus or minus] 3% to 440 psig [plus or minus] 3% ([greater than or equal to] 426.8 psig and [less than or equal to] 453.2 psig) does not change the operation of the residual heat removal system, reactor coolant system or any system component during normal or accident evaluations. The proposed change to the setpoint of the residual heat removal suction relief valves from 450 psig [plus or minus] 3% to 440 psig [plus or minus] 3% ([greater than or equal to] 426.8 psig and [less than or equal to] 453.2 psig) also ensures protection of the reactor coolant system against cold overpressurization transients in accordance with the requirements of 10CFR50, Appendix G.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The proposed change to Technical Specification 3.4.9.3 to decrease the setpoint of the residual heat removal suction relief valves from 450 psig [plus or minus] 3% to 440 psig [plus or minus] 3% ([greater than or equal to] 426.8 psig and [less than or equal to] 453.2 psig) provides an acceptable allowance between the maximum relief valve setpoint ([less than or equal to] 453.2 psig) and 10CFR50, Appendix G requirements. The proposed change to the setpoint provides sufficient allowance between the minimum relief valve setpoint ([greater than or equal to] 426.8 psig) and reactor coolant system pressure when residual heat removal system is unisolated from the reactor coolant system to minimize the probability of an inadvertent residual heat removal system relief valve opening.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

In conclusion, based on the information provided, it is determined that the proposed change does not involve an SHC.

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.

Local Public Document Room location: Learning Resources Center, Three Rivers Community-Technical College, 574 New London Turnpike, Norwich, Connecticut, and the Waterford Library, ATTN: Vince Juliano, 49 Rope Ferry Road, Waterford, Connecticut

Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, CT 06141-0270

NRC Deputy Director: Phillip F. McKee

Northeast Nuclear Energy Company (NNECO), et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: April 28, 1997

Description of amendment request: Technical Specification Surveillances 4.1.2.3.1, 4.1.2.4.1, 4.5.2.f, and 4.5.2.h require the charging and safety injection pumps to be tested on a periodic basis and after modifications that alter subsystem flow characteristics. The proposed amendment would increase the required differential pressure at recirculation flow for the safety injection and centrifugal charging pumps; decrease the required individual safety injection and centrifugal charging pump injection line flow rate; increase the allowed individual safety injection pump total flow rate; and make editorial changes.

Basis for proposed no significant hazards consideration determination: 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:

NNECO has reviewed the proposed changes in accordance with 10CFR50.92 and has concluded that the changes do not involve a significant hazards consideration (SHC). The basis for this conclusion is that the three criteria of 10CFR50.92(c) are not satisfied. The proposed changes do not involve [an] SHC because the changes would not:

1. Involve a significant increase in the probability or consequence of an accident previously evaluated.

The proposed changes to Technical Specification Surveillances 4.1.2.3.1, 4.1.2.4.1, and 4.5.2.f to increase the required discharge pressure for the centrifugal charging pumps on recirculation flow during surveillance testing from [greater than or equal to] 2411 psid to [greater than or equal to] 5676 ft (2464 psid) are consistent with centrifugal charging pump design requirements. The change in the referenced units from differential pressure measured in psid to total head measured in feet for the centrifugal charging pumps and safety injection pumps during surveillance testing is an administrative change.

The proposed changes to Technical Specification Surveillance 4.5.2.f to increase the required discharge pressure for the safety injection pumps on recirculation flow during surveillance testing from [greater than or equal to] 1348 psid to [greater than or equal to] 3240 ft (1406 psid) are consistent with safety injection pump design requirements.

The proposed changes to Surveillance 4.5.2.h: to decrease the required individual centrifugal charging pump injection line flow rate sum from [greater than or equal to] 339 gpm to [greater than or equal to] 310.5 gpm, decrease the required individual safety injection pump injection line flow rate sum from [greater than or equal to] 442.5 gpm to [greater than or equal to] 423.4 gpm, increase the required individual safety injection Pump A total flow rate from [less than or equal to] 670 gpm to [less than or equal to] 675 gpm, and increase the required individual safety injection Pump B total flow rate from [less than or equal to]

650 gpm to [less than or equal to] 675 gpm are consistent with centrifugal charging pump and safety injection pump design requirements.

The proposed changes are consistent with equipment design requirements and performing surveillance testing does not involve a significant increase in the probability of an accident previously evaluated.

The proposed changes to the surveillance testing of the centrifugal charging pumps and safety injection pumps provide the necessary assurance that the pumps will function consistent with the flows used in the accident analyses and does not involve a significant increase in the consequence of an accident previously evaluated.

Therefore, the proposed changes do not involve a significant increase in the probability or consequence of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes to the surveillance testing of the centrifugal charging pumps and safety injection pumps do not change the operation of the centrifugal charging or safety injection systems or any of its components during normal or accident evaluations. The increase in the allowed maximum safety injection pump flow does not impact the cold overpressure accident analysis.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The proposed changes to Technical Specification Surveillances 4.1.2.3.1, 4.1.2.4.1 and 4.5.2.f to increase the required discharge pressure for the centrifugal charging pumps on recirculation flow during surveillance testing from [greater than or equal to] 2411 psid to [greater than or equal to] 5676 ft (2464 psid) provides an acceptable margin between the required surveillance and design pump performance to provide assurance that the pumps will operate consistent with the assumptions of the accident analysis.

The proposed changes to Technical Specification Surveillance 4.5.2.f to increase the required discharge pressure for the safety injection pumps on recirculation flow during surveillance testing from [greater than or equal to] 1348 psid to [greater than or equal to] 3240 ft (1406 psid) provides an acceptable margin between the required surveillance and design pump performance to provide assurance that the safety injection pumps will operate consistent with the assumptions of the accident analysis.

The proposed changes to Surveillance 4.5.2.h to decrease the required individual centrifugal charging pump injection line flow rate sum from [greater than or equal to] 339 gpm to [greater than or equal to] 310.5 gpm, decrease the required individual safety injection pump injection line flow rate sum from [greater than or equal to] 442.5 gpm to [greater than or equal to] 423.4 gpm, increase the required individual safety injection Pump A total flow rate from [less than or equal to] 670 gpm to [less than or equal to] 675 gpm and increase the required individual safety injection Pump B total flow rate from [less than or equal to] 650 gpm to [less than or equal to] 675 gpm are consistent with the assumptions of the accident analysis. The maximum allowed safety injection flow is consistent with the vendor recommendation for maximum continuous runout flow. Also, the safety injection

pumps are disabled during specific normal operating modes, consistent with the assumptions of the accident analysis, to ensure that they can not be an injection source when the cold overpressure system is required to be operable and thus the increase in maximum safety injection pump flow does not affect the cold overpressure accident analysis.

The change in the referenced units in Technical Specification Surveillances 4.1.2.3.1, 4.1.2.4.1 and 4.5.2.f from differential pressure measured in psid to total head measured in feet for the centrifugal charging pumps and safety injection pumps during surveillance testing is an administrative change.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

In conclusion, based on the information provided, it is determined that the proposed changes do not involve an SHC.

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.

Local Public Document Room location: Learning Resources Center, Three Rivers Community-Technical College, 574 New London Turnpike, Norwich, Connecticut, and the Waterford Library, ATTN: Vince Juliano, 49 Rope Ferry Road, Waterford, Connecticut

Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, CT 06141-0270

NRC Deputy Director: Phillip F. McKee

Northeast Nuclear Energy Company (NNECO), et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: April 28, 1997

Description of amendment request: Technical Specification 3.7.6 requires that flood protection be provided for the service water pump cubicles and components when the water level exceeds a specific value. The proposed amendment (1) adds the closing of the service water pump cubicle sump drain valves, (2) revises the wording of the action statement to be consistent with the limiting condition for operation, and (3) revises the associated Bases section.

Basis for proposed no significant hazards consideration determination: 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:

NNECO has reviewed the proposed change in accordance with 10CFR50.92 and has concluded that the change does not involve a significant hazards consideration (SHC). The bases for this conclusion is that the three criteria of 10CFR50.92(c) are not satisfied. The proposed change does not involve [an] SHC because the change would not:

1. Involve a significant increase in the probability or consequence of an accident previously evaluated.

The proposed changes to Technical Specification 3.7.6 identify additional manual actions to be performed to provide external lood protection for the service water pump cubicles in the event of high water level (13 ft MSL) [mean sea level]. The cubicle sump drain valves which are to be closed are part of a modification which installed a drain line from the sump of each cubicle to the intake bay in order to provide a passive means of removing internal leakage from the cubicle. The cubicle sump drain valves are normally maintained in the open position.

The drain valves meet the intent of RG [Regulatory Guide] 1.59 for ''hardened protection'' and RG 1.102 for ''incorporated barriers'' in a manner similar to that of the cubicle watertight doors. RG 1.59 states that hardened protection ''must be passive and in place, as it is to be used for flood protection, during normal plant operation''. RG 1.102 states that ''the plant should be designed and operated to keep doors necessary for flood protection closed during normal operation''. The Response to FSAR [Final Safety Analysis Report] Question No. 240.9 established the acceptability of the practice of maintaining one service water pump cubicle watertight door open and the other door closed during normal operations.

The proposed change in the action statement to initiate action when water level is exceeding 13 feet MSL rather than at 13 feet MSL is a clarification only which provides consistency between the limiting condition for operation and the action statements.

Therefore, the proposed changes do not involve a significant increase in the probability or consequence of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes to Technical Specification 3.7.6 identify additional, simple to perform manual actions to provide external flood protection for the service water pump cubicles.

The proposed change in the action statement to initiate action when water level is exceeding 13 feet MSL rather than at 13 feet MSL and the proposed changes to the bases are considered clarifications.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The proposed changes to Technical Specification 3.7.6 identify additional, simple to perform manual actions to provide external

flood protection for the service water pump cubicles in the event of high water level (13 ft MSL). The plant modification which made these additional actions necessary was made to provide for improved internal flood protection.

The proposed change in the action statement to initiate action when water level is exceeding 13 feet MSL rather than at 13 feet MSL and the proposed changes to the bases are considered clarifications.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

In conclusion, based on the information provided, it is determined that the proposed change does not involve an SHC.

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.

Local Public Document Room location: Learning Resources Center, Three Rivers Community-Technical College, 574 New London Turnpike,

Norwich, Connecticut, and the Waterford Library, ATTN: Vince Juliano, 49 Rope Ferry Road, Waterford, Connecticut

Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, CT 06141-0270

NRC Deputy Director: Phillip F. McKee

Northeast Nuclear Energy Company (NNECO), et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: May 1, 1997

Description of amendment request: Technical Specifications 3/4.8.2.2 and 3/4.8.3.2 specify which electrical power systems are required to be operable in Modes 5 and 6. The proposed amendment would clarify the requirements by identifying the specific equipment required and their alignments in Modes 5 and 6.

Basis for proposed no significant hazards consideration determination: 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:

NNECO has reviewed the proposed changes in accordance with 10CFR 50.92 and has concluded that the change does not involve a significant hazards consideration (SHC). The bases for this conclusion is that the three criteria of 10CFR 50.92(c) are not satisfied. The proposed changes do not involve [an] SHC because the changes would not:

1. Involve a significant increase in the probability or consequence of an accident previously evaluated.

The proposed change to Technical Specification 3/4.8.2.2 to replace the wording ''As a minimum, one 125 volt battery bank and its associated full capacity charger'' to ''As a minimum, one Train

(A or B) of batteries and their associated full capacity chargers'' will increase the required battery banks operable from one to two.[≥]

This change is being proposed to resolve an inconsistency with Technical Specification 3/4.8.3.2 which currently requires two battery banks energized in modes 5 and 6.

The proposed change to...Technical Specifications 3/4.8.2.2 and 3/4.8.3.2 to identify the specific equipment required and its alignment during modes 5 and 6 is being proposed to reduce the vagueness in the present Technical Specifications. This proposed change will specify the equipment required operable for the electrical distribution systems during modes 5 and 6.

These proposed changes are considered administrative and do not alter the manner in which any system or component is operated or expected to respond during an accident. Therefore, the proposed changes do not involve a significant increase in the probability or consequence of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes to Technical Specification 3/4.8.2.2 to increase the required battery banks operable from one to two and to reword Technical Specifications 3/4.8.2.2 and 3/4.8.3.2 to identify the specific equipment required operable during modes 5 and 6 do not alter the manner in which any system or component is operated or expected to respond during normal or accident conditions.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The proposed changes to Technical Specification 3/4.8.2.2 to increase the required battery banks operable from one to two is being proposed to resolve an inconsistency with Technical Specification 3/4.8.3.2 which currently requires two battery banks energized in modes 5 and 6. This is considered an administrative change.

The proposed changes to...Technical Specifications 3/4.8.2.2 and 3/4.8.3.2 are being proposed to reduce the vagueness in the present technical specifications by identifying the specific equipment required operable during modes 5 and 6. The change will provide a greater level of assurance that the electrical distribution systems will be correctly aligned and surveilled. This is also considered an administrative change.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

In conclusion, based on the information provided, it is determined that the proposed changes to not involve an SHC.

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.

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Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, CT 06141-0270

NRC Deputy Director: Phillip F. McKee

Northeast Nuclear Energy Company (NNECO), et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: May 5, 1997

Description of amendment request: Technical Specification Surveillance 4.8.4.1 requires periodic testing of lower voltage circuit breakers for all containment penetration conductor overcurrent protective devices. The proposed amendment would modify the requirements for determining the operability of lower voltage circuit breakers by using the manufacturer's curve of current versus time to test delay trip elements, clarify the use of two pole in series testing, and expand the Bases description of the testing.

Basis for proposed no significant hazards consideration determination: 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:

NNECO has reviewed the proposed revision in accordance with 10CFR50.92 and has concluded that the revision does not involve a significant hazards consideration (SHC). The bases for this conclusion is that the three criteria of 10CFR50.92(c) are not satisfied. The proposed revision does not involve [an] SHC because the revision would not:

1. Involve a significant increase in the probability or consequence of an accident previously evaluated.

The proposed change to Technical Specification Surveillance 4.8.4.1 to modify the requirements for determining the operability of lower voltage circuit breakers by using the manufacture's curve of current versus time to test long time and short-time delay trip elements will not change the requirement that periodic testing be performed to determine breaker operability. The circuit breaker testing is consistent with the design of the components and performing surveillance testing does not involve a significant increase in the probability of an accident previously evaluated. The proposed change will provide assurance that the breakers will perform consistent with accident analyses and does not involve a significant increase in the consequence of an accident previously evaluated.

The proposed change to the surveillance to modify the wording associated with the use of two pole in series testing to determine Molded Case Circuit Breaker (MCCB) operability following the failure of [an] MCCB to pass a single pole test was previously approved in License Amendment No. 13. The modified wording clarifies the testing by specifically stating in the surveillance that the two pole in series test determines MCCB operability. This is considered an administrative change.

The proposed change to expand the description of the long-time and short-time delay trip elements testing in the Bases Section is also considered an administrative change.

Therefore, the proposed changes do not involve a significant increase in the probability or consequence of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change to use a curve of current versus time instead of the description in Technical Specification Surveillance 4.8.4.1 of the [] long-time and short-time delay trip element testing does not alter the design, operation, or maintenance of the lower voltage circuit breakers.

The proposed change to the surveillance to modify the wording associated with the use of two pole in series testing to determine MCCB operability and the expanded description of the long-time and short-time delay elements testing in the Bases Section are considered administrative changes.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The current wording of Technical Specification Surveillance 4.8.4.1 requires testing of long-time delay trip elements with a current value of exactly 300% of the pickup setting and short-time delay trip elements with a current value of exactly 150% of the pickup setting. The testing [cannot] be performed at exact values. Circuit breaker manufactures develop a curve of current versus time for each breaker type that specifies the allowable time to trip for a specified current. Using the curve for a given breaker type, the operability of a circuit breaker can be verified by inserting a given current and verifying that the breaker trips within the allowable time delay band width for that current. Testing by the industry is typically performed at approximately 300% of the pickup setting for long-time delay trip elements and approximately 150% of the pickup setting for short-time delay trip elements. The proposed change to the surveillance to modify the requirements for determining the operability of circuit breakers by using the manufacturer's curve of current versus time to test delay trip elements will continue to provide assurance that lower voltage circuit breakers for all containment penetration conductor overcurrent protective devices will operate consistent with the assumptions of the accident analysis.

The proposed change to the surveillance to modify the wording associated with the use of two pole in series testing to determine MCCB operability and the expanded description of the long-time and short-time delay trip elements testing in the Bases Section are considered administrative changes.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

In conclusion, based on the information provided, it is determined that the proposed changes do not involve an SHC.

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.

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Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, CT 06141-0270

NRC Deputy Director: Phillip F. McKee

Northeast Nuclear Energy Company (NNECO), et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: May 5, 1997

Description of amendment request: Technical Specification Surveillance 4.5.2.b.1 requires that the emergency core cooling system (ECCS) piping be verified full of water at least once per 31 days. The proposed amendment would revise the surveillance to exempt the operating charging pump(s) and associated piping from the requirement to be verified full of water and move the description of the verification method from the surveillance to the Bases section.

Basis for proposed no significant hazards consideration determination: 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:

NNECO has reviewed the proposed revision in accordance with 10CFR50.92 and has concluded that the revision does not involve a significant hazards consideration (SHC). The bases for this conclusion is that the three criteria of 10CFR50.92(c) are not satisfied. The proposed revision does not involve [an] SHC because the revision would not:

1. Involve a significant increase in the probability or consequence of an accident previously evaluated.

The proposed change to Technical Specification Surveillance 4.5.2.b.1 to exempt the operating centrifugal charging pump(s) and associated piping from the requirement to be vented will not effect the requirement the ECCS piping be full of water. An operating centrifugal charging pump and the associated piping is self venting and cannot develop voids and pockets of entrained gases. This change is consistent with the design of the charging system and ensuring that ECCS piping is full of water does not involve a significant increase in the probability or consequence of an accident previously evaluated.

The proposed change Technical Specification Surveillance 4.5.2.b.1 to move and expand the description of the venting method from the surveillance to the Bases Section are considered administrative changes.

Therefore, the proposed changes do not involve a significant increase in the probability or consequence of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change to exempt the operating centrifugal charging pump(s) and associated piping from the requirement to be periodically vented by crediting its self venting capabilities does not change the operation of the charging system or any of its components during normal or accident evaluations.

The proposed changes to move and expand the description of the venting method from the surveillance to the Bases Section are considered administrative changes.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The proposed change to Technical Specification Surveillance 4.5.2.b.1 to exempt the operating centrifugal charging pump(s) and associated piping from the requirement to be manually vented by crediting its self venting capabilities, is consistent with the design of the charging system. This proposed change continues to ensure that ECCS piping is full of water and thus, does not involve a significant reduction in a margin of safety.

The proposed change to Technical Specification Surveillance 4.5.2.b.1 to move the description of the venting method from thesurveillance to the Bases Section is considered an administrative change. Currently the surveillance identifies that ECCS piping is to be verified full of water by venting ECCS pump casings and accessible discharge piping high points except for the RSS [recirculation spray system] pump, RSS heat exchanger and associated RSS piping that are not maintained filled with water during plant operation. The venting description will be expanded when moved to the bases to include an exclusion for the above described operating centrifugal charging pump(s) and associated piping and the venting method used for nonoperating centrifugal charging pumps. The centrifugal charging pumps have top mounted suction and discharge nozzles and do not have casing vents. The pump manufacturer has indicated that venting the pump suction pipe will assure that the pump is full of water. This venting of the nonoperating centrifugal charging pumps is accomplished by using a pump suction line test connection.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

In conclusion, based on the information provided, it is determined that the proposed change does not involve an SHC.

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.

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Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, CT 06141-0270

NRC Deputy Director: Phillip F. McKee

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment request: April 17, 1997

Description of amendment request: This license amendment request revises Technical Specification (TS) 2.12, ''Control Room System,'' to delete the Limiting Conditions of Operation (LCO) and associated surveillance for the control room temperature and replace it with an LCO and surveillance on the control room air conditioning (A/C) system. The remainder of TS 2.12 is being rewritten consistent with the requirements of the Combustion Engineering Standard TS (NUREG-1432, Rev. 1). In reviewing requirements for refueling and shutdown operations, additional TS improvement were identified. Therefore, the definition section, TS 2.1 ''Reactor Coolant System,'' 2.6 ''Containment System,'' 2.8 ''Refueling Operations,'' and associated surveillance requirements are proposed for revision to incorporate the design basis requirements for refueling operations and to correspond to NUREG-1432.

Basis for proposed no significant hazards consideration determination: 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 change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change will incorporate new requirements for the control room air conditioning system, control room filtration system, and refueling operations. In addition, the proposed change will ensure that the Limiting Condition for Operations and surveillance requirements are consistent with the design basis of a fuel handling accident as documented in the FCS Updated Safety Analysis Report (USAR).

CONTROL ROOM SYSTEMS

The control room air conditioning (A/C) system consists of two redundant A/C units, VA-46A and VA-46B. Each unit has sufficient capacity to meet the cooling requirements for personnel and equipment inside the control room envelope. Each A/C unit is equipped with an air-cooled condenser located inside a protective enclosure outdoors on the roof of the Auxiliary Building. Each A/C unit's refrigerant compressor, air cooling coils, fans, and dampers are located inside of the control room envelope. Each unit has a waterside economizer coil that allows air cooling with Component Cooling Water (CCW). When cooling water temperature is sufficiently low, a temperature-activated valve at each A/C unit allows cooling water flow through the waterside economizer. This valve also diverts flow away from the waterside economizer if cooling water temperature is too high. The air-operated CCW isolation valves to the A/C units fail closed and are automatically closed on a Ventilation Isolation Actuation Signal (VIAS) to prevent CCW flow through the waterside economizers in a post-accident situation.

Technical Specification (TS) 2.12(1) requires that the temperature within the control room and control cabinets be maintained below 120°F does not meet any of the four criteria contained in 10 CFR 50.36 for inclusion in TS. However, the equipment required to maintain this temperature, the control room air conditioning system, meets Criterion 3 of 10 CFR 50.36 in that the system functions to mitigate a design basis accident by maintaining the control room in a habitable environment.

Therefore, it is proposed that this TS be revised to delete the control room temperature as a LCO and require that two control room air conditioning trains be operable when the reactor coolant temperature is above 210°F. The design temperature limits of instrumentation and controls inside of the control room will be maintained in the Basis Section of TS 2.12.

The allowed outage time for one train of control room air conditioning is proposed as 30 days. This is consistent with Combustion Engineering Standard TS 3.7.12 (NUREG-1432 Rev. 1). In addition, the FCS Probabilistic Risk Assessment model was reviewed and validated a 30 day outage time as being non-risk significant. The impact on Core Damage Frequency (CDF) from a 30 day LCO was based on the assumption that one cooling unit was always inoperable and thus under the LCO for an entire year. This allows the analysis to consider unlimited entries into the LCO and a full LCO duration for each entry. Using this assumption, the baseline (annually) CDF of 1.53E-5 would increase by 21.6% to a frequency of 1.86E-5. In accordance with EPRI's ''PSA Applications Guide,'' this small increase in CDF can be classified as ''non-risk significant.''

Specification 2.12(2)

Specification 2.12(2) requires that a thermometer be in the control room at all times. This instrumentation does not meet any of the four criteria contained in 10 CFR 50.36 for inclusion in the FCS TS. Therefore, the requirement is proposed for relocation to the FCS USAR.

Specification 2.12(3)

Specification 2.12(3) requires that all areas of the plant containing safety related instrumentation be observed during hot functional testing to determine local temperatures and monitored during operation if normal plant ventilation is not available. It is proposed to delete this TS. The requirement to monitor and determine local temperatures during hot functional testing was met during the initial startup phase of FCS and is no longer applicable. The requirement to monitor temperatures within the plant during normal operation does not meet any of the four criteria contained in 10 CFR 50.36 for inclusion in TS and therefore is being deleted.

The requirement to control temperatures for safety related instrumentation and controls, and initiate supplementary cooling if required, is currently described in USAR Section 9.10. These USAR requirements are controlled by plant procedures. Any changes to these requirements would require an evaluation be conducted in accordance with 10 CFR 50.59.

Specification 2.12(4)

Specification 2.12(4) allows one control room air filtration system to be inoperable for 7 days or a plant shutdown be commenced. This specification does not state which modes of operation it applies to.

Therefore, it is proposed to revise this specification to require two trains of control room air filtration systems to be operable when the reactor coolant temperature is above 210°F. The allowed outage time will be maintained at 7 days and a total of 42 hours will be allowed to take the plant to cold shutdown. The 42 hour time period is consistent with TS 2.0.1 which addresses equipment outages in excess of what is specifically allowed by individual specifications.

The proposed changes for the control room systems consist of providing additional restrictions on operation of the control room air filtration systems and control room air conditioning system. These changes ensure that equipment required to mitigate the consequences of an accident are operable. Therefore, the proposed changes do not increase the probability or consequences of an accident previously evaluated.

REFUELING OPERATIONS

The design bases of the fuel handling accident and refueling operations were reviewed and several inadequacies were identified related to refueling operations. Therefore, revisions are proposed for the TS Definition section, TS 2.6 on containment integrity, and TS 2.8 on refueling operations to reflect NUREG-1432.

Definitions

Cold Shutdown Condition & Refueling Shutdown Condition

The changes proposed for the definitions of Cold Shutdown Condition, and Refueling Shutdown Condition clarify these definitions. The plant is in Cold Shutdown when T_{cold} is less than 210°F, and the reactor coolant is at least Shutdown Boron Concentration but less than Refueling Boron Concentration. Similarly, the definition for Refueling Shutdown is clarified to apply when T_{cold} is less than 210°F and the reactor

coolant is at least Refueling Boron Concentration. This change does not propose any new operating modes but merely clarifies when the definitions are applicable.

Core Alterations

The definition for Core Alterations is being revised to reflect the requirements of NUREG-1432. This revision deletes ''any component'' from the definition and clarifies that the components considered by this definition are those that could affect reactivity. In addition, the revision adds nuclear fuel to the definition such that movement of fuel within the reactor vessel will be defined as a core alteration and not a refueling operation.

Refueling Operations

The definition of Refueling Operations is being revised to delete control element assemblies (CEA) or startup sources from the definition since these are items that are included in the definition of Core Alterations. Additionally, it is being revised to specify that the definition is limited to movement of irradiated fuel outside of the reactor pressure vessel since fuel movement inside the reactor vessel is included in the definition of Core Alteration. Finally, a clarification is being added to state that suspension of refueling operations shall not preclude completion of movement of irradiated fuel to a safe, conservative position.

In Operation

The definition of In Operation is being revised to include the definition of operable. This is a more conservative interpretation than currently exists.

Specification 2.1 ''Reactor Coolant System''

It is proposed to revise TS 2.1.1(3) to include shutdown cooling requirements when the reactor coolant system (RCS) temperature is below 210°F with fuel in the reactor and the reactor vessel head fully tensioned. The definitions of Cold Shutdown (Mode 4) and Refueling Shutdown (Mode 5) contained in the TS make no distinction as to the status of the reactor vessel head or RCS temperature. The only difference between the two defined modes is boron concentration. Higher or lower boron concentration affects shutdown margin but does not affect decay heat load, which is the basis for this specification.

Technical Specification 2.1.1(4) was intended to address shutdown cooling requirements during refueling operations. However, this is already addressed in TS 2.8. Therefore, it is proposed to delete TS 2.1.1(4) and the exception since new specifications addressing shutdown cooling loop requirements during Mode 5 with fuel in the reactor and with one or more reactor vessel head closure bolts less than fully tensioned are proposed for inclusion in TS 2.8 (Refueling Operations).

The associated statements supporting these items in the Basis section are also proposed for deletion. Prior to any reactor vessel head closure bolts being loosened, TS 2.1.1 will be applicable which will require two shutdown cooling loops. As soon as a closure bolt is loosened, the new proposed TS 2.8 would be applicable which also requires two shutdown cooling loops whenever there is less than 23 feet of water above the core. The requirements of TS 2.1.1(3) are similar to NUREG-1432, Specifications 3.4.7 and 3.4.8.

Specification 2.6 ''Containment System''

Currently, TS 2.6(1)c states that containment integrity shall not be violated when the reactor vessel head is removed if the boron concentration is less than refueling concentration. However, Specification 2.6(1)c has no required actions and therefore, TS 2.0.1 must be entered when the LCO is not met. In this situation, (reactor vessel head removed), TS 2.0.1 is ineffective because the plant would already be in Refueling Shutdown. Thus, TS 2.6(1)c is proposed for deletion.

Currently, Specification 2.6(1)d requires that except for testing one control element drive mechanism at a time, positive reactivity changes shall not be made by CEA motion or boron dilution unless containment integrity is intact. Specification 2.6(1)d is proposed for deletion as it is unnecessarily restrictive.

Specification 2.8.1(1) as proposed eliminates the need for containment integrity when the reactor is in Refueling Shutdown. Specification 2.8.1(1) requires sufficient shutdown margin to preclude a criticality event and also prescribes actions to restore the shutdown margin if necessary. Small positive reactivity increases whether by CEA motion or boron dilution will not cause a criticality event due to the need to maintain at least a 5% shutdown margin. Therefore, the requirement to maintain containment integrity is unnecessarily restrictive since a criticality event cannot occur when a shutdown margin of at least 5% exists. Specification 2.8.1(1) is consistent with the requirements of NUREG-1432, Specification 3.9.1.

A new specification (TS 2.8.2(1)) is proposed that provides requirements for containment closure during core alterations and refueling operations inside of containment. The design basis of the Fort Calhoun Station does not require full containment integrity during a fuel handling accident. As stated in USAR Section 14.18, the fuel handling accident does not take credit for containment isolation. Therefore, requiring full containment integrity is inappropriate and requirements for containment closure are proposed for addition to TS 2.8 consistent with NUREG-1432 Specification 3.9.2.

Specification 2.10.2 governs operation of CEAs and monitoring of selected core parameters. Specification 2.10.2 ensures (1) adequate shutdown margin following a reactor trip, (2) that the moderator temperature coefficient (MTC) is within the limits of the safety analysis, and (3) CEA operation is within the limits of the setpoint and safety analysis. Specification 2.10.2 ensures that the reactor will be maintained sufficiently subcritical to preclude inadvertent criticality and provides actions (i.e., boration) to be taken to ensure that the required shutdown margin is available. Thus, TS 2.10.2 precludes the need for containment integrity when the plant is in cold shutdown.

Specification 2.8 ''Refueling Operations''

It is proposed that TS 2.8 be rewritten to reflect NUREG-1432. Currently, this specification applies to any refueling operation. However, no distinction is made between refueling operations within containment and refueling operations within the spent fuel pool. In addition, several initial assumptions of a fuel handling accident are not addressed by the current TS 2.8.

Specification 2.8(1)

The current TS 2.8(1) is inadequate. This specification requires that the equipment hatch and one door in the Personnel Air Lock be properly closed, and all automatic containment isolation valves be operable or at least one valve closed. The specification does not define what is meant by a properly closed equipment hatch; that information is currently contained in the Basis of TS 2.1.1. In addition, inclusion of all automatic containment isolation valves instead of those providing direct access to the outside atmosphere is incorrect.

The containment isolation system is defined in USAR Section 5.9.5 as those devices actuated by a Containment Isolation Actuation Signal (CIAS) or a Steam Generator Isolation Signal (SGIS). This includes many valves that have no design basis function during a fuel handling accident. A CIAS is initiated by a Containment Pressure High Signal or a Pressurizer Pressure Low Signal. Neither of these signals are required to be operable during refueling operations as these signals would/could not respond to a fuel handling accident.

The correct requirements are specified in TS 2.8(2) which only requires that closure be initiated by the Ventilation Isolation Actuation Signal (VIAS) for the containment pressure relief, air sample, and purge system valves. Due to these inadequacies, it is proposed to delete TS 2.8(1) and replace it with a new Specification 2.8.2(1) which is consistent with NUREG-1432 Specification 3.9.3.

Specification 2.8(2)

It is proposed that TS 2.8(2) be deleted and replaced by new Specifications 2.8.2(3) and 2.8.3(5). The requirement to maintain an operable Ventilation Isolation Actuation Signal with input from the containment atmosphere gaseous and auxiliary building exhaust stack gaseous radiation monitors is consistent with current requirements and required actions are consistent with NUREG-1432, Specification 3.3.8. Radiation Monitor RM-052 functions as a ''swing'' monitor, i.e., it can be aligned to monitor either containment or the auxiliary building exhaust ventilation stack. Radiation Monitor RM-052 is powered by either MCC-3B1/AI-40C (like RM-051) or MCC-4C2/AI-40D (like RM-062).

Technical Specification 2.7, Electrical System is not required to be applied when the RCS is below 300°F. Above 300°F, TS 2.7 requires both 4160-VAC buses to be operable. Thus, above 300°F the required radiation monitors must be powered from independent 480-VAC buses supplied by independent 4160-VAC buses. During refueling outages, bus alignments other than those used during power operation are used to permit electrical system maintenance and modifications.

In the loss of offsite power event, the radiation monitor sample pumps and control room HVAC units stop and will not restart

until the emergency diesel generators (EDGs) reenergize the system. The fuel handling equipment also stops and does not restart when the EDGs reenergize the system, thus minimizing the potential of a fuel handling accident. When the EDGs reenergize the buses, VIAS will operate as designed. Therefore, when the RCS is below 300°F, the required monitors need only be powered from independent 480-VAC buses supplied by a single 4160-VAC bus.

There is no need to assume that a fuel handling accident occurs immediately followed by a loss of offsite power. However, in the unlikely event that this should occur, there would be no effect on the site boundary dose since VIAS is not credited in USAR Section 14.18 (Fuel Handling Accident). In this situation, when the EDGs reenergize the buses, the control room HVAC units will restart in the filtered air makeup mode and the stack radiation monitor sample pump will restart. However, the containment radiation monitor sample lines remain isolated preventing the restart of the monitor sample pump after receipt of a VIAS.

Specification 2.8(3)

It is proposed that TS 2.8(3) be deleted. This requirement does not meet any of the four criteria contained in 10 CFR 50.36 for inclusion in the TS. The requirement that radiation levels in containment and the spent fuel pool shall be monitored during refueling operations will be incorporated into the FCS USAR.

Specification 2.8(6)

It is proposed that TS 2.8(6) be deleted. This requirement does not meet any of the four criteria contained in 10 CFR 50.36 for inclusion in the TS. The requirements that direct communication between personnel in the control room and at the refueling machine shall be available whenever core alterations are taking place will be incorporated into the FCS USAR.

Specification 2.8(7)

It is proposed that TS 2.8(7) be deleted and replaced with a new Specification 2.8.3(4). The requirement to place the spent fuel pool ventilation system in operation prior to refueling operations is consistent with the current TS. It is being clarified that this specification only applies to refueling operations in the spent fuel pool, and not when conducting refueling operations inside of containment. Additionally, it is being clarified that TS 2.0.1 is not applicable to this activity, as reactor operation is independent of fuel movements in the spent fuel pool.

Specification 2.8(9)

The current Specification 2.8(9) is inadequate. This specification requires a minimum of 23 feet of water above the top of the core. This does not meet the initial conditions assumed in the fuel handling accident as documented in USAR Section 14.18. USAR Section 14.18 assumes 23 feet of water above where the fuel could land if dropped. In order to meet this initial condition, a minimum of 23 feet of water above the reactor vessel flange is required, as this is the highest point where a fuel bundle could land if dropped. Procedures reflect the requirement to maintain 23 feet of water above the reactor vessel flange during refueling operations. The proposed revision is consistent with NUREG-1432, Specification 3.7.16.

Specification 2.8(11)

The current specification is inadequate. The specification provides restrictions on storage of fuel in the spent fuel pool; however, there are no required actions to address situations when the specification is not met. It is proposed that TS 2.8(11) be deleted and replaced with a new Specification 2.8.3(1) that requires that a misloaded fuel assembly be moved immediately. Additionally, it is being clarified that TS 2.0.1 is not applicable to this activity, as reactor operation is independent of fuel movements in the spent fuel pool.

Specification 2.8(12)

It is proposed that TS 2.8(12) be deleted and replaced with a new Specification 2.8.3(3). The requirement to maintain 500 ppm boron concentration in the spent fuel pool whenever unirradiated fuel is stored there is consistent with the current TS and the required actions are consistent with NUREG-1432, Specification 3.7.17.

Restriction on Movement of Irradiated Fuel from the Reactor Core

The restriction on irradiated fuel movement unless the core has been subcritical for at least 72 hours if the reactor has been operated at power levels above 2% is proposed for relocation to the Bases of TS 2.8.2(2). This requirement does not meet any of the four criteria contained in 10 CFR 50.36 for inclusion in the TS. This is consistent with NUREG-1432, B 3.9.6.

Reactor Coolant System Boron Concentration

Currently, there is no specification for boron concentration. Refueling boron concentration is included in the definition of Mode 5. However, there are no required actions to be taken if the boron concentration should be below refueling concentration. Therefore, it is proposed that a new Specification 2.8.1(1) be incorporated consistent with NUREG-1432, Specification 3.9.1.

Spent Fuel Pool Water Level

Currently, there is no specification for spent fuel pool water level. The water level of the spent fuel pool is an initial condition assumed in USAR Section 14.18. It is proposed that a new Specification 2.8.3(2) be incorporated into TS 2.8, which is consistent with NUREG-1432, Specification 3.7.16.

The proposed changes for the RCS and containment during shutdown, and requirements for refueling operations, consist of providing additional restrictions on operation, and changes to make the requirements of the TS Limiting Conditions for Operation consistent with the initial conditions and assumptions of the fuel handling accident as documented in USAR Section 14.18. Therefore, the proposed changes do not increase the probability or consequences of an accident previously evaluated.

SURVEILLANCE REQUIREMENTS

CONTROL ROOM

Specification 3.1, Table 3-3, Item 13.

Specification 3.1, Table 3-3, Item 13 requires that the thermometer in the control room be compared with a calibrated thermometer and replaced if out of tolerance on a refueling frequency. It is proposed that this surveillance be deleted to be consistent with deletion of the LCO requirement to maintain a thermometer in the control room.

A new surveillance is proposed to verify that the control room air conditioning system has the capability to remove the assumed heat load. This surveillance will ensure the operability requirements for TS 2.12 are met. The test and frequency is consistent with NUREG-1432.

The air-operated CCW isolation valves to the A/C units fail closed and are automatically closed on a VIAS to prevent CCW flow through the waterside economizers in a post-accident situation. These valves are currently tested in accordance with TS 3.3 (FCS Inservice Testing Program). Prior to the modification, the valves were tested as fail-open valves. No TS changes are necessary.

The control room air filtration system is currently tested on a refueling frequency in accordance with TS 3.2, Table 3-5, Item 10a. No TS changes are necessary.

REFUELING OPERATIONS

Reactor Coolant Boron Concentration During Refueling Operations

The Reactor Coolant System boron concentration is currently sampled in accordance with TS 3.2, Table 3-4, Item 1(e). It is proposed to revise the frequency from once per shift during refueling operations to once per 3 days which is consistent with NUREG-1432. As stated in the basis of TS 2.8 and USAR Section 14.18, the reactor cavity is filled with over 200,000 gallons of borated water prior to the start of refueling operations. The requirements for sampling the reactor coolant during the remainder of Mode 5 is performed once per 3 days in accordance with Table 3-4, Item 1(d). This proposed change will make the sampling consistent with the requirements of Item 1(d) and NUREG-1432.

Spent Fuel Pool Boron Concentration

The spent fuel pool boron concentration is currently sampled in accordance with TS 3.2, Table 3-4, Item 5. It is proposed to revise the frequency of the sampling to prior to movement of unirradiated fuel in the spent fuel pool and once per week whenever unirradiated fuel is stored there to be consistent with the requirements of the LCO.

Source Range Neutron Monitors

Currently, a channel check and calibration of the wide range neutron monitors is performed in accordance with TS 3.1, Table 3-1, Item 2.

Containment Penetrations

Currently, there is no surveillance to determine the status of containment penetrations during refueling operations. Therefore, a new surveillance is proposed for TS 3.2, Table 3-5 to verify the status of required containment penetrations once per 7 days consistent with NUREG-1432.

The requirement of NUREG-1432 to verify that the containment purge and exhaust valves actuate to the isolation position on a refueling frequency is currently tested as part of the Containment Radiation High Signal test required by TS 3.1, Table 3-2. Item 4.

Shutdown Cooling Loops

Currently, there is no surveillance requirement to verify that the required

shutdown cooling loops are operable and in operation or to verify correct breaker lineup for the shutdown cooling loop that is not in operation. Therefore a new surveillance is proposed to be incorporated into TS 3.2, Table 3-5 consistent with NUREG-1432.

Refueling Water Level

Currently, there is no surveillance requirement to verify the refueling water level during refueling operations. Therefore, a new surveillance is proposed for incorporation into TS 3.2, Table 3-5 consistent with NUREG-1432.

Spent Fuel Pool Water Level

Currently, there is no surveillance requirement to verify the spent fuel pool water level during refueling operations. Therefore, a new surveillance is proposed for incorporation into TS 3.2, Table 3-5 consistent with NUREG-1432.

Spent Fuel Initial Enrichment/Burnup Verification

Currently, the requirement to conduct a verification of initial enrichment and burnup of spent fuel that will be stored in Region 2 is included as a general requirement of TS 2.8. It is proposed to relocate this requirement into a surveillance in TS 3.2, Table 3-5, consistent with NUREG-1432.

The proposed changes for the surveillance requirements consist of providing additional testing requirements to ensure that the Limiting Condition for Operations will be met. One surveillance frequency related to the sampling of the reactor coolant system boron concentration during refueling operations is being reduced from a frequency of once per shift to once every 3 days. However, this frequency is consistent with the frequency of sampling during the remainder of Mode 5 when fuel is in the

reactor and is more than adequate due to the large volume (over 200,000 gallons) of borated water required during refueling operations. Therefore, the proposed changes do not increase the probability or consequences of an accident previously evaluated.

ADMINISTRATIVE CHANGES

The remainder of TS 2.8 requirements of refueling operations are proposed to be reformatted into individual TS LCOs. It is also proposed that sampling frequencies of items contained in TS 3.2, Table 3-4, (page 3-19), be revised to incorporate frequencies defined in TS 3.0.2. Therefore, frequencies stated as once per 31 days will be noted as ''M,'' and frequencies stated as once per 7 days will be noted as ''W.'' These proposed changes have no effect on the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

There will be no physical alterations to the plant configuration. No changes in operating modes are proposed although minor changes to the definitions of Cold Shutdown Condition and Refueling Shutdown Condition are proposed for clarification purposes. The proposed changes incorporate additional restrictions on the operation and testing of equipment required to mitigate an accident and to ensure the initial conditions and assumptions of the design basis accidents are maintained and controlled by the Technical Specifications.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed changes ensure that assumptions of the fuel handling accident are maintained by Technical Specification Limiting Condition for Operation and surveillance requirements. The assumptions of the fuel handling accident that may affect a margin of safety are not being changed. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: W. Dale Clark Library, 215 South 15th Street, Omaha, Nebraska 68102

Attorney for licensee: Perry D. Robinson, Winston & Strawn, 1400 L Street, N.W., Washington, DC 20005-3502

NRC Project Director: William H. Bateman

Philadelphia Electric Company, Docket Nos. 50-352 and 50-353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of amendment request: February 25, 1997

Description of amendment request: The proposed Technical Specifications (TS) changes would amend the Limerick Generating Station (LGS) Unit 1 and Unit 2 Facility Operating Licenses (FOLs), and Appendix B of the licenses (i.e., Environmental Protection Plan (EPP)), reflecting a corporate name change from Philadelphia Electric Company to PECO Energy Company. In addition, the application would make changes to the LGS Units 1 and 2, FOL, and Appendix A (i.e., TS) of the licenses, which would remove obsolete information and correct typographical errors.

Basis for proposed no significant hazards consideration determination: 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 TS changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The company name change and typographical corrections are editorial and will not alter the operation of equipment assumed to be an initiator of any analyzed event or transients previously evaluated. The license provisions were satisfactorily completed, and as such, have no effect on any previously evaluated accident scenario. The changes will not alter the operation of equipment assumed to be available for the mitigation of accidents or transients, nor will they alter the operation of equipment important to safety previously evaluated.

Therefore, the changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed TS changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The company name change and typographical corrections are editorial and will not involve any physical changes to the plant systems, structures, or components. The license provisions were satisfactorily completed, and as such, have no effect on any previously evaluated accident scenario. The proposed changes do not allow plant operation in any mode that is not already evaluated. The changes will not alter the operation of equipment important to safety previously evaluated.

Therefore, the changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed TS changes do not involve a significant reduction in a margin of safety.

The company name change and typographical corrections are editorial and will not affect the manner in which the facility is operated, or change equipment or features which affect the operational characteristics of the facility. There is no margin of safety as defined in the bases of any TS regarding the name of the company, or affected by the corrections or deletion of obsolete license provisions.

Therefore, these proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, PA 19464

Attorney for licensee: J. W. Durham, Sr., Esquire, Sr. V. P. and General Counsel, Philadelphia Electric Company, 2301 Market Street, Philadelphia, PA 19101

NRC Project Director: John F. Stolz

Philadelphia Electric Company, Docket Nos. 50-352 and 50-353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of amendment request: March 24, 1997

Description of amendment request: The proposed Technical specifications (TS) changes would delete the Drywell and Suppression Chamber Purge System operational time limit, and add a surveillance requirement to ensure the purge system large supply and exhaust valves are closed as required.

Basis for proposed no significant hazards consideration determination: 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 Technical Specifications changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

This activity does not increase the probability of occurrence of an accident previously evaluated in the SAR [Safety Analysis Report]. This activity involves deleting the allowable operating limit (180 hours each 365 days) for the Drywell and Suppression Chamber Purge system, while maintaining specific criteria for when the valves are allowed to be open. These changes do not increase the probability that this system will be in service should a LOCA [loss-of-coolant-accident] occur and does not increase the probability that a LOCA will occur. These changes also do not impact the probability of occurrence of any anticipated operational occurrence, other postulated design basis accident, or other event in which the plant was designed to respond.

This activity does not increase the consequences of an accident previously evaluated in the SAR. UFSAR [Updated Final Safety Analysis Report] Section 9.4.5.1.2.2 for high volume purging, although limiting the operating time the vent and purge system is to be in service, evaluates the consequences of a LOCA should the vent and purge valves be open. System operating procedures for venting and purging assure the availability of SGTS [standby gas treatment system] should a LOCA occur.

This activity will not increase the probability of a LOCA occurring during the time the Drywell and Suppression Chamber Purge system is in operation as previously evaluated. The Improved TS do not identify a specific time limit value as long as the valves are operated under the stated conditions (inerting, de inerting, pressure control, ALARA [as low as reasonably achievable] or air quality considerations for personnel entry or Surveillances that require that the valves be open). These proposed changes will incorporate the ITS [Improved Technical Specifications] operational controls which will result in the same order of magnitude of equipment malfunction probability as that provided by limiting purging to 180 hours per 365 days. A LGS [Limerick Generating Station] Level 2 PSA [Probability Risk Assessment] Analysis was performed to determine the additional risk associated with changing the operating limit from 90 hours to a nominal 500 hours each 365 days. This analysis concluded that the increase in risk of containment failure is well within the bounds of the EPRI [Electric Power Research Institute] PSA Applications Guideline for permanent changes and the NRC [Nuclear Regulatory Commission] Staff's safety goal value of 1.0 E-6 per year of reactor operation. Industry and LGS historical operating experience confirms that the purging lines are opened only for the specified reasons stated in ITS and for periods which do not exceed the current magnitude of equipment malfunction probability. Therefore, earlier engineering judgment is being replaced by operating experience.

Failure of the operating SGTS filter bank following a LOCA has been found to be acceptable due to the limited benefit derived from SGTS for accident sequences important to plant risk and the possibility that the backup filter bank would be available. Additionally, as discussed in UFSAR Section 9.4.5.1.2.2, the failure of SGTS during a LOCA does not contribute to any significant releases and is bounded by the analysis performed to address containment overpressure rupture.

Deleting the time limit restriction that the vent and purge line isolation valves may be open does not increase the probability that these valves will not perform as designed (close upon isolation signal) in response to a LOCA. Removing the 180 hour requirement will not increase the likelihood that the vent and purge valves will be called upon to close from that previously evaluated. UFSAR Section 6.2 states that the containment purge valves have undergone extensive testing and analyses to demonstrate the operability of these valves following a LOCA.

These changes do not directly or indirectly degrade the performance of any other safety system (assumed to function in the accident analysis) design basis. The potential for other equipment failures in the reactor enclosure due to duct impact, impingement, and the resulting environmental conditions was previously evaluated in the LGS SAR. It was concluded that the environmental qualifications for the LGS equipment are sufficient to ensure operability under the predicted environmental condition, and, the potential does not exist for impact or impingement - related damage to essential equipment. Maintaining the existing SAR analysis and retaining operating criteria for opening the containment purge valves, demonstrates that the risk of equipment failure and resulting radiological consequences will not increase.

Therefore, deleting the TS operating limit for the Drywell and Suppression Chamber Purge system from 180 hours each 365 days and the addition of a TS Surveillance Requirement verifying that the purge valves are closed under certain conditions does not increase the probability or consequences of an accident previously evaluated.

2. The proposed Technical Specifications changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

This activity does not change the function of the Drywell and Suppression Chamber Purge system, the containment isolation system, or SGTS as previously evaluated. Deleting the operational time limit that the vent and purge system is in service and the addition of a surveillance requirement does not create an accident initiator not already considered.

In addition, this activity does not create a failure mode not considered. All evaluated equipment failures that could occur as a result of a LOCA during high volume purging have previously been identified and evaluated. Therefore, these changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed Technical Specifications changes do not involve a significant reduction in a margin of safety.

The bases of TS 3.6.1.8 state that the 180 hour each 365 day operating limit for the Drywell and Suppression Chamber Purge system is imposed to protect the integrity of the SGTS filters. The LGS Offsite Dose Calculation Manual assures the availability of the backup SGTS filter train during operation of the vent and purge system. Furthermore, deleting the operating limit (180 hours each 365 days) does not reduce the margin of safety since specific criteria for opening the purge valves is being maintained and does not involve an increase in risk. Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, PA 19464

Attorney for licensee: J. W. Durham, Sr., Esquire, Sr. V. P. and General Counsel, Philadelphia Electric Company, 2301 Market Street, Philadelphia, PA 19101

NRC Project Director: John F. Stolz

Philadelphia Electric Company, Docket Nos. 50-352 and 50-353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of amendment request: April 9, 1997

Description of amendment request: The proposed Technical Specifications (TS) changes would clarify existing battery specific gravity requirements, delete the requirement to correct specific gravity values based on electrolyte level, and allow the use of charging current measurements to verify the battery—s state of charge.

Basis for proposed no significant hazards consideration determination:

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 Technical Specifications changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

Changes to Technical Specifications surveillance requirements for specific gravity and Technical Specifications Bases commitments do not change the frequency or consequences of any accident previously evaluated. The proposed changes which commit to IEEE Standard 450-1995 for specific gravity testing, providing battery charging current as an alternate method to specific gravity measurements, and eliminating the commitment to perform electrolyte level correction do not prevent the DC system from performing its intended safety function. The proposed changes to the Technical Specification battery surveillance requirements and commitment to IEEE Standard 450-1995 for specific gravity are in accordance with current industry practices. These changes do not reduce the readiness and performance of the 1E DC power system to perform its intended function during a design basis event.

The proposed changes do not affect seismic specifications, separation criteria or environmental qualifications. The proposed changes do not impose an increase in or more severe test requirements, an increase in the frequency of operation, reduce independence or redundancy, modify the system or equipment protective features, introduce new equipment failures or impose additional loads than any previously evaluated. The Class 1E battery system will continue to meet all of the design standards applicable to the system and will not cause the system to operate outside of its design or testing limits.

Batteries or battery chargers and their failure are not initiators of the accidents previously evaluated. The proposed changes do not affect, degrade or prevent the response of active or passive systems described or assumed in the LGS accidents previously evaluated. In addition, the proposed TS changes will improve the availability of the station batteries.

Therefore, the changes will not increase the probability or consequences of an accident previously evaluated.

2. The proposed Technical Specifications changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed Technical Specifications changes which will revise the surveillance requirements and the TS Bases, do not increase the failure rate of the battery. The proposed changes clarify and enhance Operation's focus on the key battery parameters which will improve the availability of the station batteries. The station batteries are not accident initiators. The single failure of an electrical component was previously evaluated in the LGS accident analysis. Unexpected failures beyond the postulated single failure are no more likely to occur under the clarified surveillance requirements.

Therefore, these changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed Technical Specifications changes do not involve a significant reduction in a margin of safety.

The revision clarifies and reduces the battery surveillance requirements for specific gravity. The revision eliminates the possibility for misinterpretation and provides consistency of the surveillance requirements. The specific gravity value for each connected cell is being revised to reflect a discrete number which meets the existing manufacturer's recommendations and does not differ from the value described in the present bases. LGS is currently committed to earlier revisions of IEEE Standard 450 (i.e., 1975 and 1980), and the incorporation of IEEE Standard 450-1995 for specific gravity will reflect current industry practices regarding specific gravity.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, PA 19464

Attorney for licensee: J. W. Durham, Sr., Esquire, Sr. V. P. and General Counsel, Philadelphia Electric Company, 2301 Market Street, Philadelphia, PA 19101

NRC Project Director: John F. Stolz

Tennessee Valley Authority, Docket No. 50-390 Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee

Date of amendment request: April 30, 1997 (TS 97-01)

Description of amendment request: The proposed amendment would change the design features section of the Technical Specifications to provide for insertion of Lead Test Assemblies (LTAs) containing Tritium Producing Burnable Absorber Rods (TPBARs) in the Watts Bar Nuclear Plant (WBN) reactor core during Cycle 2. The purpose of the change is to provide irradiation services to support U.S. Department of Energy (DOE) investigations into the feasibility of using commercial light water reactors to maintain the DOE inventory of tritium.

Basis for proposed no significant hazards consideration determination: 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:

A. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

LTAs do not adversely affect reactor neutronic or thermal-hydraulic performance; therefore, they do not significantly increase the probability of accidents or equipment malfunctions while in the reactor. The neutronic behavior of the LTAs mimics that of standard burnable absorbers with only slight differences which are accommodated in the core design. The reload safety analysis performed for WBN Unit 1, Cycle 2 will confirm that any minor effects of LTAs on the reload core will be within established fuel design limits.

As described in DOE Technical Report PNNL-11419, Revision 1, the LTA design is robust to all accident conditions except the large loss of coolant accident where the rods are susceptible to failure. However, the failure of the small number of TPBARS rods has been determined to have an insignificant effect on the thermal hydraulic response of the core to this event.

The impacts of LTAs on the radiological consequences for certain postulated events [as shown in Table 6-1 of the licensee's submittal, including Large Break LOCAs□ are very small, and they remain within 10 CFR 100 regulatory limits. The additional offsite doses due to tritium leakage from the containment are small with respect to loss of coolant accident source terms and are well within regulatory limits.

The LTAs will not result in an increase in combustible gas released to the containment. Therefore, the LTAs do not result in a significant increase in the consequences of those previously considered.

Analysis has shown that TPBARs will not fail during Condition I through IV events, with the exception of a Large Break LOCA. The radiological consequences of the non-Large-Break LOCA events are essentially unchanged by the expected TPBAR tritium leakage to reactor coolant, and doses remain within a small fraction of 10 CFR 100 regulatory limits. Therefore, there is no significant increase in the consequences of these previously evaluated accidents.

The expected occupational and offsite doses, as reported in Technical report PNNL-11419, Revision 1, resulting from release of tritium from TPBARs over the plant operating cycle, including refueling, are not significantly increased and are within applicable regulatory limits.

B. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

LTAs have been designed to be compatible with existing Westinghouse 17x17 fuel assemblies and conventional Burnable Poison Rod Assembly (BPRA) handling tools, equipment, and procedures, and therefore no new accidents or equipment malfunctions are created by the handling of LTAs.

LTAs use materials with known and predictable performance characteristics and are compatible with PWR coolant. The LTA design has specifically included material similar to those used in standard burnable absorber rods with the exception of internal

assemblies used in the production and retention of tritium. As described in the technical report, these materials are compatible with the reactor coolant system and the core design. For the irradiation proposed, the quantities of these materials is small. Therefore, no new accidents or equipment malfunctions are created by the presence of the LTAs in the reactor coolant system.

Thermal-hydraulic criteria have been established to ensure that TPBARs will not fail during Condition I or II events. Analysis has shown that TPBARs, appropriately positioned in the core, operate within the established thermal-hydraulic criteria. Therefore, no new accidents or equipment malfunctions are created by the presence of the LTAs in the reactor.

Analysis has shown that TPBARs will not fail during Condition III and IV events, with the exception of a large-break loss-of-coolant-accident. The radiological consequences of these events are small, with doses that are a small fraction of the 10 CFR 100 limits. Therefore there is no significant increase in consequences of these previously evaluated accidents.

LTAs do not adversely affect reactor neutronic or thermal-hydraulic performance; therefore, they do not create the possibility of accidents or equipment malfunctions of a different type than previously evaluated while in the reactor.

C. The proposed amendment does not involve a significant reduction in a margin of safety.

LTAs do not adversely affect reactor neutronic or thermal-hydraulic performance. Analysis indicates that reactor core behavior and offsite doses remain relatively unchanged. TPBAR performance under Condition I, II, III, and IV events are very similar to standard burnable absorber rods previously evaluated. For these reasons, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, TN 37402

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET l0H, Knoxville, Tennessee 37902

NRC Project Director: Frederick J. Hebdon

Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: April 18, 1997

Description of amendment request: The proposed amendment would revise Technical Specification (TS) Section 3/4.3.2, ''Safety System Instrumentation,'' and TS Section 3/4.5.2, ''Emergency Core Cooling Systems - ECCS Subsystems - Tavg (greater than or equal to) 280°F.'' Certain surveillance intervals would be changed from 18 months to once each refueling interval, and certain setpoints would be changed. The associated bases would also be changed.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensees have provided their analysis of the issue of no significant hazards consideration, which is presented below:

The Davis-Besse Nuclear Power Station, Unit No. 1 (DBNPS) has reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the DBNPS, in accordance with these changes would:

1a. Not involve a significant increase in the probability of an accident previously evaluated because the initiation of such accidents are not affected by the proposed revisions to increase the surveillance test intervals from 18 to 24 months for TS 3/4.3.2.1, ''Safety Features Actuation System Instrumentation,'' and TS 3/4.5.2, ''Emergency Core Cooling Systems - ECCS Subsystems - Tavg (greater than or equal to) 280—F.'' Initiating conditions and assumptions remain as previously analyzed for accidents in the DBNPS Updated Safety Analysis Report.

Results of the instrument drift study analysis and review of historical 18-month surveillance data and applicable maintenance records support an increase in the surveillance test intervals from 18 to 24 months (and up to 30 months on a non-routine basis) because: the projected instrument errors caused by drift are bounded by the existing setpoint analysis or a new analysis has been performed incorporating a more conservative setpoint; and no potential for a significant increase in a failure rate of a system or component was identified during surveillance data and applicable maintenance records reviews.

These proposed revisions are consistent with the NRC guidance on evaluating and proposing such revisions as provided in Generic Letter 91-04, ''Changes in Technical Specification Surveillance Intervals to Accommodate a 24-Month Fuel Cycle,'' dated April 2, 1991.

The proposed revisions to Allowable Values for Safety Features Actuation System (SFAS) Reactor Coolant System (RCS) Pressure - Low, RCS Pressure - Low-Low, RCS Pressure - Low-Low bypass permissive, and Decay Heat Isolation Valve and Pressurizer Heater Interlocks have no bearing on the probability of the initiation of an accident previously evaluated.

The application of the Allowable Value to only the Channel Functional Test and not the Channel Calibration, the proposed deletion of the Trip Setpoints, the proposed revision of the TS 3.3.2.1 Limiting Condition for Operation (LCO) and Action Statement 3.3.2.1.a, and the proposed revisions to Actions 13 and 14 of TS Table 3.3-3, are associated with the proposed revision of the Allowable Values for SFAS RCS Pressure - Low, RCS Pressure - Low-Low, and Decay Heat Isolation Valve and Pressurizer Heater Interlocks, and are consistent with NUREG-1430, Revision 1, ''Standard Technical Specifications, Babcock and Wilcox Plants,'' dated April 1995. The proposed revisions have no bearing on the probability of the initiation of an accident previously evaluated.

The proposed changes to TS Bases 3/4.3.1 and 3/4.3.2, ''Reactor Protection System and Safety System Instrumentation,'' and TS Bases 3/4.5.2 and 3/4.5.3, ''ECCS Subsystems,'' are administrative changes associated with the other proposed changes, and do not affect previously analyzed accidents.

1b. Not involve a significant increase in the consequences of an accident previously evaluated because the slight increase in doses due to a letdown line break event as a result of the proposed change to the SFAS RCS Pressure - Low Allowable Value still satisfy the NRC Standard Review Plan Section 15.6.2 acceptance criteria that doses do not exceed a small fraction (10%) of the 10 CFR 100 guideline values. The remaining proposed changes to Allowable Values, and the other changes proposed by this License Amendment Request do not increase the radiological consequences of previously analyzed accidents because the source term, containment isolation, or radiological releases are not being changed by the proposed revisions.

2. Not create the possibility of a new or different kind of accident from any accident previously evaluated, for the reasons discussed below.

No changes are being proposed to the type of testing currently being performed, only to the length of the surveillance test interval.

Results of the instrument drift study analysis and review of historical 18-month surveillance data and maintenance records support an increase in the surveillance test intervals from 18 to 24 months (and up to 30 months on a non-routine basis) because: the projected instrument errors caused by drift are bounded by the existing setpoint analysis or a new analysis has been performed incorporating a more conservative setpoint; and no potential for a significant increase in a failure rate of a system or component was identified during surveillance data and applicable maintenance records reviews.

The proposed revisions to Allowable Values for SFAS RCS Pressure - Low, RCS Pressure - Low-Low, RCS Pressure Low-Low bypass permissive, and Decay Heat Isolation Valve and Pressurizer Heater Interlocks, do not alter the type of any testing currently being performed.

The application of the Allowable Value to only the Channel Functional Test and not the Channel Calibration, the proposed deletion of the Trip Setpoints, revision of the TS 3.3.2.1 LCO and Action Statement 3.3.2.1.a, and the proposed revisions to Actions 13 and 14 of

TS Table 3.3-3, are associated with the proposed revision to the Allowable Values for SFAS RCS Pressure - Low, RCS Pressure - Low-Low, RCS Pressure Low-Low bypass permissive, and Decay Heat Isolation Valve and Pressurizer Heater Interlocks, and are consistent with NUREG-1430, Revision 1, ''Standard Technical Specifications, Babcock and Wilcox Plants,'' dated April 1995. The proposed revisions do not alter the type of testing currently being performed.

The proposed changes to TS Bases 3/4.3.1 and 3/4.3.2, ''Reactor Protection System and Safety System Instrumentation,'' and TS Bases 3/4.5.2 and 3/4.5.3, ''ECCS Subsystems,'' are administrative changes associated with the other proposed changes, and do not alter any testing currently being performed.

3. Not involve a significant reduction in a margin of safety. The results of the instrument drift study analysis and review of historical 18-month surveillance data and applicable maintenance records support an increase in the surveillance test intervals from 18 to 24 months (and up to 30 months on a non-routine basis) because: the projected instrument errors caused by drift are bounded by the existing setpoint analysis or a new analysis has been performed incorporating a more conservative setpoint; and no potential for a significant increase in a failure rate of a system or component was identified during surveillance data and applicable maintenance records reviews. Existing system and component redundancy is not affected by these proposed changes.

There are no new or significant changes to the initial conditions contributing to accident severity or consequences, consequently there are no significant reductions in a margin of safety.

The NRC staff has reviewed the licensees' 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.

Local Public Document Room location: University of Toledo, William Carlson Library, Government Documents Collection, 2801 West Bancroft Avenue, Toledo, Ohio 43606.

Attorney for licensees: Jay E. Silberg, Esquire, Shaw, Pittman, Potts, and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Gail H. Marcus

Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: April 18, 1997

Description of amendment request: The proposed amendment would revise Technical Specification (TS) Section 3/4.7.6, ''Plant Systems - Control Room Emergency Ventilation System.'' Additional Limiting Conditions for Operation (LCO) would be added related to the availability of the station vent normal range radiation monitoring instrumentation. The associated TS bases would also be modified consistent with these changes.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensees have provided their analysis of the issue of no significant hazards consideration, which is presented below:

The Davis-Besse Nuclear Power Station has reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the Davis-Besse Nuclear Power Station (DBNPS), Unit No. 1, in accordance with this change would not:

1a. Involve a significant increase in the probability of an accident previously evaluated because no accident initiators, conditions, or assumptions are affected by the proposed changes.

The proposed change to LCO 3.7.6.1 would include new required Action statements in the event that one or both channels of station vent normal range radiation monitoring instrumentation become inoperable. In the event that one channel is inoperable for greater than 7 days, or in the event that both channels are inoperable, the proposed Action statement would require that the control room normal ventilation system be isolated and at least one Control Room Emergency Ventilation System (CREVS) train be placed in operation.

Under the proposed actions, the ventilation systems would be placed in a state equivalent to that which occurs were a high radiation isolation to occur. These proposed changes have no bearing on the probability of an accident.

The proposed change to the terminology utilized in Surveillance Requirement (SR) 4.7.6.1.e is an administrative change made to make the terminology consistent with the proposed new Action statements. The proposed changes to Bases 3/4.7.6 are administrative changes consistent with the proposed changes to LCO 3.7.6.1. These changes have no bearing on the probability of an accident.

1b. Involve a significant increase in the consequences of an accident previously evaluated because the proposed changes do not change the source term, containment isolation, or allowable releases.

As described above, under the proposed new LCO 3.7.6.1 Actions, in the event that one station vent normal range radiation monitoring instrumentation channel is inoperable for greater than 7 days, or in the event that both channels are inoperable, the ventilation systems would be placed in a state equivalent to that which occurs were a high radiation isolation to occur. Therefore, in the unlikely event of an accident requiring control room isolation while in this condition, the dose consequences to control room operators would be unchanged.

The proposed change to the terminology utilized in SR 4.7.6.1.e is an administrative change made to make the terminology consistent with the proposed new Action statements. The proposed changes to Bases 3/4.7.6 are administrative changes consistent with the proposed changes to LCO 3.7.6.1. These changes have no bearing on the consequences of an accident.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated because no new accident initiators or assumptions are introduced by the proposed changes.

As described above, under the proposed new LCO 3.7.6.1 Actions, in the event that one station vent normal range radiation monitoring instrumentation channel is inoperable for greater than 7 days, or in the event that both channels are inoperable, theventilation systems would be placed in a state equivalent to that which occurs were a high radiation isolation to occur. Operation of the equipment and components in this manner would not introduce the possibility of any new or different kinds of accidents.

The proposed change to the terminology utilized in SR 4.7.6.1.e is an administrative change made to make the terminology consistent with the proposed new Action statements. The proposed changes to Bases 3/4.7.6 are administrative changes consistent with the proposed changes to LCO 3.7.6.1. These changes would not introduce the possibility of any new or different kinds of accidents.

3. Involve a significant reduction in a margin of safety because the proposed changes to the Action under LCO 3.7.6.1 ensure that control room isolation capability is maintained in the event a station vent radiation monitor is inoperable. The proposed allowable outage time of 7 days for one inoperable channel is consistent with the presently allowable outage time for one inoperable CREVS. The proposed Action to place at least one CREVS train in operation within 1 hour, in the event both channels of radiation monitoring become inoperable, is more conservative than the present Action which requires that a plant shutdown commence within 1 hour, but does not require the CREVS be placed in operation.

The proposed change to the terminology utilized in SR 4.7.6.1.e is an administrative change made to make the terminology consistent with the proposed new Action statements. The proposed changes to Bases 3/4.7.6 are administrative changes consistent with the proposed changes to LCO 3.7.6.1. These changes would not affect the margin of safety.The NRC staff has reviewed the licensees' 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.

Local Public Document Room location: University of Toledo, William Carlson Library, Government Documents Collection, 2801 West Bancroft Avenue, Toledo, Ohio 43606.

Basis for proposed no significant hazards consideration determination:

Attorney for licensees: Jay E. Silberg, Esquire, Shaw, Pittman, Potts, and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Gail H. Marcus

Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of amendment request: August 22, 1996

Description of amendment request: The proposed change would remove the action statement of Technical Specification (TS) Section 3.2.G, Table 3.2.6, Note 7, requiring reactor shutdown after 30 days of inoperability of the high range stack gas monitor and substitute an action statement consistent with the guidance provided in NRC Generic Letter 83-36.

The high range stack monitor provides an estimate of gross stack activity that has exceeded the upper limit of the normal range instrumentation. The high range monitor reading serves as input to dose projection systems for initial estimation of off-site conditions. The monitor reading would be used prior to the acquisition of stack isotopic sample data which would provide a more accurate indication of stack activity.

The licensee stated, among other things, that due to the passivefunction of the instruments and the ability to monitor this parameter utilizing alternate methods, it is not appropriate to impose stringentrequirements on the operation of the unit. This monitor is identified in the Vermont Yankee Regulatory Guide 1.97 submittal as Category 2, Type E. This monitor provides post-accident information for use in determining the magnitude of the release of radioactive materials and for monitoring such release. However, the high range stack monitor does not have any safety function associated with the prevention or automatic mitigation of design-basis accidents, neither does it provide primary information needed to permit the control room operating personnel to take required manually controlled actions.

Basis for proposed no significant hazards consideration determination: 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 TS change does not involve a significant increase in the probability or consequences of an accident previously evaluated.]

The High Range Stack Monitor is a RG [Regulatory Guide] 1.97, Category 2, Type E instrument with no specified safety function associated with the prevention or automatic mitigation of design basis accidents, neither does it provide primary information needed to permit the control room operating personnel to take required manually controlled actions. The proposed change to the action statement associated with this monitor will not change the function of this monitor, and since the monitor is not assumed to initiate any accidents, nor function to mitigate any accidents, this change will not significantly increase the probability or consequences of any previously analyzed accident.

[(2) The proposed TS change does not create the possibility of a new or different kind of accident from any accident previously evaluated.]

The proposed change does not necessitate a physical alteration of the plant (no new or different type of equipment will be installed) or changes in parameters governing normal plant operation. The proposed change will still ensure effective methods are available to assess post accident conditions. Thus, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

[(3) The proposed TS change does not involve a significant reduction in a margin of safety.]

The proposed change to the action statement associated with this monitor will not change the function of this monitor, and since the monitor is not assumed to function for the prevention or mitigation of any previously evaluated accidents, this change will not significantly reduce a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301

Attorney for licensee: R. K. Gad, III, Ropes and Gray, One International Place, Boston, MA 02110-2624

NRC Project Director: Patrick D. Milano, Acting

Wisconsin Electric Power Company, Docket Nos. 50-266 and 50-301, Point Beach Nuclear Power Plant, Unit Nos. 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of amendment request: January 24, 1997, as supplemented on May 15, 1997 (TSCR 193)

Description of amendment request: The proposed amendments (Point Beach Nuclear Plant (PBNP) Technical Specifications (TS) Change Request (TSCR) 193) would revise TS 15.5.4, ''Fuel Storage,'' to increase fuel assembly enrichment limits to 5.0 w/o U-235 while maintaining K_{eff} in the storage pools (spent fuel pool and new fuel storage racks) less than 0.95. The May 15, 1997, supplement provided a revised no significant hazards consideration determination that superseded the licensee's determination noticed in the **Federal Register** on April 23, 1997 (62 FR 19837).

Basis for proposed no significant hazards consideration determination: 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. Operation of this facility under the proposed Technical Specifications will not create a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not involve a change to structures, systems, or components that would affect the probability or consequences of an accident previously evaluated in the PBNP Final Safety Analysis Report (FSAR). The only relevant concern with respect to increasing enrichment limits in the spent fuel pool and new fuel storage racks is one of criticality. The proposed changes use the same criticality limit used in the current Technical Specifications. Therefore, margin to safe operation of Units 1 and 2 is maintained. The probability and consequences of an accident previously evaluated are dependent on this criticality limit. Because the limit will not change, the probability and consequences of those accidents previously evaluated will not change.

2. Operation of this facility under the proposed Technical Specifications change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes do not involve a change to the physical structure of the spent fuel pool or of the plant. The proposed increase in spent fuel pool and new fuel storage racks fuel assembly enrichment limits maintains the margin to safe operation of Units 1 and 2 because the criticality limit for the spent fuel pool and new fuel storage racks will not change. The enrichment increase does not affect any of the parameters or conditions that contribute to the initiation of any accidents. Because the criticality limit remains the same, these changes have no effect on plant operation or on the initiation of any accidents. Therefore, the proposed changes will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Operation of this facility under the proposed Technical Specifications change will not create a significant reduction in a margin of safety.

The proposed changes maintain the margin to safe operation of Units 1 and 2. The margin of safety is based on the criticality limit of the spent fuel pool and the new fuel storage racks. Because this limit will not change, the margin of safety will not be affected. Therefore, the proposed changes will not create a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Joseph P. Mann Library, 1516 Sixteenth Street, Two Rivers, Wisconsin 54241

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts, and Trowbridge, 2300 N Street, NW., Washington, DC 20037

NRC Project Director: John N. Hannon

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: April 23, 1997

Description of amendment request: This request proposes to revise Technical Specification 3/4.9.4, Containment Building Penetrations, and its associated Bases section, to allow selected containment isolation valves to be opened under administrative controls during periods of core alterations or movement of irradiated fuel inside containment.

Basis for proposed no significant hazards consideration determination: 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 change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change involves changes to the Technical Specification requirements for containment closure which is an accident mitigating feature. The changes would not affect the likelihood of occurrence of any accidents previously evaluated. The proposed change does not involve any hardware or plant design changes. The containment leakage value is not assumed to be an initiator of any analyzed event. Containment isolation valves and temporary closure devices serve to limit the radiological consequences of accidents. The proposed change would ensure the service air and breathing air manual isolation valves will perform their required containment closure function and will serve to limit the consequences of a fuel handling accident as described in the USAR, such that the results of the analyses in the USAR remain bounding. In considering the consequences of a design basis fuel handling accident inside containment, the assumptions in the analysis take no credit for the containment as a barrier to prevent the postulated release of radioactivity. For events that could occur during CORE ALTERATIONS or movement of irradiated fuel assemblies, containment closure is considered a defense-in-depth boundary to prevent uncontrolled release of radioactivity. Additionally, the proposed change does not impose any new safety analyses limits or alter the plant's ability to detect and mitigate events. Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change involves reliance on manual actuation of containment penetration valves (Service Air valves KA V-039 and KA V-118 and Breathing Air valves KB V-001 and KB V-002 are manual valves) to block the unimpeded flow of the containment atmosphere to the environment under certain conditions. The proposed change would not necessitate a physical alteration of the plant features that provide core cooling or subcriticality (no new or different type of equipment will be installed) or changes in parameters governing plant operation during CORE ALTERATIONS or movement of irradiated fuel in containment. Thus, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed change is similar to the use of administrative controls to isolate an open containment airlock door. The use of administrative controls in this manner has been approved by the NRC (WCGS Technical Specification Amendment 95) for plant operations that would not require the containment to maintain a pressure boundary. This scenario is applicable during plant shutdown for refueling when CORE ALTERATIONS and movement of irradiated fuel assemblies in the containment occur. Accidental damage to spent fuel during these operations is classified as a fuel handling accident. The proposed change has been developed considering the importance of the containment boundary in limiting the consequences of a design basis fuel handling accident. The proposed change allows for protection equivalent to that provided by previously approved methods of containment closure. Considering the probability of an event that would challenge the containment boundary, the alternative protection provided by this change, and the operational requirements to occasionally open these penetrations, the proposed change is acceptable and any reduction in the margin of safety is insignificant.

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.

Local Public Document Room locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, D.C. 20037

NRC Project Director: William H. Bateman

Notice Of Issuance Of Amendments To Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document rooms for the particular facilities involved.

Boston Edison Company, Docket No. 50-293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: January 24, 1997, as supplemented March 27, 1997

Brief description of amendment: The proposed amendment will update the

Safety Limit Minimum Critical Power Ratio (SLMCPR) in Technical Specification 2.1.2 and the associated Bases section to reflect the results of the latest cycle-specific calculation performed for the Pilgrim Nuclear Power Station Operating Cycle 12. In addition, the values provided in Note 5 of Table 3.2.C.1, which are based on the SLMCPR values, have been revised as a result of the changes to the SLMCPR value.

Date of issuance: April 7, 1997

Effective date: April 7, 1997

Amendment No.: 171

Facility Operating License No. DPR-35: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** February 12, 1997 (62 FR 6568) The March 27, 1997, supplemental letter provided clarifying information that did not change the initial proposed no significant hazards consideration. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 7, 1997 No significant hazards consideration comments received: No

Local Public Document Room location: Plymouth Public Library, 11 North Street, Plymouth, Massachusetts 02360.

Commonwealth Edison Company, Docket Nos. STN 50-456 and STN 50-457, Braidwood Station, Unit Nos. 1 and 2, Will County, Illinois

Date of application for amendments: August 19, 1996, as supplemented on February 5, March 13, April 29 and April 30, 1997.

Brief description of amendments: The amendment would revise Technical Specification (TS) Section 4.4.5.2 to extend, for one additional operating cycle (i.e., Cycle 7), the 1.0 volt and 3.0 volt interim plugging criteria (IPC) which were added to the Braidwood, Unit 1, TSs by License Amendment No. 69, issued on November 9, 1995. Additionally, this amendment to the Braidwood, Unit 1, license added some definitions and reporting requirements to TS Section 4.4.5.2 and modified the designations for the IPC models in TS Bases Section 3/4.4.4.5. Braidwood, Unit 1, Cycle 7, will end in fall 1998. While there are no revisions to the TS for Braidwood, Unit 2, both units are being amended to maintain the continuity of the amendment numbers.

Date of issuance: May 14, 1997.

Date of effective: Immediately, to be implemented within 30 days.

Amendment Nos.: 82

Facility Operating License Nos. NPF-72 and NPF-77: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** February 12, 1997 (62 FR 6570). The February 5, March 13, April 29 and April 30, 1997, submittals provided clarifying technical information that did not affect the initial proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 14, 1997. No significant hazards consideration comments received: No

Local Public Document Room location: Wilmington Public Library, 201 S. Kankakee Street, Wilmington, Illinois 60481.

Commonwealth Edison Company, Docket Nos. 50-237 and 50-249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois

Date of application for amendments: June 20, 1996, as supplemented December 30, 1996, and March 5, 1997.

Brief description of amendments: The amendments would change the TSs by incorporating an NRC-approved thermal limit licensing methodology in the list of approved methodologies used in establishing the fuel cycle-specific thermal limits. In addition, the proposed amendments would change the TSs to reflect the use of Siemens Power Corporation (SPC) ATRIUM-9B fuel for the first time at Dresden, Units 2 or 3. The proposed amendments would also correct minor editorial items in the TSs.

In March 1997, the NRC staff performed an audit of the application of Advanced Nuclear Fuel for Boiling Water Reactors (ANFB) to ATRIUM-9 fuel. The staff raised concerns associated with the ATRIUM-9B fuel additive constant uncertainty used as input to the NRC-approved methodology for the calculation of minimum critical power ratio (MCPR). In response to the audit findings, by letter dated April 18, 1997, SPC submitted a generic topical report (ANF-1125(P) Supplement 1 Appendix D), which is currently under staff review, for the future reload analysis in the safety limit MCPR calculation. The staff schedule for the review of the topical report will not be timely enough for the resolution of the ATRIUM-9B MCPR issue to support reload and restart of Dresden, Unit 3. Therefore, by letters dated May 2 and May 6, 1997, ComEd provided additional information concerning the MCPR issues and how it will affect the Dresden, Unit 3, D3R15 fuel cycle and provided additional information concerning the ATRIUM-9B fuel design and shutdown margin that are applicable during refueling and shutdown.

The staff is currently reviewing the licensee's May 2 and May 6, 1997, letters. To be more timely and support the reload schedule for Dresden, Unit 3 (currently scheduled for May 20, 1997), the staff has chosen to split its consideration of the proposed amendments into two parts. The first part of the amendment package now being evaluated would modify Section 5.3.A, ''Design Features'' of the TSs to reflect use of the ATRIUM-9B fuel design and would include two SPC topical reports in TS Section 6.9.A.6, ''Core Operating Limits Report,'' to reflect mechanical design criteria for this fuel. This change would allow this fuel to be loaded into the core only under Operational Modes 3 (Hot Shutdown), 4 (Cold Shutdown), and 5 (Refueling) and does not permit startup or power operation using the ATRIUM-9B fuel.

Date of issuance: May 16, 1997

Date of effective: Immediately, to be implemented within 30 days.

Amendment Nos.: 159 and 154

Facility Operating License Nos. DPR-19 and DPR-25: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 9, 1997 (62 FR 17227). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 16, 1997 No significant hazards consideration comments received: No

Local Public Document Room location: Morris Area Public Library District, 604 Liberty Street, Morris, Illinois 60450.

Commonwealth Edison Company, Docket No. 50-265, Quad Cities Nuclear Power Station, Unit 2, Rock Island County, Illinois

Date of application for amendment: April 21, 1997

Brief description of amendment: The amendment increases the minimum critical power ratio safety limit for Unit 2 and adds a Siemens Power Corporation reference to the Technical Specifications (TS) to allow plant operation in Operational Modes 1 and 2.

Date of issuance: May 22, 1997

Date of effective: Immediately, to be implemented within 30 days.

Amendment No.: 174

Facility Operating License No. DPR-30: The amendment revised the TSs. Public comments requested as to proposed no significant hazards consideration: Yes (62 FR 23499 dated April 30, 1997). This notice provided an opportunity to submit comments on the Commission's proposed no significant

hazards consideration determination. No comments have been received. The notice also provided for an opportunity to request a hearing by May 30, 1997, but indicated that if the Commission makes a final no significant hazards consideration determination any such hearing would take place after issuance of the amendment. The Commission's related evaluation of the amendment, finding of exigent circumstances, and final no significant hazards consideration determination are contained in a Safety Evaluation dated May 22, 1997.

Local Public Document Room location: Dixon Public Library, 221 Hennepin Avenue, Dixon, Illinois 61021.

Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan Date of application for amendment: December 2, 1996 (NRC-96-0134)

Brief description of amendment: The amendment revises TS 3.1.4.3, TS Table 3.3.6-1, and TS Table 4.3.6-1 to change the operability requirements for the Rod Block Monitor (RBM). Specifically, the revision requires the RBM to be operable when reactor thermal power is greater than or equal to 30 percent of rated thermal power.

Date of issuance: May 15, 1997

Date of effective: May 15, 1997, with full implementation within 60 days

Amendment No.: 112

Facility Operating License No. NPF-43. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** January 2, 1997 (62 FR 124) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 15, 1997. No significant hazards consideration comments received: No.

Local Public Document Room location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161

Duke Power Company, Docket Nos. 50-269, 50-270, and 50-287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of application of amendments: April 29, 1997

Brief description of amendments: The amendments incorporate a license condition that will allow revisions to the Oconee Updated Final Safety Analysis Report (UFSAR) that clarifies the main turbine-generated missile protection criteria.

Date of issuance: May 16, 1997

Date of effective: As of the date of issuance and implementation is the incorporation in the UFSAR the changes described in Duke Power Company's application dated April 29, 1997

Amendment Nos.: 224, 224, and 221

Facility Operating License Nos. DPR-38, DPR-47, and DPR-55: The amendments revised the UFSAR and added a new License Condition. Public comments requested as to proposed no significant hazards consideration: Yes. (62 FR 24512 dated May 5, 1997). The notice provided an opportunity to submit comments on the Commission's proposed no significant hazards consideration determination. No comments have been received as of the date of issuance. The notice also provided for an opportunity to request a hearing by June 9, 1997, but indicated that if the Commission makes a final no significant hazards consideration determination, any such hearing would take place after issuance of the amendments.

The Commission's related evaluation of the amendments, finding of exigent circumstances, and final determination of no significant hazards consideration are contained in a Safety Evaluation dated May 16, 1997.

Attorney for licensee: J. Michael McGarry, III, Winston and Strawn, 1200 17th Street, NW., Washington, DC 20036

Local Public Document Room location: Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina 29691

Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One, Unit No. 2, Pope County, Arkansas

Date of application for amendment: November 26, 1996, as supplemented February 12, 1997.

Brief description of amendment: The amendment changes the allowable primary-to-secondary leak rate and in the Surveillance Requirements section of the TSs it changes the acceptance criteria for steam generator tubes. The amendment changes the reference that is included in the tube acceptance criteria from Combustion Engineering topical report CEN-601-P Revision 01-P to CEN-630-P, Revision 01.

Date of issuance: May 20, 1997

Date of effective: May 20, 1997, to be implemented within 30 days.

Amendment No.: 184

Facility Operating License No. NPF-6: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** December 4, 1996 (61 FR 64376) The February 12, 1997, submittal provided clarifying information that did not change the initial proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 20, 1997. No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, AR 72801

Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One, Unit No. 2, Pope County, Arkansas

Date of application for amendment: April 4, 1995, as supplemented by letters dated August 25, 1995, and April 18, 1997.

Brief description of amendment: The amendment changes the required frequency for inspecting reactor coolant pump flywheels.

Date of issuance: May 20, 1997

Date of effective: May 20, 1997, to be implemented within 30 days.

Amendment No.: 185

Facility Operating License No. NPF-6: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 5, 1995, (60 FR 35069) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 20, 1997. No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, AR 72801

Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One,Unit No. 2, Pope County, Arkansas

Date of application for amendment: October 7, 1996, as supplemented February 10, and May 8, 1997

Brief description of amendment: The amendment changes the channel functional testing frequency for most of the Reactor Protection System (RPS) and Engineered Safety Feature Actuation System (ESFAS) instrumentation from monthly to every four months. In addition, the amendment allows the use of Cycle Independent Shape Annealing Matrix (CISAM) methodology in the Core Protection Calculators (CPCs). Finally, the amendment makes a number of administrative changes to the Technical Specifications (TS) to clarify the existing TS or correct previous errors in the TS.

Date of issuance: May 21, 1997

Date of effective: May 21, 1997

Amendment No.: 186

Facility Operating License No. NPF-6: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** January 29, 1997 (62 FR 4346) The Commission's related evaluation of the amendment is contained in a Safety

Evaluation dated May 21, 1997 No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, AR 72801

Entergy Operations, Inc., Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: March 27, 1997

Brief description of amendment: The amendment changes TSs surveillance requirements 4.5.2.d.3 and 4.5.2.d.4 by increasing the required amount of trisodium phosphate dodecahydrate (TSP) stored in the containment sump from 97.5 cubic feet to 380 cubic feet, and adjusts the TSP sampling requirement accordingly.

Date of issuance: May 15, 1997

Date of effective: May 15, 1997, to be implemented within 60 days.

Amendment No.: 127

Facility Operating License No. NPF-38: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 9, 1997 (62 FR 17234) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 15, 1997 No significant hazards consideration comments received: No.

Local Public Document Room location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, LA 70122.

Entergy Operations, Inc., Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: August 21, 1996, as supplemented by letter dated March 17, 1997

Brief description of amendment: The amendment approves revision of Attachment 1 to the operating license concerning design and testing modifications in the Containment Vacuum Relief System (CVR) that penetrate the primary containment at Waterford Steam Electric Station, Unit 3. The penetrations affected are commonly referred to as Penetrations 53 and 65.

Date of issuance: May 20, 1997

Date of effective: May 20, 1997, to be implemented within 90 days.

Amendment No.: 128

Facility Operating License No. NPF-38: Amendment revised the Operating License.

Date of initial notice in **Federal Register:** November 6, 1996 (61 FR 57484) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 20, 1997. No significant hazards consideration comments received: No.

Local Public Document Room location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, LA 70122.

Maine Yankee Atomic Power Company, Docket No. 50-309, Maine Yankee Atomic Power Station, Lincoln County, Maine

Date of application for amendment: September 13, 1996, as supplemented by letter dated January 15, 1997.

Brief description of amendment: The amendment revised the Technical Specifications to permit the use of 10 CFR Part 50, Appendix J, Option B, performance-based containment leakage rate testing.

Date of issuance: May 19, 1997

Date of effective: May 19, 1997, to be implemented within 60 days of the date of issuance.

Amendment No.: 158

Facility Operating License No. DPR-36: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 6, 1996 (61 FR 57487) The January 15, 1997, supplemental letter provided additional clarifying information and did not change the initial no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 19, 1997. No significant hazards consideration comments received: Yes. Comments were submitted by Patrick J. Dostie on behalf of the State of Maine by letter dated April 15, 1997. The staff responded by letter dated May 19, 1997.

Local Public Document Room location: Wiscasset Public Library, High Street, P.O. Box 367, Wiscasset, ME 04578.

North Atlantic Energy Service Corporation, Docket No. 50-443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: February 18, 1997, as supplemented by letter dated February 26, 1997.

Description of amendment request: The amendment revises the Appendix A Technical Specifications relating to the reactor core fuel assembly design features requirements contained in Technical Specification 5.3.1, Fuel Assemblies. The changes made by this amendment allow for the limited replacement of failed or damaged fuel rods in fuel assemblies with solid stainless steel or zirconium alloy filler rods.

Date of issuance: May 13, 1997

Date of effective: May 13, 1997

Amendment No.: 51

Facility Operating License No. NPF-86. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 12, 1997 (62 FR 11496) The licensee's letter dated February 26, 1997, provided a correction to a typographical error in the original application but does not change the initial proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 13, 1997. No significant hazards consideration comments received: No.

Local Public Document Room location: Exeter Public Library, Founders Park, Exeter, NH 03833

Portland General Electric Company, et al., Docket No. 50-344, Trojan Nuclear Plant, Columbia County, Oregon

Date of application for amendment: November 2, 1995.

Brief description of amendment: This amendment changes the TS to reflect changes in the organization as they apply to oversite and management of the Trojan Nuclear Plant.

Date of issuance: October 31, 1996

Date of effective: October 31, 1996

Amendment No.: 195

Facility Operating License No. NPF-1: The amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 27, 1995 (60 FR 58404) No significant hazards consideration comments received: No.

Local Public Document Room location: Branford Price Millar Library, Portland State University, 934 S.W. Harrison Street, P.O. Box 1151, Portland, Oregon 97207

Public Service Electric & Gas Company, Docket Nos. 50-272 and 50-311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of application for amendments: January 7, 1997

Brief description of amendments: These amendments revise Technical Specification (TS) 3/4.2.5 to incorporate an exception to the provisions of TS 4.0.4 and to clarify the time at which the surveillance can be performed by adding that the surveillance is to be performed within 24 hours after attaining steady state conditions at or above 90% rated thermal power. The revised surveillance contains editorial enhancements that clarify the

surveillance requirement. Salem Unit 1 TS Table 3.2-1 is also being revised to delete reference to three loop operation.

Date of issuance: May 8, 1997

Date of effective: Both units, as of date of issuance, to be implemented prior to entry into Mode 1 from the current outage. Amendment Nos. 193 and 176

Facility Operating License Nos. DPR-70 and DPR-75. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** January 29, 1997 (62 FR 4353) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 8, 1997. No significant hazards consideration comments received: No

Local Public Document Room location: Salem Free Public Library, 112 West Broadway, Salem, NJ 08079

Southern Nuclear Operating Company, Inc., Docket No. 50-348, Joseph M. Farley Nuclear Plant, Unit 1, Houston County, Alabama

Date of amendment request: March 25, 1997

Brief description of amendments: The amendment changes Technical Specification 3/4.4.9, ''Specific Activity,'' and the associated Bases to reduce the limit associated with dose equivalent iodine-131. The steady-state dose equivalent iodine-131 limit would be reduced by 40 percent from 0.5 [micro]Ci/gram to 0.3 [micro]Ci/gram and the maximum instantaneous value would be reduced by 40 percent from 30 [micro]Ci/gram to 18 [micro]Ci/gram.

Date of issuance: May 19, 1997

Date of effective: As of the date of issuance to be implemented within 30 days

Amendment Nos.: 128

Facility Operating License Nos. NPF-2 and NPF-8: Amendments revise the Technical Specifications.

Date of initial notice in **Federal Register:** April 4, 1997 (62 FR 16201) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 19, 1997. No significant hazards consideration comments received: No

Local Public Document Room location: Houston-Love Memorial Library, 212 W. Burdeshaw Street, Post Office Box 1369, Dothan, Alabama 36302

Dated at Rockville, Maryland, this 28th day of May, 1997.

For the Nuclear Regulatory Commission

Jack W. Roe,

Director, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation

[Doc. 97–14395 Filed 6–3–97; 8:45 am]

BILLING CODE 7590–01–F

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22686; 811–4068]

Pacifica Funds Trust; Notice of Application

May 28, 1997.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the ''Act'').

APPLICANT: Pacifica Funds Trust.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATES: The application was filed on January 31, 1997, and amended on May 9, 1997.

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 applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 23, 1997, and should be accompanied by proof of service on applicant, 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, N.W., Washington, D.C. 20549. Applicant, 237 Park Avenue, Suite 910, New York, NY 10017.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Staff Attorney, at (202) 942–0574, or H.R. Hallock, Jr., Special Counsel, at (202) 942–0564 (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.

Applicant's Representations

1. Applicant is an open-end management investment company organized as a Massachusetts business trust. On July 16, 1984, applicant registered under the Act and filed a registration statement on Form N–1A pursuant to section 8(b) of the Act. The registration statement became effective on November 30, 1984. Applicant commenced an initial public offering of the first of its 23 series on December 26, 1985, and commenced its last initial public offering of a series on November 15, 1995. Shares of five series were never offered to the public.

2. First Interstate Capital Management, Inc., served as applicant's investment adviser prior to April 1, 1996, when its parent company, First Interstate Bancorp, merged into Wells Fargo & Company. At a meeting on May 17, 1996, applicant's board of trustees, including a majority of the trustees who are not ''interested persons'' of applicant, approved entry into an Agreement and Plan of Reorganization (the ''Reorganization Agreement'') by and between applicant and Stagecoach Funds, Inc. (''Stagecoach''), an open-end investment company advised by Wells Fargo Bank, N.A. In reviewing the proposed reorganization, applicant's board considered the potential impact of the reorganization on applicant's shareholders, including (a) provisions intended to avoid the dilution of shareholder interests; (b) the capabilities, practices, and resources of the organizations that provided investment advisory and certain other services to applicant and Stagecoach; (c) the shareholder services provided to applicant's shareholders, compared with the shareholder services provided to Stagecoach shareholders; (d) the investment objectives, policies and limitations of each series of applicant and the corresponding series of Stagecoach; (e) the historical investment performance of each series of applicant and the corresponding series of Stagecoach; (f) the historical and projected operating expenses of each series of applicant and the corresponding series of Stagecoach; and (g) the anticipated tax consequences of the reorganization.

3. Based upon its evaluation of the information presented, applicant's board of trustees determined that the reorganization was in the best interests of the shareholders of each series of applicant, and that the interests of the shareholders of each series would not be diluted. An amendment to the Reorganization Agreement was subsequently approved by the applicant's board of trustees on August 15, 1996, which provided that, because of tax considerations, certain liabilities of one of applicant's 23 series (Pacifica Asset Preservation Fund) would be retained by that series rather than transferred to its corresponding series of Stagecoach.

4. On or about June 6, 1996, proxy materials for a special shareholders meeting were distributed to applicant's

shareholders. At the special meeting of applicant's shareholders held on July 16, 1997, the shareholders approved the Reorganization Agreement. On September 6, 1996, each series of applicant transferred all of its assets and liabilities to a corresponding series of Stagecoach in exchange for shares of such corresponding series of Stagecoach, except that, as noted above, Pacifica Asset Preservation Fund retained certain liabilities and received cash from its corresponding series of Stagecoach in an amount equal to such retained liabilities. Subsequent to the reorganization, Pacifica Asset Preservation Fund utilized the cash it received to repay all of the retained liabilities.

5. Immediately after the reorganization, each series of applicant made a liquidating distribution to each of its shareholders. Applicant's shareholders of record received full and fractional shares of the corresponding class of the Stagecoach series having an aggregate net asset value equal to the aggregate net asset value of shares of applicant's series exchanged therefor. In addition, applicant's shareholders received all unpaid dividends and distributions that were declared prior to September 6, 1996. Shares of all 18 of applicant's series that had been publicly sold were exchanged for shares of the corresponding series and class of Stagecoach as follows: Arizona Tax-Exempt Fund into Arizona Tax-Free Fund; Asset Preservation Fund into Money Market Mutual Fund; Balanced Fund into Balanced Fund; California Short-Term Tax-Exempt Fund into California Tax-Free Income Fund; California Tax-Exempt Fund into California Tax-Free Bond Fund; Equity Value Fund into Equity Value Fund; Government Income Fund into Short-Intermediate U.S. Government Income Fund; Government Money Market Fund into Government Money Market Mutual Fund; Growth Fund into Growth and Income Fund; Intermediate Bond Fund into Intermediate Bond Fund; Intermediate Government Bond Fund into Ginnie Mae Fund; Money Market Fund into Money Market Mutual Fund; Money Market Trust into Money Market Trust; National Tax-Exempt Fund into National Tax-Free Fund; Oregon Tax-Exempt Fund into Oregon Tax-Free Fund; Prime Money Market Fund into Prime Money Market Mutual Fund; Short-Term Government Bond Fund into Short-Intermediate U.S. Government Income Fund; and Treasury Money Market Fund into Treasury Money Market Mutual Fund.

6. The expenses incurred in connection with the reorganization between applicant and Stagecoach were approximately $1,145,107.11. The expenses were assumed by Wells Fargo Bank, the investment adviser to Stagecoach, and the parent company of applicant's investment adviser, Wells Fargo Investment Management, Inc. (previously First Interstate Capital Management, Inc.). No brokerage commissions were paid in connection with the transfer of assets from applicant's series to corresponding series of Stagecoach.

7. At the time the application was initially filed, applicant had no security holders or assets. Applicant has no debts or liabilities which remain outstanding. Applicant is not currently a party to any litigation or administrative proceeding.

8. Applicant is not now engaged, nor does it propose to engage, in any business activities other than those necessary for the winding up of its affairs. Applicant will file a certificate of termination with the Commonwealth of Massachusetts.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–14540 Filed 6–3–97; 8:45 am]

BILLING CODE 8010–01–M

SOCIAL SECURITY ADMINISTRATION

Information Collection Activities: Proposed Collection Requests and Comment Requests

This notice lists information collection packages that will require submission to the Office of Management and Budget (OMB), as well as information collection packages submitted to OMB for clearance, in compliance with P.L. 104–13 effective October 1, 1995, The Paperwork Reduction Act of 1995.

I. The information collection(s) listed below require(s) extension(s) of the current OMB approval(s) or are proposed new collection(s):

1. Employer Report of Special Wage Payments—*0960–0565*. The information collected on form SSA–131 will be used to verify wage information in order to prevent earnings-related overpayments or to avoid erroneous withholding of benefits. Only a small segment of employers, estimated at about 1,000, will need to complete the entire form. For these employers, the estimated average burden to complete a single form is 22 minutes. It will take an estimated average burden of 20 minutes to complete a single form for the majority of the employers. The respondents are employers who need to report an event which requires special wage payment verification.

Number of Respondents: 100,000.

Frequency of Response: 1.

Average Burden Per Response: 20–22 Minutes.

Estimated Annual Burden: 33,367.

2. Social Security Tax and Benefit Statement Survey—*0960-New*. Public Law 104–121 requires SSA to conduct and report to Congress on a pilot study of the efficacy of providing beneficiaries with information about their Social Security benefits, earnings and taxes paid on those earnings. SSA will conduct a one-time survey to solicit beneficiaries' reactions to such a statement and to determine whether the statement promotes better understanding of their contributions and benefits under the Social Security programs. The respondents are a sample of Social Security beneficiaries who are randomly selected and agree to participate in the survey.

Number of Respondents: 1,600.

Frequency of Response: 1.

Average Burden Per Response: 10 minutes.

Estimated Annual Burden: 267 hours.

3. Subpart T—State Supplementation Provisions; Agreement; Payments, 20 CFR 416.2099—0960–0240. Section 1618 of the Social Security Act contains pass-along provisions of the Social Security amendments. These provisions require that States which supplement the Federal SSI benefit pass along Federal cost-of-living increases to individuals who are eligible for State supplementary payments. If a State fails to keep payments at the required level, it becomes ineligible for Medicaid reimbursement under title XIX of the Social Security Act. Regulations at 20 CFR 416.2099 require States to report mandatory minimum and optional supplementary payment data to SSA. The information is used to determine compliance with laws and regulations. The respondents are States which supplement Federal SSI payments.

Number of Respondents: 26.

Frequency of Response: 15 States report quarterly, 11 States report annually.

Average Burden Per Response: 1 hour.

Estimated Annual Burden: 71 hours.

4. Work Activity Report—*Employee—0960–0059*. The form SSA–821–BK is used by the Social Security Administration to obtain information on work activity. The information is needed to determine if disabled individuals are performing substantial gainful activity and, if so, whether they continue to meet the disability criteria

of the law. The respondents are Social Security and SSI disability applicants and recipients.

Number of Respondents: 300,000.

Frequency of Response: On occasion.

Average Burden Per Response: 45 minutes.

Estimated Annual Burden: 225,000 hours.

Written comments and recommendations regarding the information collection(s) should be sent within 60 days from the date of this publication, directly to the SSA Reports Clearance Officer at the following address: Social Security Administration, DCFAM, Attn: Nicholas E. Tagliareni, 6401 Security Blvd., 1–A–21 Operations Bldg., Baltimore, MD 21235.

In addition to your comments on the accuracy of the agency's burden estimate, we are soliciting comments on the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology.

II. The information collection(s) listed below have been submitted to OMB:

1. Request for Withdrawal of Application—*0960–0015.* In certain situations receiving social security benefits may be to the applicant's disadvantage and they wish to withdraw their application. The information collected on Form SSA–521 is used by the Social Security Administration to process a request for withdrawal of an application for benefits. The respondents are individuals who file a claim and later wish to withdraw it.

Number of Respondents: 100,000.

Frequency of Response: 1.

Average Burden Per Response: 5 minutes.

Estimated Annual Burden: 8,333 hours.

2. SSA/DDS Cost-Effectiveness Measurement System Data Reporting Form—*0960–0384.* The information collected on Form SSA–1461 is used by the Social Security Administration (SSA) to analyze and evaluate the costs incurred by the State Disability Determination Services (DDS) in making determinations of disability for SSA. The data is also used in determining funding levels. The respondents are the State DDS offices.

Number of Respondents: 52.

Frequency of Response: 4 per year.

Average Burden Per Response: 6 hours.

Estimated Annual Burden: 1,248 hours.

3. Claim for Amounts Due in the Case of a Deceased Beneficiary—*0960–0101.* Section 204(d) of the Social Security Act provides that if a beneficiary dies before payment of Social Security title II benefits has been completed, the amount due will be paid to persons meeting specified qualifications. The information collected on Form SSA–1724 is used by the Social Security Administration to determine whether an individual is entitled to the underpayment. The respondents are applicants for the underpayment of a deceased beneficiary.

Number of Respondents: 300,000.

Frequency of Response: 1.

Average Burden Per Response: 10 minutes.

Estimated Annual Burden: 50,000 hours.

4. Supplement to Claim of Person Outside the United States—*0960–0051.* The information collected on Form SSA–21 is used to determine the continuing entitlement to Social Security benefits and the proper benefit amounts of alien beneficiaries living outside the United States. It is also used to determine whether benefits are subject to tax withholding. The respondents are individuals entitled to Social Security benefits who are, will be, or have been residing outside the United States.

Number of Respondents: 35,000.

Frequency of Response: 1.

Average Burden Per Response: 5 minutes.

Estimated Annual Burden: 2,917 hours.

5. Statement of Claimant or Other Person—*0960–0045.* Form SSA–795 is completed by Social Security or SSI applicants when additional information is needed and there is no standard form which collects the information. The information is used by the Social Security Administration to process claims for benefits. The respondents are applicants for Social Security or SSI benefits.

Number of Respondents: 305,500.

Frequency of Response: 1.

Average Burden Per Response: 15 minutes.

Estimated Annual Burden: 76,375 hours.

6. Application for Disability Insurance Benefits—*0960–0060.* The information collected on Form SSA–16 by the Social Security Administration is used to determine an applicant's entitlement to Social Security disability benefits. The respondents are applicants for Social Security disability benefits.

Number of Respondents: 1,000,000.

Frequency of Response: 1.

Average Burden Per Response: 20 minutes.

Estimated Annual Burden: 333,333.

7. Statement for Determining Continuing Eligibility for Supplemental Security Income Payment—*0960–0145.* The information collected on Form SSA–8202 is used by the Social Security Administration to determine a beneficiary's continuing eligibility for and the amount of their SSI payments. The information collected also assists SSI recipients to obtain food stamps and is used by agencies administering Medicaid programs in ascertaining the legal liability of third parties to pay for care and services. The respondents are recipients of SSI benefits.

Number of Respondents: 818,000.

Frequency of Response: 1.

Average Burden Per Response: 11 minutes.

Estimated Annual Burden: 149,967 hours.

8. Statement of Care and Responsibility for Beneficiary—*0960-0109.* When an individual requests to act as representative payee for someone not in their custody, the Social Security Administration must determine if this individual is the most qualified to serve in the beneficiary's best interests. The information collected on Form SSA–788 is used to corroborate the statements of concern made by the representative payee applicant and to identify other potential representative payees. The respondents are individuals who have custody of the beneficiaries for whom someone else has filed to be the representative payee.

Number of Respondents: 130,000.

Frequency of Response: 1.

Average Burden of Response: 10 minutes.

Estimated Annual Burden: 21,667 hours.

9. Third Party Liability Information Statement—*0960–0323.* Form SSA–8019 is used by the Social Security Administration to gather information or to make changes in existing information about third party insurance (other than Medicare or Medicaid), which could be responsible for payment for a beneficiary's medical care. The respondents are third-party insurers other than Medicare or Medicaid.

Number of Respondents: 1,500,000.

Frequency of Response: 1.

Average Burden Per Response: 5 minutes.

Estimated Annual Burden: 125,000 hours.

Written comments and recommendations regarding the information collection(s) should be directed within 30 days to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses:

(OMB)

Office of Management and Budget, OIRA, Attn: Laura Oliven, New Executive Office Building, Room 10230, 725 17th St., NW, Washington, D.C. 20503

(SSA)

Social Security Administration, DCFAM, Attn: Nicholas E. Tagliareni, 1–A–21 Operations Bldg., 6401 Security Blvd., Baltimore, MD 21235

To receive a copy of any of the forms or clearance packages, call the SSA Reports Clearance Officer on (410) 965–4125 or write to him at the address listed above.

Nicholas E. Tagliareni,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 97–14542 Filed 6–3–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings, Agreements Filed During the Week of May 23, 1997

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. Sections 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST–97–2543.
Date Filed: May 20, 1997.
Parties: Members of the International Air Transport Association.
Subject: PTC12 MATL–EUR 0008 dated May 16, 1997, Mid Atlantic-Europe Resos r1–30, Minutes—PTC12 MATL–EUR 0010 dated May 16, 1997, TABLE—PTC12 MATL–EUR 0003 dated May 16, 1997, Intended effective date: October 1, 1997.

Docket Number: OST–97–2544.
Date Filed: May 20, 1997.
Parties: Members of the International Air Transport Association.
Subject: PTC2 EUR 0062 dated May 16, 1997 r1–22, PTC2 EUR 0063 dated May 16, 1997 r–23–38, PTC2 EUR 0064 dated May 16, 1997 r39, PTC2 EUR 0065 dated May 16, 1997 r40, PTC2 EUR 0066 dated May 16, 1997 r41, PTC2 EUR 0067 dated May 16, 1997 r42–57, PTC2 EUR 0068 dated May 16, 1997 r58–63, PTC2 EUR 0069 dated May 16, 1997 r64, PTC2 EUR 0070 dated May 16, 1997 r65–72, PTC2 EUR 0071 dated May 16, 1997 r73–76, PTC2 EUR 0072 dated May 16, 1997 r77, PTC2 EUR 0073 dated May 16, 1997 (EC), PTC2 EUR 0074 dated May 16, 1997 (Non-EC). A summary is attached. Intended effective date: as early as June 15, 1997.

Docket Number: OST–97–2556.
Date Filed: May 23, 1997.
Parties: Members of the International Air Transport Association.
Subject: PTC3 0105 dated April 29, 1996, Mail Vote 869—Fares from Sri Lanka to TC3 points, (Reso 010p) r1, TC3 Telex Mail Vote 872, Bangkok-Vientiane fares, (Resos 043b/063b) r2–3. Intended effective date: June 1/June 15, 1997.

Paulette V. Twine,

Chief, Documentary Services.

[FR Doc. 97–14507 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Notice of Application for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending May 23, 1997

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 *et. seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–97–2553.
Date Filed: May 22, 1997.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 19, 1997.
Description: Application of Delta Air Lines, Inc., pursuant to the Department's Notice served May 8, 1997, requests (1) a new or amended certificate of public convenience and necessity authorizing Delta to provide scheduled foreign air transportation between the United States and South Africa, pursuant to 49 U.S.C. Section 41101 and Subpart Q of the Department's Procedural Regulations; and (2) one of the two third-country code-share designations available for service to South Africa beginning November 1, 1997, under the terms of the U.S.-South Africa Air Transport Agreement. Delta proposes to operate third-country code-share service to Johannesburg and Cape Town, South Africa, via Zurich, Switzerland in cooperation with its alliance partner, Swissair, Swiss Air Transport Company Ltd. (''Swissair'').

Docket Number: OST–97–2554.
Date Filed: May 22, 1997.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 19, 1997.
Description: Application of Continental Airlines, Inc., in response to the Department's Notice on U.S.-South Africa Third-Country Code-Share Services, served May 8, 1997, applies for a certificate of public convenience and necessity authorizing it to conduct foreign air transportation of persons, property and mail between points in the United States, on the one hand, and Cape Town and Johannesburg, South Africa, on the other hand. Continental proposes to provide service between U.S. points and Cape Town and Johannesburg via Paris (CDG) under a code-share arrangement with Air France.

Paulette V. Twine,

Chief, Documentary Services.

[FR Doc. 97–14506 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

RTCA, Inc. (Utilized as an Advisory Committee)

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of charter renewal, RTCA, Inc. (utilized as an advisory committee).

SUMMARY: Notice is hereby given of the renewal of the charter for RTCA, Inc. (utilized as an advisory committee) for 2 years, effective March 13, 1997. The Administrator is the sponsor of the committee. The objective of the advisory committee is to seek solutions to problems involving the application of technology (e.g., electronics, computers, and telecommunications) to aeronautical operations that impact the future air traffic management system. The solutions are frequently in the nature of recommended minimum operational performance standards and technical guidance documents which are acceptable to Government, industry, and users. Standards ensure equivalent performance of the same generic equipment built by different manufacturers. RTCA standards are generally referenced or used (with or without modification) in Government regulatory and procurement activities.

The Secretary of Transportation has determined that the information and use of the committee are necessary in the public interest in connection with the performance of duties imposed on the

FAA by law. Meetings of the committee will be open to the public except as authorized by Section 10(d) of the Federal Advisory Committee Act.

FOR FURTHER INFORMATION CONTACT: Office of System Architecture and Investment Analysis (ASD–1), 800 Independence Avenue, SW., Washington, DC, 20591, Telephone: 202/358–5243.

Issued in Washington, DC, on May 28, 1997.

Janice L. Peters,

Federal Official, System Architecture and Investment Analysis.

[FR Doc. 97–14498 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–97–30]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before June 24, 1997.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

Comments may also be sent electronically to the following internet address: 9–NPRM–CMNTS@faa.dot.gov.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Heather Thorson (202) 267–7470 or Angela Anderson (202) 267–9681 Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on May 29, 1997.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 28400.
Petitioner: Skydive, Inc.
Sections of the FAR Affected: 14 CFR 105.43(a)(1).
Description of Relief Sought: To permit Skydive to permit individuals who have completed a course of instruction in main parachute packing administered by a Federal Aviation Administration-certificated parachute rigger to pack main parachutes for others to make parachute jumps.

Dispositions of Petitions

Docket No.: 25052.
Petitioner: Taquan Air Service, Inc.
Sections of the FAR Affected: 14 CFR 135.203(a)(1).
Description of Relief Sought/ Disposition: To permit Ketchikan Air Service, Inc., Taquan Air Service, Inc., Misty Fjords Air and Outfitting, and Promech, Inc., conducting operations under part 135 to operate seaplanes inside the Ketchikan, Alaska, Class E airspace under Special Visual Flight Rules below 500 feet above the surface. *Grant, May 14, 1997, Exemption No. 4760G.*

Docket No.: 27953.
Petitioner: Aero Sports Connection.
Sections of the FAR Affected: 14 CFR 103.1(a) and (e)(1) through (e)(4).
Description of Relief Sought/ Disposition: To permit individuals authorized by ASC to give instruction in powered ultralights that have a maximum empty weight of not more than 496 pounds, have a maximum fuel capacity of not more than 10 U.S. gallons, are not capable of more than 75 knots calibrated airspeed at full power in level flight, and have a power-off stall speed that does not exceed 35 knots calibrated airspeed. *Grant, May 20, 1997, Exemption No. 6080A.*

Docket No.: 28837.
Petitioner: Temsco Helicopters, Inc.
Sections of the FAR Affected: 14 CFR 145.45(f).
Description of Relief Sought/ Disposition: To allow Temsco to make available one copy of its Repair Station Inspection Procedures Manual to all of its supervisory and inspection personnel, rather than providing a copy of the manual to each of those individuals. *Grant, May 19, 1997, Exemption No. 6623.*

Docket No.: 27430.
Petitioner: Midwest Flying Service, Inc.
Sections of the FAR Affected: 14 CFR 135.143(c)(2).
Description of Relief Sought/ Disposition: To allow Midwest Flying Service, Inc., to conduct operations under part 135 without a TSO–C112 (Mode S) transponder installed on its aircraft. *Grant, May 20, 1997, Exemption No. 5757B.*

Docket No.: 24237.
Petitioner: Department of the Air Force.
Sections of the FAR Affected: 14 CFR 91.177(a)(2) and 91.179(b)(1).
Description of Relief Sought/ Disposition: To permit the Air Force to conduct low-level operations without complying with en route minimum altitudes for flight under instrument flight rules (IFR) or direction of flight requirements for IFR en route segments in uncontrolled airspace. *Grant, May 20, 1997, Exemption No. 4371D.*

Docket No.: 28867.
Petitioner: William K. Herndon.
Sections of the FAR Affected: 14 CFR 121.383(c).
Description of Relief Sought/ Disposition: To allow the petitioner to act as a pilot in operations conducted under part 121 until May 22, 2000. *Denied, May 20, 1997, Exemption No. 6624.*

[FR Doc. 97–14499 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Automotive Fuel Economy Program Report to Congress

The attached document, *Automotive Fuel Economy Program, Twenty-first Annual Report to the Congress,* was prepared pursuant to 49 U.S.C. 32916 *et seq.* which requires that ''the Secretary

shall transmit to each House of Congress, and publish in the **Federal Register**, a review of the average fuel economy standards under this part.''

Issued: May 29, 1997.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

Automotive Fuel Economy Program

Twenty-First Annual Report to Congress

Calendar Year 1996

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Section I: Introduction

The Twenty-first Annual Report to Congress on the Automotive Fuel Economy Program summarizes the activities of the National Highway Traffic Safety Administration (NHTSA) during 1996, in accordance with 49 U.S.C. 32916 *et seq.*, which requires the submission of a report each year. Included in this report is a section summarizing rulemaking activities during 1996. The Federal Reports Elimination Act of 1995 (Pub. L. 104–66) repealed Section 305, Title III, of the Department of Energy Act of 1978 (P.L. 95–238), ''a discussion of the use of advanced automotive technology by the industry.'' Accordingly, the advanced automotive technology section is permanently eliminated from these annual reports beginning with this edition.

The Secretary of Transportation is required to administer a program for regulating the fuel economy of new passenger cars and light trucks in the United States market. The authority to administer the program was delegated by the Secretary to the Administrator of NHTSA, 49 CFR 1.50(f).

NHTSA's responsibilities in the fuel economy area include:

(1) Establishing and amending average fuel economy standards for manufacturers of passenger cars and light trucks, as necessary;

(2) Promulgating regulations concerning procedures, definitions, and reports necessary to support the fuel economy standards;

(3) Considering petitions for exemption from established fuel economy standards by low volume manufacturers (those producing fewer than 10,000 passenger cars annually worldwide) and establishing alternative standards for them;

(4) Preparing reports to Congress annually on the fuel economy program;

(5) Enforcing fuel economy standards and regulations; and

(6) Responding to petitions concerning domestic production by foreign manufacturers, and other matters.

Passenger car fuel economy standards were established by Congress for Model Year (MY) 1985 and thereafter at a level of 27.5 miles per gallon (mpg). NHTSA is authorized to amend the standard above or below that level. Standards for light trucks were established by NHTSA for MYs 1979 through 1998. NHTSA set a combined standard of 20.7 mpg for light truck fleets for MY 1998. All current standards are listed in Table I–1.

TABLE I–1.—FUEL ECONOMY STANDARDS FOR PASSENGER CARS AND LIGHT TRUCKS; MODEL YEARS 1978 THROUGH 1998 (IN MPG)

Model year	Passenger cars	Light trucks [1]		
		Two-wheel drive	Four-wheel drive	Combined [2 3]
1978	[4] 18.0	.....	.....	.....
1979	[4] 19.0	17.2	15.8	
1980	[4] 20.0	16.0	14.0	([5])
1981	22.0	[6] 16.7	15.0	([5])
1982	24.0	18.0	16.0	17.5
1983	26.0	19.5	17.5	19.0
1984	27.0	20.3	18.5	20.0
1985	[4] 27.5	[7] 19.7	[7] 18.9	[7] 19.5
1986	[8] 26.0	20.5	19.5	20.0
1987	[9] 26.0	21.0	19.5	20.5
1988	[9] 26.0	21.0	19.5	20.5
1989	[10] 26.5	21.5	19.0	20.5
1990	[4] 27.5	20.5	19.0	20.0
1991	[4] 27.5	20.7	19.1	20.2
1992	[4] 27.5	.....	.....	20.2
1993	[4] 27.5	.....	.....	20.4
1994	[4] 27.5	.....	.....	20.5
1995	[4] 27.5	.....	.....	20.6
1996	[4] 27.5	.....	.....	20.7
1997	[4] 27.5	.....	.....	20.7
1998	[4] 27.5	.....	.....	20.7

[1] Standards for MY 1979 light trucks were established for vehicles with a gross vehicle weight rating (GVWR) of 6,000 pounds or less. Standards for MY 1980 and beyond are for light trucks with a GVWR of 8,500 pounds or less.

[2] For MY 1979, light truck manufacturers could comply separately with standards for four-wheel drive, general utility vehicles and all other light trucks, or combine their trucks into a single fleet and comply with the standard of 17.2 mpg.

[3] For MYs 1982–1991, manufacturers could comply with the two-wheel and four-wheel drive standards or could combine all light trucks and comply with the combined standard.

[4] Established by Congress in Title V of the Act.

[5] A manufacturer whose light truck fleet was powered exclusively by basic engines which were not also used in passenger cars could meet standards of 14 mpg and 14.5 mpg in MYs 1980 and 1981, respectively.

[6] Revised in June 1979 from 18.0 mpg.
[7] Revised in October 1984 from 21.6 mpg for two-wheel drive, 19.0 mpg for four-wheel drive, and 21.0 mpg for combined.
[8] Revised in October 1985 from 27.5 mpg.
[9] Revised in October 1986 from 27.5 mpg.
[10] Revised in September 1988 from 27.5 mpg.

Section II: Fuel Economy Improvement by Manufacturers

A. Fuel Economy Performance by Manufacturer

The fuel economy achievements for domestic and foreign-based manufacturers in MY 1995 were updated to include final Environmental Protection Agency (EPA) calculations, where available, since the publication of the Twentieth Annual Report to the Congress. These fuel economy achievements and current projected data for MY 1996 are listed in Tables II–1 and II–2.

Overall fleet fuel economy for passenger cars was 28.7 mpg in MY 1996, an increase of 0.1 mpg from the MY 1995 level. For MY 1996, Corporate Average Fuel Economy (CAFE) values increased above MY 1995 levels for seven of 23 passenger car manufacturers' fleets. (See Table II–1.) These seven companies accounted for more than 42 percent of the total MY 1996 production. Manufacturers continued to introduce new technologies and more fuel-efficient models, and some larger, less fuel-efficient models. For MY 1996, the overall domestic manufacturers' fleet average fuel economy was 28.3 mpg. For MY 1996, General Motors domestic passenger car CAFE value rose 0.9 mpg from its 1995 level, while Chrysler, Ford, Mazda, and Toyota fell 0.8 mpg, 0.9 mpg, 0.5 mpg, and 0.2 mpg, respectively, from their MY 1995 levels. Overall, the domestic manufacturers' combined CAFE increased 0.6 mpg above MY 1995 level.

TABLE II–1.—PASSENGER CAR FUEL ECONOMY PERFORMANCE BY MANUFACTURER [1] MODEL YEARS 1995 AND 1996

Manufacturer	Model year CAFE (MPG)	
	1995	1996
Domestic:		
Chrysler	28.4	27.6
Ford	27.7	26.8
General Motors	27.4	28.3
Honda	([2])	33.2
Mazda	30.3	29.8
Toyota	28.5	28.3
Sales Weighted Average (Domestic)	27.7	28.3
Import:		
BMW	25.3	27.3
Chrysler Imports	28.6	28.2

TABLE II–1.—PASSENGER CAR FUEL ECONOMY PERFORMANCE BY MANUFACTURER [1] MODEL YEARS 1995 AND 1996—Continued

Manufacturer	Model year CAFE (MPG)	
	1995	1996
Fiat	15.7	13.8
Ford Imports	34.0	31.5
GM Imports	36.7	35.8
Honda	32.7	27.8
Hyundai	31.2	32.9
Kia	31.2	29.0
Mazda	31.4	32.7
Mercedes-Benz	24.7	25.1
Mitsubishi	29.9	29.9
Nissan	29.5	30.4
Porsche	22.7	21.5
Subaru	28.9	27.7
Suzuki	40.8	34.0
Toyota	30.4	29.8
Volvo	26.0	26.1
Volkswagen	29.0	28.2
Sales Weighted Average (Import)	30.3	29.7
Total Fleet Average	28.6	28.7
Fuel Economy Standards	27.5	27.5

[1] Manufacturers or importers of fewer than 1,000 passenger cars annually are not listed.
[2] In MY 1996 Honda achieved 75 percent domestic content for its United States built passenger cars to become the third foreign-based manufacturer with a domestic fleet.

NOTE: Some MY 1995 CAFE values differ from those used in the Twentieth Annual Report to the Congress due to the use of final EPA calculations.

TABLE II–2.—LIGHT TRUCK FUEL ECONOMY PERFORMANCE BY MANUFACTURER

[Model Years 1995 and 1996]

Manufacturer	Model year CAFE (MPG)	
	Combined	
	1995	1996
Domestic:		
Chrysler	20.1	20.3
Ford	20.8	20.6
General Motors	20.1	20.7
Sales Weighted Average (Domestic)	20.3	20.5
Import:		
Isuzu	20.3	19.5
Land Rover	16.3	17.2
Mazda	20.9	20.7
Mitsubishi	20.2	19.1
Nissan	22.4	23.0
Suzuki	28.1	27.5
Toyota	21.2	23.2
Volkswagen	19.6	([1])

TABLE II–2.—LIGHT TRUCK FUEL ECONOMY PERFORMANCE BY MANUFACTURER—Continued

[Model Years 1995 and 1996]

Manufacturer	Model year CAFE (MPG)	
	Combined	
	1995	1996
Sales Weighted Average (Import)	21.5	22.1
Total Fleet Average	20.5	20.7
Fuel Economy Standards	20.6	20.7

[1] Volkswagen did not produce light trucks for MY 1996.

NOTE: Some MY 1995 CAFE values differ from those used in the Twentieth Annual Report to the Congress due to the use of final EPA calculations.

In MY 1996, the fleet average fuel economy for import passenger cars decreased by 0.6 mpg from the MY 1995 CAFE level to 29.7 mpg. Six of the 18 import car manufacturers increased their CAFE values between MYs 1995 and 1996, including three of the nine Asian manufacturers.

Fleet average fuel economy for all MY 1996 passenger cars combined exceeded the level of the MY 1996 standard by 1.2 mpg. Figure II–1 illustrates the changes in total new passenger car fleet CAFE from MY 1978 to MY 1996.

The total light truck fleet CAFE increased 0.2 mpg above the MY 1995 CAFE level of 20.5 mpg (see Table II–2). Figure II–2 illustrates the trends in total light truck fleet CAFE from MY 1979 to MY 1996.

Several passenger cars and a few light truck manufacturers are projected to fail to achieve the levels of the MY 1996 CAFE standards. However, NHTSA is not yet able to determine which of these manufacturers may be liable for civil penalties for non-compliance. Some MY 1996 CAFE values may change when final figures are provided to NHTSA by EPA, in mid-1997. In addition, several manufacturers are not expected to pay civil penalties because the credits they earned by exceeding the fuel economy standards in earlier years offset later shortfalls. Other manufacturers may file carryback plans to demonstrate that they anticipate earning credits in future model years to offset current deficits.

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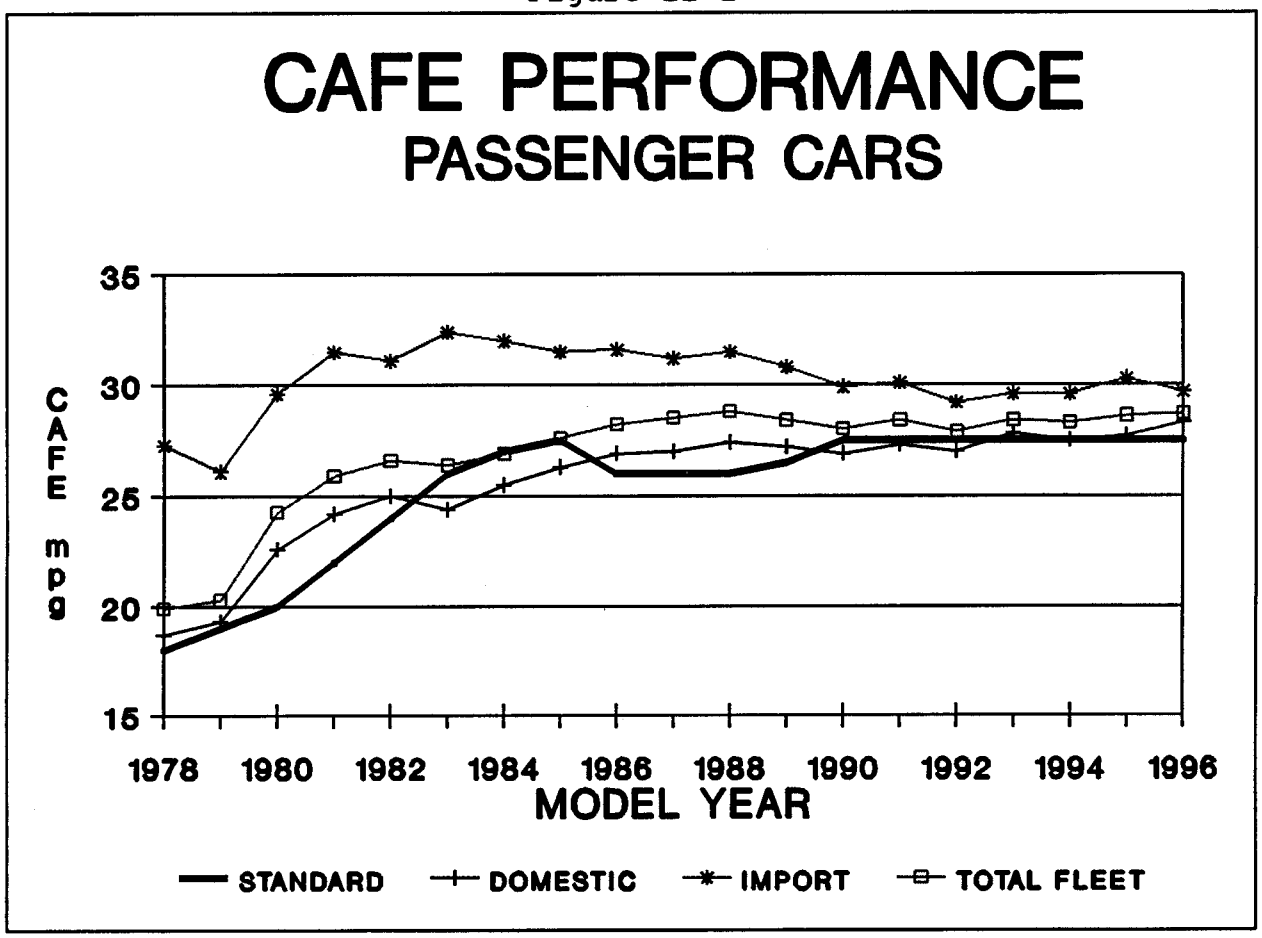
Figure II-1


CAFE PERFORMANCE
PASSENGER CARS
CAFE mpg
35
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1978
1980
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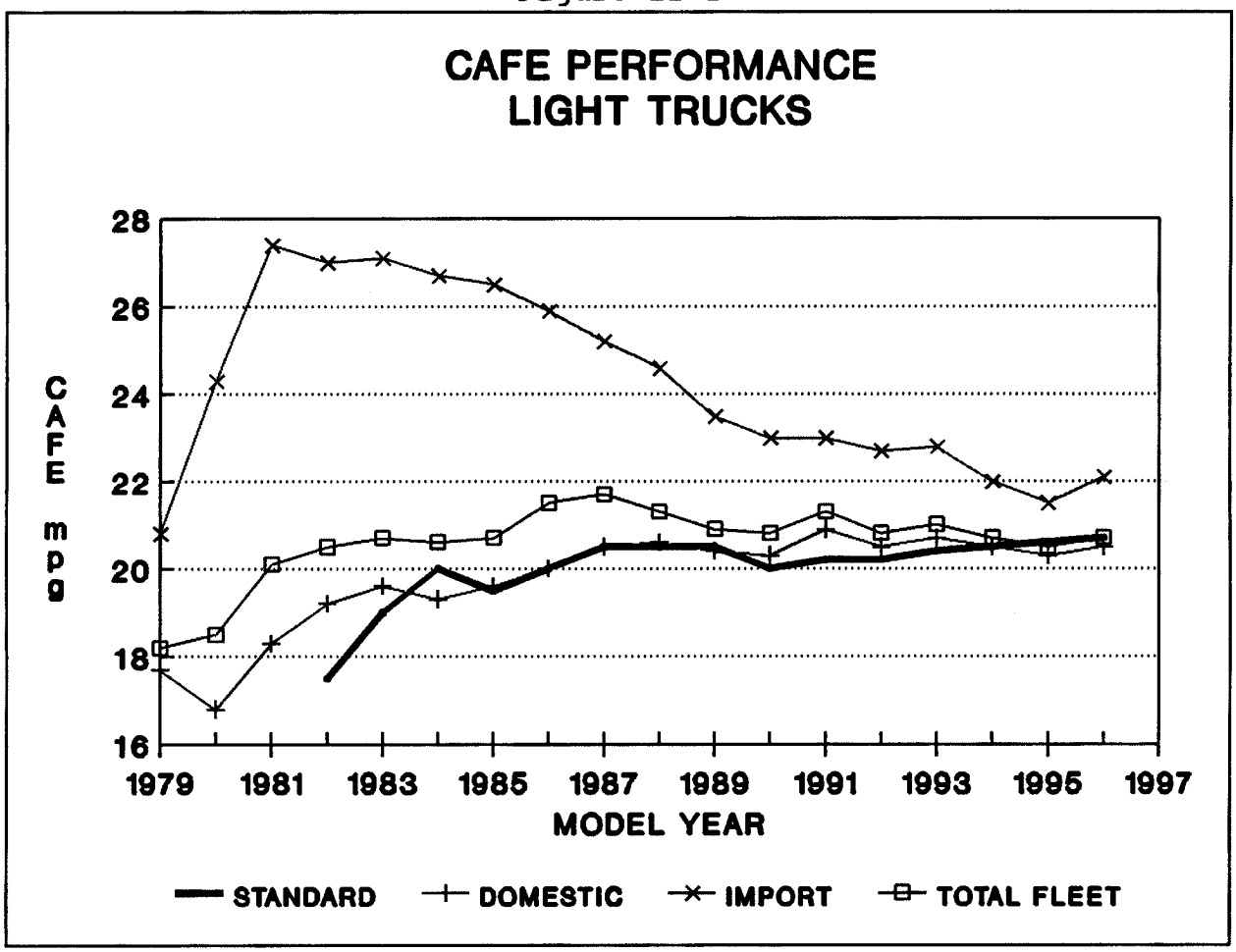
1994
1996
MODEL YEAR
STANDARD
DOMESTIC
IMPORT
TOTAL FLEET

Figure II-2



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B. Characteristics of the MY 1996 Passenger Car Fleet

The characteristics of the MY 1996 passenger car fleet reflect a continuing trend toward satisfying consumer demand for higher performance cars. (See Table II–3.) From MY 1995 to MY 1996, horsepower/100 pounds, a measure of vehicle performance, increased from 4.93 to 5.00 for domestic passenger cars. However, it decreased slightly from 4.77 to 4.76 for import passenger cars. The total fleet average for passenger cars increased from 4.87 horsepower/100 pounds in MY 1995 to 4.92 in MY 1996. Compared with MY 1995, the average curb weight for MY 1996 decreased by 35 pounds for the domestic fleet and increased 25 pounds for the import fleet. The total new passenger car fleet weight remained constant at 3,047 pounds, as in MY 1995. Average engine displacement decreased from 188 to 178 cubic inches for domestic passenger cars, and increased from 131 to 134 cubic inches for import passenger cars, from MY 1995 to MY 1996.

The 0.6 mpg fuel economy improvement for the MY 1996 domestic passenger car fleet may be attributed in part to weight reduction, mix shifts, and an increase in the use of more automatic transmissions with four speeds and front-wheel drive.

The size/class breakdown shows an increased trend primarily toward compact passenger cars with the reduction of subcompact passenger cars for the overall fleet. The size/class mix in the domestic fleet shifted from mid-size and large passenger cars to minicompact, subcompact and compact passenger cars. The size/class mix in the import fleet shifted from minicompact, subcompact, and compact passenger cars to two-seater, mid-size and large passenger cars. The import share of the passenger car market declined in MY 1996, as more foreign-based manufacturers achieved 75 percent domestic content for their U.S. and Canadian-assembled passenger cars.

TABLE II–3.—PASSENGER CAR FLEET CHARACTERISTICS FOR MYS 1995 AND 1996

Characteristics	Total fleet		Domestic fleet		Import fleet	
	1995	1996	1995	1996	1995	1996
Fleet Average Fuel Economy, mpg	28.6	28.7	27.7	28.3	30.2	29.7
Fleet Average Curb Weight, lbs.	3047	3047	3146	3111	2881	2906
Fleet Average Engine Displacement, cu. in.	166	164	188	178	131	134
Fleet Average Horsepower/Weight ratio, HP/100 lbs.	4.87	4.92	4.93	5.00	4.77	4.76

TABLE II–3.—PASSENGER CAR FLEET CHARACTERISTICS FOR MYS 1995 AND 1996—Continued

Characteristics	Total fleet		Domestic fleet		Import fleet	
	1995	1996	1995	1996	1995	1996
Percent of Fleet	100	100	62.7	68.6	37.3	31.4
Segmentation by EPA Size Class, Percent						
Two-Seater	0.8	1.1	0.4	0.5	1.5	2.3
Minicompact	0.7	0.5	0.0	0.0	1.9	1.5
Subcompact [1]	17.1	15.5	8.9	10.9	30.9	25.6
Compact [1]	39.3	41.3	36.1	40.5	44.7	43.0
Mid-Size [1]	28.5	28.3	33.5	29.2	20.2	26.1
Large [1]	13.6	13.4	21.1	18.9	0.9	1.5
Diesel Engines	0.06	0.09	0.0	0.0	0.2	0.3
Turbo or Supercharged Engines	0.7	0.8	0.0	0.0	1.8	2.5
Fuel Injection	100	100	100	100	100	100
Front-Wheel Drive	84.8	85.6	84.6	86.8	85.1	83.0
Automatic Transmissions	83.2	84.1	89.8	87.9	72.1	75.7
Automatic Transmissions with Lockup Clutches	98.0	97.9	100	100	93.7	92.4
Automatic Transmissions with Four or more Forward Speeds	87.9	88.8	85.5	89.0	92.7	88.2

[1] Includes associated station wagons.

The import fleet rose above its MY 1996 level in the share of turbocharged and supercharged engines. Diesel engine share increased slightly in MY 1996, and diesels were offered by two import manufacturers.

Passenger car fleet average characteristics have changed significantly since MY 1978 (the first year of fuel economy standards). (See Table II–4.) After substantial initial weight loss (from MY 1978 to MY 1982, the average passenger car fleet curb weight decreased from 3,349 to 2,808 pounds), the curb weight stabilized between 2,800 and 3,050 pounds. Table II–4 shows that the MY 1996 passenger car fleet has nearly equal interior volume and higher performance, but with more than 40 percent better fuel economy, than the MY 1978 fleet. (See Figure II–3.)

C. Characteristics of the MY 1996 Light Truck Fleet

The characteristics of the MY 1996 light truck fleet are shown in Table II–5. Light truck manufacturers are not required to divide their fleets into domestic and import fleets based on the 75-percent domestic content threshold used for passenger car fleets. Therefore, beginning with this report, the light truck fleet is subdivided in this table according to drive wheels: two-wheel drive or four-wheel drive.

TABLE II–4.—NEW PASSENGER CAR FLEET AVERAGE CHARACTERISTICS

[Model Years 1978–1996]

Model year	Fuel economy (mpg)	Curb weight (lb.)	Interior space (cu. ft.)	Engine size (cu. in.)	Horse-power/ weight (hp/100 lb.)
1978	19.9	3349	112	260	3.68
1979	20.3	3180	110	238	3.72
1980	24.3	2867	105	187	3.51
1981	25.9	2883	108	182	3.43
1982	26.6	2808	107	173	3.47
1983	26.4	2908	109	182	3.57
1984	26.9	2878	108	178	3.66
1985	27.6	2867	108	177	3.84
1986	28.2	2821	106	169	3.89
1987	28.5	2805	109	162	3.98
1988	28.8	2831	107	161	4.11
1989	28.4	2879	109	163	4.24
1990	28.0	2908	108	163	4.53
1991	28.4	2934	108	164	4.42
1992	27.9	3007	108	169	4.56
1993	28.4	2971	109	164	4.62
1994	28.3	3011	109	169	4.79
1995	28.6	3047	109	166	4.87
1996	28.7	3047	109	164	4.92

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Figure II-3

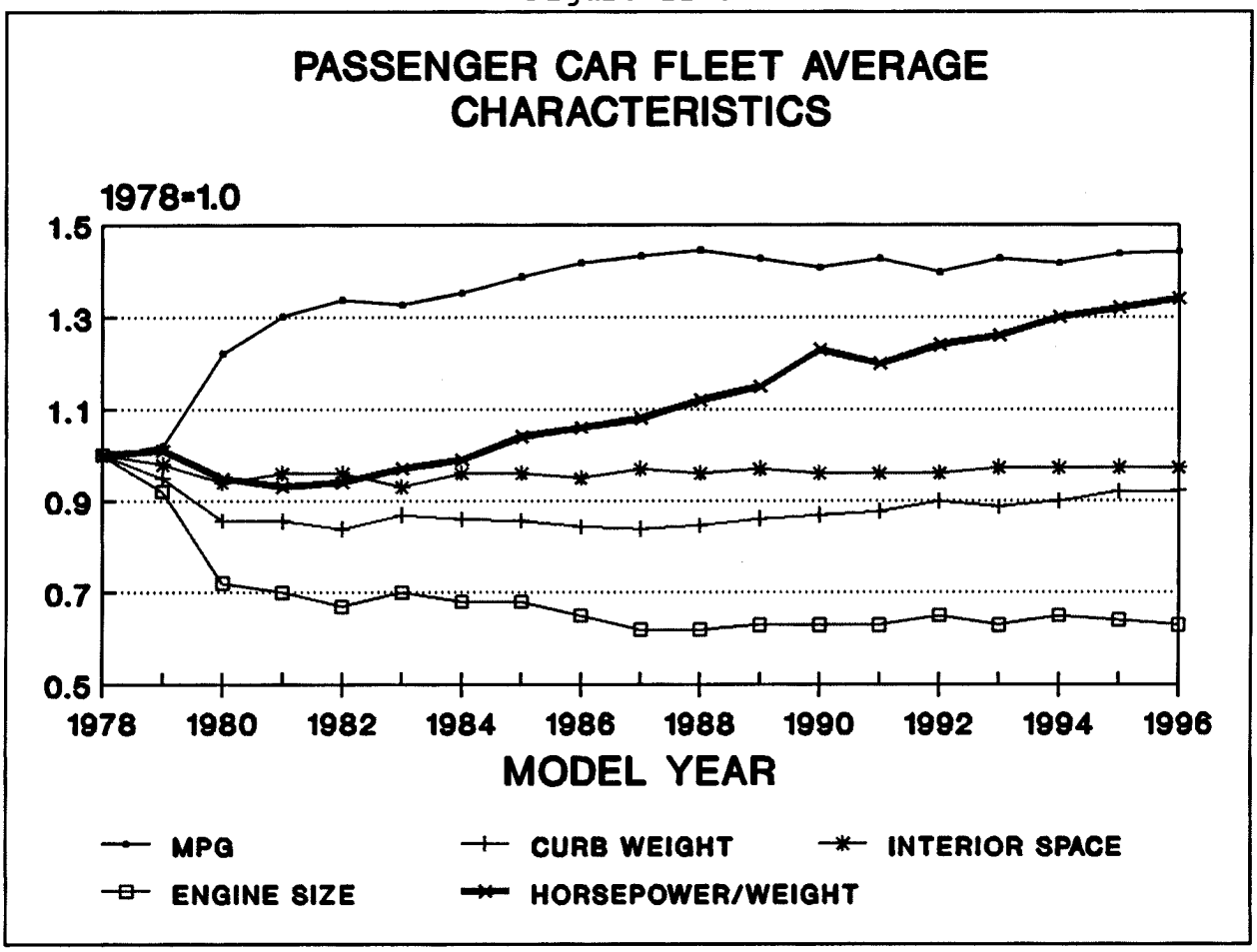

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TABLE II–5.—LIGHT TRUCK FLEET CHARACTERISTICS FOR MYS 1995 AND 1996

Characteristics	Total fleet		Two-wheel drive		Four-wheel drive	
	1995	1996	1995	1996	1995	1996
Fleet Average Fuel Economy, mpg	20.5	20.7	21.6	21.9	18.9	19.3
Fleet Average Equivalent Test Weight, lbs	4339	4355	4192	4201	4575	4602
Fleet Average Engine Displacement, cu. in	245	244	235	231	261	265
Fleet Average Horsepower/Weight ratio, HP/100 lbs	3.88	4.07	3.83	4.00	3.96	4.19
Percent of Fleet	100	100	61.7	61.6	38.3	38.4
Percent of Fleet from Foreign-Based Manufacturers	14.7	12.2	10.9	8.9	20.8	17.6
Segmentation by Type, Percent						
Passenger Van	22.3	22.7	34.7	36.1	2.3	1.3
Cargo Van	6.4	3.7	10.1	5.9	0.5	0.2
Small Pickup.						
Two-Wheel Drive	7.7	7.0	12.5	11.3	.....	.....
Four-Wheel Drive	.....	.....	.....	.....	.....	.....
Large Pickup.						
Two-Wheel Drive	19.0	19.4	30.8	31.5	.....	.....
Four-Wheel Drive	12.9	10.8	.....	.....	33.8	28.2
Special Purpose.						
Two-Wheel Drive	7.3	9.3	11.9	15.1	.....	.....
Four-Wheel Drive	24.3	27.0	.....	.....	63.4	70.3
Diesel Engines	0.20	0.07	0.11	0.04	0.34	0.12
Turbo/Supercharged Engines	0.20	0.07	0.09	0.04	0.34	0.12
Fuel Injection	100	100	100	100	100	100
Automatic Transmissions	79.5	84.3	78.7	82.2	80.8	87.6
Automatic Transmissions with Lockup Clutches	98.9	98.9	98.3	98.1	100	100

TABLE II–5.—LIGHT TRUCK FLEET CHARACTERISTICS FOR MYS 1995 AND 1996—Continued

Characteristics	Total fleet		Two-wheel drive		Four-wheel drive	
	1995	1996	1995	1996	1995	1996
Automatic Transmissions with Four or More Forward Speeds	93.4	93.8	90.5	90.0	97.9	99.4

The MY 1996 average test weight of the total light truck fleet increased by 16 pounds over that for MY 1995. The average fuel economy of the fleet increased by 0.2 mpg to 20.7 mpg. Diesel engine usage decreased in light trucks to 0.07 percent in MY 1996 from 0.20 percent in MY 1995. The share of the MY 1996 two-wheel drive fleet remained near the MY 1995 level of 61.7 percent.

CAFE levels for light trucks in the 0–8,500 pounds gross vehicle weight (GVW) class increased from 18.5 mpg in MY 1980 to 21.7 mpg in MY 1987, before declining to 20.7 mpg in MY 1996, influenced by an increase in average weight, engine size, and performance. Light truck production increased from 1.9 million in MY 1980 to 5.2 million in MY 1996. Light trucks comprised 40 percent of the total light duty vehicle fleet production in MY 1996, more than triple the share in MY 1980.

D. Passenger Car and Light Truck Fleet Economy Averages

Figure II–4 illustrates an increase in the light duty fleet (combined passenger cars and light trucks) average fuel economy through MY 1987, followed by a gradual decline. (See also Table II–6.) Passenger car average fuel economy remained relatively constant for MYs 1987–1996. The overall decline in fuel economy illustrates the growing influence of light trucks and their significant impact on the light duty fleet.

While passenger car and light truck fleet fuel economies increased from MY 1995 to MY 1996 by 1.2 mpg and 0.2 mpg, respectively, the total fleet fuel economy for MY 1996 remains at the MY 1995 level of 24.9 mpg. The shift to light trucks for general transportation is an important trend in consumers' preference and has a significant fleet fuel consumption effect.

E. Domestic and Import Fleet Fuel Economy Averages

Domestic and import passenger car fleet average fuel economies have improved since MY 1978, although the increase is far more dramatic for the domestic fleet. In MY 1996, the domestic passenger car fleet average fuel economy increased from the prior year to 28.3 mpg, the highest level since fuel economy standards were established. Import passenger car fleet average fuel economy decreased to 29.7 mpg. Compared to MY 1978, this reflects an increase of 9.6 mpg for domestic cars and 2.4 mpg for import cars.

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Figure II-4

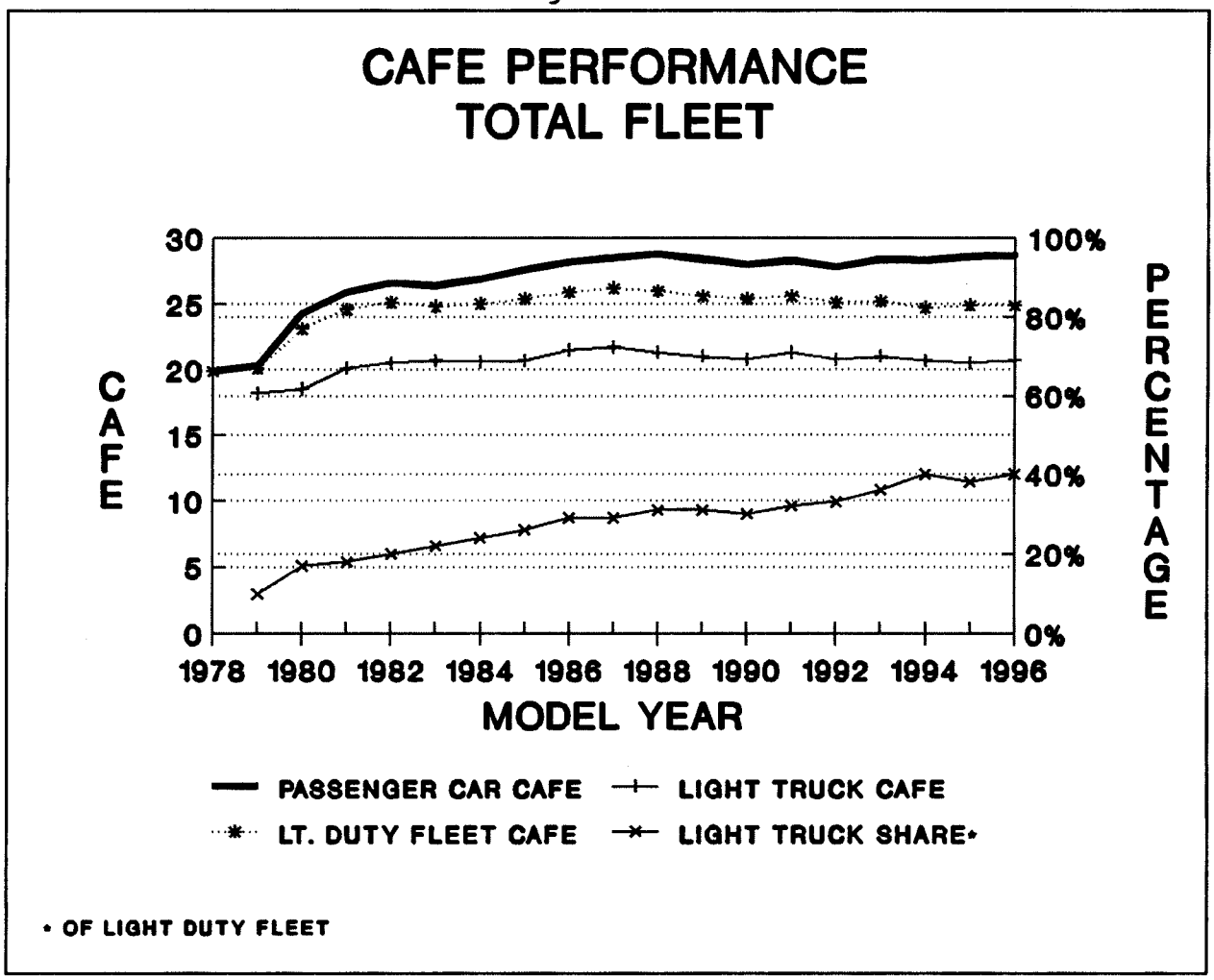

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TABLE II–6.—DOMESTIC AND IMPORT PASSENGER CAR AND LIGHT TRUCK FUEL ECONOMY AVERAGES FOR MODEL YEARS 1978–1996

[in MPG]

Model Year	Domestic			Import			All cars	All light trucks	Total fleet
	Car	Light Truck	Combined	Car	Light truck [1]	Combined			
1978	18.7	.....	.....	27.3	.....	.....	19.9	.....	.....
1979	19.3	17.7	19.1	26.1	20.8	25.5	20.3	18.2	20.1
1980	22.6	16.8	21.4	29.6	24.3	28.6	24.3	18.5	23.1
1981	24.2	18.3	22.9	31.5	27.4	30.7	25.9	20.1	24.6
1982	25.0	19.2	23.5	31.1	27.0	30.4	26.6	20.5	25.1
1983	24.4	19.6	23.0	32.4	27.1	31.5	26.4	20.7	24.8
1984	25.5	19.3	23.6	32.0	26.7	30.6	26.9	20.6	25.0
1985	26.3	19.6	24.0	31.5	26.5	30.3	27.6	20.7	25.4
1986	26.9	20.0	24.4	31.6	25.9	29.8	28.2	21.5	25.9
1987	27.0	20.5	24.6	31.2	25.2	29.6	28.5	21.7	26.2
1988	27.4	20.6	24.5	31.5	24.6	30.0	28.8	21.3	26.0
1989	27.2	20.4	24.2	30.8	23.5	29.2	28.4	20.9	25.6
1990	26.9	20.3	23.9	29.9	23.0	28.5	28.0	20.8	25.4
1991	27.3	20.9	24.4	30.1	23.0	28.4	28.4	21.3	25.6
1992	27.0	20.5	23.8	29.2	22.7	27.9	27.9	20.8	25.1
1993	27.8	20.7	24.2	29.6	22.8	28.1	28.4	21.0	25.2
1994	27.5	20.5	23.5	29.6	22.0	27.8	28.3	20.7	24.7
1995	27.7	20.3	23.8	30.3	21.5	27.9	28.6	20.5	24.9
1996	28.3	20.5	24.1	29.7	22.1	27.7	28.7	20.7	24.9

[1] Light trucks from foreign-based manufacturers.

Since MY 1980, the total light truck fleet average fuel economy and the average for domestic light truck manufacturers have improved overall, but both have remained below the fuel economy level for the imported light truck fleet. The imported light truck average fuel economy has decreased significantly since its highest level of 27.4 mpg for MY 1981 to 22.1 mpg for MY 1996. For MY 1996, the domestic light truck fleet has an average fuel economy level of 20.5 mpg, which is 1.6 mpg lower than the import light truck fleet. For MY 1996, the imported light truck fleet fuel economy increased 0.6 mpg above the MY 1995 level to 22.1 mpg. The domestic manufacturers continued to dominate the light truck market, comprising 87 percent of the total light truck fleet.

The disparity between the average CAFEs of the import and domestic manufacturers has declined in recent years as domestic manufacturers have maintained relatively stable CAFE values while the import manufacturers moved to larger vehicles, and more four-wheel drive light trucks, thus lowering their CAFE values.

Section III: 1996 Activities

A. Light Truck CAFE Standards

On April 3, 1996, NHTSA published a final rule establishing a combined standard of 20.7 mpg for light trucks for MY 1998. The Department of Transportation and Related Agencies Appropriations Act for Fiscal Year 1996, Pub. L. 104–50, precludes the agency from setting the MY 1998 standard at a level other than the level for MY 1997.

B. Low Volume Petitions

49 U.S.C. 32902(d) provides that a low volume manufacturer of passenger cars may be exempted from the generally applicable passenger car fuel economy standards if these standards are more stringent than the maximum feasible average fuel economy for that manufacturer and if NHTSA establishes an alternative standard for that manufacturer at its maximum feasible level. A low volume manufacturer is one that manufactured fewer than 10,000 passenger cars worldwide, in the model year for which the exemption is sought (the affected model year) and in the second model year preceding that model year.

NHTSA acted on four low volume petitions in 1996, which were filed by Lotus, Rolls-Royce (2), and Lamborghini. Lotus, once controlled by Bugatti International, submitted to the agency its low volume petition for MYs 1994, 1995, 1997, and 1998 separately from its previous owner, Bugatti, because of that automaker's financial instability. Lotus is now under new ownership. A Malaysian automaker, Perusahaan Otomobil Nasional Berhad (Proton), acquired controlling interest in Lotus. The agency is reviewing Lotus' petition and will respond in early 1997.

Lamborghini filed a joint low volume petition for Lamborghini and Vector high performance vehicles since these two manufacturers are under common ownership by V-Power Corporation. Lamborghini requested alternative standards for its passenger cars for MYs 1995, 1996, and 1997. NHTSA issued a proposed decision to grant alternative standards of 12.8 mpg for MY 1995, 12.6 mpg for MY 1996, and 12.5 mpg for MY 1997 (61 FR 39429; July 29, 1996).

Rolls-Royce requested an alternative standard for its passenger cars for MY 1997. NHTSA established an alternative standard of 15.1 mpg for MY 1997 (61 FR 4369; February 6, 1996). In December 1995, Rolls Royce also filed a low volume petition for MYs 1998 and 1999. NHTSA issued a proposed decision to grant an alternative standard of 16.3 mpg for MYs 1998 and 1999 (61 FR 46756; September 5, 1996).

C. Enforcement

49 U.S.C. 32912(b) imposes a civil penalty of $5 for each tenth of a mpg by which a manufacturer's CAFE level falls short of the standard, multiplied by the total number of passenger automobiles or light trucks produced by the manufacturer in that model year. Credits that were earned for exceeding the standard in any of the three model years immediately prior to or subsequent to the model years in question can be used to offset the penalty.

Table III–1 shows CAFE fines paid by manufacturers in calendar year 1996. In calendar year 1996, manufacturers paid penalties totaling $52,339,165 for failing to comply to the fuel economy standards of 27.5 mpg for passenger

cars, 20.5 mpg and 20.6 mpg for light trucks in MYs 1994 and 1995, respectively.

TABLE III–1.—CAFE FINES COLLECTED DURING CALENDAR YEAR 1996

Model year and manufacturer	Amount fined	Date paid
1994:		
BMW	$10,140,120	12/96
Land Rover	1,734,915	12/96
Porsche	804,600	12/96
Volvo	7,173,630	12/96
1995:		
BMW	13,136,530	12/96
Land Rover	4,499,090	12/96
Mercedes-Benz	6,525,085	12/96
Porsche	1,949,520	12/96
Volvo	6,375,675	12/96

D. Contract Activities

• *Database Maintenance:* Products and Production Capabilities of North American Automobile Manufacturing Plants.

During 1996, NHTSA continued to fund the maintenance of a database that details the products and production capacities of North American automobile manufacturing plants. This program is administered by the Volpe National Transportation Systems Center (the Volpe Center) with annual funding of $60,000.

• *Published Report:* Light Truck Capabilities, Utility Requirements and Uses: Implications for Fuel Economy.

In FY 1995, the House Appropriations Committee funded NHTSA with $300,000 to prepare a report to identify the unique capabilities, utility requirements, and use of light trucks that result in design constraints for fuel economy improvements. The agency contracted with the Volpe Center to conduct this study. In April 1996, the Volpe Center concluded the study and the final results were published in a report titled, Light Truck Capabilities, Utility Requirements and Uses: Implications for Fuel Economy (DOT Report Number: HS 808 378). This report was forwarded to Congress on May 22, 1996.

The report addresses two key questions:

1. What are the unique capabilities, utility requirements, and uses of light trucks?

2. Do these requirements and other regulatory requirements constrain the ability to improve light truck fuel economy?

The capabilities of light trucks that are notably superior to those of passenger cars are referred to as enhanced capabilities of light trucks. Five enhanced capabilities are identified, qualified, and quantified: load carrying (passengers), load carrying (weight), load carrying (volume), towing and off-road operation. Utility requirements are treated as the functions and capabilities that truck buyers need. Public domain survey data are used to identify utility requirements for both personal and commercial uses. Two major surveys, the 1992 Truck Inventory and Use Survey and the 1990 Nationwide Personal Transportation Survey, are used to identify and quantify the actual uses of light trucks for both personal and commercial purposes.

Observations on the relationships between light truck capabilities and fuel economy are based on manufacturer specifications and EPA fuel economy ratings for a sample of MY 1994 light trucks. Existing fuel economy studies are referenced to identify potential fuel economy technologies for MYs 1998–2006. The estimated fuel economy gain for implementation of each fuel economy technology is presented. Potential conflicts between the application of each fuel economy technology and light truck capabilities, future emissions and safety standards, and consumer choice attributes are also presented.

• *Published Report:* Updated Vehicle Survivability and Travel Mileage Schedules.

In November 1995, NHTSA published a report titled, Updated Vehicle Survivability and Travel Mileage Schedules. This report authored by NHTSA staff member, Alan Berkowitz, discusses the development of revised survivability and vehicle miles traveled schedules for passenger cars and light trucks by using current registration data and government-sponsored vehicle mileage survey data. The registration data source used is the National Vehicle Population Profile compiled by R. L. Polk & Company. The recent government-sponsored mileage survey data sources used are the Nationwide Personal Transportation Survey conducted by the Bureau of the Census, U.S. Department of Commerce, for the Federal Highway Administration, U.S. Department of Transportation; the Truck Inventory and Use Survey developed by the Bureau of Census; and the Residential Transportation Energy Consumption Survey designed by the Energy Information Administration, U.S. Department of Energy.

The amended projections confirmed that passenger vehicles, especially light trucks, have extended vehicle life and are driven farther than previous schedules have indicated. These new survivability and travel mileage schedules may be used to compute the total weighted travel mileage over the vehicle lifetime, which is used to estimate the impact of proposed fuel economy standards on future fuel consumption and operating costs. The survivability schedule will also be used to estimate the phase-in of new safety equipment into the vehicle fleet.

• *Study Initiative:* Fuel Economy Effects and Cost and Leadtime Impacts of Variable Valve Timing Engine Technology.

A study was initiated with consultants to evaluate the fuel economy effects and cost and leadtime impacts of variable valve timing engine technology. The report of this effort, along with an in-house study of retail costs, will be published in early 1997.

[FR Doc. 97–14558 Filed 6–3–97; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33403]

Union Pacific Railroad Company—Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway Company

The Burlington Northern and Santa Fe Railway Company has agreed to grant overhead trackage rights to Union Pacific Railroad Company over trackage extending generally in a northeast direction from milepost 59.06, near 10th Street and Avery Avenue, to milepost 56.92, a distance of 2.14 miles in Lincoln, Lancaster County, NE.

The transaction is scheduled to be consummated on May 28, 1997.

The purpose of the trackage rights is to facilitate efficient train operations and coordination of rail operations in the City of Lincoln, NE, in connection with the plan of the Lincoln-Lancaster County Railroad Transportation Safety District.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in Norfolk and Western Ry. Co.—Trackage Rights—BN, 354 I.C.C. 605 (1978), as modified in Mendocino Coast Ry., Inc.—Lease and Operate, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33403, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Joseph D. Anthofer, Esq., 1416 Dodge Street, #830, Omaha, NE 68179.

Decided: May 27, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–14588 Filed 6–3–97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–103 (Sub-No. 11X)]

The Kansas City Southern Railway Company—Abandonment Exemption—in Hempstead, Lafayette and Columbia Counties, AR

The Kansas City Southern Railway Company (KCS) has filed a notice of exemption under 49 CFR 1152 Subpart F—Exempt Abandonments to abandon a 42.78-mile line of railroad between milepost 4.00 at or near Hope, and milepost 46.78 at the Arkansas-Louisiana State Line, in Hempstead, Lafayette and Columbia Counties, AR. The line traverses United States Postal Service Zip Codes 71860 and 71861.

KCS has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) There is no overhead traffic on the line; (3) No formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) The requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on July 4, 1997, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29[3] must be filed by June 16, 1997. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by June 24, 1997, with: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant's representative: Thomas F. McFarland, Jr., McFarland and Herman, 20 North Wacker Drive, Suite 1330, Chicago, IL 60606–2902.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

KCS has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by June 9, 1997. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423) or by calling SEA, at (202) 565–1545. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), KCS shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by KCS's filing of a notice of consummation by June 4, 1998, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Decided: May 28, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–14587 Filed 6–3–97; 8:45 am]

BILLING CODE 4915–00–P

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each offer of financial assistance must be accompanied by the filing fee, which currently is set at $900. See 49 CFR 1002.2(f)(25).

[3] The Board will accept late-filed trail use requests as long as the abandonment has not been consummated and the abandoning railroad is willing to negotiate an agreement.

DEPARTMENT OF THE TREASURY

[Treasury Directive 16–14]

Debt Collection Improvement Act of 1996—Waiver of the Requirements of 5 U.S.C. 552a (o) and (p) for Administrative Offset

Dated: May 28, 1997.

1. *Delegation.* By virtue of the authority granted to the Fiscal Assistant Secretary by Treasury Order (TO) 101–05, this Directive delegates to the Commissioner, Financial Management Service, the authority vested in the Secretary of the Treasury by 31 U.S.C. § 3716(f) to waive the requirements of 5 U.S.C. §§ 552a (o) and (p) for administrative offset upon written certification by the head of an agency or State seeking to collect a claim that the requirements of 31 U.S.C. § 3716(a) have been met.

2. *Redelegation.* The Commissioner, Financial Management Service, may redelegate this authority in writing to officials within the Financial Management Service, and it may be exercised in the individual capacity and under the individual title of each official receiving such authority.

3. *Authorities.*

a. Section 31001(e) of the Debt Collection Improvement Act of 1996, Public Law 104–134 (110 Stat. 1321–358 *et seq.*), codified at 31 U.S.C. § 3716(f).

b. TO 101–05, ''Reporting Relationships and Supervision of Officials, Offices and Bureaus, Delegation of Certain Authority, and Order of Succession in the Department of the Treasury.''

4. *Referemce.* See Treasury Directive 25–06, ''The Treasury Data Integrity Board,'' regarding the responsibility of the Treasury Data Integrity Board for oversight and coordination of computer matching programs.

5. *Expiration Date.* This Directive shall expire three years from the date of issuance unless superseded or cancelled prior to that date.

6. *Office of Primary Interest.* Office of the Commissioner, Financial Management Service.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 97–14538 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Usual and Customary Business Records Relating to Tax-Free Alcohol.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESS: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Steve Simon, Wine, Beer and Spirits Regulations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8183.

SUPPLEMENTARY INFORMATION:

Title: Usual and Customary Business Records Relating to Tax-Free Alcohol.

OMB Number: 1512–0334.

Recordkeeping Requirement ID Number: ATF REC 5150/3.

Abstract: Tax-free alcohol is used for nonbeverage purposes by educational organizations, hospitals, laboratories, etc. The use of alcohol free of tax is regulated to prevent illegal diversion to taxable beverage use. Records maintain spirits accountability and protect tax revenue and public safety. The record retention requirement for this information collection is 3 years.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Not-for-profit institutions, Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents: 4,560.

Estimated Time Per Respondent: The recordkeeping requirement involves usual and customary business records only; therefore, there is no burden imposed on the respondent.

Estimated Total Annual Burden Hours: 1 hour.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 27, 1997.

John W. Magaw,

Director.

[FR Doc. 97–14562 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Tobacco Products Manufacturers—Records of Operations.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Cliff Mullen, Wine, Beer and Spirits Regulations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8181.

SUPPLEMENTARY INFORMATION:

Title: Tobacco Products Manufacturers—Records of Operations.

OMB Number: 1512–0358.

Recordkeeping Requirement ID Number: ATF REC 5210/1.

Abstract: Tobacco manufacturers must maintain a system of records that provide accountability over tobacco products received and produced. The information collection is needed to ensure tobacco transactions can be traced and ensure that tax liabilities have been totally satisfied. The record retention requirement for this information collection is 3 years.

Current Actions: The only change to this information collection is an increase in burden hours due to a recalculation of the number of respondents.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 108.

Estimated Time Per Respondent: 150 hours per year.

Estimated Total Annual Burden Hours: 16,200.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 27, 1997.

John W. Magaw,

Director.

[FR Doc. 97–14563 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Statement of Process—Marking of Plastic Explosives for the Purpose of Detection.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Gail Hosey Davis, Firearms and Explosives Operations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8310.

SUPPLEMENTARY INFORMATION:

Title: Statement of Process—Marking of Plastic Explosives for the Purpose of Detection.

OMB Number: 1512–0539.

Abstract: The information contained in the statement of process is required to ensure compliance with the provisions of Public Law 104–132. This information will be used to ensure that plastic explosives contain a detection agent as required by law. The record retention requirement for this information collection is 20 years.

Current Actions: The only change to this information collection is a decrease in burden hours due to an error of calculation in the previous submission.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 8.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 16.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 27, 1997.

John W. Magaw,

Director.

[FR Doc. 97–14564 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within

the Department of the Treasury is soliciting comments concerning the Tobacco Products Importer or Manufacturer—Records of Large Cigar Wholesale Prices.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Cliff Mullen, Wine, Beer and Spirits Regulations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8181.

SUPPLEMENTARY INFORMATION:

Title: Tobacco Products Importer or Manufacturer—Records of Large Cigar Wholesale Prices.

OMB Number: 1512–0368.

Recordkeeping Requirement ID Number: ATF REC 5230/1.

Abstract: This information collection is used by tobacco products importers or manufacturers who import or make large cigars. Records are needed to verify wholesale prices of those cigars and tax is based on those prices. The collection also ensures that all tax revenues due to the government are collected. The record retention period for this information collection is 3 years.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 108.

Estimated Time Per Respondent: 2 hours and 30 minutes.

Estimated Total Annual Burden Hours: 252.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 27, 1997.

John W. Magaw,

Director.

[FR Doc. 97–14565 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Notice of Removal of Tobacco Products, Cigarette Papers, or Cigarette Tubes.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Cliff Mullen, Wine, Beer and Spirits Regulations Branch, 650 Massachusetts Avenue, Washington, DC 20226, (202) 927–8181.

SUPPLEMENTARY INFORMATION:

Title: Notice of Removal of Tobacco Products, Cigarette Papers, or Cigarette Tubes.

OMB Number: 1512–0119.

Form Number: ATF F 2149/2150 (5200.14).

Abstract: Tobacco manufacturers or export warehouse proprietors are liable for tax on tobacco products removed from their premises. Tobacco products, cigarette papers and tubes may be removed without payment of tax for special purposes. This form verifies these removals. The record retention requirement for this information collection is 3 years after the close of the year in which evidence of clearance or delivery was received.

Current Actions: There is a change in burden hours due to a decrease in the number of respondents. A change to U.S. Customs regulations provides for duty free stores which may receive non tax paid cigarettes directly from manufacturers or export warehouses. This programatic change necessitated a change to ATF F 2149/2150 (5200.14) to allow for reporting of this transaction.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 221.

Estimated Time Per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 18,225.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 27, 1997.

John W. Magaw,

Director.

[FR Doc. 97–14566 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Inventory—Manufacturer of Tobacco Products.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Cliff Mullen, Wine, Beer and Spirits Regulations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8181.

SUPPLEMENTARY INFORMATION:

Title: Inventory—Manufacturer of Tobacco Products.

OMB Number: 1512–0162.

Form Number: ATF F 3067 (5210.9).

Abstract: ATF F 3067 (5210.9) is used by tobacco product manufacturers to record inventories that are required by law. This form provides a uniform format for recording inventories and establishes tax liability on tobacco products enabling ATF to determine that correct taxes have been or will be paid. The record retention requirement for this information collection is 3 years after the close of the year for which inventories and reports are filed.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 34.

Estimated Time Per Respondent: 5 hours.

Estimated Total Annual Burden Hours: 170.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 27, 1997.

John W. Magaw,

Director.

[FR Doc. 97–14567 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Letterhead Applications and Notices Relating to Denatured Spirits.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Tami Light, Wine, Beer and Spirits Regulations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8210.

SUPPLEMENTARY INFORMATION:

Title: Letterhead Applications and Notices Relating to Denatured Spirits.

OMB Number: 1512–0336.

Recordkeeping Requirement ID Number: ATF REC 5150/2.

Abstract: Denatured spirits are used for nonbeverage industrial purposes in the manufacture of personal and household products. Permits and applications control the authorized use and flow. Tax revenue and public safety is protected. The record retention requirement for this information collection is 3 years.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 3111.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 1556.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 27, 1997.

John W. Magaw,

Director.

[FR Doc. 97–14568 Filed 6–3–97; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 97–43]

Revocation of Customs Broker License

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Broker license revocation.

SUMMARY: Notice is hereby given that the Commissioner of Customs, pursuant to Section 641, Tariff Act of 1930, as amended, (19 U.S.C. 1641), and parts 111.51 and 111.74 of the Customs Regulations, as amended (19 CFR 111.51 and 111.74), canceled the following Customs broker license with prejudice.

Port	Individual	License No.
New York ...	Mark V Customhouse Brokers, Inc.	9719

Dated: May 23, 1997.

Philip Metzger,

Director, Trade Compliance.

[FR Doc. 97–14504 Filed 6–3–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 97–42]

Revocation of Customs Broker License

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Broker license revocation.

SUMMARY: Notice is hereby given that the Commissioner of Customs, pursuant to Section 641, Tariff Act of 1930, as amended, (19 U.S.C. 1641), and parts 111.51 and 111.74 of the Customs Regulations, as amended (19 CFR 111.51 and 111.74), canceled the following Customs broker license without prejudice.

Port	Individual	License No.
Chicago	ASG Forwarding, Inc.	5898
New York ...	Joseph DiSano	2567
New York ...	Albert Weber	2245
Seattle	Alexandrer M. Bryce, Jr.	2668
Seattle	Susanne J. Theuer	6767
Mobile	Steve Mace	12254
St. Louis	Ruth M. Stewart, C.H.B.	3883

Dated: May 23, 1997.

Philip Metzger,

Director, Trade Compliance.

[FR Doc. 97–14503 Filed 6–3–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 97–44]

Revocation of Customs Broker License

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: General notice.

SUMMARY: The following Customs broker license number was erroneously included in a list of revoked Customs brokers licenses. License 7114, issued in the Los Angeles Customs port, remains a valid license.

Abraham Shiepe—7114

Dated: May 23, 1997.

Philip Metzger,

Director, Trade Compliance.

[FR Doc. 97–14505 Filed 6–3–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Customs Service

Procedures if the Generalized System of Preferences Program Expires

AGENCY: Customs Service, Treasury.

ACTION: General notice.

SUMMARY: The Generalized System of Preferences (GSP) is a preferential trade program that allows eligible products of many developing countries to enter the United States duty-free. The GSP is currently scheduled to expire at midnight on May 31, 1997, unless its provisions are extended by Congress. This document provides notice to importers that claims for duty-free treatment under the GSP may not be made for merchandise entered or withdrawn from a warehouse on or after June 1, 1997, if the program is not extended before that date. The document also sets forth mechanisms to facilitate refunds, if the GSP is renewed retroactively.

DATES: The plan set forth in this document will become effective as of June 1, 1997, if Congress does not extend the GSP program before that date.

FOR FURTHER INFORMATION CONTACT: For specific questions relating to the Automated Commercial System:

Arthur Versich, Office of Automated Commercial System, 202–927–1042.

For general operational questions:

Formal entries
John Pierce, 202–927–1249
Informal entries
Thomas Wygant, 202–927–1167
Mail entries
Dan Norman, 202–927–0542
Passenger claims
Robert Jacksta, 202–927–1311

SUPPLEMENTARY INFORMATION:

Background

Section 501 of the Trade Act of 1974 (the Act), as amended (19 U.S.C. 2461) authorizes the President to establish a Generalized System of Preferences (GSP) to provide duty-free treatment for eligible articles imported from designated beneficiary countries. Beneficiary developing countries and articles eligible for duty-free treatment under the GSP are designated by the President by Presidential Proclamation in accordance with sections 502(a) and 503(a) of the Act (19 U.S.C. 2462(a) and 2463(a)). Pursuant to 19 U.S.C. 2465(a), as amended by the GSP Renewal Act of 1996 (the Act, Pub.L. 104–188, 110 Stat. 1775, at Stat. 1917), duty-free treatment under the GSP is presently scheduled to expire on May 31, 1997.

Congress is currently considering whether to extend the GSP program. If legislation is enacted but does not become law before the GSP expires, language may be included that would renew the GSP retroactively to the date of its presently scheduled expiration and Customs will need to reliquidate numerous entries to make refunds of duties collected. However, if Congress does not pass legislation renewing the GSP before midnight, May 31, 1997, no claims for duty-free treatment under the program may be allowed on entries made after that time.

Recognizing the impact that retroactive renewal and consequent numerous reliquidations would have on both importers and Customs, Customs has developed a mechanism to facilitate refunds, should GSP be renewed retroactively. Set forth below is Customs plan that will be implemented on June 1, 1997, if the GSP has not been extended by that date.

Formal Entries

Claims—Duties Must Be Deposited

No claims for duty-free treatment under the GSP may be made for merchandise entered, or withdrawn from warehouse for consumption on or after June 1, 1997. Duties at the most-favored-nation rate must be deposited, or a claim may be made under another

preferential program for which the merchandise may qualify (for example, the Andean Trade Preference Act or the Caribbean Basin Economic Recovery Act).

While estimated duties must be deposited, all filers who file entry summaries through the Automated Broker Interface (ABI) may continue to file using the Special Program Indicator (SPI) for the GSP (the letter ''A'') as a prefix to the tariff number for all merchandise that would have qualified for the GSP if the GSP were still in effect. Customs Automated Commercial System (ACS) will be reprogrammed to accept the SPI ''A'' with the payment of duty.

Filers using the ABI may reprogram their software so that the SPI ''A'' can still be used as a prefix to the tariff number, but with the payment of duty. While reprogramming is strictly voluntary, continued use of the SPI ''A'' has some benefits. One benefit of continued use of the SPI ''A'' is that the filer will not have to write a letter to Customs requesting a refund if the GSP is renewed with retroactive effect. Use of the SPI ''A'' will enable Customs to identify affected line items and refund duties without a written request from the importer. In other words, after May 31, 1997, the SPI ''A'' will constitute an importer's request for a refund of duties paid for GSP line items, should GSP renewal be retroactive. Other benefits are that ACS will perform its usual edits on the information transmitted by the filer, thereby ensuring that GSP claims are for acceptable country/tariff combinations and eliminating the need for numerous statistical corrections.

This plan was used when the GSP expired on September 30, 1994, and was later renewed with retroactive effect and again when the GSP expired on July 31, 1995, and was later renewed with retroactive effect.

If the GSP expires, the Customs Headquarters-developed computer program will refund all duties deposited for imports that otherwise would have been eligible for GSP duty-free treatment if the GSP is later renewed with retroactive effect. The computer program will identify those entries filed through the Automated Broker Interface (ABI) using the SPI ''A'' and will be able to process most refunds without requiring further action by ABI filers.

Filers who do not wish to reprogram will be required to request refunds identifying the affected entry numbers in writing if the GSP is renewed retroactively.

ABI filers continuing to use the SPI ''A'' may use it as they do now (for example, for warehouse entries and for formal consumption entries).

Importers may not use the SPI ''A'' if they intend to later claim drawback. Use of the SPI ''A'' is the importer's indication that he wishes to receive a refund if the GSP is renewed retroactively. To claim both this refund and drawback would be to request a refund in excess of duties actually deposited. Importers who are unsure as to whether they will claim drawback are advised not to use the SPI ''A''. If the GSP is renewed retroactively, and they have not yet claimed drawback, they may request a refund by writing to the port director at the port of entry. If the GSP is not renewed retroactively, they will still have the option of filing a drawback entry.

Continued use of the SPI ''A'' is not available to non-ABI filers.

Statistics

For statistical purposes, ACS will internally convert any SPI ''A'' transmitted via ABI after May 31, 1997, into a SPI ''Q''. If the GSP is renewed retroactively to that date, Census will convert all ''Q'' statistics into ''A'' statistics, thereby ensuring that next year's competitive need limitations under the GSP are accurate. This will also vastly reduce the number of statistical corrections that would have to be done by import specialists.

Refunds

If the GSP is renewed with retroactive effect, Customs will reliquidate all affected ABI entry summaries with a refund for the GSP line items. Field locations shall not issue GSP refunds except as instructed to do so by Customs Headquarters.

If a filer files an ABI entry summary with the SPI ''A'', no further action will need to be taken by the filer to request a refund; filing with the SPI ''A'' constitutes a valid claim for a refund. Refunds for summaries filed without the SPI ''A'' must be requested in writing. Instructions on how to request a refund in writing will be issued if the GSP is renewed with retroactive effect.

Informal Entries

Refunds on informal entries filed via ABI on a Customs Form 7501 with the SPI ''A'' will be processed in accordance with the procedures outlined above.

Baggage Declarations and Non-ABI Informals

When merchandise is presented for clearance, travelers and importers will be advised verbally or by a written notice that they may be eligible for a refund of GSP duties.

Travelers/importers may write a statement directly on their Customs declarations (CF 6059B) or informal entries (CF 363 or CF 7501) indicating their desire for a refund. If GSP duty-free status is reenacted with a retroactive provision, no further action to obtain a refund will be required on the part of the importer who has written such a statement. Failure to request a refund in this manner does not preclude them from making a timely written request in the future.

Mail Entries

A written notice will be sent to the addressees with the CF 3419A (Mail Entry) informing them that they may be eligible for a refund of GSP duties.

The addressees may submit a claim requesting a refund of GSP duties and return it, along with a copy of the CF 3419A to the appropriate International Mail Branch (address listed on bottom right hand corner of CF 3419A). It is essential that a copy of the CF 3419A be included as this will be the only method of identifying GSP products and ensuring that duties and fees have been paid.

Dated: May 30, 1997.

A.W. Tennant,

Field Operations Acting Assistant Commissioner.

[FR Doc. 97–14539 Filed 6–3–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 97–29

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 97–29, Model Amendments and Prototype Programs for Simple IRAs.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5569, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Model Amendments and Prototype Program for SIMPLE IRAs.

OMB Number: 1545–1543.

Revenue Procedure Number: Revenue Procedure 97–29.

Abstract: The revenue procedure (1) provides a model amendment that may be used prior to January 1, 1999, by a sponsor of a prototype IRA, (2) provides guidance to drafters of prototype SIMPLE IRAs on obtaining opinion letters, (3) provides permissive amendments to sponsors of nonSIMPLE IRAs, (4) announces the opening of a prototype program for SIMPLE IRA Plans, and (5) provides transitional relief for users of SIMPLE IRAs and SIMPLE IRA Plans that have not been approved by the IRS.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 3,205.

Estimated Time Per Respondent: 8 hours, 4 minutes.

Estimated Total Annual Burden Hours: 25,870.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 29, 1997.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 97–14589 Filed 6–3–97; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8633

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8633, Application to Participate in the Electronic Filing Program.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5569, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Application to Participate in the Electronic Filing Program.

OMB Number: 1545–0991.

Form Number: Form 8633.

Abstract: Form 8633 is used by tax preparers, electronic return collectors, software firms, service bureaus and electronic transmitters as an application to participate in the electronic filing program covering individual income tax returns.

Current Actions: On page 1 of Form 8633, lines 1e, 1f, 1g, 1h, 1i, and 1j were deleted because the information was no longer needed.

On page 3, ''When to File'', the application period to apply for participation in the Electronic Filing Program has changed from August 1 through December 2 to September 2 through December 1 for 1997. ''Where to File'' has been revised to show that all applications should be mailed to the Andover Service Center.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, and non-profit institutions.

Estimated Number of Respondents: 50,000.

Estimated Time Per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 50,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital

or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 29, 1997.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 97–14590 Filed 6–3–97; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1120, Schedule D, Schedule H, and Schedule PH

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1120, U.S. Corporation Income Tax Return, Schedule D, Capital Gains and Losses, Schedule H, Section 280H Limitations for a Personal Service Corporation (PSC), and Schedule PH, U.S. Personal Holding Company (PHC) Tax.

DATES: Written comments should be received on or before August 4, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, (202) 622–3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: 1120, U.S. Corporation Income Tax Return, Schedule D, Capital Gains and Losses, Schedule H, Section 280H Limitations for a Personal Service Corporation (PSC), and Schedule PH, U.S. Personal Holding Company (PHC) Tax.

OMB Number: 1545–0123.

Form Number: 1120, Schedule D, Schedule H, and Schedule PH.

Abstract: Form 1120 is used by corporations to compute their taxable income and tax liability. Schedule D (Form 1120) is used by corporations to report gains and losses from the sale of capital assets. Schedule H (Form 1120) is used by personal service corporations to determine if they have met the minimum distribution requirements of Internal Revenue Code section 280H. Schedule PH (Form 1120) is used by personal holding companies to compute their tax liability.

Current Actions: On the balance sheet (Schedule L, Form 1120), a new line was added for adjustments to shareholders' equity. These adjustments include unrealized gains and losses on securities held available for sale, foreign currency translation adjustments, excess of additional pension liability over unrecognized prior service cost, and compensation related to employee stock award plans.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations and farms.

Estimated Number of Respondents: 2,462,931.

Estimated Time Per Respondent: 196 hr., 8 min.

Estimated Total Annual Burden Hours: 483,052,775.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 29, 1997.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 97–14591 Filed 6–3–97; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Art Advisory Panel, Notice of Closed Meeting

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of closed meeting of Art Advisory Panel.

SUMMARY: Closed meeting of the Art Advisory Panel will be held in Washington, DC.

DATE: The meeting will be held June 25, 1997.

ADDRESSES: The closed meeting of the Art Advisory Panel will be held on June 25, 1997, in Room 224 beginning at 10 a.m., Aerospace Center Building, 901 D Street, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Karen Carolan, C:AP:AS:4 901 D Street, SW, Washington, DC 20024. Telephone (202) 401–4128, (not a toll free number).

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988), that a closed meeting of the Art Advisory Panel will be held on June 25, 1997, in Room 224 beginning at 10 a.m., Aerospace Center Building, 901 D Street, SW., Washington, DC 20024.

The agenda will consist of the review and evaluation of the acceptability of fair market value appraisals of works of art involved in federal income, estate, or gift tax returns. This will involve the discussion of material in individual tax returns made confidential by the provisions of section 6103 of Title 26 of the United States Code.

A determination as required by section 10(d) of the Federal Advisory Committee Act has been made that this meeting is concerned with matters listed in section 552b(c) (3), (4), (6), and (7) of Title 5 of the United States Code, and that the meeting will not be open to the public.

The Commissioner of Internal Revenue has determined that this document is not a significant regulatory action as defined in Executive Order

12866 and that a regulatory impact analysis therefore is not required. Neither does this document constitute a rule subject to the Regulatory Flexibility Act (5 U.S.C. Chapter 6).

Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 97–14592 Filed 6–3–97; 8:45 am]

BILLING CODE 4830–01–U

federal register

Wednesday
June 4, 1997

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 111

Dietary Supplements Containing Ephedrine Alkaloids; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 95N–0304]

RIN 0901–AA59

Dietary Supplements Containing Ephedrine Alkaloids

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to make a finding, which will have the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in intake of 8 mg or more in a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids; require that the label of dietary supplements that contain ephedrine alkaloids state ''Do not use this product for more than 7 days''; prohibit the use of ephedrine alkaloids with ingredients, or with ingredients that contain substances, that have a known stimulant effect (e.g., sources of caffeine or yohimbine), which may interact with ephedrine alkaloids; prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., weight loss and body building); require a statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect (e.g., energy) that ''Taking more than the recommended serving may result in heart attack, stroke, seizure or death''; and require specific warning statements to appear on product labels. FDA is proposing these actions in response to serious illnesses and injuries, including multiple deaths, associated with the use of dietary supplement products that contain ephedrine alkaloids and the agency's investigations and analyses of these illnesses and injuries. FDA is also incorporating by reference its Laboratory Information Bulletin (LIB) No. 4053, that FDA will use in determining the level of ephedrine alkaloids in a dietary supplement.

DATES: Written comments by August 18, 1997. The agency proposes that any final rule that may issue based on this proposal become effective 180 days after date of publication of the final rule.

ADDRESSES: Submit written requests for single copies of the analytical method LIB No. 4053 to the Director, Office of Constituent Operations, Industry Activities Staff (HFS–565), Food and Drug Administration, 200 C St. SW., rm. 5827, Washington, DC 20204. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12410 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the analytical method LIB No. 4053, redacted adverse event reports (AER's) associated with the use of dietary supplements containing ephedrine alkaloids as well as copies of any accompanying medical records, and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Margaret C. Binzer, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–401–9859, FAX 202–260–8957, or E-mail M2B@FDACF.SSW.DHHS.GOV.

SUPPLEMENTARY INFORMATION:

I. Background

A. Characteristics of Ephedrine Alkaloids

Dietary supplements containing ephedrine alkaloids are widely sold in the United States (Refs. 1 through 3). The ingredient sources of the ephedrine alkaloids include raw botanicals and extracts from botanical sources. Ma huang, *Ephedra*, Chinese *Ephedra*, and epitonin are several names used for botanical products, primarily from *Ephedra sinica* Stapf, *E. equistestina* Bunge, *E. intermedia* var. *tibetica* Stapf and *E. distachya* L. (the *Ephedras*), that are sources of ephedrine alkaloids. These alkaloids, ephedrine, pseudoephedrine, norpseudoephedrine, norephedrine, methylephedrine, methylpseudoephedrine, and related alkaloids, are naturally occurring chemical stimulants (Refs. 4 through 8). Although the proportions of the various ephedrine alkaloids in botanical species vary from one species to another, in most species used commercially, ephedrine is the most predominant alkaloid.

The ephedrine and related alkaloids are amphetamine-like compounds. They exhibit some common types of effects but vary in the relative intensity of these effects (Table 1) (Refs. 5, 6, and 9 through 15). For example, ephedrine is a cardiovascular system (CVS) and nervous system (NS) stimulant. Pseudoephedrine has some CVS and NS stimulatory effects but is less potent than ephedrine. Norephedrine (also called phenylpropanolamine) is similar to ephedrine in its NS stimulant effects but has fewer CVS stimulant effects than ephedrine (Refs. 12 and 16 through 18). Although norephedrine is often a minor ephedrine alkaloid constituent, in humans it can be produced from ingested ephedrine through normal metabolic processes (Refs. 9, 19, and 20). Thus, its presence in body tissues and fluids may be detected, and its physiological effects can occur, even if norephedrine is not contained in meaningful amounts in the original supplement product. Data on the other ephedrine alkaloids and related alkaloids are limited, and thus their physiological and pharmacological effects are largely unknown (Ref. 15).

TABLE 1.—PATTERNS OF SIGNS AND SYMPTOMS ASSOCIATED WITH DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS

Organ/system involved	Clinical significance	Signs and symptoms
Cardiovascular system	Serious	Dysrhythmias, severe hypertension, cardiac arrest, angina, myocardial infarction, and stroke [1]
	Less clinically significant	Tachycardia, mild hypertension, palpitations.
Nervous system	Serious	Psychosis, suicidal, altered or loss of consciousness (including disorientation or confusion), and seizures.
	Less clinically significant	Anxiety, nervousness, tremor, hyperactivity, insomnia, altered behavior, memory changes.
Gastrointestinal (GI)	Serious	Altered serum enzymes, hepatitis.
	Less clinically significant	GI distress (nausea, vomiting, diarrhea, constipation).

TABLE 1.—PATTERNS OF SIGNS AND SYMPTOMS ASSOCIATED WITH DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS—Continued

Organ/system involved	Clinical significance	Signs and symptoms
Dermatologic	Serious	Exfoliative dermatitis.
	Less clinically significant	Nonspecific rashes.
General manifestations		Numbness, tingling, dizziness, fatigue, lethargy, weakness.

[1] For the purposes of this document, strokes (i.e., cerebrovascular accidents) are considered to be related to the cardiovascular system, because predisposing or inciting factors include hypertension, dysrhythmias and ischemia, although it is recognized that the consequences affect the central nervous system.

B. The Availability of Ephedrine Alkaloids

To determine the types of ephedrine alkaloid-containing dietary supplements available in the marketplace, the agency has collected over 125 dietary supplement products labeled as containing a known source of ephedrine alkaloids during the past 2 years (Refs. 1 and 2). These products show that ephedrine alkaloid-containing-dietary supplements are marketed in a variety of forms, including capsules, tablets, powders, and liquids. The source of the ephedrine alkaloids in these supplements vary from the raw botanical to powdered plant material and concentrated extracts; however, most of the products contain concentrated extracts. Although FDA is aware that some companies have changed their labeling and formulation since the market review, this review of the marketplace reflects the general contours of products currently sold in the United States.

Ephedrine alkaloids are present in some products as a single ingredient, but more commonly, they are combined with other ingredients, including vitamins, minerals, amino acids, and other botanicals (Refs. 1, 2, and 21). Most of the dietary supplements that contain an ingredient source of the ephedrine alkaloids also contain between 6 and 20 other ingredients. Some of these other ingredients have known or suspected physiological and pharmacological activities that have the potential for interacting with the ephedrine alkaloids so as to increase their effects. For example, the majority of dietary supplements containing ephedrine alkaloids also contain a source of xanthine alkaloids (e.g., caffeine), another stimulant substance that is known to increase the effects of ephedrine alkaloids (Refs. 7, 16, 22, and 23).

Because product labels do not usually provide information on product composition (Ref. 24), and there are no data bases containing such data, FDA laboratories analyzed the products collected to quantify the levels of ephedrine alkaloids (Refs. 1, 2, 21, and 25). Results of the analyses show that these products, taking into account the labeled recommended serving instructions, are likely to provide intakes of ephedrine alkaloids that range from below the detectible limits of FDA's analytical method to 110 mg per serving (i.e., per single use) (Refs. 1, 2, 21, 25, and 26). Most of the products, regardless of their promoted use, had ephedrine alkaloid levels at or above 10 mg per serving.

Many of the dietary supplement products that FDA collected were promoted for uses such as weight loss, body building, increased energy, increased mental concentration, increased sexual sensations, or euphoria or as alternatives to illicit street drugs (Refs. 1, 2, and 25). The majority of the products collected also bore warning statements on their labels (Refs. 1, 2, and 27). The warning statements varied from general precautions, suggesting that the consumer check with a health care professional before beginning any diet or exercise program, to more specific warning statements. The more specific warning statements contained several elements, including cautions that the consumer not use the product if they have certain diseases or health conditions or are using certain drugs, and to stop the use of the product if they develop certain symptoms (Refs. 1, 2, 25, and 27).

C. Adverse Events Associated With Ephedrine Alkaloids

Since 1993, FDA has received more than 800 reports of illnesses and injuries (AER's) associated with the use of more than 100 different dietary supplement products that contained, or were suspected to contain, ephedrine alkaloids. These adverse events tended to involve CVS effects and NS effects. FDA evaluated the AER's showing CVS and NS effects and found that the single most common element was that the products contained, or were thought to contain, a source of ephedrine alkaloids. Approximately 50 to 60 percent of the AER's associated with use of dietary supplements were for such products.

The AER's associated with the ephedrine alkaloid-containing products included consistent patterns of signs and symptoms among both otherwise healthy individuals and those with underlying diseases or conditions. These signs and symptoms included rapid and irregular heart rhythms, increased blood pressure, chest pain, anxiety, nervousness, tremor, hyperactivity, and insomnia (i.e., inability or difficulty in sleeping) and were associated with clinically significant conditions, including heart attack, stroke, psychoses, seizure, and, in a few cases, death. Many of these signs and symptoms occurred in young adults who generally would not have been expected to be at high risk for such conditions (e.g., heart attack and stroke). Many adverse events were reported to occur with the first use or within the first 2 weeks of use. Although the majority occurred in women, men also reported experiencing adverse events.

The nature and patterns of these AER's are consistent with the known physiological and pharmacological effects of ephedrine alkaloids as described in: (1) Pharmacology texts for single ephedrine alkaloid products, (2) case reports of adverse effects from the scientific literature related to the pharmaceutical use of ephedrine alkaloids, (3) adverse events reported in controlled clinical trials using ephedrine in the treatment of obesity, and (4) known safety concerns with traditional medical uses of botanicals that contain ephedrine alkaloids. As a result, FDA focused its investigation on ephedrine alkaloids as a likely factor in the rapidly increasing number of serious AER's associated with the use of dietary supplement products.

D. Review Activities

The growing number and consistency of reports of serious adverse events associated with a wide variety of ephedrine alkaloid-containing dietary supplements, and the virtual absence of publicly available safety data on these supplements, prompted FDA to convene an ad hoc Working Group of its Food

Advisory Committee (the Working Group) (Refs. 27 through 29).

1. The Food Advisory Committee Working Group Meeting on Dietary Supplements Containing Ephedrine Alkaloids

On October 11 and 12, 1995, the Working Group, which consisted of medical and other scientific experts from outside FDA as well as industry and consumer representatives, considered the potential public health problems associated with the use of dietary supplements and other food products containing ephedrine alkaloids.

The Working Group reviewed the evidence on the occurrence of adverse events associated with the use of ephedrine alkaloids. This evidence included the known pharmacology of ephedrine alkaloids, numerous case reports published in the scientific literature, and published findings from clinical studies investigating the use of ephedrine in the treatment of obesity (Ref. 30). The evidence also included over 325 AER's that had been received by FDA that were associated with the consumption of dietary supplements known to contain, or suspected of containing, ephedrine alkaloids (Refs. 29 and 31). The Working Group also considered public comments made during the meeting (Ref. 27).

Following their review of this evidence, the members of the Working Group agreed that the use of certain dietary supplements containing ephedrine alkaloids may cause consumers to experience serious adverse events. On this basis, the Working Group recommended that FDA: (1) Establish single serving and daily total use limits for ephedrine and total ephedrine alkaloids; (2) require warning or cautionary statements on the labels of these products; and (3) establish good manufacturing practice (GMP) requirements, including proper botanical identification and standardization of the ephedrine alkaloid and ephedrine content in concentrated extracts. Several members of the Working Group suggested that ephedrine alkaloids be limited to 25 mg per single serving and 100 mg total daily use. Other members suggested a variety of lower levels of ephedrine alkaloids per serving. The Working Group also discussed specific warning label statements but failed to agree on the wording of the warning statements.

2. The Food Advisory Committee Meeting

In the 6 months that followed the Working Group meeting, the number of reports of adverse events associated with the use of dietary supplements thought to contain ephedrine alkaloids doubled. In addition, FDA received information on two deaths of young adult males in which the medical examiners specifically attributed the cause of death to use of ephedrine alkaloid-containing dietary supplements (see medical examiners' reports in Adverse Reaction Monitoring System (ARMS) No. 10862 and 11134). FDA analyzed samples of products that consumers claimed that they had consumed and suffered an adverse event and found that the ephedrine alkaloid levels in many of these products were below the 25-mg limit suggested by certain members of the Working Group.

In light of the rapidly increasing numbers of adverse events as well as of the new analytical information on AER-related intakes of ephedrine alkaloids, FDA recognized that a determination on how to deal with dietary supplements that contained these substances could not be further delayed. Thus, FDA convened its Food Advisory Committee in conjunction with the Working Group to review and provide final recommendations on what to do with ephedrine alkaloid-containing dietary supplements.

The Food Advisory Committee met on August 27 and 28, 1996. The meeting included all members from the Working Group who were available to attend the meeting, as well as additional experts to replace those experts unable to attend or to fill out the range of expertise needed to appropriately evaluate the subject. FDA asked the Food Advisory Committee to consider the safety of using dietary supplements containing ephedrine alkaloids and to make specific recommendations on how to resolve the public health concerns surrounding their use (Ref. 25). The Food Advisory Committee reviewed the evidence that had been presented to the Working Group as well as new data and information that had become available since the October 1995 Working Group meeting.

Following a review of the totality of the available evidence, the October 1995 recommendations of the Working Group, public comments, and considerable discussion, the Food Advisory Committee agreed that FDA should take action to address the rapidly evolving and serious public health concerns associated with the use of ephedrine alkaloid-containing dietary supplements (Ref. 25). The Food Advisory Committee could not, however, come to consensus on a specific approach to the public health concerns. Over half of the Food Advisory Committee members stated that, based on the available data, no safe level of ephedrine alkaloids could be identified for use in dietary supplements (Ref. 25). Many of these members expressed concern that many individuals who would be at risk if they were to use products were unaware of that risk because many of the conditions that increase the risk of adverse events may not be self-evident (Ref. 25). Consequently, they recommended removing dietary supplements containing ephedrine alkaloids from the market (Ref. 25). Other members of the Food Advisory Committee suggested that the agency establish conditions of use that would reduce the risk of adverse events, including establishing ''reasonably'' safe per serving and daily use levels for both ephedrine alkaloids and ephedrine as well as other requirements (Ref. 25).

II. FDA's Response

Following the August 1996 meeting of the Food Advisory Committee, the agency completed its review of the majority of the AER's associated with these products and reviewed the discussions and the recommendations of the Food Advisory Committee, the scientific literature, the views expressed in public comments, and other data. Based on this information, the agency has tentatively concluded that use of ephedrine alkaloids raises important public health concerns, that the risks these substances create are potentially very serious, and that action must be taken to protect the public health.

A. Summary of Initial Considerations

Between 1993 and 1996, FDA received a rapidly escalating number of AER's associated with the use of dietary supplements, some that contained ephedrine alkaloids, some that did not (Refs. 32 through 34). Figure 1 shows that in the 3 years since the initiation of an adverse event monitoring system for special nutritional products, the number of AER's received by the agency on dietary supplements has quadrupled.

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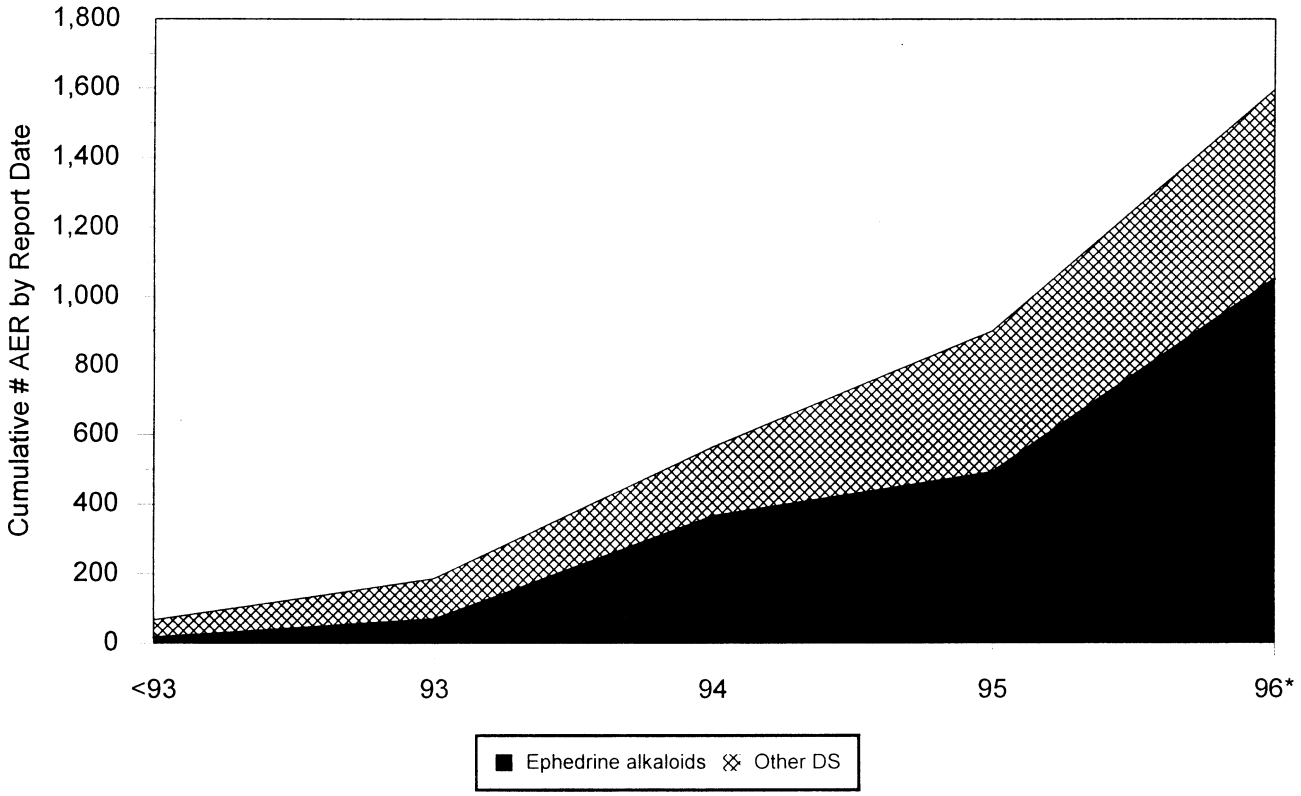
Figure 1: Time Trends in Adverse Events Associated with Dietary Supplements



* 1996 estimated from data as available 08/26/96 (DS=461, ephedrine = 371)

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Many of these reports have been for clinically significant events (e.g., heart attack, stroke, seizures) that were observed most often in young adults for whom the risk of these types of events are generally low (see Figure 2, which summarizes data from the AER's relative to the age and gender of individuals experiencing an adverse event). When FDA examined the products reported to be associated with the CVS and NS effects, the most common element among them was that they involved products that contained or were believed to contain an ingredient source of ephedrine alkaloids. Thus, FDA focused its investigation on the ephedrine alkaloids in dietary supplement products.

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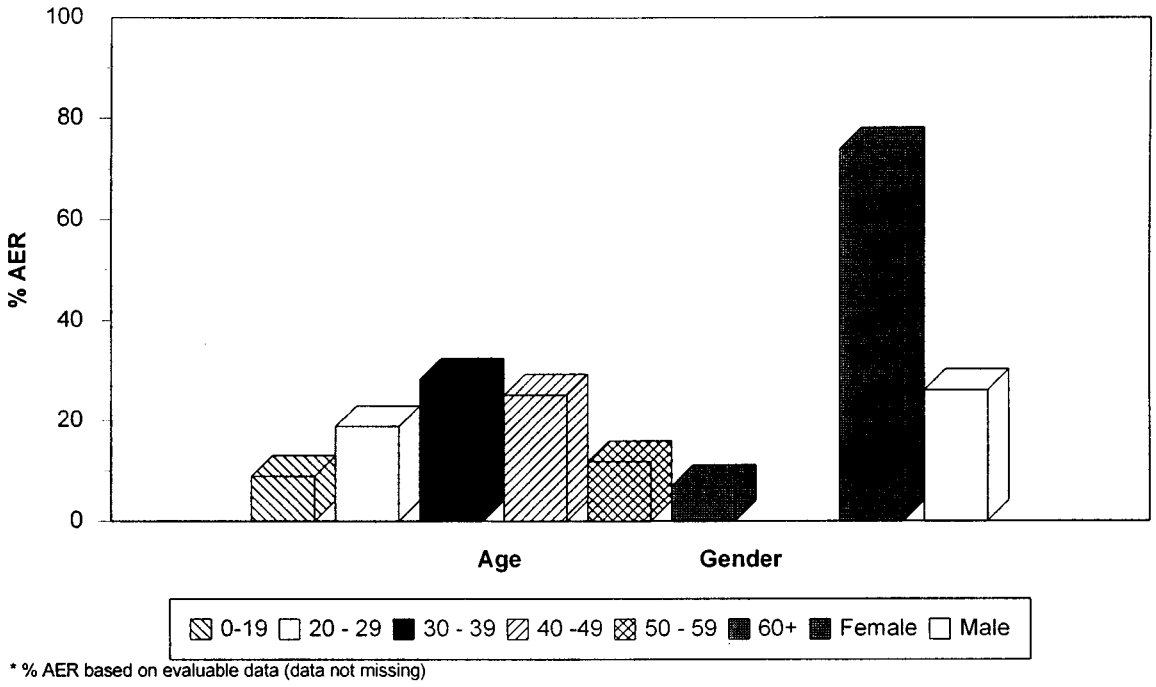
Figure 2: Age and Gender Associated with Adverse Events



* % AER based on evaluable data (data not missing)

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However, many of the ephedrine alkaloid-containing products also contained other ingredients (e.g., amino acids, vitamins and minerals, other botanicals) whose possible influence on the observed AER's could not be ignored. Upon examination of the types of other ingredients, FDA tentatively concluded that these other ingredients should not be the primary focus of its evaluation because these ingredients, unlike the ephedrine alkaloids, did not have a history (in the amounts likely to be found in dietary supplements) of being able to produce the types of serious adverse events being observed. For example, many ephedrine alkaloid-containing dietary supplements also contain known stimulants (e.g., sources of caffeine). While caffeine is known to stimulate the NS, in the amounts likely to be found in dietary supplements it is not expected to produce effects such as stroke, heart attack, and seizure. Nonetheless, FDA remained aware of the possibility that other ingredients in these dietary supplement products contributed to the adverse events reported. For example, other stimulants in the ephedrine-containing dietary supplements could enhance the known stimulant effects of ephedrine alkaloids. Likewise, substances that affect kidney function (e.g., sources of salicin, concentrated amino acids) could influence the body's ability to ''clear'' or rid itself of ingested ephedrine alkaloids.

The agency also considered in its evaluation the fact that botanical sources contain mixtures of ephedrine alkaloids that may have slightly different effects (e.g., additive or interactive effects) than those from a single ephedrine alkaloid, as found in over-the-counter (OTC) products. The agency compared the observed effects of supplement products with the known physiological and pharmacological effects of single sources of the alkaloids that are used as ingredients in several drugs (e.g., ephedrine in OTC bronchodilator products, pseudoephedrine in cough and cold preparations, and phenylpropanolamine in anoretic products). However, the agency was not able to find definitive evidence to evaluate whether ephedrine alkaloids from botanical sources are metabolized differently than those from pharmaceutical sources, and in the absence of more directly relevant data for dietary supplement products, the agency considered it appropriate to rely on evidence from pharmaceutical sources of single ephedrine alkaloids in assessing the effects of botanical sources (see section II.C.2. of this document).

B. FDA's Strategy for Evaluation

FDA considered five questions in evaluating the reports of adverse events involving ephedrine alkaloids that it

had received. These questions were designed to help the agency discern relationships among AER's where direct and readily interpretable clinical studies were not available, and where multiple host or product factors may have affected any association (Refs. 35 through 37). The questions focused the evaluation on whether there was a likely association between the ephedrine alkaloids and the adverse events that had been reported and on the strength, nature, and biological plausibility of any association. These questions were:

(1) Using the AER's on marketed ephedrine alkaloid-containing dietary supplements from FDA's passive surveillance system, are there consistent patterns of signs and symptoms associated with the use of a number of different ephedrine alkaloid-containing dietary supplement products?

(2) Are the patterns of the signs and symptoms consistent with the available scientific evidence and known physiologic and pharmacologic effects of ephedrine alkaloids?

(3) Is there sufficient evidence that the relationships are temporally correct, that is, does exposure occur temporally before the onset of the observed patterns of signs and symptoms?

(4) Is there other evidence of causality, even in the absence of controlled trials, e.g., evidence of dechallenge (improvement or resolution of the signs and symptoms when use of the product is discontinued) or positive rechallenge (reoccurrence of the signs and symptoms when reexposed to ephedrine alkaloids)?

(5) Considering the totality of the available information, is there a biologically plausible explanation for the adverse events?

Finally, in fully evaluating the public health concerns associated with these products, the agency evaluated the potential impact of other factors that could influence final decisions on the best approach to addressing the public health concerns.

C. Evaluation and Tentative Conclusions of the Agency

1. Using the AER's From FDA's Passive Surveillance System for Dietary Supplements, FDA Has Tentatively Concluded That There Are Consistent Patterns of Signs and Symptoms Associated With the Use of a Number of Different Ephedrine Alkaloid-Containing Dietary Supplement Products

In preparation for its August 27 and 28, 1996, Food Advisory Meeting, FDA reviewed each of the approximately 600 AER's that it had received before June 7, 1996 (Refs. 31 and 38). The adverse events associated with ephedrine alkaloid-containing dietary supplement products ranged from those with clinically serious sequelae (such as abnormal heart rhythms, chest pain, heart attack, stroke, significant elevations in blood pressure, seizure, hepatitis, coma, psychosis, and death) to those with less clinically significant signs and symptoms (such as nervousness, dizziness, tremor, minor alterations in blood pressure or heart rate, headache, and gastrointestinal distress) (see Table 1). Although many of the AER's crossed clinical categories, approximately 15 percent of the reports described serious cardiovascular effects, including abnormal heart rhythms, stroke, heart attack, and cardiomyopathy (disease of the heart muscle). Approximately 16 percent of the reports mentioned serious NS effects, including seizure, psychosis, mania, severe depression, vestibular (inner ear) disturbances, and loss of consciousness. Other clinically serious or potentially serious adverse effects reported to be associated with the use of these products included elevations of liver function tests or overt hepatitis (4 percent), myopathies (disease of muscle, particularly skeletal muscle) (3 percent), disturbances of the genitourinary system (e.g., urinary retention, urinary infection, prostatitis (inflammation of the prostate gland), and epididymitis (inflammation of the epididymis, part of the male genitourinary tract)) (3 percent), and dermatologic manifestations (including systemic rashes which appear to be immune mediated or allergic in nature) (6 percent). Approximately 30 percent of the reports mentioned other effects, including gastrointestinal distress, abnormal blood sugar levels or diabetes, blood disorders (including increased bleeding tendencies and abnormal blood cell counts), thyroid disorders, and addiction to the product. Finally, approximately 60 percent of the adverse events were characterized by general stimulant effects on the CVS and NS of a ''less clinically serious'' nature, including anxiety, nervousness, hyperactivity, tremor, insomnia, and altered heart rate or rhythms. However, FDA recognized that these reports of less clinically significant effects could be indicative of early warnings of serious cardiovascular or nervous system risks if product use were to continue.

Serious adverse events were reported for a number of different products promoted for a variety of uses and marketed in a variety of formulations (Refs. 27, 31, and 38). Of these, where there was sufficient information to evaluate how the product was marketed or used, approximately 92 percent of the adverse events were related to the use of products marketed for weight loss and energy purposes, and 5 percent were related to products promoted for enhancing athletic performance or body building, although there was overlap among these uses. Approximately 2 percent of the adverse events were related to products marketed as alternatives to illicit street drugs or for euphoric purposes. (This distribution of types of products parallels the observations made from FDA's market review, which found that most of the dietary supplements containing ephedrine alkaloids bear weight loss and energy claims on their labels or in their labeling (Refs. 1 and 2).) Moreover, specific types of adverse events did not appear to be limited to products promoted for any single use, such as weight loss, energy, or euphoria.

The adverse events were reported to occur in both healthy individuals and in individuals with underlying diseases or conditions that may have influenced the frequency, pattern, or severity of the adverse event (Refs. 25, 27, 31, and 38). Of great concern to the agency are the heart attacks, strokes, seizures, and other clinically serious illnesses and injuries reported to occur in young adults (Figure 2). In approximately 56 percent of the reported adverse events, the injured party was less than 40 years of age, and approximately 25 percent of injuries occurred in those between 40 and 49 years of age. Generally, significant CVS or NS risk factors are not expected in these age groups. Almost 75 percent of the adverse events were reported to occur in females, often using products promoted for weight loss. The higher frequency of adverse events in women most likely reflects a difference in product use (i.e., women predominantly use products marketed for weight loss and energy purposes). However, gender predominance in these ratios may also occur because of gender-related differences in metabolism of ephedrine alkaloids, or gender-related differences in the numbers and types of tissue receptors interacting with ephedrine alkaloids (Refs. 39 through 41).

Data on duration of use of ephedrine alkaloid-containing dietary supplements relative to the occurrence of AER's can also be used to examine the similarity of patterns of adverse events across different types of exposures and individual sensitivities. Figure 3 summarizes the duration of use data collected from the AER's associated

with products containing ephedrine alkaloids. As shown in Figure 3, this information reveals that about 59 percent of the adverse events were reported to occur within 4 weeks of starting to use the product. About 14 percent of the reported adverse events occurred on the first day of using the dietary supplement (Ref. 38) (see ARMS No. 10009 and 11619 in the Appendix to this document) and, in a few cases, on the initial use (Ref. 38) (ARMS No. 11401 in the Appendix to this document). Of equal concern to the agency are reports of serious adverse events occurring within a relatively short time period after consumers began to use the products or consumers began to start using the products after having stopped use for a period of time (ARMS No. 11076 in the Appendix to this document).

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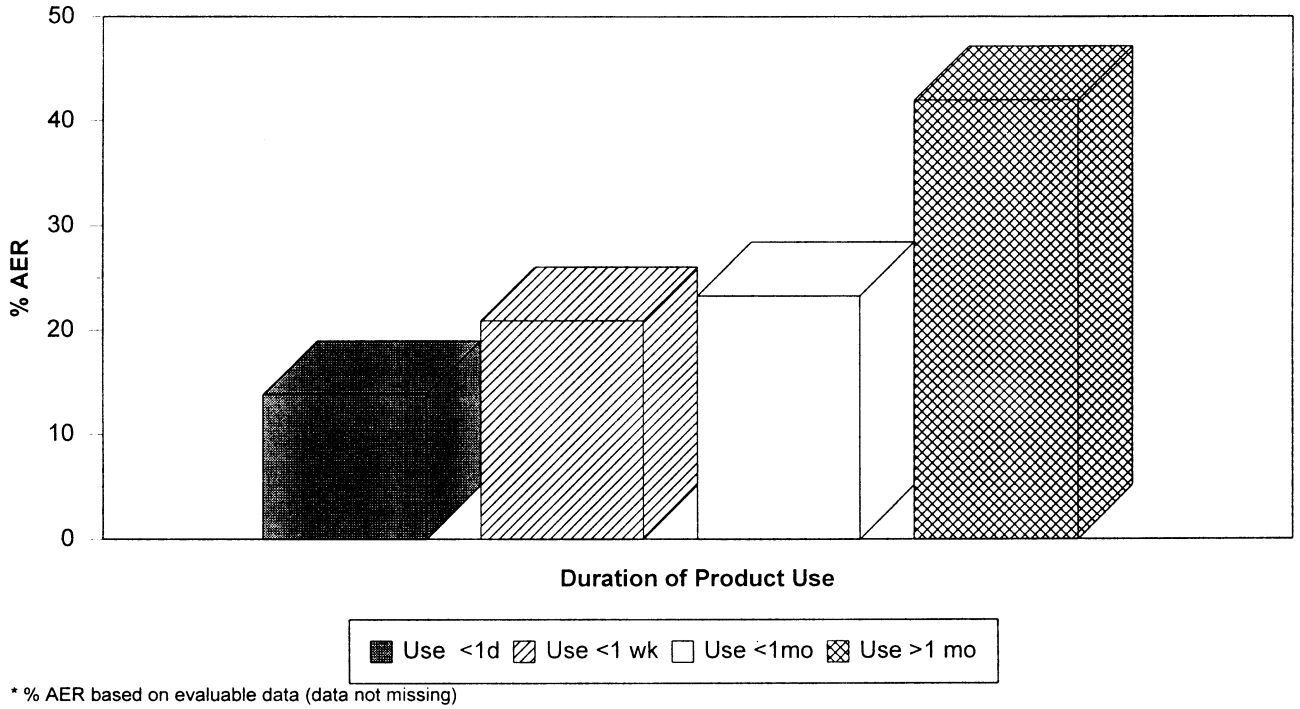
Figure 3: Durations of Product Use Associated with Adverse Events



* % AER based on evaluable data (data not missing)

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Adverse events appear to reflect different inherent types of individual sensitivities relative to dose levels, frequency or duration of use, and subsequent results of sympathomimetic stimulation. In some cases, particular events appear to occur as the result of increased individual susceptibility to the effects of sympathetic stimulation (Refs. 39 through 42). For example, in one report (ARMS No. 10862 in the Appendix to this document), three young adult males consumed similar amounts of a dietary supplement containing ephedrine alkaloids, yet only one male experienced serious adverse effects, which resulted in his death (see Police and Medical Examiner's Reports in ARMS No. 10862 in public docket number 95N–0304). This report is illustrative of numerous AER's suggesting an unpredictable pattern and severity of adverse events when consuming ephedrine alkaloid-containing dietary supplements, even when used according to package directions or under ordinary conditions of use. In other cases, some of the adverse events were associated with consumption of relatively low levels of ephedrine alkaloids (e.g., approximately 10 mg or less total ephedrine alkaloids per serving), some occurring shortly after onset of use.

These variations in the occurrence of adverse events relative to duration, frequency, and levels of exposure are suggestive that multiple factors influence sensitivity to ephedrine alkaloid intakes and could be indicative that some of the adverse effects are the result of increased individual susceptibility to the acute or chronic effects of ephedrine alkaloids.

In summary, in reviewing the AER's associated with ephedrine alkaloid-containing dietary supplements, the agency noted a consistency of signs and symptoms across a large number of products, across a range of products with a variety of intended uses, across products with many different formulations, and across a heterogeneous group of individuals with respect to gender, age, and health condition. Generally, the overall pattern of observed results was consistent with stimulant CVS and NS effects, even though not every product showed the same effect or the same seriousness of effect, not every case involved CVS or NS effects, and not all reports were complete or uncomplicated. The patterns of duration of use and dosage

levels suggest patterns of adverse events that are influenced by variations in individual sensitivities. Overall, however, there was a remarkable consistency in the types of signs and symptoms of adverse effects reported. This consistency was recognized by the Working Group (Ref. 27).

The foregoing discussion summarizes the AER's from a descriptive statistical perspective. Many of these reports are summarized in the Appendix to this document. An abbreviated description of all reports is in public docket number 95N–0304. A few examples of experiences of particular individuals are given below.

ARMS No. 11134—A 23-year-old male college student used an ephedrine alkaloid-containing ergogenic product for approximately 2 years, along with several other dietary supplement products. He was previously healthy and was known to have a healthy life style. He was found dead by his sister in the apartment that they shared. The Medical Examiner's report stated that the cause of death was due to ''patchy myocardial necrosis associated with ephedrine toxicity from protein drink containing Ma huang extract.''

ARMS No. 9552—A 35-year-old female, who was on no medications and who had a negative past medical history, developed a non-Q wave myocardial infarction (heart attack) while using an ephedrine alkaloid-containing dietary supplement within the dosage recommended on the label. She used the product for approximately 30 days, stopped for 1 week while on vacation, and then reinitiated the use of the product. About 11 days after restarting the product, she developed acute throbbing, anterior chest pain at rest, with radiation to the left shoulder, numbness of the left arm and hand, diaphoresis (sweating), and shortness of breath. In the hospital, clinical evaluations (electrocardiogram and cardiac enzymes) indicated an acute non-Q wave myocardial infarction, thought to be secondary to coronary artery spasm. Cardiac catheterization showed normal coronary arteries.

ARMS No. 10009—A 35-year-old male took an ephedrine alkaloid-containing dietary supplement (2 capsules at noon, 3 capsules at 4:30 pm). He worked out from 5:30 to 6:30 pm, developing chest pain at 7:30 pm. He was admitted to the hospital with an acute myocardial infarction (by electrocardiogram and cardiac enzymes) and was treated medically. Subsequent cardiac catheterization demonstrated normal coronary arteries.

ARMS No. 11144—A 28-year-old man used an ephedrine alkaloid-containing product for 10 months (1 capsule per day) for energy. His father found him bloody and responding inappropriately. In the emergency department, his blood pressure was 168/90, with a pulse of 116. Results of extensive clinical and laboratory evaluations were all within normal limits. He was diagnosed with syncope and a closed head injury. His neurologist concluded that ''most likely he had a seizure secondary to ephedrine'' from the health food substance he was taking. He was advised to avoid the product and dispose of it. This man was on no other medications and had no significant past medical history. In particular, he never had problems with dizziness or passing out.

ARMS No. 10974—A 19-year-old woman took an ephedrine alkaloid-containing product, one before each meal, three times per day (½ of recommended amount) for 1 month, for weight loss. Her family witnessed seizure activity at mealtime and took her to the emergency room. Evaluations there were essentially normal (CT scan of the head and electroencephalogram or EEG). The neurologist's evaluation found no other risk factors for seizure. No other products had been used, and there was no significant past medical history.

ARMS No. 10088—A 38-year-old female took two products containing ephedrine alkaloids for 4 days, and she developed syncope (light-headedness) and an extremely elevated blood pressure, measured at 180/110. She was seen in the emergency department with severe headache, nausea, and sweating. The consumer had been seen every 3 to 4 months for the 5 years before this event and had no history of high blood pressure. After stopping the products, her blood pressure returned to normal.

ARMS No. 10919—A 49-year-old woman used an ephedrine alkaloid-containing product, 3 capsules three times daily for 3 weeks for weight loss. She developed weakness, dizziness, nausea, vomiting, and palpitations and went to the emergency room, where she was found to have vertigo (type of dizziness), serous otitis media (middle ear inflammation) bilaterally, hypertension (150/102), and elevated liver enzymes. The consumer reported that when she stopped the product, her blood pressure returned to normal without any medical treatment. She did not have a history of high blood pressure.

ARMS No. 10946—A 42-year-old female used an ephedrine alkaloid-containing product, 1 capsule twice daily for 3 days for weight loss. She was also taking vitamin B_{12} and an antioxidant supplement. She developed a rash over her entire body and stopped all three products. She restarted the ephedrine alkaloid-containing product 3 days after the onset of her rash. Three days later, on a visit to her doctor for a nonproductive cough and congestion, she was found to be seriously hypertensive (170/114). She had no history of hypertension and had been seen by her gynecologist 1 week before starting the ephedrine alkaloid-containing product, where a normal blood pressure (120/78) was documented.

2. The Patterns of the Signs and Symptoms of Adverse Events Associated With Ephedrine Alkaloid-Containing Dietary Supplements Are Consistent With the Available Scientific Evidence and Known Physiologic and Pharmacologic Effects of Ephedrine Alkaloids

The observed CVS and NS effects associated with use of ephedrine alkaloid-containing dietary supplements are consistent with the known pharmacologic and physiologic effects of ephedrine alkaloids. Because there is a general paucity of scientific data or other information on the physiologic or pharmacologic properties of ephedrine alkaloids from botanical sources, and particularly from marketed dietary supplement products, FDA reviewed other available evidence on ephedrine and other ephedrine alkaloids for information on their effects. This evidence included data from clinical and animal studies in support of drugs containing a single, synthetic ephedrine alkaloid in a well-defined and characterized product, case reports from the literature of adverse events with ephedrine alkaloid-containing products, and traditional medical uses of ephedrine alkaloid-containing botanicals.

Although there may be some differences in the pharmacokinetic properties of synthetic ephedrine alkaloids used in drug products as compared to the botanical sources of these alkaloids as used in dietary supplements (e.g., differences in enantiomer forms, dissolution, absorption, and bioavailability or differences that result from interactions with other components of the botanical), given that once absorbed, the botanical and synthetic sources of ephedrine alkaloids undergo similar metabolic processes (Refs. 24 and 43), the agency considered it appropriate to rely on evidence from pharmaceutical sources of single ephedrine alkaloids in assessing the effects of botanical sources. This judgment is supported by

the fact that adverse events reported for dietary supplements containing ephedrine alkaloids from botanical sources are similar to those that are reported in the literature for drugs containing an ephedrine alkaloid from synthetic sources. FDA's Working Group agreed that evidence on synthetic sources of ephedrine alkaloids could be considered in evaluating botanical sources (Ref. 27).

Ephedrine and its related alkaloids are known to elicit physiological responses similar to catecholamines (i.e., groups of chemically related neurotransmitters, such as epinephrine, norepinephrine, and dopamine) that have stimulant effects on the sympathetic nervous system and thus are classified as sympathomimetic agents (i.e., agents stimulating the sympathetic nervous system) (Refs. 7, 9 through 13, and 44 through 48). Ephedrine, pseudoephedrine, and norephedrine are naturally occurring sympathomimetic amines in some botanicals. Ephedrine, pseudoephedrine, and norephedrine each have varying effects because of interaction with specific receptors in the human body (i.e., alpha, beta-1, and beta-2 adrenergic receptors) (Refs. 9 through 13). (Table 2 summarizes some of the major receptor effects, and Table 3 summarizes the adrenergic activity of ephedrine, pseudoephedrine, phenylpropanolamine (dl-norephedrine), and norepinephrine.) Some of the physiological roles of alpha receptors are central NS stimulation, vasoconstriction (i.e., narrowing of blood vessels), uterine contraction, centrally mediated cardiovascular depression, and decreased insulin secretion. Alpha receptors also have an effect on the urinary bladder, which can result in urinary retention. The major physiological roles of beta receptors include cardiac (i.e., heart) stimulation and bronchodilation (enlargement of the bronchial or breathing tube secondary to relaxation of bronchial smooth muscle).

TABLE 2.—ADRENERGIC ACTIVITY OF SYMPATHOMIMETIC AGENTS (MODIFIED FROM REF. 9)

Organ/system	Type of effects adrenergic receptors			Other effects
	α	β_1	β_2	
Nervous system (NS)	Central NS Stimulation			Indirect Effects on Neurotransmitters Result in NS Stimulation.
Cardiovascular system	Vasoconstriction	Cardiac stimulation: ↑contractility (force & velocity). ↑heart rate ↑impulse conduction ↑cardiac output ↑O_2 consumption ↑stroke volume ⇄diastolic coronary perfusion time. ⇄ventricular filling ⇄residual (end-systolic) volume.	Cardiac stimulation: ↑heart rate ⇄arteriolar tone ⇄peripheral resistance ⇄diastolic pressure ⇄cardiac afterload vasodilation.	
Other	↑uterine contraction ↑ureter motility & tone pupillary dilation ⇄GI motility & tone ⇄pancreatic secretion (islets/acini). contraction, urinary, bladder, sphincter & trigone.	lypolytic activity ↑renin secretion	bronchodilation ↑insulin secretion muscle & liver glycogenolysis. ⇄GI motility & tone urinary bladder—relaxation of detrusor muscle. relaxation of uterus cerebellum— synaptic remodeling.	

TABLE 3.—ADRENERGIC ACTIVITY OF SYMPATHOMIMETIC AGENTS (MODIFIED FROM REF. 9)

Sympathomimetic agent	α-Receptor effects	β_1-Receptor effects	β_2-Receptor effects	CNS effects
Ephedrine	moderate	strong	strong	strong.
Pseudoephedrine	moderate	moderate	moderate	moderate.
Phenylpropanolamine (dl-norephedrine)	strong	very little	very little	strong.
Norepinephrine	very strong	very little	none	none.

The different types of ephedrine alkaloids exhibit some similar effects but vary in the intensity of these effects (Refs. 10 through 13). For example, ephedrine increases arterial blood pressure in humans both by peripheral vasoconstriction (narrowing of the blood vessels in the periphery of the body) and by cardiac stimulation, resulting in increased heart rate and cardiac output. The magnitude of these cardiovascular responses can vary on an individual basis and may be dependent on a number of factors, including genetic characteristics, a history of certain diseases or conditions, or the use of certain medications. Other actions of ephedrine include stimulation of oxygen uptake and thermogenesis (heat or energy production). Pseudoephedrine is less potent than ephedrine both in its bronchodilatory and vasopressor effects (i.e., effect of elevating blood pressure). It produces about one half the

bronchodilation and one quarter of the vasopressor effects of ephedrine (Refs. 9 and 13).

a. *Physiologic and pharmacologic evidence: cardiovascular effects of ephedrine alkaloids.* The adverse events involving the CVS reported to FDA that are associated with dietary supplements containing ephedrine alkaloids are consistent with the known effects of sympathomimetic agents on the CVS. Cardiovascular effects resulting from the use of sympathomimetic agents are well documented in the literature (Refs. 49 through 52). For example, use of ephedrine has been reported to interfere with the regulation of serum potassium levels (Refs. 53 through 55) and thus may predispose certain individuals to cardiac dysrhythmias (i.e., abnormal heart rhythms) (Refs. 18 and 56); myocardial ischemia (i.e., inadequate circulation of blood and oxygen to the heart muscle); and infarction (i.e., death or damage of heart cells, also called heart attack) (Refs. 57 through 61). Cardiac damage has also been reported with the use of pseudoephedrine and phenylpropanolamine (norephedrine) (Refs. 16, 56, 60, and 62 through 64). Results of several studies on blood pressure effects with the use of ephedrine alkaloids have indicated that individuals with hypertension may be at greater risk of blood pressure elevations with the use of ephedrine (reviewed in (Ref. 64)).

The signs and symptoms observed in the AER's are consistent with the available scientific literature on the effects of ephedrine alkaloids. Serious cardiovascular adverse events are the major cause of death reported in the AER's with the use of ephedrine alkaloid-containing products and primarily involve ischemia (inadequate blood flow) which can cause heart attacks and strokes. These events have occurred in asymptomatic, otherwise healthy young adults with normal coronary or cerebral blood vessels (Ref. 25), a finding also noted with pharmaceutical preparations of ephedrine alkaloids (Refs. 60, 61, and 65), where vasospasm with subsequent ischemia is a proposed mechanism of tissue injury. Besides causing damage by affecting blood flow, sympathomimetic agents, such as ephedrine, can damage the heart and other tissues or organs by other mechanisms. Cardiomyopathy (i.e., disease of the heart muscle) related to catecholamine mediated cytotoxicity (cell damage) has been reported with chronic use of ephedrine alkaloids (durations of use generally at or above the recommended dose that occur over many months or years) (Refs. 62 and 66 through 68). Fatal cardiomyopathies have also been reported with chronic use of ephedrine alkaloid-containing dietary supplements (ARMS No. 11134 in Ref. 149a).

Ephedrine and pseudoephedrine have been implicated also in stroke secondary to intracranial (i.e., inside the brain) and subarachnoid (i.e., underneath the membrane that covers the brain and spinal cord) hemorrhage and vasculitis (i.e., inflammation of blood vessels), as well as in ischemic strokes (Refs. 9 and 69 through 71), particularly when used in combinations with phenylpropanolamine (norephedrine) or caffeine (Refs. 65 and 72 through 78) or in the presence of monoamine oxidase inhibitors (MAOI) (Ref. 72). These effects are noted to be similar to the necrotizing angiitis (severe inflammation with destruction of the blood vessels) seen in chronic amphetamine abuse (Refs. 16, 74, and 77 through 79).

b. *Physiologic and pharmacologic evidence: NS effects of ephedrine alkaloids.* The adverse events involving the NS reported to FDA that are associated with dietary supplements containing ephedrine alkaloids are consistent with the known effects of sympathomimetic agents on the NS. These effects, such as seizure (Refs. 63, 65, and 80), psychosis, and mania (Refs. 81 through 99), have been reported with the use and the abuse of ephedrine alkaloids. More recently, a case report in the scientific literature reported ephedrine-induced mania associated with the use of a botanical dietary supplement (Ref. 100).

Neuropsychiatric effects reported in AER's related to ephedrine alkaloid-containing dietary supplements also are consistent with the known physiologic and pharmacologic actions of ephedrine alkaloids documented in the scientific literature. Mania and psychosis have occurred in individuals without identifiable risk factors who have used these products, as well as in people who used them who had possible predisposing factors, such as a personal history of mood disorders (i.e., depression or manic depression), a family history of manic depression, or concurrent use of products that increase sensitivity of an individual to the effects of ephedrine alkaloids (see Table 4). AER's noting neuropsychiatric adverse effects in persons using non-MAOI antidepressant drugs concurrently with dietary supplements containing ephedrine alkaloids are consistent with a report of the serotonin syndrome associated with the concurrent use of serotonin reuptake inhibitors (a new class of antidepressant drugs) and OTC cold remedies containing pseudoephedrine (Ref. 101).

TABLE 4.—FACTORS INFLUENCING SENSITIVITY TO SYMPATHOMIMETIC AGENTS

Factor	Examples
Age	Children, elderly.
Genetics	Metabolizer genotype; adrenergic receptor genotype and numbers.
Physiological states	Hyperdynamic (exercise), underweight.
Dieting practices	Severe caloric or fluid restriction.
Medications and food	MAOI, methyldopa, β-receptor blocking agent, caffeine or other stimulants.
Diseases or health-related conditions	Heart disease, thyroid disease, diabetes, renal disease, high blood pressure, depression, psychiatric conditions, glaucoma, prostate enlargement, seizure disorder.
Duration of use	Vascular spasm; stroke and myocardial infarction may influence the type and severity of adverse events in the sensitive individual.

c. *Variability in individual responses to ephedrine alkaloids.* The unpredictability of individual responses to ephedrine alkaloid-containing dietary supplement products, as reported in AER's, is also consistent with what is known about the physiological and pharmacological properties of these alkaloids (Refs. 7, 10 through 12, 39 through 41, and 48). Individual variability in the effects of ephedrine has been reported in several clinical investigations (Refs. 5 and 102 through 104). The marked sensitivity of some individuals to the effects of ephedrine has been recognized in the Western scientific literature almost from the time that ephedrine was introduced as a

therapeutic agent in the mid-1920's (Refs. 5 and 102). Two early studies by different investigators recommended a 10 mg initial oral test dose to assess the individual's sensitivity to sources of ephedrine (Refs. 5 and 102).

Factors that appear to influence individual susceptibility to sympathomimetic agents are diverse (see Table 4) and are not yet well defined by biological bases. These factors include genetics, particularly those genes controlling metabolic functions; receptor numbers and types; gender; age; and certain physiological states or disease conditions (reviewed in Refs. 39 through 42). In addition, the dosage and duration of use may influence the effects seen with ephedrine alkaloids, as tachyphylaxis (i.e., decrease or diminution of some effect) is known to occur with chronic use of these agents (i.e., there are decreases in certain effects with chronic use that are thought to be due to occupation of all adrenergic receptor sites; discontinuation of ephedrines for a few days results in receptor availability and receptor mediated effects). An example of tachyphylaxis could be tremor or insomnia, which occurs soon after starting ephedrine alkaloid-containing products but which may resolve in certain individuals with continued use of ephedrine alkaloids.

d. *Clinical trials using ephedrine in the treatment of obesity.* Although many dietary supplements containing ephedrine alkaloids are marketed for weight loss or energy purposes, there is a paucity of meaningful data on the safe use of these products for this purpose.

A number of controlled clinical trials reported in the scientific literature evaluated the effects of pharmaceutical preparations of ephedrine, either singly or combined with caffeine or aspirin, on weight loss in the treatment of obesity (Refs. 105 through 119). While the primary purpose of these trials was to evaluate efficacy of ephedrine for purposes of weight loss in grossly obese individuals, these clinical trials also document that clinically significant adverse effects can occur in populations with no known risk factors with the use of ephedrine, and that synergistic adverse effects can result when ephedrine and caffeine are combined. The patterns and types of the adverse effects reported in these trials are consistent with the known effects of sympathomimetic agents, that is, they mainly involved NS and CVS effects. A summary of these studies follows. (In this document, the agency makes no evaluation or judgment of the effectiveness of the use of ephedrine in the treatment of obesity.)

A Danish group of researchers investigated the usefulness of ephedrine and caffeine alone and in combination for the treatment of obesity (Refs. 105, 106, and 112). One hundred and eighty subjects were randomized to one of four treatment groups: (1) Ephedrine—20 mg, (2) ephedrine—20 mg and caffeine—200 mg, (3) caffeine—200 mg, and (4) placebo control. The treatments were administered three times a day for 24 weeks in conjunction with a defined low calorie diet. One hundred and forty-one individuals completed the trial. Subject withdrawals were reported to be equally distributed across the four groups with no statistical differences among the groups. More side effects were noted in the treatment groups compared to the placebo control group in both those subjects continuing in, and those withdrawing from, the trial. Study results showed that 60 percent of the ephedrine and caffeine treatment group, 44 percent of the ephedrine treatment group, and 36 percent of the caffeine treatment group experienced side effects compared to 24 percent of the placebo control group. These results were statistically significant ($p<0.05$) (Ref. 105). This study showed that there was a possibility of rebound symptoms (symptoms occurring as a consequence of withdrawal of an agent, especially headache and fatigue) once the treatment was stopped. Rebound symptoms were seen most in the ephedrine and caffeine treatment group but also occurred in the ephedrine alone group (Refs. 105 and 106).

Astrup et al. enrolled 127 of the subjects completing the above clinical trial into an open label study where all subjects received the same treatment (diet and ephedrine plus caffeine) for 24 weeks (Refs. 106 through 108). Five of the 38 subjects that withdrew or dropped out of this study did so because they experienced adverse drug reactions (NS and CVS effects). Adverse drug reactions occurred in 102 subjects during weeks 1 through 24 of the open trial. Most symptoms (75 percent) started during the first 4 weeks of treatment and lasted about 4 weeks. Symptoms related to the CVS were primarily palpitations and tachycardia. The most frequent NS symptoms were tremor, agitation, insomnia, increased sweating, and nervousness.

Breum et al., in another clinical trial in which the effects of ephedrine plus caffeine (EC) were evaluated, conducted a randomized, double blind, controlled 15 week clinical trial comparing the effects of EC to that of dexfenfluramine (DF), a serotoninergic agonist, in the treatment of obesity (Ref. 113). Fifty four percent of the subjects in the EC group compared to 43 percent of the DF group experienced adverse reactions. The majority of these occurred within the first 4 weeks. At week one, 38 percent of the EC group subjects experienced adverse drug reactions compared to 30 percent in the DF group. NS effects (particularly insomnia and agitation) were statistically increased ($p < 0.05$) in the EC treatment group (46 percent) compared to the DF group (26 percent), whereas gastrointestinal adverse effects were significantly increased in the DF group. Eight percent of the EC group reported cardiovascular symptoms. All symptoms remitted after cessation of the trial drugs.

The above studies demonstrate that adverse effects can occur with the use of ephedrine in the treatment of obesity even in carefully designed and conducted, physician-monitored clinical trials and even in persons prescreened to be in good health, free of known risk factors, and not using medications or other products known to adversely interact with ephedrine-like drugs. Furthermore, the study population of obese individuals is recognized to be less sensitive to the effects of sympathomimetic agents than the general population (Ref. 120). Certain of these studies also evidence that there is an increased frequency of adverse effects occurring in lean subjects, secondary to sympathetic stimulation, compared to obese subjects that is unrelated to dose per body weight (Ref. 119). Thus, these studies suggest that the general population may be more sensitive to the effects of ephedrine alkaloids than the obese population.

There are a number of recognized limitations inherent in these published trials, including those associated with study design, methods, and conduct (e.g., small number of subjects enrolled in these trials, narrow targeted populations, short evaluation periods, and selective presentation of data are among the concerns) as are the multiple publications of the same data. Yet despite these factors, the adverse effects observed in these studies remain a cause for concern, although these factors make it difficult to identify subpopulations that may be particularly sensitive to the effects of ephedrine or to identify adverse effects that occur infrequently. These studies were carefully monitored, so that subjects were withdrawn from the study when adverse effects became evident. Therefore, although the observed adverse effects in these studies were not as severe or as serious as some observed with dietary supplement use (e.g., heart attacks, seizures, strokes), they are indicative of the potential for

greater risk with continued use. Moreover, their occurrence is remarkable given the careful prescreening of study subjects such that high risk persons were not included in the study.

The greatest limitation, however, is that these studies were designed to evaluate the effectiveness of ephedrine in the treatment of obesity. They were not designed to test the safety of the use of ephedrine in the obese, or any other population (Ref. 121), or to test its safety under the conditions under which marketed dietary supplements containing sources of ephedrine alkaloids are used. Therefore, these study results cannot be used to definitively demonstrate safety, or the lack of safety, of ephedrine alkaloid-containing supplements for use by the general population. Nonetheless, despite the shortcomings of these studies, the results raise serious concerns about the safety of using ephedrine, from any source, including dietary supplements, in both obese individuals and the general public in nonmedically monitored situations.

e. *Other physiologic and pharmacologic effects.* Some of the adverse events reported to FDA that were unrelated to the CVS and NS also bear a recognized relationship to the known physiologic and pharmacologic effects of ephedrine alkaloids. For example, urinary retention, particularly in males with no history of prostatic hypertrophy (enlargement of the prostate gland), has been associated with the use of ephedrine (Refs. 102, 103, and 122 through 124). Urinary retention has a well recognized relationship with urinary tract infections, which have been reported to FDA with the use of products containing ephedrine alkaloids. Myopathy (disease of muscle), besides being reported for the heart (Refs. 62 and 66 through 68), is also recognized to involve skeletal muscles and may result in acute renal failure (Ref. 125). Certain gastrointestinal adverse effects, including impaired colonic motility and ischemic colitis, have been associated with the usage of amphetamines (Refs. 102 and 126). Similarly, ischemic colitis has also been reported with the usage of a long-acting decongestant containing pseudoephedrine (Ref. 127). Additionally, acute hepatitis (inflammation in the liver) has been associated with the use of a Chinese medicinal product containing Ma huang (Ref. 128).

Other types of adverse effects, such as the reports of dermatologic reactions, while not known to be related to the recognized physiologic or pharmacologic effects of ephedrine alkaloids, are consistent with adverse effects reported in published case reports. For example, there are more than 11 published case reports, at least 12 patients, of systemic dermatologic reactions, including rashes occurring in a particular distribution on the body, contact dermatitis (inflammation of the skin resulting usually from local contact with a substance), a toxic shock-like syndrome, angioedema (extreme swelling of tissues and structures of the body secondary to leaking of fluids from capillaries (small blood vessels)), and erythematous (reddish) rash and subsequent desquamation (loss of part of the skin surface) that occurred with the use of ephedrine or pseudoephedrine (Refs. 114 and 129 through 138).

Concerns about toxicity to the fetus with maternal exposure to ephedrine alkaloids during pregnancy remain unresolved. Increased fetal heart rate has been associated with maternal use of pseudoephedrine (Ref. 139). In addition, the administration of intramuscular ephedrine to treat maternal hypotension has been associated with increases in fetal heart rate and beat-to-beat variability (cited in Ref. 139). Certain animal studies also raise concern about potential teratogenic effects that may be caused by the use of ephedrine during pregnancy (Refs. 140 through 143). Potential toxicity for a breast-fed infant whose mother is using a dietary supplement containing ephedrine alkaloids is unknown, but toxicity has been reported in a breast-fed infant whose mother had been taking a long-acting oral decongestant containing d-isoephedrine for the relief of allergy symptoms (Ref. 144).

Little is known about the potential consequences of long term use of ephedrine alkaloids, other than the risk of cardiomyopathy as stated above. Park et al., however, recently implicated β-adrenergic agents like ephedrine in the etiology of a type of lung cancer, particularly in persons simultaneously exposed to carcinogenic environmental factors such as smoking (Ref. 145). This report indicates the need for long-term followup to adequately assess the risks associated with product use, as well as the importance of particular group characteristics (e.g., smoking status) in evaluating risk.

f. *Traditional uses of botanical sources of ephedrine alkaloids: adverse effects.* In the traditional medicinal use of *Ephedra,* the raw botanical was administered, either alone or more commonly combined with other specific botanicals, in the form of a water infusion (tea), three times a day. Traditional treatment was prescribed by a trained health practitioner based on the evaluation of a particular patient and was predominately for short term use. Commonly used dosages of the raw botanical ranged from 1.5 to 9 grams (g), generally averaging 5 to 6 g of *Ephedra* per dose (Refs. 14 and 146). Tyler has estimated that a tea made from 2 g of the raw botanical *Ephedra* (containing 1.25 percent ephedrine) will yield a dose of 15 to 30 mg ephedrine (cited in Ref. 147). Thus, use of 5 to 6 g of the raw botanical *Ephedra,* an average amount used in a tea could yield a dose of ephedrine ranging from approximately 38 mg to 75 mg.

FDA has no knowledge of any systematic collection of morbidity and mortality data on individuals treated with *Ephedra* in traditional medicine. *Ephedra* was historically considered a medium or middle class herb, meaning that recognized toxicities could be associated with its use (Refs. 14, 146, and 148). Several reference texts, in fact, list precautions and contraindications for the use of the botanical *Ephedra* in traditional medicinal preparations (Refs. 14 and 146). Another reference warns against overdosage (Ref. 25).

While there is a paucity of data in the scientific literature on the safety of the use of *Ephedra,* several scientific references report adverse effects associated with the use of *Ephedra.* One early study in the United States reported two cases of urinary retention in men aged 56 and 65 years. These men all noted bladder pain and difficulty in voiding which developed after one to three doses of a fluid extract of *Ephedra.* The symptoms resolved after the use of the extract was discontinued. More recently, a published case report notes the occurrence of erythroderma associated with the use of an herbal product containing Ma huang which was obtained from a Chinese herbalist for the relief of cold-like symptoms (Ref. 138). The woman who was the subject of this report had a history of similar episodes following usage of OTC cold preparations containing ephedrine alkaloids. These references document that adverse effects occurred with the traditional use of *Ephedra,* and that these effects are consistent with effects occurring with modern pharmaceutical preparations of synthetic ephedrine.

3. The Relationship is Temporally Correct

One possible source of serious error in evaluating observational data, such as that found in FDA's postmarketing surveillance system, is the potential for inappropriately assuming that a cause and effect relationship exists between a

particular exposure and a particular adverse event without evaluating the true relationship of the adverse event to the exposure. Unless there are data that ensure that there is the correct temporal relationship between exposure and effect (i.e., that the adverse effects follow exposure), there is a potential for serious misinterpretation of data. To evaluate this potential source of serious error, FDA evaluated the AER's to determine whether there was clear evidence of the correct temporal sequence having occurred. FDA found evidence of the correct relationship in the AER's that it received (see, e.g., ARMS Nos. 10088, 8475, 9747, and 11112).

Further support that the temporal relationship is correct can be found in clinical studies that described the pharmacological and physiological effects of different ephedrine alkaloids and in the clinical trials with obese subjects.

4. There is Other Evidence, Even in the Absence of Controlled Trials, Such as Evidence of Dechallenge That Suggests a Causal Relationship Between the Use of Ephedrine Alkaloid-Containing Dietary Supplements and Adverse Events

Causality is most readily demonstrated in well-designed and conducted clinical trials, in which the multiple factors that may influence study results and interpretations can be controlled. However, evidence of causality can be inferred from observational studies, including individual case reports, particularly where there is evidence of positive dechallenge and rechallenge, that is, where, when the consumer stopped using the product, the signs and symptoms resolved or improved, and when the consumer began using the product again, the symptoms reoccurred. Although many of the AER's did not provide enough information to adequately evaluate these questions, over 26 percent of AER's provided information suggesting successful dechallenge, and 4 percent of reports provided information of rechallenge, suggesting that the product was the direct cause of the adverse event. A number of the previously described cases are particularly good examples of positive dechallenge in that symptoms resolved spontaneously on cessation of use of the product without medical treatment (see Arms Nos. 10088, 11065, and 11112 in the Appendix to this document).

Furthermore, some specific AER's suggest that a pattern of starting and stopping use of dietary supplements containing ephedrine alkaloids may increase an individual's susceptibility to experiencing adverse events as has been suggested in reviews of adverse events occurring with the use of phenylpropanolamine (Ref. 73). One case described above, ARMS No. 9552, in which a woman suffered a heart attack soon after she restarted using an ephedrine alkaloid-containing product, may be an example of such increased sensitivity.

Thus, FDA tentatively concludes that there is evidence of dechallenge and rechallenge from the AER's that supports a causal relationship between the ingestion of ephedrine alkaloids and the types of CVS and NS and other effects observed with use of the ephedrine alkaloid-containing dietary supplement products. Additional support for this conclusion is also provided in the published clinical trials in the treatment of obesity described above.

5. A Biologically Plausible Explanation for the Adverse Events

Considering the totality of the available information, FDA tentatively concludes that the available evidence strongly supports that the adverse effects that are occurring with the use of dietary supplements containing ephedrine alkaloids are caused by the ephedrine alkaloids. This tentative conclusion derives from the previous discussions in this document. The observed adverse effects predominately involve the CVS and NS and are consistent with the known physiological and pharmacological effects of ephedrine alkaloids noted in medical/pharmacological texts. Furthermore, similar patterns of CVS and NS effects have been documented both in anecdotal reports in the scientific literature and in the published results of controlled clinical trials using pharmaceutical preparations of various ephedrine alkaloids. The available data further suggest that these types of adverse events should be anticipated and expected with the use of ephedrine alkaloid-containing products by the general population.

D. Additional Concerns

The agency is aware of a number of factors related to currently marketed dietary supplements that may contribute to the likelihood of adverse events but that the available data are inadequate to evaluate fully. These factors weighed heavily on the minds of many members of the Food Advisory Committee as they discussed the public health concerns associated with the use of these products. These factors include:

(1) The size of the population that is susceptible to experiencing adverse events with the use of ephedrine alkaloids, because there are neither good data on the number and pattern of supplement users in the United States nor good data on the full range of characteristics that cause or increase risk. Nonetheless, the potential population at risk is quite large if one considers the following likely risk factors:

(a) The large number of persons who have diseases or conditions, or who are at risk for such conditions, for whom the use of ephedrine alkaloid-containing dietary supplements is inappropriate (Table 5).

TABLE 5.—IDENTIFIABLE AT RISK POPULATION WITH USE OF EPHEDRINE ALKALOIDS

Disease or condition	Estimated number of affected persons in the United States (in millions)
Cardiovascular disease	50 (Ref. 158).
Hypertension	50 (Ref. 158).
Kidney trouble	3.5 (Ref. 159).
Prostate disease	2.6 (Ref. 159).
Glaucoma	2.4 (Ref. 160).
Diabetes	16 (8 million undiagnosed) (Ref. 161).
Depressive, anxiety or schizophrenic disorders	42.3 (Ref. 162).
Thyroid disease	11 (6 million undiagnosed) (Ref. 163).
Pregnancy	4 (each year) (Ref. 179).

(b) The large number of factors that may increase susceptibility or sensitivity to the effects of ephedrine alkaloids and other sympathomimetic agents (Table 4). These variables include gender, age, genetics, certain physiologic states, and the use of certain products (e.g., foods and drugs) (Ref. 25).

(2) The potential for interactive and unpredictable effects from the mixture of ephedrine alkaloids found in botanical sources, which may serve to increase the likelihood, frequency, or severity of an adverse event. Unlike drugs which contain only a single, well-characterized ephedrine alkaloid, botanical sources contain a mixture of these alkaloids. The potential for interactive effects among these alkaloids is likely but largely unknown (Ref. 25).

(3) The potential for other ingredients in the dietary supplement products to interact with the ephedrine alkaloids to increase the likelihood or severity of an adverse event (Ref. 25).

(4) The natural or formulation variations in levels and relative proportions of the ephedrine alkaloids in marketed dietary supplement products and the resultant risk for persons who can tolerate one level or mixture but who unknowingly are exposed to different levels or mixtures because they change brands, or because the composition of the brand that they typically use is altered (Ref. 25).

(5) The formulations of the products themselves (including the numbers, types, and forms of ingredients used in the product and the form of the final product) may influence the likelihood, frequency, or severity of adverse effects because product characteristics may influence dissolution, absorption, bioavailability, and metabolism of active and inactive ingredients in the product and thus influence the effects of the product (Ref. 25).

E. General Summary and Tentative Conclusions

FDA has received more than 800 AER's involving more than 100 dietary supplement products. Among these products the most common and consistent finding is the presence of ephedrine alkaloids. The products associated with these adverse events are marketed in diverse formulations and for a variety of uses.

Sympathetic nervous system and cardiovascular system stimulant effects account for the majority of the reported adverse events associated with dietary supplements containing ephedrine alkaloids. These effects include heart attack, stroke, seizure, chest pain, psychosis, anxiety, nervousness, tremor, and hyperactivity (Refs. 25 and 27). The type and patterns of these adverse effects are consistent with the CVS and NS effects known and expected to occur with the use of sympathomimetic agents, such as the ephedrine alkaloids. The known physiological and pharmacological activities of ephedrine alkaloids and the adverse events that have occurred in controlled clinical trials using ephedrine corroborate this conclusion. The biological plausibility of these types of adverse events occurring with the use of ephedrine alkaloids, the temporal relationship between the use of the dietary supplements and the onset of the adverse events, and the evidence of dechallenge and rechallenge also support a causal relationship between the use of ephedrine alkaloid-containing products and subsequent adverse events.

Both the Working Group and the Food Advisory Committee reviewed the available data and information on the occurrence of adverse events associated with the use of dietary supplements containing ephedrine alkaloids in certain individuals. The Working Group was specifically asked whether the available information contains sufficient evidence to demonstrate that the use of dietary supplements containing ephedrine alkaloids may cause consumers to experience serious adverse events. The Working Group concluded that it was. Although not asked this question, those members of the Food Advisory Committee who addressed the question agreed with the Working Groups's conclusion.

Thus, FDA tentatively concludes that there is a consistent, large, and growing body of evidence that establishes a causal association between the use of ephedrine alkaloids and subsequent adverse events. The agency also tentatively concludes that the use of ephedrine alkaloid-containing dietary supplements is associated with a serious and significant public health concern because of the nature of the adverse events and the size of the population at risk.

III. The Proposed Regulation

A. The Scope of This Proposal

This proposal applies to dietary supplements containing one or more ephedrine alkaloids and related alkaloids, including those from the botanical species *Ephedra sinica* Stapf, *Ephedra equistestina* Bunge, *Ephedra intermedia* var., *tibetica* Stapf, *Ephedra distachya* L., and *Sida cordifolia* or their extracts.

Conventional food products that contain ephedrine alkaloids, including snack bars, cookies, and beverages, are not covered by this proposal. Conventional food products are subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) and, given the adverse events associated with the use of ephedrine alkaloids, these substances are unapproved food additives when used in conventional foods.

Use of botanical sources of ephedrine alkaloids in traditional herbal therapies is beyond the scope of this proposal. Although several *Ephedra* species (including those considered as Ma huang) have been reported to have a long history of use in traditional Asian medicine for the treatment of the symptoms of colds, to relieve respiratory symptoms, and to regulate water metabolism (Refs. 4, 6, 14, and 146), products bearing claims evidencing that they are intended for therapeutic use are regulated as drugs under the act.

This proposal also does not cover OTC or prescription drugs that contain ephedrine alkaloids. Ephedrine is approved as an active ingredient in oral OTC bronchodilator drugs for use in the treatment of medically diagnosed mild asthma (21 CFR 341.76). However, in the **Federal Register** of July 27, 1995 (60 F.R. 38643), FDA proposed to amend the final monograph for OTC bronchodilator drug products to remove the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride and to classify these ingredients as not generally recognized as safe and effective for OTC use.

FDA issued the proposal to amend the final monograph for OTC bronchodilator products in response to a request from the U.S. Department of Justice, Drug Enforcement Administration (DEA), to restrict OTC availability of ephedrine because of its illicit use as the primary precursor in the synthesis of the controlled substances methamphetamine and methylcathinone. The agency also issued the proposal because of new information that showed that misuse and abuse of OTC ephedrine drug products can cause potential harm, and because of comments made by FDA's Pulmonary-Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee. FDA is currently evaluating public comments to that proposal and will be addressing this subject in a future issue of the **Federal Register**.

B. Rationale for the Proposal

It is incumbent upon the agency to respond to the concerns raised by the number, seriousness, and pattern of adverse events associated with the use of ephedrine alkaloid-containing dietary supplements. Given the AER's, the case reports in the scientific literature, controlled clinical trials, published reports of adverse effects with traditional uses of ephedrine alkaloid-containing botanicals, and other data, it is apparent that there are serious and well-documented public health risks attendant to the use of ephedrine alkaloids in marketed dietary supplement products, and that the agency needs to propose actions to address these risks.

Over the years, FDA has employed a variety of strategies in addressing food ingredients that created significant public health risks. In cases where small subpopulations have faced serious, even potentially deadly, risks because of ingredients with allergic potential (e.g., nuts and shellfish), FDA has required that the presence of the allergen be declared on the food label so that consumers who are at risk can avoid products that contain the problem ingredient (§ 101.4 (21 CFR 101.4)). In other cases where a food or food ingredient has presented special health risks to consumers under certain use conditions, the agency has required warning label statements to ensure that consumers are alerted to the potential health hazards associated with use of the product. For example, FDA has required a special warning statement to appear on the label of protein products intended for use in weight reduction, stating in part that very low calorie protein diets may cause serious illness or death (§ 101.17(d) (21 CFR 101.17(d))). In other cases, e.g., the proposed regulations for poisonings in young children because of high intakes of iron-containing dietary supplements, the agency was concerned that, for high potency products, warning labels alone would not be effective in preventing serious harm. Therefore, the agency has decided to require, at least in some cases, warning labels plus special packaging requirements to reduce the risk of serious harm (Ref. 150).

In other cases, where a substance contained in a food may be harmful to health, it has been the agency's policy to define a level at which the harmful substance may render the food adulterated. For example, to address the public health problem of histamine poisoning associated with the consumption of certain fish, the agency issued guidance on the level of histamine at which FDA is likely to take action against the fish because it is adulterated (Ref. 151). Moreover, in § 109.4(b) (21 CFR 109.4(b)), the agency has said that it will establish regulatory limits that represent the level at which an added poisonous or deleterious substance adulterates a food within the meaning of section 402(a)(1) of the act (21 U.S.C. 342(a)(1)).

The agency has attempted to be flexible and practical in tailoring its strategy for dealing with public health risks, taking into account the nature and type of the risk and the potential effectiveness of various alternative approaches. In the case of ephedrine alkaloids in dietary supplements, there are many factors and underlying etiologies that can influence individual sensitivity to these substances. Some of these factors are easily identified or readily controlled; many are not. Factors that are known to influence the likelihood, frequency, and severity of adverse events associated with the use of sympathomimetic agents, including ephedrine alkaloids, include genetics, age (e.g., children and the elderly are at increased risk), preexisting conditions (e.g., kidney disease, heart disease, hypertension, diabetes, thyroid disease, glaucoma, and enlarged prostate), pregnancy, concurrent use of medications (e.g., MAOI, methyldopa), or excessive consumption (see Table 4) (Refs. 39 through 42, 152, and 153). Other factors that may increase an individual's susceptibility to experience adverse events with the use of ephedrine alkaloids include exercise, body size (i.e., lean and normal weight individuals appear to be more susceptible than obese individuals), and dietary intake (i.e., severe caloric and fluid restrictions increase the likelihood of adverse events) (Refs. 39, 42, 119, and 154 through 156).

Significantly, however, many adverse events associated with ephedrine alkaloid-containing dietary supplements occur in individuals who have no apparent risk factors, or who are unaware that they are at risk. Additionally, approximately 40 percent of the reported adverse events occur with the first use or within 1 week of first use, providing little or no warning to consumers of potential risk (see Figure 3). The agency tentatively concludes, therefore, that neither disclosure of the presence of ephedrine alkaloids on the product label nor the use of a warning statement, alone, will be sufficient to protect consumers because many individuals are not aware, and are unable to determine, that they are at risk from consuming ephedrine alkaloids, and serious adverse events may occur on the first use or with very short-term use.

Therefore, the agency has tentatively determined that several measures are needed if the observed adverse events associated with the use of ephedrine alkaloid-containing dietary supplements are to be effectively addressed. These measures are discussed below.

C. Proposal for Dietary Supplements Containing Ephedrine Alkaloids

1. Dietary Ingredient Limit for Ephedrine Alkaloids: Per Serving Basis

One possible strategy for addressing the significant number of adverse effects associated with ephedrine alkaloids in dietary supplements is to restrict the level of the ephedrine alkaloids in these products. In considering this possibility, FDA evaluated two issues: (a) Is there a level at which ephedrine alkaloids cause safety concerns; and (b) if there is, will restricting dietary supplements from containing ephedrine alkaloids at or above that level be adequate, alone, to protect the public health, or will additional steps be necessary.

In considering these questions, FDA evaluated the evidence that provides information on the adverse effects of ephedrine alkaloids that is most relevant to the uses and formulations of marketed dietary supplement products: (a) The published findings from the clinical studies investigating the use of ephedrine for weight loss for the treatment of obesity, and (b) the numerous AER's associated with the consumption of dietary supplements containing ephedrine alkaloids.

First, the agency reviewed clinical trials that have been performed to explore therapeutic uses for ephedrine alone and in combination with other pharmaceutical substances (see earlier discussion in section II.C.2.d. of this document (Refs. 105 through 119)). Information from these trials show that 20 mg ephedrine per dose can cause adverse events to occur in a significant percentage of obese persons (up to 60 percent) prescreened to be free of known risk factors while using these products for a relatively short time (i.e., most adverse events occurred during the first 4 weeks of use). Thus, these studies establish that 20 mg per serving of ephedrine presents potential risks for a subpopulation of morbidly obese persons but provide no information on risk at levels below 20 mg per serving for obese persons. These studies also provide no information on risk at levels below 20 mg per serving for use by persons in the general population (e.g., lean or moderately overweight persons), who are known to be more sensitive to

sympathomimetic substances like ephedrine alkaloids than are the morbidly obese persons who constituted the study population (see section II.C.2.d. of this document). FDA is not aware of any well-designed and conducted studies that evaluate the risks of intakes of ephedrine levels below 20 mg per serving in any population group.

Second, FDA, through its postmarketing surveillance program, has found consistent patterns of adverse events across a broad range of marketed dietary supplement products that contain a variety of ephedrine alkaloid levels per serving. FDA's laboratory analyses of the ephedrine alkaloid levels in the small number of available dietary supplement products that consumers who suffered adverse events turned over to the agency showed that these adverse events were related to ephedrine alkaloid levels from approximately 1 to over 50 mg per serving (Ref. 149). These data, as well as analytical data from samples collected from the marketplace after FDA received AER's from consumers who no longer possessed the product, show a pattern of clinically significant adverse events, including neuropsychiatric effects (e.g., severe depression, seizure), malignant (i.e., extremely high) blood pressure, and myocardial necrosis (i.e., death of the heart muscle) with subsequent cardiac arrest and death, with the use of ephedrine alkaloids at levels approaching and above 10 mg per serving (e.g., seven reports of clinically serious adverse events were associated with products that contained 10 to 15 mg per serving) (Ref. 149a). Clinically significant adverse events were also reported with the use of ephedrine alkaloids at levels that exceeded this range.

FDA has also received a few reports of adverse events, some clinically significant, including tremor, extremely high blood pressure, severe headache, nausea, chest pain, increased heart rate, and insomnia, associated with the use of ephedrine alkaloids at levels below 8 mg (e.g., 2 to 8 mg ephedrine alkaloids per serving) (Ref. 149a). The true clinical significance of these levels of ephedrine alkaloids is difficult to interpret because of the lack of the data (e.g., too few reports with analysis to identify a pattern of clinically serious adverse events at any specific level). Thus, the available information from the AER's and the scientific literature does not provide sufficient data to adequately evaluate risk below approximately 10 mg per serving.

Given the available evidence, it is difficult to ascertain whether there is a threshold level of ephedrine alkaloids below which the general population and susceptible individuals will not experience serious adverse events. The shape of an intake-response curve for any particular adverse effect related to ephedrine alkaloid intakes is not known. In the absence of data that allow a systematic evaluation of intakes of ephedrine and other related alkaloids below 10 mg per serving, it is not possible to adequately define or describe the potential risks and at-risk groups from ephedrine alkaloids. However, the available data, including the AER's and the known physiological and pharmacological effects of ephedrine, provide convincing evidence that clinically serious adverse events will occur at intake levels above 10 mg ephedrine alkaloids per serving.

FDA recognizes, however, that this 10-mg level is also subject to some uncertainty because of such factors as intra-assay variabilities (i.e., difference in analytical results from one run to the next with the same method), natural variabilities in the alkaloid content of botanical ingredients, variations in formulation levels from batch to batch, and inaccuracies in the amounts reported to be taken by consumers. When these sources of variability are considered, given that they are likely to be additive, the range around the 10 mg per serving estimated intake can be expected to deviate by ±10 to 20 percent. Thus, FDA tentatively concludes that the life-threatening adverse events associated with the use of ephedrine alkaloids can reasonably be expected to occur at intake levels as low as 8 to 9 mg ephedrine alkaloids per serving. However, given the limitations in the available data, the agency requests comments on whether it is more appropriate to focus on the 10 mg level.

Based on the available evidence and the likely sources of measurement error around estimated intake levels, the agency tentatively concludes that the use of dietary supplements containing 8 mg or more ephedrine alkaloids per serving may render the dietary supplement injurious to health. The agency also tentatively concludes that consumption of dietary supplements that contain this level or more of ephedrine alkaloids presents a significant and unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling or under ordinary conditions of use, and that, therefore, products that contain this or higher levels of ephedrine alkaloids are adulterated. [1]

To reflect this tentative conclusion, FDA is proposing to adopt § 111.100(a)(1) which states that dietary supplements that contain 8 mg or more ephedrine alkaloids (the total of ephedrine, pseudoephedrine, norpseudoephedrine, norephedrine, methylephedrine, methylpseudoephedrine and related alkaloids) per single serving shall be deemed to be adulterated under section 402(a)(1) and (f)(1)(A) of the act. FDA is proposing to adopt this provision under sections 402(a)(1), (f)(1)(A), and 701(a) (21 U.S.C. 371(a)) of the act.

Under section 402(a)(1) of the act, a food, including a dietary supplement, is adulterated if it bears or contains any added poisonous or deleterious substance that may render it injurious to health. Section 402(f)(1)(A) of the act provides that a dietary supplement is adulterated if it, or one of its ingredients, poses a significant or unreasonable risk of injury or illness when used as directed or under ordinary conditions of use. Under section 701(a) of the act, FDA has authority to issue regulations for the efficient enforcement of the act. These sections authorize FDA to issue a regulation that establishes a level of ephedrine alkaloids that, the available evidence makes clear, will render a dietary supplement adulterated as a matter of law.

FDA tentatively concludes that such a regulation will advance the purposes of the act in two significant ways. First, it will provide guidance to the dietary supplement industry as to a level of ephedrine alkaloids that can be used in their products with some confidence that such products will not be subject to regulatory action. Second, it will make clear that if products that contain higher levels of ephedrine alkaloids are marketed; such products will be considered unsafe and adulterated and will be subject to all the relevant sanctions under the act.

Eight mg per serving and above represent levels at which the presence of ephedrine alkaloids in a dietary supplement may render the product injurious to health and presents a significant and unreasonable risk. FDA cannot say that it is a safe level, nor has

[1] FDA has limited information on which ingredients dietary supplement manufacturers are likely to substitute for ephedrine alkaloids. Given this uncertainty, FDA cannot comment on the safety of potential substitutes. FDA notes that manufacturers bear the burden of ensuring that any ingredients that they may substitute for sources of ephedrine alkaloids meet all safety standards for dietary supplements.

it been arrived at in a way that factored in some margin of safety. The evidence does not exist to establish a safe level. FDA notes that many members of the Food Advisory Committee stated that they were unaware of a basis for determining a safe level (Ref. 25). Thus, the agency is concerned about the potential for risk at levels below 8 mg per serving for individuals who are particularly sensitive to the effects of ephedrine alkaloids, or whose sensitivity could be increased through chronic use of these products or other processes (e.g., physical exercise).

Given the seriousness of the public health concerns and the uncertainty surrounding the risks attendant upon consumption of ephedrine alkaloids below 8 mg per serving, the agency solicits comments, and asks that they include data, particularly clinical data, on the safety of the use of less than 8 mg of ephedrine alkaloids per serving in dietary supplements. Should data and information become available that demonstrate that the use of less than 8 mg of ephedrine alkaloids per serving in dietary supplements poses a hazard to the public health, or that the level of ephedrine alkaloids that will render a product adulterated is higher than 8 mg per serving, the agency will consider modifying § 111.100 accordingly.

At this time, the agency is not proposing a level at which ephedrine, as opposed to the mixture of ephedrine alkaloids found in products containing botanicals, may render a product adulterated, even though some members of FDA's Working Group and of the Food Advisory Committee recommended that the agency establish a separate level for ephedrine (Refs. 25 and 27). There is some reason to believe that ephedrine may be particularly significant in contributing to the occurrence of many of the cardiovascular effects seen in the reports of adverse events because ephedrine is often the predominant alkaloid in botanical sources. In addition, ephedrine is known to exhibit more intense cardiovascular effects relative to the other ephedrine alkaloids (Refs. 5 and 9 through 13). For example, serious adverse events have been reported with the use of dietary supplements containing less than 5 mg ephedrine. However, the available data are difficult to interpret because of the uncertainties about the potentially interactive effects of the other ephedrine alkaloids in the raw botanical or botanical extract and the presence of other physiologically and pharmacologically active ingredients in the dietary supplement products that may act to potentiate the overall NS and CVS stimulatory effects of ephedrine and thus exacerbate the adverse effect. The agency requests comments on whether a separate dietary ingredient limit should be established for ephedrine in addition to ephedrine alkaloids, and if so, what that limit should be.

2. Proposed Compliance Procedures

In proposed § 111.100(a)(2), the agency states that it will use the high performance liquid chromatography (HPLC) method as specified in LIB No. 4053 to determine the level of ephedrine alkaloids in a dietary supplement. The agency developed this HPLC analytical method to identify and quantify ephedrine alkaloids from botanical sources. It was necessary for the agency to develop an analytical method because the official analytical methods used for the determination of ephedrine alkaloids in pharmaceutical dosage forms are unsuitable for botanical products. Current official analytical methods do not discriminate between ephedrine alkaloids and other alkaloids that may be in the botanicals (e.g., ephedroxane and methylbenzylamine) (Ref. 157). This HPLC method has made possible the resolution and quantification of the several different ephedrine alkaloids known to occur in the *Ephedras* and other botanicals, including ephedrine, pseudoephedrine, norephedrine, methylephedrine, methylpsuedoephedrine, norpseudoephedrine, and related alkaloids. This method is currently undergoing collaborative evaluation and testing.

FDA strongly recommends that manufacturers also use this or other methods that the agency adopts, although manufacturers will be free to use any alternative method that they find appropriate. However, FDA will use whatever method it adopts in this proceeding as the basis for its enforcement actions, and this method will be the legally established method. Therefore, manufacturers would be advised to compare their method of choice to the HPLC method to ensure that the alternative method produces similar results.

3. Proposed Limit for Ephedrine Alkaloids: Frequency and Per Total Daily Intake Basis

In addition to proposing a level for ephedrine alkaloids in dietary supplements at or above which their presence will render the product adulterated, the agency is proposing to address its concern that products containing ephedrine alkaloids below the dietary ingredient limit may be used in a manner that increases the likelihood, frequency, and severity of adverse events. Intake of multiple servings of ephedrine alkaloid-containing dietary supplements, particularly when such intake occurs within a relatively short timeframe (e.g., hours or within a day), can result in an excessive level of ephedrine alkaloids in the body that will increase the likelihood of an acute adverse event and the severity of the event that occurs. Concern over the hazards of taking several servings of ephedrine alkaloid-containing dietary supplements in a short period of time led several members of the Working Group and of the Food Advisory Committee to recommend that FDA limit the intake of dietary supplements containing ephedrine alkaloids to no more than four to five times per day and establish daily use limits, e.g., the amount of ephedrine alkaloids the consumer should not exceed in a day. In light of this, FDA evaluated the risks associated with different patterns of daily intake of ephedrine alkaloid-containing dietary supplements.

The average plasma half-lives for pharmaceutical ephedrine, pseudoephedrine, and phenylpropanolamine are approximately 6 hours (range 3 to 11 hours), 6 hours, and 4 hours, respectively (Refs. 10 through 12, 20, and 46). Generally, this means that after one half-life (e.g., 4 to 6 hours) half of the ephedrine alkaloids still remain in the blood. More than 24 hours are needed for complete clearance of a single serving of ephedrine alkaloids from the body. Because ephedrine alkaloids remain in the body for hours, when additional servings of an ephedrine alkaloid-containing dietary supplement are consumed, the ingested alkaloids are additive to those already in the body. This process will result in an increase in blood and tissue concentrations of ephedrine alkaloids. Generally, the higher the blood and other body tissue levels of ephedrine alkaloids, the greater the likelihood and severity of adverse events (Ref. 46).

Given the pharmacological evidence that average plasma half-lives of ephedrine alkaloids are approximately 4 to 6 hours, elevated blood levels of ephedrine alkaloids will be maintained if a serving is consumed every 4 to 6 hours. Because ephedrine alkaloids are stimulant substances, they can cause insomnia if taken close to sleeping hours. Thus, if 6 to 8 hours in a day are typically used for sleeping, there is a period of 16 to 18 hours per day in which consumers of ephedrine-containing dietary supplements would

have interest in consuming this substance. By dividing the 16 to 18 waking hours in a day by the largest average half-life for ephedrine alkaloids (i.e., 6 hours), the results reveal the possibility of taking a maximum of three servings per day.

Three servings of a dietary supplement that contains the proposed maximum per serving amount of ephedrine alkaloids (less than 8 mg) would yield a daily intake level of less than 24 mg ephedrine alkaloids. Thus, a dietary supplement product that contains ephedrine alkaloids and whose label or labeling instructs consumers to take 24 mg or more per day would present a significant and unreasonable risk of injury and illness under the conditions of use suggested or recommended in the labeling and thus would render the product adulterated under section 402(f)(1)(A) of the act. Similarly, an ephedrine alkaloid-containing product whose label or labeling instructs consumers to take 8 mg or more during a 6-hour period would instruct consumers to consume an amount of ephedrine alkaloids that has been shown to cause injury. This labeling also would present a significant and unreasonable risk and render the product adulterated under section 402(f)(1)(A) of the act.

FDA tentatively concludes that without a daily use limit, the per serving limit cannot be effective in reducing the potential for adverse events because consumers may unknowingly consume an excessive amount of ephedrine alkaloids by taking several servings of dietary supplements in a relatively short period of time. Therefore, FDA is proposing in § 111.100(b) that the labeling of dietary supplements that contain ephedrine alkaloids shall not suggest or recommend conditions of use that would result in intake of 8 mg or more ephedrine alkaloids within a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids. FDA is proposing this regulation under sections 402(f)(1)(A) and 701(a) of the act to ensure that ephedrine alkaloid-containing dietary supplements do not bear directions for use that will create a significant and unreasonable risk.

In some cases, the label directions for use of dietary supplements containing ephedrine alkaloids can cause consumers to exceed the per serving limit or to consume servings more frequently than every 6 hours. For example, FDA would consider the following label instructions to increase the risk of adverse events: ''take what your body needs'' or ''take 1 tablet (containing 7 mg ephedrine alkaloids) per serving, not to exceed 3 tablets per day.'' In the later example, the consumer may believe that it is safe to consume 3 tablets (21 mg ephedrine alkaloids) at one serving or servings separated by less than 6 hours. Examples where the agency would not consider that the directions for use would cause consumers to exceed the per serving limit or take serving more frequently than every 6 hours include ''take 1 tablet per day,'' ''take 1 tablet every 6 hours, do not take more than 3 tablets per day,'' or ''take 1 tablet not more than every 8 hours, do not take more than 2 tablets per day.''

4. Proposed Limitation on Duration of Use

The available data suggest that some types of adverse events may be related to the duration of using ephedrine alkaloids. Long-term use of sympathomimetic agents, such as ephedrine alkaloids, even at relatively low levels, is related to serious adverse events, including cardiomyopathy (i.e., disease of the heart muscle) and myocardial necrosis (death of heart cells and tissue), that can result in death (Refs. 7, 16, 49, 51, and 52). The scientific literature establishes that use of ephedrine alkaloids for a period of several months or years can result in cardiomyopathy (Refs. 66 through 68). Similarly, fatal cardiomyopathies have been seen in the AER's associated with chronic use of ephedrine alkaloid-containing dietary supplements at serving levels close to the dietary ingredient limit the agency proposed above (ARMS No. 11134 in Refs. 29 and 149a).

Concern about these types of adverse events with the long-term use of ephedrine alkaloids led several members of the Working Group (Ref. 27) and of the Food Advisory Committee (Ref. 25) to recommend that, in conjunction with a per serving dietary ingredient limit, FDA require a statement on the label of ephedrine alkaloid-containing dietary supplements to warn consumers not to use the product for a period longer than 7 days. These members stated that a 7-day use limit is standard guidance for the use of pharmacoactive drug substances, including ephedrine alkaloids, and may reduce the occurrence of adverse events related to long-term use of ephedrine alkaloids (Ref. 25). Moreover, a 7-day limit on the use of ephedrine alkaloids is supported by the AER's data, which show that over 60 percent of the adverse events occurred when ephedrine alkaloid-containing dietary supplements were used for more than 7 days.

For these reasons, FDA tentatively concludes that ephedrine alkaloid-containing dietary supplements that do not bear the statement ''Do not use this product for more than 7 days'' present a significant and unreasonable risk of injury and illness under the recommended or suggested conditions of use. Therefore, under sections 402(f)(1)(A) and 701(a) of the act, to reduce the potential for adverse events occurring as a result of consumers using ephedrine alkaloids for more than a period of 7 days, FDA is proposing to require in § 111.100(c) that the label of dietary supplements that contain ephedrine alkaloids state ''Do not use this product for more than 7 days.''

The agency notes that this warning focuses on duration of use, not on when reinstitution of use of ephedrine alkaloids is appropriate. FDA is not aware of definitive data on whether there is a period of time when the reinstitution of use of ephedrine alkaloids will not present a risk of adverse events. FDA solicits comments, particularly data, on this matter. In addition, FDA solicits comments on how consumers will interpret this label statement in terms of reintroducing dietary supplements containing ephedrine alkaloids in their diets.

5. Proposed Prohibition of Ingredients With Stimulant Effects

As previously discussed, because the nature and patterns of adverse events observed in the AER's were consistent with the known physiological and pharmacological effects of the ephedrine alkaloids, the agency focused its evaluation on the ephedrine alkaloids. However, the majority of the adverse events that have been reported to FDA have involved the use of dietary supplements that contain ephedrine alkaloids in combination with other ingredients, some with known physiological or pharmacological effects, including kola nut, yohimbe, willow bark, senna, and Uva ursi (Ref. 164). In many cases, the AER's showed that more severe adverse effects (e.g., heart attack, stroke, seizure) occurred with the use of dietary supplements that contained ephedrine alkaloids at levels below 20 mg together with other ingredients than were noted in the scientific literature with the use of ephedrine at 20 mg (Ref. 149a). These observations suggest that the other ingredients may act, in combination with the ephedrine alkaloids, to produce more frequent, more severe, or potentially different patterns of adverse effects than those noted with the use of an ephedrine alkaloid alone.

Moreover, the clinically significant adverse events that occurred with amounts of ephedrine alkaloids below the 8 mg per serving limit may have been related to the compounding effects of ephedrine alkaloids in combination with other ingredients. Because of the known additive effects that occur when ephedrine alkaloids are combined with certain types of other ingredients, such as stimulants, proposed § 111.100(a)(1), by itself, will likely not be effective in reducing the potential for adverse events. Certain types of other substances interact with the ephedrine alkaloids to increase the effects of the ephedrine alkaloids, thereby acting like more ephedrine alkaloids were contained in the product.

For example, caffeine is a nervous system stimulant that can induce nervousness, insomnia, and tachycardia (increased heart rate) (Refs. 7, 165, and 166). Intake of toxic levels of caffeine can cause death resulting from CV stimulatory effects (Ref. 46). Various botanicals are known to be sources of caffeine, including green tea, guarana, yerba mate (also known as *Ilex paraguariensis*), and kola nut (Refs. 167 through 172).

The scientific literature reveals that the frequency and severity of adverse effects increase when ephedrine alkaloids and caffeine are combined (Refs. 22, 73, 105, and 106). Recent clinical trials have focused on whether a combination of ephedrine and caffeine would be more effective in the treatment of obesity than ephedrine alone. The usual dosage of ephedrine and caffeine was 20 mg and 200 mg, respectively, given three times a day before meals. The results of these trials, certain of which were carefully designed and conducted to eliminate potential confounders to the interpretation of study results (e.g., concurrent medication usage, underlying diseases and conditions or other risk factors), indicate that the effects, including adverse effects, of combining ephedrine and caffeine are synergistic (Refs. 105, 173, and 174).

Caffeine and ephedrine also appear to be synergistic in thermogenesis, i.e., they increase the rate of thermogenesis by influencing different parts of the metabolic pathways (Refs. 173 and 175). While the resulting effects of combining ephedrine and caffeine could have a potentially positive impact on thermogenesis because of their effects on metabolic pathways, it may also account for increased adverse effects seen with combinations of these agents because of increased sympathetic stimulation of other organ-systems (e.g., CVS and NS). The synergistic adverse effects include an increased frequency of certain signs and symptoms, e.g., increased heart rate, insomnia, nervousness, and increased blood pressure, that are considered characteristic of sympathomimetic stimulation.

Other substances with stimulant effects in combination with ephedrine alkaloids may act to increase the likelihood of an adverse event. Yohimbine from the botanical yohimbe, in small doses, is reported to stimulate part of the nervous system and to cause elevated blood pressure, increased heart rate, tremor, and anxiety (Refs. 176 through 178). Because of their stimulant effects on the nervous system, combining sources of yohimbine with the ephedrine alkaloids may increase the likelihood, frequency, and severity of adverse events.

Therefore, the agency tentatively concludes that, based on the available evidence, adverse events may be related to the interactive or additive effects of stimulant substances in combination with ephedrine alkaloids in dietary supplements. This tentative conclusion is supported by statements made by several members of the Food Advisory Committee at the August 27 and 28, 1996, meeting (Ref. 25). For these reasons, the agency tentatively concludes that any dietary supplement that contains ephedrine alkaloids in combination with ingredients that produce the aforementioned effects presents a significant or unreasonable risk of injury or illness under the conditions of use suggested in the labeling or under ordinary conditions of use and are adulterated. To eliminate this risk, under sections 402(f)(1)(A) and 701(a) of the act, FDA is proposing § 111.100(d), which states that no ingredient, or ingredient that contains a substance, that has a known stimulant effect (e.g., sources of caffeine, yohimbine) may be included in a dietary supplement that contains ephedrine alkaloids.

The agency is aware that several manufacturers and distributors of ephedrine alkaloid-containing dietary supplements also market caffeine-containing dietary supplements that are intended to be used with a ''companion'' ephedrine alkaloid-containing dietary supplement. The caffeine-containing dietary supplements are often promoted as ''boosters'' or ''enhancers'' for the ephedrine alkaloid-containing product. Under these conditions of use, both the caffeine-containing and the ephedrine alkaloid-containing dietary supplement products present a significant and unreasonable risk of illness and injury under their labeled conditions of use and consequently are adulterated under section 402(f)(1)(A) of the act.

The agency is concerned that many of the dietary supplements implicated in the AER's contained substances that are known to have physiological or pharmacological effects that could increase the risk of adverse events when taken in combination with ephedrine alkaloids. For example, substances that reduce renal clearance interfere with the elimination of ephedrine alkaloids from the body by the kidneys (i.e., renal excretion) (Refs. 180 and 181) and thus may increase the risk of adverse effects when consumed in combination with ephedrine alkaloids. These substances include salicin, which is found in the botanical commonly known as willow bark, and amino acids in high concentrations (Refs. 181 and 182). By reducing renal clearance, higher levels of ephedrine alkaloids are maintained in the blood for longer periods of time, thus prolonging the effects of ephedrine alkaloids. The maintenance of high blood levels of ephedrine alkaloids increases the likelihood of adverse events, particularly in those who may be sensitive to the effects of ephedrine alkaloids. In addition, consumers may experience adverse events if more ephedrine alkaloids are consumed while blood levels are maintained because the absorption of additional ephedrine alkaloids into the bloodstream will result in even higher blood and tissue concentrations of ephedrine alkaloids and in any effects that may follow. Generally, the higher the blood levels of ephedrine alkaloids, the greater the risk of adverse events and the greater the likelihood that the adverse effects that do occur will be severe (Ref. 46).

Diuretics and laxative substances in an ephedrine-alkaloid-containing dietary supplement may also increase the likelihood, frequency, and severity of adverse events (Refs. 182 through 186). Uva ursi is a botanical diuretic contained in many ephedrine alkaloid products (Ref. 184). The compounds ursolic acid and isoquercetin found in Uva ursi are mild diuretics. The ephedrine alkaloids also exhibit diuretic effects (Ref. 4). For example, ephedrine has a mild diuretic effect, and pseudoephedrine has a marked diuretic effect. The use of a product that contains ephedrine alkaloids in combination with other substances with diuretic effects increases the likelihood and severity of consequent fluid and electrolyte imbalances, both of which could affect CVS and NS risks.

Senna and Cascara are examples of botanicals that contain potent stimulant laxative substances called

anthraquinone glucosides (Refs. 185 through 187). Use of excessive amounts of stimulant laxatives can cause stomach cramps, nausea, vomiting, and diarrhea. Chronic use may lead to laxative dependence, diarrhea, and, in severe cases, dehydration and electrolyte disorders (Ref. 188). Ephedrine is known to influence cellular potassium (an electrolyte) concentrations (Refs. 53 and 54). Use of laxative substances in combination with ephedrine alkaloids may act to increase the likelihood, frequency, and severity of adverse events. The agency requests comments, particularly data, on the interactive effects of other ingredients and the ephedrine alkaloids in dietary supplements. Based on the comments and data received by FDA, the agency may prohibit the use of ingredients that produce the aforementioned effects in a dietary supplement that contain ephedrine alkaloids.

6. Proposed Prohibitions on Claims

As described previously in section II.C.1. of this document, FDA has received numerous reports of adverse events associated with ephedrine alkaloid-containing dietary supplements promoted for use for weight loss, increased energy, body building, enhanced athletic performance, increased mental concentration, and enhanced well-being and with products promoted to be used as an alternative to illicit street drugs. While many of the products that were associated with adverse events contained more than one type of claim or representation on their label or in their labeling, the majority of adverse events reported to FDA are related to the use of products promoted or used for weight loss or energy purposes. Although fewer of the AER's were associated with products promoted for body building and enhanced well-being, clinically serious adverse events, including seizure, heart attack, and death, have been reported to FDA that were associated with the use of products represented for these purposes. At least one death in a young man has been reported with the use of a product promoted as an alternative to an illicit street drug.

In reviewing the AER's, it was evident that specific types of claims contained in the labeling of dietary supplements containing ephedrine alkaloids promoted different patterns of use. Claims such as weight loss and body building encouraged long-term use to achieve the product's purported effect (Ref. 189). In addition, claims of increased energy, increased mental concentration, or enhanced well-being, in a number of cases, encouraged short-term excessive consumption to achieve more of the product's purported effect (Ref. 190). Finally, the agency found that claims that suggest that the product is intended to be used as a substitute for an illicit street drug fostered abuse. Because claims in product labeling may influence how a consumer uses the product, claims in product labeling are a condition of use for dietary supplements.

Several Food Advisory Committee members identified a number of significant risks attendant to using dietary supplements containing ephedrine alkaloids for purposes such as weight loss, energy, or as an illicit street drug alternative, including adverse events that are associated with long-term use, excessive consumption, and abuse of ephedrine alkaloids (Ref. 25). Because the identified types of claims promote use patterns that are associated with adverse events, the agency has tentatively concluded that claim restrictions are necessary to maintain the integrity of the limit on the level of ephedrine alkaloids in dietary supplements that it is proposing in § 111.100(a)(1) and of the other proposed restrictions on the conditions of use of these dietary supplements.

a. *Claims that promote long-term use.* Claims in the labeling of dietary supplements that use of a product may result in effects such as weight loss or body building promote long-term use of the product because these effects cannot be achieved in a short period of time. Weight loss occurs when caloric intake is reduced or energy expenditure (e.g., exercise) is increased. To lose 1 pound (lb), approximately 3,500 kilocalories (kcal) must be expended by reducing caloric intake or by increasing energy expenditures (e.g., physical activity) or both (Ref. 191). Rapid weight loss is associated with health risks, including increased protein loss from the body stores and increased risk of gallstone formation (Ref. 27). In fasting, over 50 percent of rapid weight reduction is attributable to the loss of body fluids. Risks associated with rapid loss of fluids from the body include hypotension (i.e., reduction in blood pressure) and electrolyte disturbances. Steady weight loss over a longer period of time results in a true weight loss with a reduction of fat stores (Ref. 193). Guidelines recommend that a safe rate of weight loss is ½ to 1 lb per week (Ref. 194). Therefore, depending upon the amount of weight loss that the individual desires to achieve, weight loss programs may extend from weeks to months (Ref. 195).

Long-term weight loss practices have been documented in the scientific literature. A survey of weight control practices among 1,431 adults indicated that the average respondent participating in the survey had a weight loss attempt lasting from 5 to 6 months and had averaged one attempt a year for the past 2 years (Ref. 196). In addition, approximately 30 percent of persons trying to lose weight were chronic dieters and had been on weight loss plans at least 1 year (Ref. 196). Thus, this survey indicates that common weight loss practices can be characterized as long-term in duration and recurrent in nature.

Conversely, body building involves the building of lean muscle mass by strength and endurance training. The addition of muscle mass can be accomplished only through regular muscle work (weight training or similar conditions) coupled with a caloric increase (Ref. 197). To increase size and strength, a muscle must be exercised at 60 to 80 percent of its capacity several times a week. In addition, a gain of 1 lb of muscle requires about 2,500 extra calories, in addition to the calories needed for the training (Ref. 197). An increase of 700 to 1,000 calories (cal) to the daily diet should support a gain of 1 to 2 lb of lean muscle in 7 days (Ref. 197). Body building systems that include intensive physical training programs, controlled diet, and dietary supplementation purport to achieve results in 6 weeks (Ref. 198), and the individual must continue a training program to maintain or increase the muscle mass.

As previously mentioned in section III.C.4. of this document, long-term use of ephedrine alkaloids, even at relatively low levels, is related to serious adverse events, including cardiomyopathy (i.e., disease of the heart muscle) and myocardial necrosis (death of heart cells and tissue), that can result in death. After reviewing the scientific literature and the AER's as well as recommendations by the Working Group and by the Food Advisory Committee, FDA has tentatively concluded that ephedrine alkaloid-containing dietary supplements must bear the statement ''Do not use this product for more than 7 days,'' and that those that do not present a significant and unreasonable risk of injury and illness under the recommended or suggested conditions of use.

Significant and safe results from weight loss or body building should not and cannot be achieved within a period of 7 days. An individual could lose approximately 4 lb of body fat in 7 days under complete fasting conditions if the normal energy requirements are 2,000 cal per day. (This assumption is based

on the fact that 3,500 kcal must be expended to achieve 1 lb of weight loss.) As discussed above, however, this rate of weight loss is not safe or recommended.

Regarding body building, lean muscle mass cannot be built in 7 days (Ref. 197). Moreover, the scientific literature evidences that the use of ephedrine alkaloids during intense physical activity, such as body building, increases the risks of serious adverse events. Use of ephedrine alkaloids during periods of intense physical activity results in enhanced or synergistic actions on the sympathetic nervous system. It is through such enhanced physiological processes that chronic effects on the heart, such as myocardial necrosis (i.e., death of heart cells and tissue), can occur with prolonged use of ephedrine alkaloids (Refs. 16 and 197a).

Because safe and significant weight loss and body building cannot be achieved in a 7-day period, claims that promote these uses promote long-term use of ephedrine alkaloid-containing dietary supplements, which has been associated with serious adverse events. For this reason, FDA tentatively concludes that any claims that promote long-term use of ephedrine alkaloid dietary supplements, such as those for weight loss and body building, promote conditions of use that present a significant and unreasonable risk of illness and injury. Therefore, under sections 402(f)(1)(A) and 701(a) of the act, the agency is proposing in § 111.100(e) to prohibit dietary supplements that contain ephedrine alkaloids from being represented, either expressly or implicitly, for use for long-term effects such as weight loss or body building.

b. *Claims that promote short-term excessive consumption.* Many claims found on the labels of, or in the labeling for, ephedrine alkaloid-containing dietary supplements, including increased energy, increased mental concentration, and enhanced well-being, encourage the consumer to take more of the product than is indicated on the label to achieve more of the purported effect. Several members of the Food Advisory Committee stated that when a product is promoted to increase these types of effects, the claim encourages the consumer to exceed the labeled directions for use to gain more of the desired effects (Ref. 25). For example, if a product is promoted for energy, the consumer is encouraged to take more to gain greater energy.

Many of the AER's received by the agency were associated with dietary supplements containing ephedrine alkaloids that were promoted for one or more of these purposes. In a number of instances, the consumer took more than directed on the product label and experienced an adverse event (Ref. 190). Claims that promote excessive consumption, even for one or a very limited number of uses, are inconsistent with proposed § 111.100 (a)(1) and (b), because they encourage the consumer to take more than directed in the conditions of use set out on the label so that the consumer can achieve the purported effect.

In section II.C.2.a. and II.C.2.b. of this document, FDA described data from the clinical literature and AER's that show that consumption of an excessive amount of ephedrine alkaloids in a relatively short period of time is associated with serious adverse events, including seizure, psychosis, mania, heart attack, and death. The agency tentatively concludes that the potential for these serious adverse events to occur with excessive consumption of ephedrine alkaloids is a material fact with respect to consequences that may result from the use of a dietary supplement promoted for short-term effects that encourage excessive consumption, and therefore a material fact that must be disclosed on the label.

FDA's authority to require disclosure statements in the labeling of dietary supplement products derives from sections 201(n), 403(a)(1), and 701(a) of the act. Section 201(n) of the act states, ''If an article (e.g., a food or dietary supplement product) is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations or material with respect to consequences that may result from the use of the article to which the labeling or advertising thereof or under such conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.'' Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Thus, the omission of a material fact from the label or labeling would misbrand a product. These statutory provisions, combined with section 701(a) of the act, authorize FDA to issue a regulation designed to ensure that persons using ephedrine alkaloid-containing dietary supplements will receive information that is material with respect to consequences that may result from the use of the supplement under its labeled conditions.

Therefore, FDA is proposing in § 111.100(f)(1) that the label or labeling for dietary supplements that contain ephedrine alkaloids that purport to be or are represented, either expressly or implicitly, to be used for short-term effects, such as increased energy, increased mental concentration, or enhanced well-being, must state ''Taking more than the recommended serving may cause heart attack, stroke, seizure, or death.'' However, given the significance and the potentially life-threatening nature of the adverse events that may occur when individuals consume excessive amounts of ephedrine alkaloids, the agency requests comments on whether this statement should appear on the label of dietary supplements containing ephedrine alkaloids, regardless of any claims appearing on the label or in labeling.

FDA wants to provide an approach to placement of this information that will give it a prominence that will ensure that it will be read and understood by consumers but that will result in its presentation only once on the label panel or on each page of the labeling. Because the consequences of excessive use of ephedrine alkaloids can be serious, the agency tentatively concludes that this information should be on the same label panel or on the same page of the labeling (i.e., the same field of vision) as the claim. However, FDA is proposing to provide for the use of one disclaimer on the label panel or on each page of labeling in situations in which multiple claims appear on the label panel or page of labeling where repetitive presentation of the disclaimer could be burdensome. FDA tentatively concludes that where the label panel or page of labeling contains multiple claims, and the relationship between each of those statements and the disclaimer can be made obvious, the disclaimer need only appear once on each label panel or in each page of labeling.

FDA experience has been that one of the most effective ways of tying two label statements that are physically separate on the same panel is through the use of a symbol such as an asterisk. Symbols have been used within nutrition labeling since its inception in 1973 and have proven to be an effective way of relating labeling information to explanatory footnotes. For example, asterisks have been used adjacent to names of vitamins and minerals present at very low levels to refer the consumer to a footnote stating ''Contains less than

2 percent of the Daily Value (formerly the U.S. Recommended Daily Allowance).'' FDA is unaware of any data indicating consumer difficulties with such use of symbols. The use of symbols would also help differentiate between the label statements to which the disclaimer is referring and the other label claims to which the disclaimer does not apply (e.g., authorized health claims or nutrient content claims).

The agency points out that the proposed requirements for the disclaimer also extend to labeling: There are potentially many vehicles (e.g., placards, pamphlets, catalogs, books) that would have to bear the disclaimer. The agency is concerned that the disclaimer be prominent in these forms of labeling. Even with the flexibility of the use of an asterisk to tie the claim and the disclaimer to a single claim, the disclaimer could be obscured in pages of text of a package insert, pamphlet, or book if it did not appear on the same page or panel (i.e., in the same field of vision) as the claim itself. Because of the variety of possibilities for the presentation of the disclaimer, the agency tentatively concludes that for labeling, as for labels, it is important that the disclaimer appear within the same field of vision, that is, on each package panel or page where a claim is made.

Section 403(f) of the act requires mandatory label or labeling information to be prominently placed on the label with such conspicuousness (compared with other words, statements, designs, or devices, in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of use. In other instances where information must appear in a prominent and conspicuous manner on the product label, FDA has proposed that the information be ''in easily legible print or type in distinct contrast to other printed or graphic matter'' (e.g., § 101.13(d)(2)). Therefore, to be consistent with previous actions and to ensure that the information is presented in a way that makes it likely to be read, FDA tentatively concludes that the information be presented in easily legible print or type in distinct contrast to other printed or graphic matter.

FDA has long held that accompanying information should be in a size reasonably related to that of the information it modifies (e.g., §§ 101.22(i)(2) and 102.5(b)(2)(ii)). More recently, this relative prominence has been expressed as a size no less than that required by § 101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the accompanying information can be no less than one-half the type size of the information modified, but no smaller than one-sixteenth of an inch (see e.g., § 101.13(g) (1) and (i)(2)). The agency also has long held that one-sixteenth of an inch is the minimum type size for disclaimer statements, unless the package complies with § 101.2(c)(5) (see e.g., § 101.13(g)(1) and (i)(2)). One-sixteenth of an inch is specified in § 101.2(c) as the minimum type size for most other mandatory information on the principal display panel or information panel, e.g., designation of ingredients, name and place of business, and quantitative information for relative claims. Consequently, the agency tentatively concludes that the minimum type size for such information should be one-sixteenth of an inch.

Accordingly, FDA is proposing to provide for the disclaimer, as outlined above, in § 111.100(f)(2). If FDA adopts § 111.100(f)(2), the labeling of a dietary supplement that contains ephedrine alkaloids and that purports to be, or that is represented as, useful for short-term effects, such as increased energy, increased mental concentration, or enhanced well-being, would be misleading, and thus misbranded, if it does not include the disclaimer set out in § 111.100(f)(1).

The agency recognizes that most of the claims that will require the use of the disclaimer, if this proposal is adopted, will be statements that are made subject to section 403(r)(6) of the act. That provision also requires that a disclaimer accompany the statements. In the **Federal Register** of December 28, 1995 (60 FR 67176), FDA proposed requirements for the disclaimer that is required to accompany statements made under section 403(r)(6) of the act. FDA requests comments on how best to place the disclaimer proposed in this document in conjunction with the disclaimer required under section 403(r)(6) of the act on the label or in labeling of dietary supplements so that both disclaimers will be read and understood by consumers.

c. *Claims that suggest that the product is intended to be used as a substitute for an illicit street drug.* FDA is aware that some ephedrine alkaloid-containing products are being promoted as alternatives or substitutes for such illicit street drugs as MDMA (4-methyl-2, dimethoxyamphetamine), a methamphetamine analogue. MDMA is also known as ''ecstasy,'' ''XTC,'' and ''X.'' The precursor of MDMA is MDA (3,4 methylene dioxyamphetamine), an amphetamine whose use results in destruction of serotonin-producing neurons that play a direct role in regulating aggression, mood, sexual activity, and tolerance to pain (Ref. 16). Many products claiming to be herbal alternatives to MDMA bear claims on their label or in the labeling that highlight these mood-or mind-altering effects.

Such street drug alternative claims do not fall within the scope of the claims that Congress intended to permit on the labels or in the labeling of dietary supplements. The Dietary Supplement Health and Education Act of 1994 (the DSHEA) added section 201(ff) to the act (21 U.S.C. 321(ff)), which provides, in part, that the term dietary supplement means a product ''intended to supplement the diet'' that bears or contains one or more dietary ingredients. While Congress did not elaborate in the legislative history on what it intended the phrase ''intended to supplement the diet'' to mean, many of the congressional findings set forth in the DSHEA suggest that Congress intended dietary supplements to augment the diet to promote health and reduce the risk of disease.

In using the term ''diet'' in section 201(ff) of the act, Congress did not define this term in either the act or the legislative history. The term ''diet'' is defined in Webster's Dictionary as ''an organism's usual food and drink'' (Ref. 200). Dorland's Medical Dictionary defines ''diet'' as ''the customary allowance of food and drink taken by any person from day-to-day, particularly one especially planned to meet specific requirements of the individual, and including or excluding certain items of food'' (Ref. 201). These definitions suggest that the diet is composed of usual food and drink that may be designed to meet specific nutritional requirements. Under section 201(ff) of the act, dietary supplements are food except for purposes of section 201(g) of the act and thus may be part of, or augment, the diet. These common sense definitions for the term ''diet'' do not encompass alternatives to illicit street drugs.

Products promoted to be an alternative to or substitute for an illicit street drug are intended to be used for recreational purposes to effect psychological states (e.g., to ''get high'' or to promote feelings of euphoria). Illicit street drugs are not food or drink and thus, cannot supplement the diet. In addition, use of products claiming to be alternatives to illicit street drugs does not promote health or reduce the risk of disease, the intended use for dietary supplements suggested in the

congressional findings listed in the DSHEA. In fact, serious adverse events, including cardiac arrhythmia that resulted in death, are associated with the use and abuse of products promoted for use as an alternative to MDMA (see ARMS No. 10862 in Ref. 149a).

Because alternatives to illicit street drugs are not intended to be used to supplement the diet, products that purport to be or that are represented, either expressly or implicitly, for use as an alternative to a street drug are not dietary supplements within the meaning of section 201(ff) of the act. Therefore, manufacturers, packers, and distributors cannot take advantage of the exemption for structure function claims from the drug definition in section 403(r)(6) of the act. Because these products are intended to be used to affect the structure and function of the body, they are drugs within the meaning of section 201(g)(1)(C) of the act.

7. Warning Label Statements

Several members of the Working Group and of the Food Advisory Committee recommended that specific information be conveyed in a warning or cautionary statement for ephedrine alkaloid-containing dietary supplements (Refs. 25 and 27). Persons having certain diseases or taking specific medications known to interact with ephedrine alkaloids are at risk of suffering adverse events with the use of dietary supplements containing ephedrine alkaloids. Generally, use of ephedrine alkaloids at any intake level by these persons is contraindicated (Refs. 10 through 12, and 55). For these persons, a warning label statement can be a useful means of alerting them to potential consequences that can result from the use of the product. Table 5 identifies groups that are at risk if they use ephedrine alkaloids. In addition, many consumers who are unaware that they are sensitive to the effects of ephedrine alkaloids may not recognize the significance of early warning signs and symptoms as potential indicators of more serious side effects (e.g., dizziness or severe headache may be early symptoms of hypertension or stroke). Under these circumstances, a warning statement could provide information on what actions the consumer should take if certain symptoms occur.

FDA has received several AER's, some clinically significant, that were associated with the use of dietary supplements containing ephedrine alkaloids at levels below the level proposed in § 111.100(a)(1) where signs and symptoms including high blood pressure, chest pain, increased heart rate, severe headache, and nausea were observed (Ref. 149a). Although these AER's are not sufficient to support a lower per serving limit, they do provide cause for concern for lower per serving levels. To reduce the potential for adverse events to occur at these lower per serving levels, FDA tentatively concludes that a warning statement on the labels of dietary supplements containing ephedrine alkaloids is necessary, in conjunction with dietary ingredient limitations and other requirements proposed in this document, to protect the public health.

FDA is therefore proposing in § 111.100(g) to require that a specific warning statement appear on the labels of dietary supplements containing ephedrine alkaloids. FDA's authority to require label warning statements on dietary supplement products derives from sections 201(n), 403(a)(1), and 701(a) of the act. These statutory provisions authorize FDA to issue a regulation designed to ensure that persons using dietary supplements will receive information that is material with respect to consequences that may result from the use of a product under its labeled conditions.

a. *Caution statement suggested by industry.* Several dietary supplement industry trade groups met with FDA on November 30, 1995, and suggested that dietary supplements containing ephedrine alkaloids bear a specific warning statement (Ref. 199). Representatives from the National Nutritional Foods Association (NNFA), the American Herbal Products Association (AHPA), the Nonprescription Drug Manufacturers Association (NDMA), and the Utah Natural Products Alliance (UNPA) (hereinafter referred to as the dietary supplement industry [2]) recommended the following statement:

CAUTION: Taking more than the recommended amount will not necessarily increase benefits. Begin use with one-half or less the recommended dose to assess your tolerance. (If Pertinent) Please note: This product contains caffeine and should not be taken by those wishing to eliminate caffeine from their diet. Seek advice from a health care practitioner if you are pregnant or nursing or if you are at risk or are being treated for high blood pressure, heart, thyroid or psychiatric disease, diabetes, depression, seizure disorder, stroke or difficulty in urination due to prostate enlargement. Consult your health care professional before use if you are taking an MAO inhibitor or any other prescription drug. Discontinue use and consult your health care professional if dizziness, nausea, sleeplessness, tremors, nervousness, headache, heart palpitations or tingling sensations occur. **NOT INTENDED FOR SALE TO OR USE BY PERSONS UNDER THE AGE OF 18. KEEP OUT OF REACH OF CHILDREN. DO NOT EXCEED RECOMMENDED DOSE.**

FDA has carefully considered proposing adoption of the statement suggested by industry. While the agency considers the industry suggestion to be a good starting point, FDA tentatively concludes that some changes are necessary in the statement if it is to fulfill its purpose of fairly warning consumers about the special risks attendant to use of dietary supplements that contain ephedrine alkaloids.

b. *Tentative conclusions.* The dietary supplement industry suggested that the warning statement begin with the term ''caution.'' FDA, however, questions whether this term is adequate to convey the severity of the harm that can result from the use of the product. Because use of ephedrine alkaloid-containing dietary supplements has the potential to cause serious injury to certain subgroups of the population, the agency tentatively concludes that the use of the term ''WARNING'' is warranted. The term ''WARNING'' is commonly used to denote danger, and, therefore, the use of this term will communicate to consumers the harm that could result to the special populations that are the subject of the warning.

The dietary supplement industry suggested that the statement include the instruction ''Seek advice from a health care provider if you are pregnant or nursing or if you are at risk or are being treated for high blood pressure, heart or thyroid disease, diabetes, difficulty in urination due to prostate enlargement.'' Several members of the Working Group and of the Food Advisory Committee recommended that a warning statement direct consumers who have certain diseases or conditions that increase the risk of adverse events not to use the product or to see a health care provider prior to using the product (Refs. 25 and 27). The feeling of these members was that a health care provider could assess the potential risks for the individual consumer if he or she uses the product.

FDA concurs with this portion of the industry's labeling recommendation. As discussed in section II.C. of this document, based on the scientific literature and the known physiological and pharmacologic effects of ephedrine alkaloids, an individual who is pregnant or nursing, has high blood pressure, heart or thyroid disease, or difficulty in

[2] FDA is using this shorthand for convenience. It does not intend to imply that these groups represent the entire dietary supplement industry.

urination because of prostate enlargement has an increased risk for experiencing serious adverse effects with the use of ephedrine alkaloids. However, FDA also tentatively finds that the warning statement should be broadened to address other individuals who may place themselves at particular risk if they consume the product. The relevant scientific literature, case reports and AER's suggest that persons suffering from depression or other psychiatric conditions, glaucoma, or seizure disorders are also at increased risk of experiencing an adverse event if they consume ephedrine alkaloid-containing products.

Use of ephedrine alkaloids during pregnancy or while nursing can cause adverse effects in the fetus or the infant. Ephedrine alkaloids can cross the placental wall and can be absorbed by the fetus when taken by a pregnant woman (Refs. 10 through 12 and 55). Similarly, ephedrine is excreted in the breast milk and can be consumed by the nursing infant. The fetus, infants, and children are sensitive to the effects of ephedrine alkaloids and thus are more likely to experience adverse events (Refs. 39 and 41).

Use of ephedrine alkaloids by persons with high blood pressure can result in blood pressure elevations or loss of adequate medical control of hypertension (Ref. 64) which increases the risk of serious consequences (e.g., stroke and heart attack) (Refs. 62 and 70). Because ephedrine alkaloids also interfere with the regulation of serum potassium levels (Refs. 53 through 55), individuals with heart disease who use ephedrine alkaloids are at greater risk of cardiac dysrhythmias (i.e., abnormal heart rhythms) (Refs. 18 and 56), myocardial ischemia (i.e., inadequate circulation of blood and oxygen to the heart muscle), and infarction (i.e., death or damage of heart cells, also called heart attack) (Refs. 57 through 61).

With respect to thyroid disease, individuals with hyperthyroidism (resulting from increased secretion of thyroid hormone) show increased sensitivity to adrenergic agents, such as ephedrine alkaloids, which can result in thyroid storm with dire consequences (e.g., cardiac dysrhythmias, congestive heart failure, coma, and death) (Refs. 39, 41, 55, and 202).

For persons with diabetes, use of sympathomimetics can result in an increase in blood sugar and loss of diabetic control (Refs. 29, 41, and 51). In addition, ephedrine can cause constriction of the urinary bladder sphincter and ultimately lead to dysuria (increased, painful, or difficulty in urination). This condition is not only associated with prostate enlargement or only seen in men. Published case reports and AER's received by the agency document the finding that urinary retention following the use of ephedrine alkaloid-containing products can occur in both females and males, including young boys without any history of prostate enlargement (see ARMS No. 10298 and 11164 in Ref. 149a and Refs. 102, 103, 123, and 124).

Use of ephedrine alkaloids by persons suffering from depression or other psychiatric conditions increases the risk for the occurrence of serious adverse events, including psychosis and mania (Refs. 81 through 96, 98, 99, 109, and 220). Because ephedrine can cause an increase in intraocular pressure (i.e., pressure inside the eyeball), use of ephedrine alkaloids by persons with glaucoma will worsen this disease, which over time, can result in blindness (Refs. 39 and 41). Finally, persons with seizure disorders who use ephedrine alkaloids have an increased risk for experiencing a seizure (Refs. 63, 65, and 80). Because the nature of the risks associated with the use of ephedrine alkaloids for persons who have the diseases and health-related conditions listed above, it is important that these consumers be advised to consult a health care provider before using ephedrine alkaloid-containing dietary supplements.

With regard to the statement in industry's suggested statement ''if you are at risk or are being treated for high blood pressure * * *,'' the agency considers it unlikely that consumers will be able to adequately evaluate their risk for developing the conditions listed in this statement. Most of these conditions are not self-diagnoseable. In addition, individuals who have a disease or condition listed in this statement, but who are not currently being treated, may believe that they are not at risk of experiencing an adverse event. Consequently, the agency tentatively concludes that the warning statement needs to include an instruction to consult a health care provider before using an ephedrine alkaloid-containing dietary supplement.

The dietary supplement industry statement only instructs the consumer to consult his or her health care professional before use if he or she is taking an MAOI or any other prescription drug. FDA tentatively concludes that this statement should be broader because of the need for professional help in assessing the risks of ephedrine alkaloid intake with a range of conditions.

However, people using MAOI drugs should not use ephedrine alkaloid-containing products at all. Several members of the Working Group and of the Food Advisory Committee recommended that the warning statement advise consumers not to use the dietary supplements containing ephedrine alkaloids if they are taking these types of drugs (Refs. 25 and 27). Because the use of MAOI drugs in combination with ephedrine alkaloids results in blood pressure elevations and increases the risk of serious consequences (e.g., stroke and heart attack), FDA is proposing to warn against use of ephedrine alkaloid-containing products in this circumstance (Refs. 10 through 12, 39, 41, and 55). Because persons remain at risk while the MAOI drug remains in the body, FDA tentatively concludes that consumers need to be informed that it may take up to 2 weeks for the MAOI drug to clear the body (Refs. 203 and 204).

Because MAOI drugs increase the effects of sympathomimetic agents, and consequently will increase the frequency and severity of adverse effects, persons taking such drugs should be given as much information as possible. The agency is concerned that some patients may not be fully informed about MAOI drugs, may not fully understand or remember all the information given to them, or with the passage of time, may forget or lose information that has been provided. Thus, the warning statement needs to be as informative as possible.

Rather than include general language, such as ''any prescription drug'' in the warning statement, FDA tentatively finds that it is important to identify specific types of prescription and OTC drugs that contain ingredients that in combination with ephedrine alkaloids are known or expected to increase the likelihood, frequency, or severity of adverse effects. Therefore, FDA tentatively concludes that consumers need to be warned not to use ephedrine alkaloid-containing dietary supplement in combination with specific drugs, such as drugs for depression, psychiatric or emotional conditions (Refs. 10 through 12, 55, and 205); drugs for Parkinson's disease (Ref. 55); methyldopa (Ref. 206); or any product containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients often found in allergy, asthma, cough/cold and weight control products) (Refs. 180 and 207 through 209).

FDA tentatively finds that the drug methyldopa needs to be identified on the label. It increases the pressor results of sympathomimetic agents, such as ephedrine alkaloids, resulting in hypertension (Ref. 206). FDA has

reached a similar tentative judgment with respect to ephedrine, pseudoephedrine, and phenylpropanolamine because each of these substances, in combination with an ephedrine alkaloid-containing dietary supplement, could lead to an additive effect and consequently increase the risk of serious adverse events. While many consumers may not be familiar with the term ''ephedrine,'' ''pseudoephedrine,'' or ''phenylpropanolamine,'' they may be aware of the type of product being taken for a specific condition or ailment, e.g., allergy, asthma, cough/cold, and weight control products.

The agency recognizes that because of the large number of drugs for depression, psychiatric or emotional conditions, and Parkinson's disease that are contraindicated for use with ephedrine alkaloids and the limited amount of space on the labels of dietary supplements, not all of them can be listed on the label. However, the conditions for which the consumer is taking the drug can be identified, using less label space. If consumers are unsure whether their drug may interact with the ephedrine alkaloids, they should be cautioned to check with their health care professional before using the dietary supplement.

The dietary supplement industry suggested that the statement include the instruction ''Discontinue use and consult your health care professional if dizziness, nausea, sleeplessness, tremors, nervousness, headache, heart palpitations or tingling sensations occur.'' Several members of the Working Group and of the Food Advisory Committee also recommended that any warning statement include information on what actions the consumer should take if certain symptoms occur (Refs. 25 and 27).

Signs and symptoms, such as dizziness, severe headache, rapid or irregular heart beat, chest pain, shortness of breath, nausea, sleeplessness, noticeable changes in behavior, or loss of consciousness are often early warning signs of serious illness or injury, including heart attack, stroke, or seizure. It is important that the consumer stop using the product if these signs or symptoms occur because continued use of the product may aggravate the adverse effects. The agency tentatively finds that the terms ''stop'' and ''call'' should be used for ''discontinue'' and ''consult,'' respectively, because they are more simple and direct terms.

The proposed warning statement instructs the consumer to call a health care professional if any of the listed symptoms occur. A health care professional will be able to evaluate the significance of the signs and symptoms, determine the risks of more serious adverse events occurring, and prescribe any treatment that may be necessary. The effects, such as tremor, sleeplessness, and tingling sensations, that are included in the instruction suggested by the industry are not usually clinically serious and will likely cease once the product use is discontinued (Refs. 210). For these reasons, FDA tentatively concludes that the statement needs to include the instruction to ''Stop use and call a health care professional immediately if dizziness, severe headache, rapid or irregular heart beat, chest pain, shortness of breath, nausea, noticeable changes in behavior, or loss of consciousness occur.''

The dietary supplement industry suggested that the statement include a direction for the consumer not to exceed the recommended dose. Members of the Working Group and of the Food Advisory Committee recommended that the warning statement include a direction for the consumer not to exceed the recommended serving or dose (Refs. 25 and 27).

The agency concurs with the industry's suggestion. FDA tentatively finds that this type of statement is necessary to provide information instructing the user not to consume the product excessively. Excessive consumption of ephedrine alkaloids is associated with adverse events, including heart attack, stroke, seizure, and death. Therefore, the statement is a material fact about the consequences of use of the product. However, FDA has used the term ''serving'' rather than ''dose,'' because the agency considers the term ''serving'' to be more appropriate for use on a food label.

The dietary supplement industry suggested that the statement include the instruction that ''Taking more than the recommended amount will not necessarily increase benefits.'' Similarly, the Working Group suggested that the warning statement contain the instruction that ''Larger quantities may not be more effective.'' The agency is not aware of any data or other information that establishes that there are benefits from the use of dietary supplements containing ephedrine alkaloids. Therefore, the agency would be concerned about requiring a statement on the label that implies a judgment (that the product has benefits) that the agency has not made. While some questions can be raised in this regard under section 403(r)(6) of the act, the agency considers them to be moot because the instruction for the consumer not to exceed the recommended serving eliminates the need for the ''Taking more than recommended * * *'' statement.

The dietary supplement industry suggested that the statement advise the consumer to: ''Begin use with one-half or less the recommended dose to assess your tolerance.'' The agency addressed limiting the levels of ephedrine alkaloids contained in dietary supplements in proposed § 111.100 (a)(1) and (b). In addition, because of label space constraints, the agency is trying to keep the warning statement as short as possible. Therefore, FDA tentatively concludes that there is no reason to require inclusion of this information.

The dietary supplement industry recommended the following in a caution statement, if appropriate for the product: ''This product contains caffeine and should not be taken by those wishing to eliminate caffeine from their diet.'' The Food Advisory Committee also suggested that other stimulants with their source, such as caffeine from Kola nut, be identified on the label of a dietary supplement containing ephedrine alkaloids. However, the agency is proposing to prohibit stimulant substances in combination with ephedrine alkaloids in dietary supplements. Therefore, FDA tentatively concludes that there is no reason to require the inclusion of such a statement.

The dietary supplement industry recommended that the direction ''Not for use by persons under the age of 18'' be included in the warning statement. Several members of the Working Group and of the Food Advisory Committee suggested that the warning statement include a direction that the product is not intended for use by persons under the age of 18. The agency has received limited reports of adolescents abusing or misusing ephedrine alkaloid-containing dietary supplements. Moreover, the agency has stated elsewhere in this document that claims implying usefulness of these products as alternatives to illicit street drugs render the product an unauthorized drug. FDA considers that removal of alternative street drug claims from the labeling of dietary supplements will significantly reduce or eliminate the appeal of these products to adolescents and therefore is not proposing to require that this direction be included in the warning. However, the agency requests comments on whether the direction ''not for persons under the age of 18'' should be included.

The industry group's statement included the instruction ''Keep out of reach of children.'' Children show increased sensitivity to the effects of sympathomimetic agents compared to adults (Refs. 39 and 41) and are, therefore, at increased risk for experiencing adverse events from the use of ephedrine alkaloids. The agency has limited data and information that dietary supplements containing ephedrine alkaloids are being given to, or are associated with accidental overdosage by, children. FDA requests comment, particularly data, on whether this statement is necessary to alert consumers to the fact that ephedrine alkaloid-containing dietary supplements should not be made available to children.

c. *The agency's proposal.* Based on FDA's authority under sections 201(n), 403(a)(1), and 701(a) of the act, the agency proposes to require manufacturers to include the warning statement set out in § 111.100(g)(1) in the labeling of their ephedrine alkaloid-containing products. The agency tentatively finds that the warning statement is necessary to disclose material facts about the consequences of using the product, and that it will help to reduce the risk that some individuals will experience an adverse event from using this type of product.

The agency solicits comments on all aspects of the warning statement, including data to support any specific instruction. The agency also solicits comments on approaches to shorten or simplify the warning statement. Because substances contained in ingredients (e.g., ephedrine alkaloids contained in *Ephedra*) are not required to be listed in the ingredient list on the label of dietary supplements, the agency is concerned that consumers and health care providers may not be aware that ephedrine alkaloids are contained in the product and thus may not necessarily recognize the seriousness of the symptoms listed in the statement, when they occur. FDA requests comments on whether the warning statement should disclose that ephedrine alkaloids are contained in the product. In addition, the agency is concerned that some AER's suggest that a pattern of starting and stopping use of dietary supplements containing ephedrine alkaloids may increase an individual's susceptibility to experiencing adverse events. FDA requests comments on whether the warning statement should disclose the possibility of increasing the risk of adverse events by a pattern of stopping and starting use. Based on the comments received by FDA, the warning statement proposed below may need to be modified.

In an effort to promote uniformity in labeling, FDA is proposing to require that the warning statement appear on the labels of ephedrine alkaloid-containing dietary supplements in the exact manner presented in proposed § 111.100(g)(1), except when the disclaimer proposed in § 111.100(f) appears on the same label panel as the warning statement, in which case the instruction ''Do not exceed recommended serving'' would not have to appear in the warning statement. However, the agency recognizes that other ingredients that may be used in ephedrine alkaloid-containing dietary supplements may have consequences of use that need to be disclosed on the label. The agency requests comments on how to allow for warning statements for other ingredients in conjunction with the ephedrine alkaloid warning statement on the label of dietary supplements. In addition, the agency solicits comments on the format of the warning statement to improve its clarity (e.g., should the statement be set out in bullets).

d. *Placement of warning statement on label.* The agency intends to provide an approach to the placement of the warning label statement to give manufacturers flexibility to design their own label warning formats, while ensuring that consumers are given adequate notice of the information contained in the warning.

Section 403(f) of the act requires that information appearing on the label or labeling be prominently placed and appear with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of use. In the agency's rulemaking that mandated warning statements on certain protein products, the agency decided not to mandate specific requirements for type size and other format elements. However, the agency did require that the warning statement appear ''prominently and conspicuously on the principal display panel of the package label'' (§ 101.17). In addressing the placement of the label warning, the agency noted that the seriousness and nature of the risks associated with the use of protein products in very low calorie diets was sufficient to require placement of the warning statement on the principal display panel (§ 101.17).

FDA tentatively concludes that the warning statement that it is proposing must appear prominently and conspicuously on the label of dietary supplements containing ephedrine alkaloids so that consumers are given adequate notice of the information contained in the warning. While the risks associated with the use of dietary supplements containing ephedrine alkaloids are serious, the agency is not proposing to require that the warning label statement for dietary supplements containing ephedrine alkaloids appear on the principal display panel. The agency recognizes that, because of the length of the required warning statement, in many cases it may be impracticable for the warning statement to appear on the principal display panel without interfering with the placement of other information that is required to appear on that panel.

The requirement in the act for prominent display means that the warning statement must be presented on the label or labeling in a manner that renders it as readily observable and likely to be read. In this regard, the agency's experience with the graphic requirements for the new nutrition label has been that a box around required label information greatly increases the prominence of the information placed inside the box. Moreover, focus group discussions regarding warning labels show that messages put in a boxed area help consumers to distinguish the message from other information as well as draw attention to it (Ref. 210a). Therefore, FDA is proposing to require in § 111.100(g)(3) that the warning statement for ephedrine alkaloid-containing dietary supplements be separated from other information by a box. If FDA adopts these regulations, manufacturers will have the flexibility to design their own label and warning label format subject to § 111.100(g)(3).

Section 201(k) of the act defines the term ''label'' as ''a display of written, printed, or graphic matter upon the immediate container of any article'' and further states a requirement that ''any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article * * *.'' Thus, if FDA adopts its proposal to require that a warning statement appear on the label of ephedrine alkaloid-containing dietary supplements, the warning statement would also have to appear on the retail package of such a product, if that package is not the immediate container.

FDA requests comments on these proposed requirements for placement of the warning statement.

In addition to this proposed regulation, the agency has issued proposed and final rules on dietary supplements, including premarket notification procedures for new dietary ingredients (61 FR 50774, September 27, 1996) and label warning statements and unit dose packaging requirements for iron containing dietary supplements (62 FR 2218, January 15, 1997). The agency has proposed to codify each of the proposed and final regulations in different parts of the Code of Federal Regulations. The agency believes that it would be easier for consumers as well as for the dietary supplement industry to find and use regulations for dietary supplements if they were consolidated into one part of the CFR. Accordingly, FDA is proposing to revise part 111 to consolidate the regulations for dietary supplements. FDA is proposing to change the title of part 111 from ''Current Good Manufacturing Practice for Dietary Supplements'' to ''Dietary Supplements.'' This is necessary to reflect that other regulations for dietary supplements in addition to regulations for current good manufacturing practice will be contained in this part. FDA is proposing to establish four subparts in part 111: Subpart A—General Provisions, Subpart B—Current Good Manufacturing Practice for Dietary Supplements, Subpart C—New Dietary Ingredients, and Subpart D—Restricted Dietary Ingredients. The labeling provisions for dietary supplements will continue to be placed in 21 CFR part 101.

D. Other Approaches Considered by the Agency

In choosing the proposed approach to limit the risks presented by ephedrine alkaloids in dietary supplements, the agency considered, but rejected, several other approaches. Because the act does not allow premarket review authority for dietary supplements, FDA has no data and information to establish conditions of use that will ensure the safe use of ephedrine alkaloid-containing dietary supplements. Therefore, the only viable approach available to FDA is one in which the agency prohibits levels of a substance in, or conditions of use for, a dietary supplement that it can prove may render the product injurious to health or that present a significant or unreasonable risk of illness and injury under the conditions of use suggested or recommended in the labeling or under ordinary conditions of use.

The agency is unaware of any classical toxicological studies whose results identify ''no adverse effect levels'' for ephedrine alkaloids directly applicable to humans, or whose results establish intake-response curves for ephedrine alkaloids in dietary supplements and that could be used to establish a level of ephedrine alkaloids that are safe for consumers to use in dietary supplements. The intake-response relationships between ephedrine alkaloids and their effects in humans are unknown for both botanical sources and marketed dietary supplement products containing ephedrine alkaloids. Moreover, because there are consumers who may be sensitive to the effects of ephedrine alkaloids because of a variety of factors that are not readily identifiable or predictable, a margin of safety based on classical toxicological principles likely cannot be determined. For these reasons, the agency tentatively finds that the use of a classical toxicological approach to determine a safe level of ephedrine alkaloids in dietary supplements is not a usable approach.

Several members of the Food Advisory Committee recommended that FDA consider the risk associated with the use of dietary supplements containing ephedrine alkaloids in the context of any benefit that the consumer may receive from the use of these products (Ref. 25). In applying a risk-to-benefit calculation, a certain amount of risk may be accepted if there is a meaningful benefit to be gained by the consumer (Ref. 25). However, the Food Advisory Committee members were unable to identify a benefit for ephedrine alkaloids in terms of supplementing the diet (Ref. 25). Moreover, risk-benefit analysis is something that is done under the act for drugs, not food.

Several members of the Working Group suggested that any limitations on the level of ephedrine alkaloids in dietary supplements be based on the use of pharmaceutical ephedrine in OTC oral bronchodilator drugs and the use of *Ephedra* in traditional herbal medicine (Ref. 27). Other members of the Working Group and several members of the Food Advisory Committee found difficulty in extrapolating from OTC drug data because the products, the populations using the products, and intended use of the products are dissimilar (Ref. 25). In addition, the latter members were concerned about the potential for adverse events to occur, particularly in populations sensitive to the effects of ephedrine alkaloids, if therapeutic levels of ephedrine are used in dietary supplements (Ref. 25). Several members of the Food Advisory Committee were also concerned about using data from the use of *Ephedra* in traditional herbal therapies to support the safety of the use of ephedrine alkaloids in dietary supplements because the therapeutic use of ephedrine alkaloids has traditionally not involved the same conditions, the same populations, or the same purposes as those under which dietary supplements are used (Ref. 25).

The agency considered the applicability of OTC drug data and tentatively concluded that these data, which involve use in a restricted population (physician-diagnosed mild asthmatics) under limited directions for use (i.e., not to exceed 12.5 to 25 mg every 4 hours, not to exceed 150 mg in 24 hours) and with warnings and contraindications for use, has no application here. The determination of safety for drugs is based on a weighing of the proven benefits of the use of the product against the risks. This approach may not be used with foods under section 402(a) of the act. The only question for food use under this section is whether it will cause harm or not. While the concept of ''unreasonable risk'' as stated in section 402(f)(1)(A) of the act, may imply that some evaluation of effects, including risks and benefits, is appropriate for dietary supplements, it is not necessary to reach that question here, because, as stated above, there are no demonstrated benefits for ephedrine alkaloids. Moreover, the risks attendant on consuming dietary supplements containing levels of ephedrine permitted in oral bronchodilator drugs (12.5 to 25 mg ephedrine per dose) are manifest.

In addition, there is no basis for extrapolating from data from a subgroup of the population, diagnosed asthmatics, who may be less sensitive to the effects of ephedrine (Ref. 25) than the general population, to the general population, among which a significant number of people are known or suspected of being very sensitive to ephedrine.

Finally, the agency finds it inappropriate to extrapolate data from the use of OTC ephedrine-containing drugs because dietary supplements contain a mixture of several ephedrine alkaloids and a variety of other ingredients, including vitamins, minerals, other botanicals, and other physiological and pharmacologically active substances, while OTC drugs contain only a single ephedrine alkaloid. The presence of other alkaloids and substances in dietary supplements may act to increase the likelihood, frequency, and severity of adverse events from the use of these products. In fact, clinical studies show that adverse events are more likely to occur when ephedrine is combined with other substances, such as caffeine. Therefore, the fact that pharmaceutical ephedrine

has been approved by FDA for an OTC use does not provide assurance of safety for the use of ephedrine alkaloids in dietary supplements.

The agency considered the applicability of traditional use of botanical sources of ephedrine alkaloids in establishing dietary ingredient levels for ephedrine alkaloids in dietary supplements. A history of long usage of a medicinal herb in traditional therapies does not provide an assurance of safety for a component of a dietary supplement because these conditions of use are so different. The history of use of *Ephedra* in traditional Asian medicine primarily for the treatment or relief of respiratory symptoms provides insufficient assurance that ephedrine alkaloids will not present a significant or an unreasonable risk of injury to consumers who use dietary supplement products containing ephedrine alkaloids to supplement the diet. Not only are dietary supplements marketed for different uses than the traditional use of *Ephedra*, most dietary supplements are marketed in a form that is different than the form in which it has been traditionally used, e.g., as a concentrated extract in capsules and tablets, in the presence of other substances rather than the raw botanical in a tea.

FDA is not aware of any systematic collection of data related to adverse effects occurring in individuals treated with *Ephedra* in traditional medicine. However, several reference texts list precautions and contraindications for the use of the botanical *Ephedra* in traditional medicine preparations (Refs. 6, 14, and 146). Thus, FDA tentatively concludes that use of ephedrine alkaloids in traditional Asian medicine does not provide the basis on which to establish a safe level of use of ephedrine alkaloids in dietary supplements.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic impact of that rule on small entities.

FDA finds that this proposed rule is an economically significant rule as defined by Executive Order 12866, and finds under the Regulatory Flexibility Act that this proposed rule will have a significant impact on a substantial number of small entities. Finally, FDA, in conjunction with the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB), finds that this proposed rule is a major rule for the purposes of congressional review (Pub. L. 104–121).

A. Market Failure

The market failure addressed by this regulation is that some consumers may not have sufficient information on the health risks associated with dietary supplements containing ephedrine alkaloids to make informed choices concerning the consumption of these products, despite the presence of warning labels of various types on many of these products. Ordinarily, consumers would be expected to seek out and pay for the level of information they consider appropriate with respect to consumption decisions. However, the level of information currently utilized by consumers with respect to these products may be less than optimal because of consumer perceptions that products marketed as foods or derived from botanical sources are inherently safe, and the cost of generating evidence to evaluate the safety of these products may be quite high. In addition, the onset of the adverse health events associated with these products is frequently quite unexpected or occurs without identifiable risk factors, and consumers may have little or no opportunity to adapt their behavior based on experience with the risks of these products prior to suffering a severe adverse event.

B. Regulatory Options

FDA has the following primary options:

1. Take no action.
2. Take no regulatory action, but generate additional information on which to base a future regulatory action.
3. Take proposed action.
4. Take proposed action, but with a higher potency limit.
5. Ban dietary supplements that contain ephedrine alkaloids.
6. Take proposed action, but do not require warning statement.
7. Require warning statements only.

C. Benefits and Costs

1. Option 1—Take No Action

By convention, the option of taking no action is the baseline in comparison with which the costs and benefits of the other options are determined. Therefore, neither additional costs nor benefits are associated with taking no action. Although no regulatory costs or benefits are generated if no regulatory action is taken, preventable adverse events will continue to occur if no regulatory action is taken. The number of such adverse events is expected to increase over time because the marketplace for these types of products has been increasing rapidly since the 1994 passage of the DSHEA, and the number of AER's associated with use of these products has also been increasing sharply over the last few years (Figure 1).

2. Option 2—Take No Regulatory Action, but Generate Additional Information on Which To Base a Future Regulatory Action

FDA has the option of taking no regulatory action but generating additional information on which to base future regulatory action on this issue. The benefit of generating additional information is a reduction in the substantial uncertainty concerning the specific nature of the relationship of the adverse events associated with dietary supplements containing ephedrine alkaloids and, possibly, a more precisely targeted regulation. A more precisely targeted regulation could imply potency limits either higher or lower than the proposed potency limits, and either more or fewer ingredient and labeling restrictions than those proposed. The cost of generating additional information is the cost of whatever activity is undertaken to generate the additional information and the health cost of any adverse events to these products that would occur if regulatory action were delayed but that would not occur if regulatory action were not delayed.

3. Option 3—Take Proposed Action

a. *Benefits.* The benefit of the proposed action is a potential reduction in the number or severity of adverse events associated with dietary supplements containing ephedrine alkaloids. The proposed rule consists of the following four actions: (1) Per day and per serving potency limits on total ephedrine alkaloids (TEA), (2) restrictions on caffeine and other

stimulants, (3) mandatory warning statement, and (4) labeling restrictions.

To estimate the benefits of these actions, a percentage decrease in the current number of adverse events associated with dietary supplements containing ephedrine alkaloids will be estimated for each regulatory action listed above. The estimated effects of all proposed actions will then be combined to obtain a total reduction in the expected annual number of adverse events. This percentage reduction will then be applied to an estimate of the current number of such adverse events to obtain an estimated number of adverse events avoided per year. The estimate of the current number of adverse events will be based on, but not identical to, the current number of relevant AER's because of uncertainty over a number of issues including, for example, the degree to which the relevant adverse events are reported. These sources of uncertainty will be discussed in greater detail later.

Each of the proposed actions may affect the number of adverse events by reducing the number of people who consume the relevant products or by modifying their use of these products in a manner that reduces the risk of an adverse effect. In addition, the potency limits and ingredient restrictions may affect the number of adverse events by reducing the probability that those who consume these products will suffer an adverse event. Each of these effects will be considered in turn, beginning with the effect of the proposed actions on the number of people who consume these products.

The proposed potency limits and other ingredient restrictions may affect the number of people consuming these products because they may affect the value placed by consumers on the use of these products. Some information on the likely effect of the proposed potency limits on the consumption of these products comes from a report from one firm that marketed an ephedrine alkaloid-free substitute for a supplement that previously contained ephedrine alkaloids. The sales of the substitute product were reportedly approximately 33 percent lower than the sales of the ephedrine alkaloid-containing product (Ref. 211). In the absence of more specific information, it is reasonable to suppose that a given reduction in sales is associated with a proportionate reduction in the number of people consuming these products.

It would not be reasonable to suppose the proposed potency limits and other ingredient restrictions would have a greater effect on the sales of these products than complete elimination of all ephedrine alkaloids from these products. First, the functional effect, as perceived by consumers, of removing all ephedrine alkaloids from a product is probably greater than the perceived functional effect of removing some of the ephedrine alkaloids and removing some ingredients that interact with those ephedrine alkaloids. Second, if only some firms remove ephedrine alkaloids from their products, relatively close substitutes will exist for the prior formulations of those products because other firms might not remove ephedrine alkaloids from their products. However, if all firms make the same changes in their products, then relatively close substitutes will not exist for the prior formulations of those products. Therefore, the proposed potency limits and other ingredient restrictions are estimated to reduce the number of people consuming these products by between 0 to 33 percent. The effect of the potency limits on the probability of an adverse event for those who continue to consume these products will be addressed later in this section.

The proposed warning statement is also likely to reduce the number of people consuming these products because a few of the relevant products do not currently have warning statements, and because, in some cases, the proposed warning statement is more comprehensive, more focused, and more strongly worded than existing warning statements. The only information available on the effect of warning statements on sales concerns diet soft drinks containing saccharin. Following the introduction of warning statements relating to saccharin, annual sales of diet soft drinks containing saccharin were reported to be 15 percent below what they would otherwise have been (Ref. 212). The effect of the proposed warning statement for dietary supplements containing ephedrine alkaloids will probably be smaller than the effect of the saccharin warning label on diet soft drinks because most such supplements already have some type of warning statement. Therefore, the proposed warning statement will probably reduce the number of people consuming these products by 0 to 15 percent.

The proposed label claim restrictions are also likely to reduce the number of people consuming these products by making the marketing of these products more difficult. The only information available on the potential effects of label claims on sales concerns ready-to-eat breakfast cereals. Following an advertising campaign relating bran consumption to a reduced risk of developing cancer, sales of high bran breakfast cereals were reported to have increased approximately 40 percent (Ref. 213). The effect of eliminating label claims on dietary supplements containing ephedrine alkaloids will probably be smaller because the claims involved are more general, and because other sources of information on the purported effects of ephedrine alkaloids are readily available or have been used recently enough that consumers are familiar with them.

However, approximately 10 percent of the AER's involved supplements labeled as alternatives to street drugs. Assuming that consumers of these products will not purchase these products if they are not labeled as alternatives to street drugs, the labeling restriction will reduce expected adverse events by at least 10 percent. Therefore, the proposed restriction on label claims will probably reduce the number of people consuming these products by between 10 percent and 40 percent.

In addition to these consumption effects, the proposed potency limits and ingredient restrictions will probably also decrease the likelihood that those who continue to consume these products will suffer an adverse event.

FDA is not aware of clinical information, particularly evidence from well-designed and conducted human studies on the relationship between intakes of ephedrine alkaloids from botanicals and the probability of an adverse event. One method of approaching the estimation of the health benefits of reduced exposure to ephedrine alkaloids is to consider the proportion of adverse event reports that involve products with TEA levels greater than that allowed under the proposed potency limits. FDA was able to obtain information on the actual exposures associated with adverse events for 13 products that provided intakes of less than 20 mg TEA per reported use by multiplying the consumer's reported use level against an FDA product analysis result. These reports provided information on the lower end of the range of estimated intakes by consumers. Among these 13 reports of adverse events associated with intakes of less than 20 mg, 9 involved consumer intakes of between 8 mg and 20 mg/per serving. This approach suggests that the proposed potency limit might reduce the expected number of adverse events by at least 80 percent, although the actual reduction is probably higher because the 13 reports did not include the many adverse event reports that occurred at intakes above 20 mg TEA per serving. On the other hand, the actual reduction might also be lower because the 13 reports did not include

all adverse event reports that occurred at intakes below 20 mg TEA per serving.

This approach to estimating the impact of the proposed potency limits assumes that the probability of an adverse event is related to intakes of TEA. If the probability of an adverse event is not related to TEA intake, then the potency limits may result in little or no reduction in the expected number of adverse event reports. For example, if individual sensitivities to ephedrine alkaloids are the major underlying factor in the reported adverse events, then it is possible that there may be no ''safe'' intake for these persons. Based on this information, all that can be said concerning the proposed potency limits is that they may reduce the expected number of adverse events by between 0 to 80 percent.

The restriction on other stimulants, including caffeine, should also reduce the probability of an adverse event. Combinations of ephedrine alkaloids and caffeine, at sufficiently high doses, are associated with an increased probability of an adverse event. For example, one study found that 60 percent of the study subjects had an adverse reaction to a combination of 20 mg ephedrine and 200 mg caffeine, while only 44 percent had an adverse reaction to 20 mg ephedrine alone (Ref. 105). Thus, in this study, the presence of 200 mg caffeine appears to have increased the probability of an adverse event from consumption of 20 mg ephedrine by about 50 percent. Comparable information is not available on the effect of combinations of ephedrine and caffeine at lower levels of either ephedrine or caffeine. Similarly, no information is available on the effect of other stimulants or other ephedrine alkaloids.

An informal review of 217 adverse event reports featuring dietary supplements suspected of containing ephedrine alkaloids found that 99 reports featured products for which labeled ingredient information was available. Of those reports, 70 percent involved products labeled as containing a source of caffeine. The levels of caffeine and ephedrine alkaloids in these products is not known. Assuming that these adverse event reports are typical of all relevant adverse event reports and that 50 percent of the reported adverse events to products labeled as containing caffeine may have been due to the presence of caffeine in conjunction with ephedrine alkaloids, the restriction on stimulants is estimated to reduce the expected number of adverse events by up to 35 percent. However, the impact of the proposed stimulant restrictions may be somewhat lower because the impact may depend on the levels of stimulants and ephedrine alkaloids involved, and the levels of stimulants and ephedrine alkaloids found in dietary supplements may be lower than the levels used in the study on which this estimate is based. In order to address this possibility, the restrictions on stimulants will be assumed to reduce the expected number of adverse reactions by 25 percent.

In order to use the estimated risk reductions discussed above to derive an expected reduction in the number of adverse events, the current number of adverse events must be estimated. There are a number of issues involved in estimating the current number of adverse events based on the number of reported adverse events.

The first issue is that the data base of over 600 AER's includes all reports thought to be related to the consumption of ephedrine alkaloid-containing dietary supplements, even though the nature of the available evidence did not allow specific cause and effect determinations for the majority of individual reports. FDA, therefore, used additional information to provide assurance that the patterns of signs and symptoms associated with the ephedrine alkaloid-containing dietary supplements were likely due to the presence of ephedrine alkaloids in these products. One approach to addressing this issue is to examine the evidence for positive dechallenge and rechallenge when product use is discontinued and reinitiated, respectively. The relationship of the reported adverse events to the consumption of dietary supplements categorized as containing ephedrine alkaloids has been corroborated by dechallenge in about 27 percent of the AER's. Positive rechallenge was reported in about 4 percent of the AER's. The majority of AER's, however, lacked sufficient information to evaluate the presence or absence of dechallenge or rechallenge effects. Therefore, the number of cases in which dechallenge alone or in combination with rechallenge was tried but did not occur is not available; nor is there information on whether dechallenge and rechallenge would have occurred in the large number of reports which lack such information. It is possible that all cases might have been associated with positive dechallenge and rechallenge results if such information were available. On the other hand, a certain number of false reports might also be expected. The proportion of reported adverse events actually related to the consumption of dietary supplements suspected of containing ephedrine alkaloids is probably between 27 and 90 percent. Within this range, FDA believes the most likely value is around 80 percent and, therefore, tentatively assumes that 80 percent of the reported adverse events are actually related to the consumption of dietary supplements. FDA requests comments on this assumption.

The second issue is the uncertainty that all 600 AER's involved products that actually contained ephedrine alkaloids. Confirmation of the presence of ephedrine alkaloids in problem products is not available in all cases. The likelihood of the presence of ephedrine alkaloids is based on the labeling of the products involved, FDA's own market survey (including laboratory analysis of 125 marketed products), and the similarity of the reported adverse events to the known effects of ephedrine alkaloids. The proportion of reported adverse events associated with dietary supplements that involve supplements containing ephedrine alkaloids is probably between 25 and 90 percent. Within this range, FDA believes the most likely value is around 80 percent and, therefore, tentatively assumes that 80 percent of the reported adverse events associated with consumption of dietary supplements involve supplements that contain ephedrine. FDA requests comments on this assumption.

The third issue is that the actual number of adverse events is likely to differ from the reported number of adverse events because all adverse events are probably not reported. This issue is particularly important with respect to passive reporting systems that rely on the voluntary submission of data, such as the system used to gather the AER's relevant to this issue.

Typical reporting rates for passive reporting systems addressed to adverse events associated with drugs are generally assumed to be on the order of 10 percent. Reporting rates are higher than usual if the potential health risks associated with a particular substance are widely publicized, if the adverse events are considered to be otherwise unusual, and if reports are gathered from a variety of sources. On the other hand, reporting rates would be lower than usual if consumers and physicians assume that dietary supplements are incapable of producing adverse events because they are not drugs or because they are ''natural.'' In order to incorporate this uncertainty, the reporting rate for the relevant adverse events is assumed to be 10 percent.

Based on the current number of reported adverse events and the assumptions discussed above

concerning the relationship between the number of reported adverse events and the underlying number of adverse events, the expected annual number of adverse events involving these products is approximately 1,100 cases. Applying the risk reductions discussed previously for the proposed actions implies a reduction in the health risks from these products such that the expected number of adverse events involving these products will be reduced by between approximately 400 cases and 1,100 cases per year. Based on published estimates of the value consumers might place on reducing the risk of the general types of adverse events involved, these benefits are valued at between $240 million and $670 million per year (Ref. 215).

Table 6 summarizes these results. The first column is the type of adverse event. ''Serious CVS'' refers to serious cardiovascular system events, including myocardial infarctions, dysrhythmias, strokes, and cardiomyopathies. ''Serious NS'' refers to serious nervous system events, including seizures, loss of consciousness, vestibular events, and psychiatric events. ''Less clinically significant'' events may include certain types of dermatological events and gastrointestinal events. The second column is the average annual number of AER's from January 1993 to June 1996. Because the sales of these products is increasing rapidly, and the reports of adverse events are also increasing rapidly (see Figure 1), FDA believes that this is a conservative estimate of benefits. The 3-year average has been used rather than the growth trend because extrapolating short-term growth trends into the future can result in large errors. The third column is the estimated average annual number of adverse events over this time period based on what FDA believes are the most likely values for the relevant assumptions. The fourth column is the estimated reduction in adverse events from all proposed actions, given as a range from low to high. These estimated reductions are based on adding the effects of the proposed actions as summarized in Table 7. The low end of this range represents a 35 percent reduction in the estimated annual adverse events and the high end represents a 100 percent reduction. The estimates have been rounded to the nearest ten. The fifth column is the value of reducing the risk of particular adverse events such that one expected adverse event is avoided per year across the at-risk population, in thousands of dollars. The sixth column is the estimated value of the annual risk reductions for the various adverse events in millions of dollars, given as a range from low to high, rounded to the nearest million.

TABLE 6.—ESTIMATED VALUE OF ANNUAL RISK REDUCTION FROM PROPOSED ACTIONS

Type of event	Annual reported cases [1]	Estimated annual cases [2]	Reduction in estimated annual cases [3]	Value of estimated risk reduction per case ($ thousands) [4]	Value of estimated risk reduction ($ millions) [5]
Death	6	40	10–40	5,000	70–190
Serious CVS	27	170	60–170	837	50–140
Serious NS	29	190	70–190	1,483	100–280
Ab. liver function	7	50	20–50	3	0
Other serious	12	80	30–80	775	20–60
Less serious	93	600	210–600	0.4	0
Total	174	1,110	390–1,110	NA	240–670

[1] Annual reported cases are based on the average number of adverse event reports per year between January 1993 and June 1996. Trends in the data were not extrapolated because of the short timeframe involved.

[2] Estimated annual cases are based on the following assumptions: (1) 80 percent of the reported adverse events involving the consumption of dietary supplements suspected of containing ephedrine alkaloids are actually related to the consumption of dietary supplements, (2) 80 percent of the supplements involved in the reported adverse events that are related to the consumption of supplements actually contain ephedrine alkaloids, and (3) 10 percent of adverse events to the dietary supplements containing ephedrine alkaloids are reported. Thus, the estimated number of annual cases is $0.8 \times 0.8 \times 10$ times the number of annual reported cases. Considerable uncertainty exists with respect to the validity of the assumptions on which this estimate is based and the actual number of annual cases may be higher or lower than the estimate.

[3] The low end of the range of the reduction in estimated annual cases represents a 35 percent reduction in estimated annual cases. The high end of this range represents a 100 percent reduction in estimated annual cases. The 35 percent and 100 percent estimates are based on adding up the estimated effects of the proposed actions, as indicated in Table 7.

[4] The value of the risk reduction per case is based on published estimates of the value consumers place on reducing the risk of the general types of adverse events involved (Ref. 215).

[5] The value of the estimated risk reduction is based on multiplying the risk reduction per case times the reduction in the estimated annual cases.

TABLE 7.—COMBINED EFFECT OF PROPOSED ACTIONS

Proposed action	Estimated reduction in adverse events (in percent)
Actions reducing consumption of supplements containing ephedrine alkaloids:	
Potency limits and ingredient restrictions	0–33
Warning statement	0–15
Label claim restrictions	10–40
Combined effect	10–88
Actions reducing probability of adverse event given consumption:	
Potency limits	0–80
Ingredient restrictions	25
Combined effect	25–100

TABLE 7.—COMBINED EFFECT OF PROPOSED ACTIONS—Continued

Proposed action	Estimated reduction in adverse events (in percent)
Combined effect of all proposed actions	35–100

b. *Costs.* The primary social costs of the proposed actions are the compliance costs, which include the one-time costs associated with relabeling and reformulating the affected supplements and the recurring costs associated with testing for the level of ephedrine alkaloids in conjunction with future product reformulations or changes in ingredients, and the value of the utility losses to any consumers who do not value the reformulated supplements as highly as supplements currently found on the market. This cost must be considered somewhat paradoxical because the cause of this loss of value, the reduction or removal of ephedrine alkaloids, would also reduce or eliminate the risks associated with using these products. In addition, indirect social costs in the form of capital losses and temporary unemployment may arise from the distributive effects of the proposed action, which are discussed below. Some portion of the compliance costs will be borne by manufacturers and distributors of these products, and some portion will be passed on to consumers of these products. Costs borne by manufactures and distributors will be borne by the owners, stockholders, and employees of those firms.

In addition to the potential impact of compliance costs, manufacturers and distributors of the dietary supplements containing ephedrine alkaloids will be adversely affected by the reduction in consumption of these products caused by the proposed actions. Also, manufacturers, distributors, and importers of raw or bulk Ma huang and other affected ingredients may be affected by these consumption effects. These effects are distributive effects rather than social costs because they do not involve the loss of productive resources, and because a loss of business in one sector of the economy is generally associated with an increase in business in competing sectors. However, as indicated above, social costs may be involved to the extent that otherwise productive capital investment is lost and temporary unemployment is generated. In addition, distributive effects are obviously very significant to the affected parties.

FDA has previously estimated the cost of relabeling all dietary supplements in the economic impact analysis for the proposal on nutrition labeling of dietary supplements that was published in the **Federal Register** of December 28, 1995 (60 FR 67184) (the December 1995 proposal). Total discounted labeling costs based on an 18 month compliance period were estimated to be between $52 and $85 million. This cost included recurring testing or analytical costs based on testing the nutrient content of each product an average of once every 5 years. Based on comments to the December 1995 proposal, these estimates were revised in the economic impact analysis of the final rule. The revised estimate was $194 million, with $91 million of these costs occurring in the first 18 months and the remainder being a discounted sum of future analytical costs. In order to use this estimate as a basis for estimating labeling costs for the current proposal, the previous estimate must be adjusted to account for the compliance period associated with this rule and the fact that not all dietary supplements contain ephedrine alkaloids.

The proposed effective date of any regulation based on this proposal will be 180 days after the date of publication of the final rule. If the nutritional labeling rule had a compliance period of 180 days rather than 18 months, the total estimated labeling costs would have been $334 million, with $286 million of these costs occurring in the first 6 months.

Adjusting the previous estimate to account for the fact that not all dietary supplements contain ephedrine alkaloids requires information on the proportion of dietary supplements that contain ephedrine alkaloids. The market surveys identified 125 dietary supplements suspected of containing ephedrine alkaloids. A public comment submitted to the Special Working Group of the Food Advisory Committee suggested the number of such products is at least 200 (Ref. 216). In the December 1995 proposal, the total number of dietary supplement products was estimated to be between 4,000 and 25,000. In the final rule entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements'' that published in the **Federal Register** of January 15, 1997 (62 FR 2218), this estimate was revised to 29,000. If 200 dietary supplements contain ephedrine alkaloids, then about 1 percent of the estimated total number of dietary supplements contain ephedrine alkaloids and the cost of changing the labels on dietary supplements containing ephedrine alkaloids would be about 1 percent of the costs estimated for changing the labels on all dietary supplements.

Another method of estimating the proportion of dietary supplements that contain ephedrine alkaloids is to use sales data. This method is complicated by the fact that sales might not be evenly distributed across dietary supplements, implying that the proportion of dietary supplement sales accounted for by supplements that contain ephedrine alkaloids may not be the same as the proportion of dietary supplement products that contain ephedrine alkaloids.

Ma huang and other ephedra products have been reported to represent 3.5 percent of individual botanical sales in selected health food stores, while individual sales of products containing single botanicals are estimated to make up about 53 percent of total botanical supplement use (Ref. 3). Information is not available on the proportion of products with multiple botanical ingredients that contain ephedrine alkaloids. Botanical supplement retail sales have been estimated to have accounted for approximately 26 percent of total dietary supplement retail sales in 1995 (Ref. 217). However, this estimate includes a number of product categories under dietary supplements that would not be considered dietary supplements under the legal definition of a dietary supplement. After adjusting for the definition of dietary supplements, supplements containing botanicals accounted for approximately 35 percent of dietary supplement retail sales in 1995. The definition of dietary supplement used in this estimate includes vitamins, minerals, and botanical (including herbal) supplements.

If all supplements containing ephedrine alkaloids are characterized as

botanical supplements, this information suggests that between 1 and 17 percent of dietary supplement use involves products that contain ephedrine alkaloids. If the proportion of dietary supplement products containing ephedrine alkaloids reflects the proportion of dietary supplement sales accounted for by products containing ephedrine alkaloids, then between 1 and 17 percent of the total number of dietary supplement products contain ephedrine alkaloids, or between 200 and 5,000 products.

Based on the preceding information, labeling costs for this proposal are estimated to be between 1 and 17 percent of the costs previously estimated for changing the labels on all dietary supplements, after adjusting those costs for the length of the compliance period. Thus, total discounted labeling costs for this proposal are estimated to be between $3 million and $60 million, with between approximately $3 million and $50 million of these costs occurring in the first year and between a minimal amount and approximately $0.5 million in every year after the first year.

If the proposed 180 day compliance period for making the proposed label changes coincided with some portion of the 18-month compliance period of the final rule requiring nutritional labeling of dietary supplements, then some portion of the combined labeling costs of the two regulations would be eliminated because some firms would be able to make both labeling changes during normally scheduled labeling changes. The degree of overlap of the compliance periods of these regulations depends on the date on which the final rule is published. If appropriate, this consideration will be addressed in the economic analyses of the final rule.

Information is not available on the cost of reformulating the affected products. Reformulation may simply involve reducing the amount of the ingredient source of the ephedrine alkaloids and removing the restricted ingredients. One method of approaching this issue is to consider the types of personnel and the amount of effort that might be required for reformulation. A reasonable assumption is that it might take a scientist from 1 to 4 weeks to develop an acceptable reformulation. In this case, the cost of reformulating a product would be between $1,000 and $5,000, based on median weekly earnings data for 1994 and 50 percent overhead (Ref. 218).

Many dietary supplements containing ephedrine alkaloids probably contain restricted ingredients or do not meet the proposed potency limits on TEA and will either have to be reformulated or removed from the market. The number of dietary supplements containing ephedrine alkaloids has been estimated, above, to be between 200 and 5,000. Under this assumption, if all products were reformulated, the one-time cost of reformulating the affected products would be between $0.2 million and $25 million. The recurring costs associated with testing for ephedrine alkaloid levels in conjunction with future product reformulations was addressed in the labeling costs.

Another cost associated with product reformulation is the cost of any inventory losses involving products produced prior to the publication of a final rule based on this proposal that cannot be sold by the date that final rule goes into effect. The proposed effective date of any final rule on this issue is 180 days after publication of the final rule. FDA has no information on the amount of inventory typically carried for these products, but tentatively assumes that 180 days will provide sufficient time to utilize existing stock.

In addition to the compliance costs discussed above, the proposed action will also lead to utility losses for some consumers because it removes products with certain characteristics from the marketplace. Theoretically, the value of this utility loss is the difference in the value consumers placed on the eliminated products and the value of the products purchased in place of the eliminated products. Estimating this loss requires estimating demand curves for the eliminated products and for the products substituted for the eliminated products.

Identifying likely substitutes for dietary supplements as currently formulated is complicated by the fact that a wide range of effects are attributed to these supplements, for example, energy, weight loss, body building, and increased mental concentration. However, little reliable information is available on the actual effects produced by these supplements. In addition, various other botanical substances exist that might be used in supplements to replace either some portion of the ephedrine alkaloids or the restricted ingredients and might produce effects that consumers may perceive to be similar to the effects that consumers attributed to these supplements as currently formulated. Finally, FDA has insufficient information to estimate demand curves for dietary supplements containing ephedrine alkaloids or potential substitutes for these products.

Based on these considerations, FDA cannot place bounds on the value of the consumer utility losses that may be associated with this action. However, if substitute products could be identified, then the absolute price difference between the affected products and the substitute products would represent a lower bound on consumer utility losses. No comparable argument is available for the upper bound of the utility loss.

In addition to compliance costs and utility losses, the proposed action will also generate distributive effects. The total reduction in the consumption of dietary supplements containing ephedrine alkaloids from all proposed actions including the potency limits, ingredient restrictions, labeling restrictions, and mandatory warning statement was estimated in the analysis of the benefits of this option to be between 10 percent and 33 percent. Total annual sales of supplements containing Ma huang have been estimated to be between $600 million and $700 million (Ref. 219). Therefore, sales of these products may be reduced by between $60 million and $230 million per year. Information is not available on the total annual sales of supplements containing sources of ephedrine alkaloids other than Ma huang.

Countervailing effects may also take place which may reduce the impact of these negative distributive effects on affected firms. For example, the proposed rule may reduce the number of product liability lawsuits brought against manufacturers of dietary supplements containing ephedrine alkaloids. FDA has insufficient information on the current incidence or cost of these lawsuits to estimate the effect of this reduction, if any, on the negative distributive effects generated by consumption changes. Of course, distributive effects that are negative with respect to a given industry will be positive with respect to some other industry.

Finally, social costs may be associated with these distributive effects. For example, some portion of the value of the capital invested in the production of these supplements may be lost and that loss might not be offset by other effects, such as an augmentation to the value of the capital invested in the production of substitutes. However, FDA has insufficient information to estimate the social costs that might be associated with these distributive effects.

Under these assumptions, the proposed action will generate total compliance costs of between $3 million and $80 million, plus unquantifiable utility losses to consumers of these products. Between $3 million and $70 million of these costs will occur in the

first 6 months after publication of the final rule. In addition, the proposed action will produce distributive effects of between $60 million and $230 million per year and social costs might be associated with those distributive effects. Because the sales of these products are increasing rapidly, FDA believes that this is a conservative estimate of cost and distributive effects. Again, extrapolations have not been made on the growth trend because extrapolating short-term trends into the future can result in large errors. Costs and sales reductions of this magnitude may threaten the viability of many firms in this industry. If some of these firms go out of business, temporary unemployment of labor and permanent loss of capital resources may result. FDA has insufficient information to estimate these costs.

4. Option 4—Take Proposed Action, but With a Higher Potency Limit

Another option is to take all proposed actions but adopt potency limits higher than the proposed potency limits. For example, some trade associations representing the dietary supplement industry have previously expressed support for potency limits of 12 mg/serving and 50 mg/day TEA (Ref. 220). With respect to benefits arising from consumption effects (i.e., the likelihood of reducing the number or seriousness of adverse events), FDA has some information to estimate the effect of variations between the proposed potency limits and higher potency limits on the consumption effects associated with those limits. That is, of the 13 reports of adverse events for which exposure data for intakes less than 20 mg per serving were also available, 5 were in the range between 8 and 12 mg per serving intake.

If consumption is sensitive to small changes in the potency limits, then higher potency limits would reduce the benefits resulting from consumption effects because higher potency limits would presumably have a smaller effect on the effects of these products than the proposed potency limits. Therefore, the effect of raising the potency limits on benefits arising from shifts in consumption will be to reduce those benefits below those generated under Option 3.

Raising the proposed potency limits will not affect the one-time compliance costs but might reduce utility losses to consumers of these products and the distributive effects produced by consumption shifts. Again, these changes may occur because higher potency limits might have a somewhat smaller impact on the perceived benefits of these products than the proposed potency limits. However, as indicated above, FDA has insufficient information to estimate the effect of small changes in the potency limits on the consumption effects produced by those limits and cannot estimate the utility losses associated with various potency limits.

5. Option 5—Ban Dietary Supplements That Contain Ephedrine Alkaloids

Based on the framework used earlier, banning dietary supplements that contain ephedrine alkaloids would lead to a somewhat higher lower bound on estimated benefits. In particular, banning these products would reduce the health risks from these products such that the expected number of adverse events are reduced by between approximately 120 cases and 1,400 cases per year.

Banning dietary supplements that contain ephedrine alkaloids will not change the one time compliance costs estimated under Option 3 because all affected products were subject to reformulation and relabeling costs under Option 3. However, banning these products would decrease access to these products by consumers who may perceive benefits, thus substantially increasing the potential utility losses to consumers. With respect to distributive effects generated by consumption changes, the total reduction in the consumption of dietary supplements that now contain ephedrine would probably be approximately 33 percent under this option, that is, at the high end of the range of 10 to 33 percent estimated under Option 3. Therefore, sales of these products would be reduced by between $200 million and $230 million per year. Costs and sales reductions of this magnitude may threaten the viability of many of the firms producing these products. However, countervailing distributive effects are also possible in that some firms that currently produce dietary supplements containing ephedrine alkaloids may also produce or be able to produce substitute products. In that case, those firms would avoid some or all of the costs associated with producing dietary supplements containing ephedrine alkaloids.

6. Option 6—Take Proposed Action, but Do Not Require Warning Statement

The purpose of the proposed warning statement is to focus existing warnings more precisely on the health risks posed by these products, particularly in cases where any use of these products may be contraindicated, and to add warnings to those products which do not already have warning statements. Even with the proposed potency limits and ingredient restrictions, some consumers may be at high risk of suffering an adverse event from consuming these products because of high individual sensitivity to these products, because of an increase in risk associated with simultaneous consumption of drug products, or because of an underlying health condition. Thus, the proposed warning statement is expected to have some benefit independent of the other proposed requirements. Eliminating the proposed mandatory warning statement will affect estimated labeling costs because, under this option, only those labels affected by the claims restrictions would have to be changed. However, the vast majority of the affected products have labels that would be affected by the claims restrictions. Among the products in the market surveys, 94 percent of the products investigated had one or more claims that would be restricted under this option. Thus, labeling costs under this option will be only approximately 6 percent lower than the labeling costs estimated for Option 3.

Finally, under the framework developed earlier, this option will have little effect on the other costs and distributive effects estimated for the proposed action under Option 3 because of the influence of the other factors involved.

7. Option 7—Require Warning Statements Only

Estimating the benefit of eliminating all proposed actions except the required warning statement involves a controversial value judgment concerning the evaluation of risks that are voluntarily accepted in the presence of the amount of information on those risks provided on the proposed warning statement.

Under the assumption that any adverse events that may occur due to such behavior cannot represent net social costs, warning statements will eliminate all net social costs associated with these adverse events. This assumption is based on the notion that the proposed warning statement provides adequate information on the risks of consuming these products and the notion that if those consuming these products have adequate information on the risks involved, then their consumption decisions reflect their personal judgments concerning the relative value of the benefits and risks of consuming these products.

If no existing warning statements provide adequate information while the proposed warning statement will

provide adequate information, then the social benefits of this option would be at least as great as the value of banning dietary supplements containing ephedrine alkaloids. On the other hand, if some existing warning statements already provide adequate information, then the benefits of this option would still be at least as great as the value of banning dietary supplements containing ephedrine alkaloids; however, the benefits of both options would be lower.

Under the assumption that any adverse events that may occur due to such behavior represent social costs, eliminating all actions other than the proposed warning statement will substantially reduce the benefits from those estimated for Option 3. This assumption is based either on the notion that the level of information provided on the proposed warning statement is inadequate to ensure that consumers can make informed consumption decisions, or on the notion that public health risks require intervention even if those risks are voluntarily undertaken in the presence of adequate information on the benefits and risks of the relevant activity. Under this assumption, this option will reduce the health risks from these products such that the expected number of adverse events will be reduced by between 0 cases and approximately 210 cases per year.

With respect to compliance costs, eliminating all actions except the warning statement would eliminate the costs associated with product reformulation and consumer utility losses.

Finally, this option would substantially reduce the distributive effects of this action. Under this option, the estimated total reduction in the consumption of dietary supplements containing ephedrine alkaloids would be between 0 and 15 percent. Therefore, sales of these products would be reduced by between $0 and $110 million per year. A reduction in sales of this magnitude would threaten the viability of fewer firms than the proposed action, as estimated under Option 3.

V. Regulatory Flexibility Analysis

In the economic impact analysis for the December 1995 proposal, FDA estimated the number of dietary supplement manufacturers to be between 150 and 600, with the majority of those firms being small businesses. Based on additional information, these estimates were revised in the economic impact analysis of the final rule on nutritional labeling. The revised estimate was 500 to 850 firms, with 95 percent of those firms classified as small businesses.

The proportion of dietary supplement manufacturers producing products containing ephedrine alkaloids is unknown. The two market surveys identified 85 manufacturers and distributors of dietary supplements suspected of containing ephedrine alkaloids. Assuming that the proportion of these firms that are small businesses is the same as the proportion of firms in the dietary supplement industry that are small businesses, 95 percent of these firms, or approximately 80 firms, are small businesses.

Total compliance costs incurred by small businesses will be virtually equal to total compliance costs incurred by all businesses estimated earlier because the vast majority of the firms affected by the proposed action are small businesses. Relabeling, reformulation, and testing costs are fixed costs on a per product basis and will disproportionately affect small businesses. Total compliance costs of the proposed action were estimated to be between $3 million and $80 million, with between $3 million and $70 million of these costs occurring in the first 6 months after publication of the final rule. However, FDA has insufficient information to estimate the portion of these costs that will be borne by the owners, stockholders, and employees of these firms and the portion that will be passed on to consumers of these products through price increases. In addition, the proposed action will generate consumption shifts that were previously estimated to produce negative distributive effects of between $60 million and $230 million per year. Countervailing distributive effects are also possible. For example, the proposed rule may reduce the number of product liability lawsuits brought against manufacturers of dietary supplements containing ephedrine alkaloids. Based on reported annual retail sales of between $600 million and $700 million for products containing Ma huang, these costs and distributive effects may be significant.

Most of the regulatory alternatives discussed earlier would reduce the impact of this rule on small businesses. The options of taking no action and taking no action other than generating additional information both reduce the impact on small businesses to zero. Requiring only warning statements would substantially reduce compliance costs to between $3 million and $60 million, with between $3 million and $50 million of these costs occurring in the first 6 months, and also substantially reduce negative distributive effects generated by consumption shifts to between $0 and $110 million per year. Taking the proposed action without requiring the warning statement would slightly reduce compliance costs to between $3 million and $80 million, with between $3 million and $70 million of these costs occurring in the first 6 months, but would not affect distributive effects because of the other factors influencing those effects. Taking the proposed action but raising the proposed potency limit to the level suggested by a trade group representing the dietary supplement industry would probably not significantly alter the impact of this rule on small businesses. Finally, banning dietary supplements containing ephedrine would not change reformulation or relabeling costs and would lead to distributive effects from consumption shifts in the range of $200 million to $230 million per year. This action would have the greatest negative impact on small businesses.

VI. Conclusions

The estimated benefits of Option 3, take the proposed action, are between $240 million and $670 million *per year.* The estimated quantifiable costs are between approximately $3 and $70 million in the first year, and between a minimal amount and about $0.5 million in every year after the first year. Thus, notwithstanding the considerable uncertainty concerning the marginal effectiveness of the individual requirements of the proposed rule, FDA is confident that it would generate benefits that far exceed the quantifiable costs. In addition to the quantifiable costs, however, the proposed action will also generate non-quantifiable utility losses for some consumers and distributive effects from consumption shifts with an estimated value of between approximately $60 million and $230 million per year, with possible countervailing distributive effects from a reduction of liability lawsuits. Social costs might be associated with these distributive effects.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. Based on the available information, FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday (Ref. 221).

The agency will reevaluate its environmental decision if new information is received suggesting that the action would have significant environmental effects.

VIII. Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IX. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 111

Drugs, Packaging and containers, Incorporation by reference, Labeling.

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 111 be revised as follows:

PART 111—RESTRICTIONS FOR SUBSTANCES USED IN DIETARY SUPPLEMENTS

Subpart A—General Provisions—[Reserved]

Subpart B—Current Good Manufacturing Practice for Dietary Supplements

Sec.
111.50 Packaging for iron-containing dietary supplements.

Subpart C—New Dietary Ingredients—[Reserved]

Subpart D—Restricted Dietary Ingredients

111.100 Dietary supplements that contain ephedrine alkaloids.

Authority: Secs. 201, 402, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 371).

PART 111—RESTRICTIONS FOR SUBSTANCES USED IN DIETARY SUPPLEMENTS

Subpart A—General Provisions—[Reserved]

Subpart B—Current Good Manufacturing Practice for Dietary Supplements

§ 111.50 Packaging of iron-containing dietary supplements.

(a) The use of iron and iron salts as iron sources in dietary supplements offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, is safe and in accordance with current good manufacturing practice only when such supplements are packaged in unit-dose packaging. ''Unit-dose packaging'' means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term ''dosage unit'' means the individual physical unit of the product (e.g., tablets or capsules). Iron-containing dietary supplements that are subject to this regulation are also subject to child-resistant special packaging requirements codified in 16 CFR parts 1700, 1701, and 1702.

(b)(1) Dietary supplements offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, are exempt from the provisions of paragraph (a) of this section until January 15, 1998, if the sole source of iron in the dietary supplement is carbonyl iron that meets the specifications of § 184.1375 of this chapter.

(2) If the temporary exemption is not extended or made permanent, such dietary supplements shall be in compliance with the provisions of paragraph (a) of this section on or before July 15, 1998.

Subpart C—New Dietary Ingredients—[Reserved]

Subpart D—Restricted Dietary Ingredients

§ 111.100 Dietary supplements that contain ephedrine alkaloids.

The ephedrine alkaloids include ephedrine, pseudoephedrine, norpseudoephedrine, norephedrine, methylephedrine, methylpseudoephedrine, and related alkaloids. These substances are chemical stimulants contained in

particular botanical products, including those from the botanical species *Ephedra sinica* Stapf., *Ephedra equistestina* Bunge, *Ephedra intermedia* var., *tibetica* Stapf., *Ephedra distachya* L., and *Sida cordifolia* or their extracts.

(a)(1) Dietary supplements that contain 8 milligrams (mg) or more of ephedrine alkaloids (the total of ephedrine, pseudoephedrine, norpseudoephedrine, norephedrine, methylephedrine, methylpseudoephedrine, and related alkaloids) per single serving shall be deemed to be adulterated under sections 402(a)(1) and 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

(2) The Food and Drug Administration will use high performance liquid chromatography (HPLC) to determine the level of ephedrine alkaloids in a dietary supplement as specified in its Laboratory Information Bulletin (LIB) No. 4053, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Director, Office of Constituent Operations, Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., rm. 5827, Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) The labeling of dietary supplements that contain ephedrine alkaloids shall not suggest or recommend conditions of use that would result in an intake of 8 mg or more ephedrine alkaloids within a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids.

(c) The label of dietary supplements that contain ephedrine alkaloids shall state ''Do not use this product for more than 7 days.''

(d) No ingredient, or ingredient that contains a substance, that has a known stimulant effect (e.g., sources of caffeine, yohimbine) may be included in a dietary supplement that contains ephedrine alkaloids.

(e) No dietary supplement that contains ephedrine alkaloids may purport to be, or be represented as, either expressly or implicitly, for use for long-term effects, such as weight loss or body building.

(f)(1) The label or labeling for dietary supplements that contain ephedrine alkaloids that purport to be or are represented, either expressly or implicitly, to be used for short-term effects, such as increased energy, increased mental concentration or enhanced well-being, shall state ''Taking more than the recommended serving may cause heart attack, stroke, seizure, or death.''

(2) This information shall appear on the same label panel or same page of labeling as the claim and shall be connected to the claim by use of an asterisk. This information shall appear in easily legible print or type, in distinct contrast to other printed or graphic matter, and in a type size no less than is required by § 101.105(i) of this chapter for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the information shall be no less than one-half the size of the claim, but no smaller than one-sixteenth of an inch. Where the label or labeling contains multiple claims, the information shall appear once on each label panel or on each page of labeling.

(g)(1) The labeling of any dietary supplement that contains ephedrine alkaloids shall bear the following warning:

WARNING: If you are pregnant or nursing, or if you have heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder consult a health care provider before using this product. Do not use if you are using monoamine oxidase inhibitors (MAOI) or for 2 weeks after stopping a MAOI drug; certain drugs for depression, psychiatric or emotional conditions; drugs for Parkinson's disease; methyldopa; or any product containing ephedrine, pseudoephedrine or phenylpropanolamine (ingredients found in allergy, asthma, cough/cold and weight control products). Stop use and call a health care professional immediately if dizziness, severe headache, rapid and/or irregular heart beat, chest pain, shortness of breath, nausea, noticeable changes in behavior, or loss of consciousness occur. Do not exceed recommended serving.

(2) The phrase ''Do not exceed recommended serving'' is not required to appear in the warning statement when the disclaimer required in paragraph (f)(1) of this section appears on the same label panel as the warning statement.

(3) The warning statement required by paragraph (g)(1) of this section shall appear prominently and conspicuously on the product label and shall be set off in a box by use of hairlines.

Dated: April 22, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

Donna E. Shalala,

Secretary of Health and Human Services.

Note: The following Appendix will not appear in the annual Code of Federal Regulations.

Appendix—AER's Associated With Ephedrine Alkaloid-Containing Dietary Supplements

ARMS No.	Product manufacturer	Clinical summary
9101	Thermojetics Herbal Tablets-Green—Herbalife International.	33 yo F used product (bid, ?dose) in 11/93 until 1st week in 1/94, when she started having dizzy spells that progressed to involve numbness of L arm & forehead, weakness of both legs, SOB, and shaky feelings. 1/30/94 seen in ER for dizziness & tachycardia, Dx labyrinthitis, Tx Valium, d/c on Antivert. 2/2/94 episodes worsened, including dizziness, severe tachycardia, and SOB. She was transported to hospital & admitted w/extensive w/u (CAT, XR echo, doppler, halter, labs). D/c on 2/8 on Tenormin and Ativan w/Dx of SVT. Normal PE in 10/93. No h/o allergies or CV disease. Mother (insomnia) & husband (blood in stool) using product w/various SSx. Sister took product w/o problems.
9316	E'OLA AMP II Pro Drops—E'OLA Biogenics, Inc.	23 yo F hospitalized w/ cardiac arrest, CPR, then ICU. Dx inferolat MI. CK > 2000 (MB+), EKG: sinus tachy & ↑ST inf leads; angio: lacerated coronary (partial dissection) & hematoma at bifurcation of circumflex artery. Used AMP II 3-4 drops in beverage night before arrest, also noted to be using other 'diet pills' (?dose/durations). Drug screen negative, doing well off product.

ARMS No.	Product manufacturer	Clinical summary
9552	Nature's Nutrition Formula One—Affiliated Consultants Inter./Alliance U.S.A. Inc.	35 yo F good health, no risk factors for CAD used product 04/94—05/94 (30 days) for WL&E, as much as 1–2 caps bid 30 days. She stopped for a week but resumed again at 3 caps qd. On 6/25/94, developed acute onset of throbbing, ant. CP at rest, w/ pain radiation to the left shoulder, numbness of left arm & hand, diaphoresis and SOB. The pain persisted, and she was taken to the ER. The pain decreased with subl nitro and was completely relieved with morphine and nitro. On admission, BP: 140/100, EKG: minor ST depressions V_1, V_2, and minor ST elevation in INF leads, elevated cardiac enzymes. Dx: Acute non-Q wave MI probably secondary to coronary spasm. Cardiac cath 6/27/94 LV angiogram very mild posterior basilar hypokinesis, normal LV function w/ good ejection fraction. Normal coronary arteries. Discharged after 4 days on Cardizem, aspirin, nitro prn, & f/u for a limited stress test.
9747	Ripped Fuel—Twin Laboratories, Inc	40 yo F reported by physician to suffer a grand mal seizure after using product for 3 days (2 bid) as directed. Her husband stated she stopped breathing and he had to administer mouth to mouth resuscitation. She was on no medication and had no personal nor family history of seizures. She had no symptoms until she felt dizzy immediately before her seizure. CT head—no abnormalities.
9751	Slim NRG—Momentum Marketing	28 yo F (weighing 95 lb) reported by MD. Used product, 1 tid for 6 months for weight loss (30 lb). Stopped product abruptly, became despondent over 10 days ending w/ attempted suicide—gunshot wound to chest. No other products used. Past mental history negative for mental illness, use of drugs/alcohol. Drug/ETOH screen neg. Tx: w/antidepressants. Positive dechallenge.
9754	Shape-Fast—Shaperite Concepts Ltd	44 yo F reported by physician's assistant to be taking product (400 mg bid) when she developed heat stroke, chest and back pain, hyperthermia and tachycardia while exercising.
9818	Power Trim—Enrich International	43 yo M who used product (details not given) over a 6 wk period and lost 30 lb., developed new onset insomnia and atrial fibrillation. Seen by health care provider and given Lanoxin, hospitalized next day when light headedness developed. Extensive w/u (EKG, CXR, echo-cardiogram, smac, myocardial enzymes), compatible with AF. Dx: ''new onset atrial fibrillation, possibly due to the stimulant effect of his dietary supplement.'' Tx: Lanoxin, Betapace, Verapamil, and Coumadin.
9864	Nature's Nutrition—Formula One—Affiliated Consultants Intl/Alliance U.S.A.	44 yo M, active swimmer and tennis player, with no known cardiovascular risks as documented by medical history, originally obtained a sample of product during a routine physical from his health care provider when he requested some substitute for his daily coffee and cocoa use. He used this product as directed, and was able to eliminate his afternoon coffee/cocoa use. On 12/18/93 (~3 weeks after starting product), after playing his routine weekly game of tennis, he came home, laid down and was found dead about noon. Resuscitative efforts were unsuccessful. Autopsy revealed an acute thrombus, 1.5 cm from the origin of the left anterior descending coronary artery, resulting in occlusion. All lumina were otherwise patent, although calcification of the coronary arteries resulting in focal narrowing to about 50 percent was noted. A drug screen performed at the time of autopsy was reportedly negative for amines.
10009	MetaboLift Thermogenic—Twin Laboratories, Inc.	35 yo M w/acute MI (inferoapical). Took product (two capsules at noon and 3 capsules at 4:30 PM) Worked out 5:30 PM—6:30 PM and developed chest pain around 7:30 PM. Consumer admitted, treated w/TPA, subsequent cardiac catheterization demonstrated normal coronaries. CPK elevated, EKG diagnostic for MI.
10026	Formula One—Affiliated Consultants Intl./Alliance U.S.A.	48 yo F took product (3 caps qd) for 6–7 months when developed weakness, syncopal episode, increased BP, increased HR, tightness in chest. Seen in ER w/ EKG which showed nonspecific STT wave abnormality, and increased cardiac enzymes. BP–120/99. Saw MD next day, complained of right sided weakness and speech difficulty. Meds: antihypertensives, hormones. Dx: ''conversion reaction'', thought to be stress related. Sxs improved over next month. MD later told about use of product, which he states could aggravate nervousness.
10063	Super Diet Max—KAL, Inc	22 yo F had been using product several months at 1 tab bid for WL. On day of adverse event she had taken 2 caps (1 q AM, 1 q PM), and experienced increased BP, pounding heart, n/v, lasting 1.5–2 hr. Event abated after product discontinued. Saw health care provider. Started on Prozac 2 wks prior to adverse event.
10088	Nature's Sunshine SN–X 100 Vegitabs—Nature's Sunshine.	38 yo F took product for 4 days and developed syncope, blood pressure = 180/110. Seen in ER with severe HA, nausea, diaphoresis. The consumer had been seen every 3–4 months for 5 years prior to this event and no history of high blood pressure. After stopping the product her blood pressure returned to normal.
10275	Nature's Nutrition Formula One—Affiliated Consultants International/Alliance U.S.A.	63 yo F reports using product for 3 weeks at recommended dose, never used maximum recommended dose, when she developed hives. The next day she had difficulty walking across room, difficulty breathing and swallowing, and vomited. She suffered ventricular fibrillation, a small non Q-wave infarct by enzymes criteria and was hospitalized 5 days where evaluation (cardiac catheterization, electrophysiology study) failed to find any sort of heart problem or heart disease to explain her arrest. She has chronic obstructive pulmonary disease secondary to cigarette smoking. Previous to arrest no medicine and only vitamin and occasional aspirin.

ARMS No.	Product manufacturer	Clinical summary
10437	Thermojetics Herbal Tablets—Beige, Thermojetics Herbal Tablets—Green, Formula 1, Formula 2, Formula 3—Herbalife International.	55 yo F reports grand mal seizure after 3 days on product per directions. No significant past history, normal CT and EEG. No meds or other dietary supplement products.
10862	Ultimate Xphoria—Alternative Health Research.	20 yo M took 8 tabs @ ~4 pm (directions: Take 4 tablets, on an empty stomach; do not exceed 4 tablets in 24 hours). Within ~30 minutes, complained of being hot, w/ sweating & HA. Found dead by friends ~8 hr later. Coroner's report notes toxic levels of ephedrines.
10919	Power Trim—Enriched International	49 yo F used Power Trim, 3 capsules three times daily for 3 weeks for weight loss. She developed weakness, dizziness, nausea, vomiting, and palpitations and went to the ER where she was found to have vertigo, serous otitis media bilaterally, hypertension (150/102) and elevated liver enzymes. The consumer reports stopping the product and her blood pressure has returned to normal without any medical treatment. She has no history of high blood pressure.
10943	Multi DS—(1) Omnitrim Tea & (2) Omni 4—Omnitrition International, Inc.	37 yo F used for 1 week, Omnitrim Tea, 2 teaspoons three times per day, and Omni 4 (a vitamin) one daily, both as directed, for weight loss. She stopped due to the development of shakes, sweats, dizziness, racing heart, and loss of hearing in R ear. Symptoms abated after stopping product. No other products in use and no significant medical history.
10946	Multi DS—(1) ThermoChrome 5000, (2) Isotonic Vitamin B12, & (3) Isotonic OPC3 (1) Health Power Products Inc./ Market America; (2) & (3)—Labels unavailable.	42 yo F used Thermochrome 5000, 1 capsule twice daily for 3 days for weight loss. She was also taking B12 and an antioxidant supplement. She developed a rash over her entire body and stopped all three products. She restarted the Thermochrome 5000 after 3 days and 3 days after that, on a visit to her doctor for a nonproductive cough and congestion, was found to be hypertensive (170/114). She has no history of hypertension and was seen by her gynecologist 1 week before starting the Thermochrome with a normal blood pressure (120/78).
10957	E'Ola Amp II Pro Drops—E'OLA Biogenics, Inc.	34 yo F used E'Ola AMP II Pro Drops according to label directions, off and on over a 2 year period for weight loss. She developed ''triple vision'' which lasted a few moments and recurred 3 days later accompanied by vertigo. She was initially seen in an ER, where examination and CT were normal and she was diagnosed with dehydration. She spent 3 days in bed with severe vertigo, nausea, and vomiting. She was unable to reach out and pick up a drinking glass. An MRI showed multiple bilateral cerebellar infarcts. No source of embolization was identified. Cardiovascular, autoimmune, and coagulopathy workups were unremarkable.
10960	Blast and Burn—Vita Labs Inc	16 yo F used Blast and Burn as directed on the package for several weeks for performance as a high school athlete. Within the first week of use she was taken to the ER with a racing heart. She had several similar episodes. She couldn't afford to buy a second bottle of the product and noticed her symptoms resolved once she stopped using the product.
10974	ShapeFast—Shaperite Concepts Ltd	19 yo F took Shaperite, one before each meal, three times per day (½ of recommended amount) for 1 month, for weight loss. Her family witnessed seizure activity at mealtime and took her to the ER. CT and EEG were normal. Neurologist's evaluation found no other risk factors for seizure. No other products used, no significant past history noted.
10977	Emphora Ecstasy—Label unavailable	18 yo F took Emphora Ecstasy, 4 pills at once, to get high. About 2 hours later she noted dizziness, racing heart and felt she would pass out if she stood up. She was unable to sleep for most of that night. The next morning she passed out in the shower, injuring her neck and back. She went to the ER where the only abnormality noted was a low potassium of 3.1 meq/L (normal 3.6–5.2). She has had dizziness in the past but no previous loss of consciousness. The product was not used again and her symptoms resolved.
10989	Herbal Ecstasy—Label unavailable	18 yo F used Herbal Ecstasy, 5 pills at once, one time as directed to get high at a Lolapalooza concert. She felt ''numb, weird'' and fell backwards. She was unable to sleep for 3 nights in a row. Over the next 8 months, she had difficulty sleeping, refused to leave the house unless her parents insisted and did not attend college as planned in the fall. She has been diagnosed with panic attacks and depression and is currently under psychiatric treatment. She has also been diagnosed with a ''weak heart valve.''
10990	Tri-Chromaleane—Achievers Unlimited	58 yo M used Tri-Chromaleane, 3 pills once daily for 6 weeks for weight loss. He developed memory problems. He couldn't remember his son's middle name, his office phone number or how to get home from a local store. He would start work and be unable to remember why he had started the task or what to do next. He stopped the product and his symptoms resolved over the next 2 weeks. At the same time he had been participating in a clinical trial of Proscar for the prevention of prostate cancer and does not know whether he had been taking Proscar or placebo. The Proscar study coordinator reported that it was unlikely that the consumer's complaints were related to Proscar. Of note, he never had prostate cancer.

ARMS No.	Product manufacturer	Clinical summary
10991	Tri-Chromaleane—Achievers Unlimited	54 yo F used Tri-Chromaleane, at less than the recommended amount, once daily for a number of weeks. She was under treatment for hypertension and was told by the distributor that the product would *lower* her blood pressure. After starting the product her blood pressure increased and her doctor added a second medication and her blood pressure improved. She was unable to pass an insurance physical due to her inadequately controlled high blood pressure. She stopped the Tri-Chromaleane and her blood pressure has improved to the point that her doctor is planning to stop the second blood pressure medication to see if she can be controlled on a single medication (as she was before using the Tri-Chromaleane).
11050	ThermoChrome 5000—Health Power Products.	63 yo F took 2–3 pills bid, for 2 months for weight loss. She was taking Lescol for hypercholesterolemia, Zantac for esophageal reflux and Vasotec for hypertension. She developed worsening of her hypertension (174/93) and episodes of palpitations. She sought medical assistance from a neighbor who is a physician after an especially severe episode of palpitations. After stopping products BP normalized (140/80) and palpitations resolved.
11062	Power Trim—Enrich International	42 yo F used 2–3 caps before meals tid as directed for 3 months for weight loss. She was taken to hospital by ambulance after family members found her seizing. She had another seizure while being examined by neurologist. She complained of increased headaches and slow thinking in the days preceding her stroke and was taking penicillin for a dental abscess. CT and MRI showed a small R-sided intracerebral hemorrhage. MRI and angiography revealed no evidence of any vascular abnormality. She was treated with Dilantin.
11065	Thermo Slim—Weight Loss Specialist	23 yo F used product, 1 tab before meals 3 times per day with The Accelerator Guarana, 1 tab before AM and noon meals, for 8 days. On the 9th day she forgot to take her noontime dose. At first she thought she might be going into withdrawal, took another dose and vomited shortly afterwards. She was taken to the ER with complaints of a racing heart, dizziness, numbness of face and arms, and disorientation. The doctor advised her to stop the products and over the next week her symptoms resolved.
11078	Formula One with Quick Start—Alliance U.S.A.	36 yo F used Formula One for 2 yrs, stopped that product and then took Quick Start 2 caps which she used once. The next morning she experienced grand mal seizures. She was taking 2 iron tablets, Ionamin 30 (a dietary supplement) and B12 liquid; also had switched to the night shift. CT, MRI, and EEG were normal.
11081	Herbal Ecstacy—Label unavailable	M used Herbal Ecstacy, 10 pills once, to get high. He states he became ''psycho,'' very active, developed a ''bad mood'' and assaulted a friend. His symptoms resolved and he did not try the product again.
11105	Trim Easy—TeamUp International Inc	31 yo F used Trim Easy for about 1 year for weight loss. She originally used 2 capsules three times daily for 1 month and then increased to 3 capsules three times daily (9 total). The directions advised beginning at 2 capsules three times per day and increasing if tolerated to 3 capsules three times per day, the maximum recommended dose. At times she would forget one of the 3 doses and double up the next time she took the product (6 capsules at once). She continued to take a total of 9 capsules this way daily for about 3 months and then decreased to a total of 6 capsules taken all at once each day for about 8 months. She developed dizzy spells which increased over 1 month's time to twice daily and eventually suffered a stroke—an intracerebral hemorrhage with Lft hemiparesis and aphasia. CT and MRI documented the bleed, showing midline shift. Cerebral angiogram did not show any additional abnormality such as an arteriovenous malformation.
11106	Therma Slim—Great American Products ...	47 yo F used 1 pill at breakfast and 1 at lunch for 2 months. She developed profuse sweating, trembling and HTN, and menstrual bleeding which lasted 6 wks. She was treated first with Megesterol and then with Premarin and Provera, by gynecologist. It was also noted that her BP had risen from 110/70 (3/18/96) to 156/98 (4/10/96). She complained to radio station where she originally heard about product and received a letter telling her side effects she was experiencing were normal and would quickly subside. 4/11/96—Consumer contacted her HMO after seeing broadcast on ephedra and was advised to stop using product. 6/1/96—This consumer later suffered a pontine stroke and requires an endotracheal tube and feeding tube for long-term ventilatory and nutritional support, respectively. Estrogen use was implicated as a possible contributing factor by health care provider.
11107	Diet Fuel—Twin Laboratories, Inc	42 yo M used Diet Fuel, 3 pills daily for 9 months. He became dizzy, nauseated, developed left sided chest pain, passed out in a meeting. Paramedics noted his pulse to be in the 30's and he was hospitalized. After cardiology evaluation and electrophysiologic studies it was concluded that the consumer had an abnormal vasodepressor response to tilt plus catecholamine administration and was placed on Tenormin. The consumer reports a similar episode many years prior and as a young man treated with Dilantin for what was diagnosed as epilepsy.
11109	Unspecified E'OLA product—E'OLA Biogenics, Inc.	46 yo F used two E'OLA products, an energy product, 2 drops twice daily, and a metabolism booster, 4–5 drops twice daily, both for 1½ weeks, for energy and weight loss. She developed a heart rate of 200 beats per minute and sought medical attention. Medical records describe evaluation for recurrent paroxysmal palpitations for 20 years. No mention of the use of E'Ola products. Blood pressure, pulse, EKG, echocardiogram, exercise stress test failed to reveal an underlying cardiac disorder.

ARMS No.	Product manufacturer	Clinical summary
11112	Thinner Jizer—Quiet Storm	34 yo F used Thinner Jizer 1 pill for 1 day, 1 pill twice daily, then 2 pills in AM and 1 pill in PM, increasing as directed. After 3 days on the highest amount (2 pills AM and 1 pill PM) she developed jitters and was advised by the distributor to cut back the dose as this response was normal. She used 1 pill AM and 1 pill PM for an additional 3 days when she developed acute visual changes in her right eye lasting 25 minutes. She sought medical care and was advised that her symptoms were likely due to vascular spasm, possibly related to her use of ephedra. She stopped the product, took aspirin for 1 week and has had no further episodes of acute visual changes. She was taking no other products and has no significant prior history.
11114	Herbal Ecstacy—Label unavailable	16 yo M used Herbal Ecstacy, 2 pills one time. Half an hour later he found himself driving down the wrong side of a road and didn't realize it until he saw a car headed towards him. He described feeling ''a major rush, tingly, hyper.'' He denies taking other products including drugs, alcohol, or street-type drugs at the time. He occasionally uses ginkgo biloba, but had not taken any that day.
11131	Multi DS—(1) Herbal Ecstacy & (2) Nirvana—(1) Global World Media & (2) Label unavailable.	20 yo M used Herbal Ecstacy, 5 pills one time as directed, for recreational purposes. He also took 6 Nirvana pills one time (directions recommend 7 pills) also for recreational purposes. He went to a club and began to feel dizzy, lightheaded and nauseous. He noted stomach cramps, thirst, and a ''real bad headache.'' His symptoms forced him to leave the dance floor, feeling he was going to pass out. He fell on his knees, started ''seeing things'' and felt his seeing and hearing were distorted. He noted shortness of breath, sleeplessness, and hives. His symptoms resolved by the next day. He denies alcohol, other drug or product use that night.
11134	Multi DS—(1) Ripped Fuel, (2) The Ultimate Whey Designer Protein, (3) Super Amino 2000, (4) Super Once-A-Day Timed Release Multiple Vitamins and Chelated Minerals—(1) Twin Laboratories, Inc. (2) Next Nutrition Inc. (3) Ultimate Nutrition Products Inc. (4) Quest Vitamins LTD.	23 yo M college student who used multiple dietary supplements for approximately 2 years with observed daily use during the year prior to being found dead at home by his sister. There was no previous medical history and no evidence of trauma or substance abuse. Toxicology screens were negative for alcohol, barbiturates, cocaine, methamphetamine, morphine, and salicylate but indicated the presence of ephedrine alkaloids in the urine. The Medical Examiner's reports states the cause of death as, ''patchy necrosis associated with ephedrine toxicity from protein drink containing ma huang extract.'' Review of health examination reports from the University Health Service indicate the consumer was in excellent health with normal weight, height, blood pressure, and laboratory measurements.
11137	Natural Trim—Starlight International	39 yo F used product for 6.5 months, 1 thermogenic pill, 1 vitamin and 1 booster pill at 10 AM, and 1 thermogenic pill at 4 PM, as directed. While on antibiotics for a sore throat, she developed upset stomach and stopped the products. She became shaky, weak, and exhausted, and felt as if she were about to pass out if she tilted her head. She was diagnosed with hyperthyroidism. She also reports her supplier has stopped selling the product as the seller has suffered seizures.
11140	Power Trim—Enrich International	59 yo F used Power Trim and later Power Prime and has had a total of 3 vertigo attacks: 2/96, 4/96, and the third at an unspecified time. She has been to the ER and seen her physician.
11144	Metabolift—Twin Laboratories, Inc.	28 yo M used Metabolift for 10 months, 1 cap 1–2 times daily for energy. While visiting a rental property with his father's truck, his father had found him bloody, walking away from the garage, and responding inappropriately. He has transient retrograde amnesia. In the emergency room his blood pressure was 168/90, and pulse was 116. CT head EKG were normal. He was diagnosed with syncope and a closed head injury. The next week the consumer had an EEG, echocardiogram, and MRI of the head—all normal. His neurologist stated ''most likely he had a seizure secondary to the ephedrine'' from the health food substance he was taking. He was advised to avoid the product and dispose of it. He was on no other medication, has no significant past medical history and has never had problems with dizziness or passing out.
11180	Nature's Nutrition Formula One—Alliance U.S.A. Inc.	41 yo F used Nature's Nutrition Formula One (Alliance) 1–2 pills in AM and 1–2 pills PM for about 6 months for energy. One morning she took 2 pills, skipped breakfast and drank a diet Pepsi. Soon after she developed hives while visiting a nursing home and was given benadryl tablets. Two hours after taking the Formula One she was found unconscious in a stairwell by nursing personnel who described seizure activity. She was taken to an ER where the evaluation including EEG and CT scan was normal. She has not used the product again and has had no further episodes.
11181	Multi DS—(1) Ripped Fuel & (2) Unspecified chromium picolinate with caffeine product—(1) Twin Laboratories, Inc., (2) GNC.	19 yo M used Ripped Fuel 2 pills 2–3 times daily, according to label directions, for 2 days for weight-loss and body-building. He was found by family members on the morning of the third day, in his bed with seizure activity and afterward complained of dizziness and a headache. He was taken to the ER and given IV Dilantin. CT and MRI were normal and EEG was nonparoxysmal. He had also been taking chromium picolinate, 1 pill daily as directed for 3–4 months; Phosphagen, 1 teaspoon with meals, three times per day as directed for 3–4 months; and B2G vanadyl sulfate, 2 capsules with meals, three times per day, as directed for 1 month at the time of the event. Based upon the test results and history of use of the Ripped Fuel, his neurologist felt the patient did not need to be treated with Dilantin. The neurologist advised the patient to stop use of all ''over-the-counter medications''. The patient suffered a second witnessed seizure 1 month later and was started on Dilantin. His past history is significant for a concussion as a child with a normal CT at the time.

ARMS No.	Product manufacturer	Clinical summary
11215	Multi DS—Ripped Fuel and Ripped Force—Label unavailable.	24 yo M used Ripped Fuel, 2 tablets three times daily for 2 years and Ripped Force, 1 bottle daily for 2 months. He used both products for body building. He went on vacation, stopped the products and within 3 days experienced 2 grand mal seizures. The second seizure was witnessed by the ambulance crew while en route to the ER. MRI of head and EEG were both reportedly normal. He was also using 'vanadyl', creatine, and amino acids as part of his body building regimen. He denied use of recreational drugs, medications, or other products.
11248	(1) Formula One, (2) Equilizer, (3) Protein Plus Chromium Picolinate, (4) Fast Start—(1) Alliance U.S.A., Inc, (2), (3), (4) Equinox Intl.	37 yo M used products 2 yr (and had used other products containing ephedrine prior to use of Formula One). (Formula One use: 1–2 cap mid AM & PM, per label instructions). Also known to consume large amount of diet cola. Experienced apparent sudden cardiac arrest, with no details known surrounding death. Coroner's report notes: cardiomegaly w/mild LVH, focal interstitial fibrosis & mild medial hypertrophy. PMH: neg for HTN. Tox screen noted pseudoephedrine in urine.
11249	Victory Turbo Pump—Joe Wider Nutrition	20 yo M took product for 3 months (once or twice per week), experienced grand mal seizure. Neg. past history and family history for seizure disorders. He was treated with Dilantin.
11286	Breathe Easy Herbal Tea—Traditional Medicinals.	36 yo F used Breathe Easy Herbal Tea on one occasion at less than recommended dose. She steeped tea for 1 minute and drank ⅓ cup instead of steeping tea for 5 min as indicated on the instructions. She used product along with 2 Advil to relieve cold/congestion symptoms. Approximately 15 min after drinking tea she experienced rapid, pounding heartbeat. Following advice of friend who is a nurse, she drank large amounts of water in effort to ''flush tea out of her system.'' She felt so bad she could hardly get out of bed, but did not seek medical care secondary to anxiety about hospitals. Symptoms resolved completely within 5 hours. Routine medical visit approx 1 month after event was unremarkable. Past medical history is significant for occasional palpitations. Consumer's husband used product on several occasions prior to event with no report of negative side effects.
11298	(1) Fast Start-The Equilizer, (2) Nigh Time, (3) Protein Plus, Chromemate—Equinox International.	41 yo M used 3 herbal products as directed on labels in an attempt to lose weight. He experienced a ''rush'', and blurred vision which influenced his ability to operate heavy equipment. On 5th day of using the product, his underwear was noted to be stained red. A physician visit confirmed hematuria, and noted BP of 136/102, and labs: SGPT 72, cholesterol 208, triglycerides 401. He stopped the product, with recovery, including normalization of BP.
11401	Ultra Energy Now—Phoenix Health Products.	42 yo M used Energy Now tablets on 2 separate occasions. He took 3 tablets as instructed on label on both occasions. First occasion was without incident. 2 weeks later when he used product for second time, he experienced severe diaphoresis, blurred vision, SOB, lightheadedness, and pounding chest pain within 1 hour of taking product. Symptoms lasted approx 15 min and had resolved completely by the time he was seen in emergency room. He was admitted to hospital overnight for evaluation including EKG, CBC, & SMA–18 which was all within normal limits. Of note, he was not using any other products. History is significant only for positive tobacco history=1.5 pack of cigarettes per day.
11417	Thermojetics Herbal Tablets—Green—Herbalife International.	34 yo F died following diagnosis of primary pulmonary hypertension (PPH). Mother of deceased found bottles of Herbalife Green & Beige tablets in home of the deceased. Duration and detail of use are unknown. Deceased appeared to be in excellent health until approx. 3 months prior to her death when she developed SOB & n/v while skiing in Colorado despite numerous previous ski trips in same location which were uneventful. She was diagnosed with ''high altitude sickness.'' Symptoms persisted and she subsequently underwent cardiac catheterization 3 months after onset of sxs. Results of cath were apparently consistent with PPH and indicated that she would need heart/lung transplant in 3–5 years. She died 3 days later in August 94. Past medical history is significant only for hospital admission 1 year prior to death for CP, SOB, and possible pneumonia.
11441	Ripped Fuel—Twin Laboratories, Inc	27 yo M died secondary to injuries sustained in motor vehicle accident. Wife of deceased reports he had been taking Ripped Fuel 2 tabs bid as instructed on label for approx. 3 years prior to death. No autopsy was performed. Post mortem blood analysis indicate: 0.05 percent ethyl alcohol & 0.31 percent mg/L phentermine. Post mortem urine analysis: Positive for phentermine, negative for cocaine, opiates, benzodiazepine, cannabinoids.
11442	Thermojetics Herbal Tablets—Green—Herbalife International.	39 yo F used Herbalife Diet Plan which consisted of the following 5 products: Formula 1 Protein Drink Mix (2 tablespoon bid); Formula 2 Multivitamin-Mineral Tablet (1 tablet tid); Formula 3 Cell Activator Capsules (2 capsule bid); Herbal Beige Tablet (1 tablet bid); Herbal Green Tablet (3 tablet bid) all taken as directed on label. No other products were being used at the time she developed the adverse events. 3–4 months after starting plan, she began experiencing blurred vision and headache. 2 weeks later she began experiencing dizziness, lightheadedness, slurred speech, and numbness on right side of her body. Evaluation by neurologist indicated patchy sensory deficit in right leg, most pronounced in foot. MRI of brain showed findings consistent with recent hemorrhage associated with cavernous malformation. Evaluation by internist indicated negative w/u for Lyme disease and no additional significant findings. Symptoms improved after consumer discontined use of products.

ARMS No.	Product manufacturer	Clinical summary
11619	AMP II Drops—E'OLA Bio-genics, Inc	35 yo F used Liquithin & AMP II Pro (both 7 drops bid) and Citrin Trim (2 tablet/day) for 1 day and developed migraine headache which she typically experiences every month. She awoke at 3 AM on morning after using products with notable right sided facial weakness, CP, palpitations, right arm weakness and numbness, photophobia, and unsteady gait. She was seen by doctor and admitted to hospital. Symptoms improved during hospitalization which was uneventful. All test results were within normal limits except cerebral arteriogram findings which suggested mycotic aneurysmal change or possible changes secondary to an unusual drug induced vasculitis or collagen vascular disease. Discharge dxs included: right facial and arm weakness, cause uncertain; improving right eye irritation; resolving headache; resolved chest pain & palpitations with neg w/u; and history of right C5–6 cervical radiculopathy, carpal tunnel syndrome. Sxs continued to improve in month following discharge. History is significant for: Classical migraine headache associated with right jaw tingling; cardiac murmur with prior evaluation; allergy to iodine dye (tachycardia); and habit of drinking 1.5 quart of caffeinated soda daily.

Abbreviations Used in Clinical Summaries in the Appendix

abn = abnormal
angio = angiography
ant = anterior
AF = atrial fibrillation
bid = twice a day
BP = blood pressure
CAD = coronary artery disease
Cap/caps = capsule(s)
cath = catheterization
CBC = complete blood count
CK (CPK) = creatine kinase
cm = centimeter
CP = chest pain
CPR = cardiopulmonary resuscitation
CT = computerized tomography
CV = cardiovascular
CXR = chest X-ray
d/c = discontinue or discharge
DTR = deep tendon reflexes
Dx(s) = diagnosis(es)
EEG = electroencephalogram
EKG = echocardiogram
EMG = electromyography
ER = emergency room
ETOH = ethanol
F = female
f/u = followup
fxn = function
GPT = alanine aminotransferase
h/o = history of
HA = headache
HTN = hypertension
ICU = intensive care unit
IEP = immunoelectrophoresis
inf = inferior
L = left or liter
LFT = left
lb = pound
LV = left ventricle
M = male
MB+ = MB positive
MD = medical doctor
meq = milliequivalents
MI = myocardial infarction
min = minutes
MRI = magnetic resonance imaging
neg = negative
nitro = nitroglycerin
n/v = nausea and vomiting
PE = physical examination
PMH = past medical history
q = every
qd = everyday
R = right
SGPT = serum GPT
SOB = shortness of breath
SSx = signs & symptoms
ST/STT = ST–T waves
subl = sublingual
SVT = supraventricular tachycardia
tab(s) = tablet(s)
tach(y) = tachycardia
tid = 3 times a day
tox = toxicological
TPA = tissue plasminogen activator
Tx = treatment
w/ = with
w/o = without
w/u = workup
WL&E = weight loss & energy
wnl = within normal limits
yo = years old
yr = year

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federal register

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June 4, 1997

Part III

Department of Agriculture

Cooperative State Research, Education, and Extension Service Agricultural Telecommunications Program; Fiscal Year 1997; Solicitation of Proposals; Notice

DEPARTMENT OF AGRICULTURE

Cooperative State Research, Education, and Extension Service

Agricultural Telecommunications Program; Fiscal Year 1997; Solicitation of Proposals

AGENCY: Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Notice of Agricultural Telecommunications Program; Fiscal Year 1997; Solicitation of Proposals.

SUMMARY: The Cooperative State Research, Education, and Extension Service is soliciting proposals under the Agricultural Telecommunications Program. The Agricultural Telecommunications Program is authorized in section 1673 of the Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. No. 101–624 (7 U.S.C. 5926). It is anticipated that grants will be awarded competitively under the program in support of the following program areas: (1) Program Delivery, (2) Innovative Program Development/Production, and (3) Capacity Building.

DATES: Applications must be received on or before August 4, 1997. Proposals received after August 4, 1997 will not be considered for funding.

ADDRESSES: Proposals sent by First Class mail must be sent to the following address: Proposal Services Unit, Grants Management Branch; Office of Extramural Programs; Cooperative State, Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW., Washington, DC 20250–2245. Telephone: (202) 401–5048.

Proposals that are delivered by Express mail, courier service, or by hand must be sent to the following address: Proposal Services Unit, Grants Management Branch, Office of Extramural Programs, Cooperative State, Research, Education, and Extension Service, U.S. Department of Agriculture, Room 303; Aerospace Center, 901 D Street, SW., Washington, DC 20024. Telephone: (202) 401–5048.

FOR FURTHER INFORMATION CONTACT: For programmatic issues contact: Cathy Bridwell; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2216; 1400 Independence Avenue, SW., Washington, D.C. 20250–2216; telephone (202) 720–6084; Internet: cbridwell@reeusda.gov. For administrative issues contact the Grants Management Branch, Office of Extramural Programs, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2245; 1400 Independence Avenue, SW., Washington, DC 20250–2245; telephone (202) 401–5050.

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Part I.—Program Description

A. Purpose

Proposals are requested for the purpose of awarding competitive grants for fiscal year (FY) 1997 under the Agricultural Telecommunications Program (Program). Grants will be awarded to eligible institutions to assist in the development and utilization of an agricultural communications network to facilitate and to strengthen agricultural extension, resident education and research, and domestic and international marketing of United States commodities and products through a partnership between eligible institutions and the U.S. Department of Agriculture (USDA). The network will employ satellite and other telecommunications technology to disseminate and to share academic instruction, cooperative extension programming, agricultural research, and marketing information. The authority for this Program is contained in section 1673 of the Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. No. 101–624 (7 U.S.C. 5926). This Program is administered by the Cooperative State Research, Education, and Extension Service (CSREES) of USDA.

B. Available Funding

For FY 1997, $1,073,640 is available for the Program. Grants under this Program may provide funds for no more than 50 percent (50%) of the cost of a proposed project, unless otherwise determined by the Secretary in accordance with the provisions of section 1673(g) of Pub. L. No. 101–624 (7 U.S.C. 5926(g)). Project funds will be awarded for one fiscal year. Applicants may recompete for additional funding, but projects will not be renewed.

C. Matching Funds Requirement

A grant awarded under this Program must be matched by the recipient with equal funds from a non-Federal source unless otherwise determined by the Secretary in accordance with the provisions of section 1673(g) of Pub. L. No. 101–624 (7 U.S.C. 5926(g)). The matching requirement must be satisfied through allowable costs incurred by the recipient or subrecipient and through third party in-kind contributions.

D. Eligibility

Proposals are invited from accredited institutions of higher education. Applicants must demonstrate that they participate in a network that distributes programs consistent with the following objectives: (1) Make optimal use of available resources for agricultural extension, resident education, and research by sharing resources between participating institutions; (2) improve the competitive position of United States agriculture in international markets by disseminating information to producers, processors, and researchers; (3) train students for careers in agriculture and food industries; (4) facilitate interaction among leading agricultural scientists; (5) enhance the ability of United States agriculture to respond to environmental and food safety concerns, and; (6) identify new uses for farm commodities and to increase the demand for United States agricultural products in both domestic and foreign markets.

Pursuant to section 1673(e) of Pub. L. No. 101–624 (7 U.S.C. 5926(e)), preferential consideration will be given to applications that—(i) Are submitted by institutions affiliated with an established agricultural telecommunications network that distributes programs to a wide geographical area; or (ii) demonstrate the need for such assistance, taking into consideration the relative needs of all applicants and the financial ability of the applicants to otherwise secure or create the telecommunications system.

These preferences will be factored into the evaluation of the Partnerships

and Collaboration and Project Need Criteria, respectively.

E. Definitions

For the purpose of awarding funding under this Program, the following definitions are applicable:

(1) *Accredited institutions of higher education* means a college or university which is an educational institution in any State which: (a) Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate; (b) is legally authorized within such State to provide a program of education beyond secondary education; (c) provides an educational program for which a baccalaureate or any other higher degree is awarded; (d) is a public or other nonprofit institution; and (e) is accredited by a nationally recognized accrediting agency or association.

(2) *Administrator* means the Administrator of the Cooperative State Research, Education, and Extension Service (CSREES) and any other officer or employee of the Department to whom the authority involved may be delegated.

(3) *Agricultural telecommunications* means those activities established to encourage development and utilization of an agricultural communications network employing satellite and other telecommunications technologies to disseminate and to share academic instruction, cooperative extension programming, agricultural research, and marketing information.

(4) *Authorized departmental officer* means the Secretary of the U.S. Department of Agriculture (USDA) or the individual acting within the scope of delegated authority, who is responsible for awarding and administering grants on behalf of the Secretary.

(5) *Authorized organizational representative* means the president or chief executive officer of the applicant organization or the official designated by the president or chief executive officer of the applicant organization, who has the authority to commit the resources of the organization.

(6) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(7) *Cash contributions* means the applicant's cash outlay, including the outlay of money contributed to the applicant by non-Federal third parties.

(8) *Communications network* refers to television or cable television origination or distribution equipment, signal conversion equipment (including both modulators and demodulators), computer hardware and software, programs or terminals, or related devices, used to process and exchange data through a telecommunications system in which signals are generated, modified or prepared for transmission, or received, via telecommunications terminal equipment or via telecommunications transmission.

(9) *Delivery* means the transmission and reception of programs by facilities that transmit, receive, or carry data between telecommunications terminal equipment at each end of a telecommunications circuit or path.

(10) *Department* or *USDA* means the United States Department of Agriculture.

(11) *Equipment* means tangible personal property including exempt property charged directly to the award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit.

(12) *Facilities* includes microwave antennae, fiberoptic cables and repeaters, coaxial cables, communications satellite ground station complexes, and copper cable electronic equipment associated with telecommunications transmission and similar items subject to the approval of the authorized departmental officer.

(13) *Grant* means the award by the authorized departmental officer of funds to an accredited institution of higher education to assist in meeting the costs of conducting, for the benefit of the public, an identified project which is intended and designed to accomplish the purpose of the program as identified in these guidelines.

(14) *Grantee* means the organization designated in the grant award document as the responsible legal entity to which a grant is awarded.

(15) *Matching* means that portion of allowable project costs not borne by the Federal Government, including the value of in-kind contributions.

(16) *Peer Review Panel* means a group of experts qualified by training and experience in particular fields to give expert advice on the merit of grant applications in such fields, who evaluate eligible proposals submitted to this program in their personal area(s) of expertise.

(17) *Prior approval* means written approval evidencing prior consent by an authorized departmental officer as defined in (4) above.

(18) *Project* means the particular activity within the scope of the program supported by a grant award.

(19) *Project director* means the single individual designated by the grantee in the grant application and approved by the authorized departmental officer who is responsible for the direction and management of the project.

(20) *Project period* means the period, as stated in the award document and modifications thereto, if any, during which Federal sponsorship begins and ends.

(21) *Satellite ground station complex* includes transmitters, receivers, and communications antennae at the Earth station site together with the interconnecting terrestrial transmission facilities (including cables, line, or microwave facilities) and modulating and demodulating equipment necessary for processing traffic received from the terrestrial distribution system prior to transmission via satellite and the traffic received from the satellite prior to transfer to terrestrial distribution systems.

Part II.—Program Areas

A. Program Delivery

1. Description

Applicants may submit a proposal in the Program Delivery area requesting funding to operate an agricultural communications network, employing satellite and other telecommunications technology, to deliver Cooperative Extension programming, academic instruction, agricultural research and marketing information through partnership(s) between eligible institutions and the Department. The project goal(s) and objective(s) must be clearly stated in the proposal. Proposals in this area must clearly target a systematic approach to building an infrastructure to deliver programming at a distance.

Each proposal will be evaluated based on three broad principles: (1) Is there a real need for the project; (2) will the strategy identified meet the need; and (3) is the project sustainable?

Each proposal must document the need for the project, based on literature review, case studies, audience analysis and/or needs assessment.

The project strategy should reflect an integrated approach to instructional design including subject-matter content, educational methodology and compatible production and delivery techniques. The approach described must meet the identified need.

Evidence must be given that the project will be supported by the institution or by other groups or institutions who may wish to continue the project.

2. Project Narrative

The narrative portion of the proposal must describe how the project meets the three broad principles identified above. It must not exceed 20 pages in length and no additional material or appendix will be considered. The narrative should contain the following sections:

(a) Project Need. Describe the background and situation leading to the need for the project. The project must be based on a need articulated by an audience or on a needs assessment. Describe the targeted audience(s) for whom the project will be designed including pertinent history identified in need, demographics, and expected impact on audience. If appropriate, describe the methodology and results of the needs assessment. Demonstrate the need for assistance under this Program, including financial ability or inability to otherwise pursue the proposed program.

(b) Strategy

(i) *Partnerships and Collaboration.* Describe partnerships and collaborations fostered through this project including expected impact and benefit to those involved such as learner, institution, agency, state, and nation. Partners are defined as all those who will collaborate on the project. Submit evidence that partnerships are in place, and that those partners have a substantial role and interest in the project. Examples of role and interest might include joint risk-taking and shared benefits. Include information about any current affiliations with established agricultural telecommunications networks that distribute programs to a wide geographical area.

(ii) *Appropriate Distance Learning Technologies.* Describe appropriate distance learning technologies including, but not limited to, internet, multimedia, audio/visual, and other telecommunications technologies to be developed or employed in this project.

(iii) *Infrastructure.* Describe a framework representing both the technological and human infrastructure for this project including, but not limited to, technical trouble-shooting, scheduling and operation management, and learner and program support. Evidence of learner support includes, but is not limited to, facilitation of access, accommodation for diversity in special needs and learning styles, and recognition of need for alternative modes of program design and delivery.

(iv) *Innovation.* Describe the innovative application of distance education/learning delivery identified in the project. Examples of innovation may include, but are not limited to, approaches in reaching audiences, methods of connectivity and/or interaction, use of existing resources with innovations in the teaching/learning transaction, and entrepreneurial approaches to distance education delivery.

(v) *Outreach Plan.* Describe a plan for informing others about positive and negative outcomes, results, lessons learned, innovative ideas, and research findings from the project.

(vi) *Evaluation Plan.* Describe both formative and summative design for evaluating specific aspects of the project. These designs may include methods for evaluating the overall effectiveness of the Program in terms of teaching and learning, behavior change/problem-solving, immediate application, meeting learner needs, and/or potential for replication.

(c) Sustainability

(i) *Project Sustainability.* Include strong evidence of the project's ability to continue and grow after receiving the funding. Examples may include replication by others; continued funding other than from this Program, or opportunities for sale of products; and/or use of ideas and results of project by others.

(ii) *Cost/Benefit.* Include a cost-benefit analysis of the proposed project, including comparison to other delivery methods, relative benefit to learner, and staffing costs versus benefits.

B. Innovative Program Development/Production

1. Description

Applicants submitting a proposal in the Innovative Program Development/Production area must demonstrate an innovation to distance education programming. The project should contribute some aspect to the body of knowledge of distance education. Examples might include innovative approaches to entrepreneurship, evaluation, and the teaching/learning transaction.

Each proposal will be evaluated based on three broad principles: (1) Is there a real need for the project; (2) will the strategy identified meet the need; and (3) is the project sustainable?

Each proposal must document the need for the project, based on literature review, case studies, audience analysis and/or needs assessment.

The project strategy should reflect an integrated approach to instructional design including subject-matter content, educational methodology and compatible production and delivery techniques. The approach described must meet the identified need.

Evidence must be given that the project will be supported by the institution or by other groups or institutions who may wish to continue the project.

2. Project Narrative

The narrative portion of the proposal must describe how the project meets the three broad principles identified above. It must not exceed 20 pages in length and no additional material or appendix will be considered. The narrative should contain the following sections:

(a) Project Need.

(i) *Project Need.* Describe the background and situation leading to the need for the project. The project must be based on a need articulated by an audience or on a needs assessment. Describe the targeted audience(s) for whom the project will be designed including pertinent history identified in need, demographics, and expected impact on the targeted audience(s). If appropriate, describe the methodology and results of the needs assessment. Demonstrate the need for assistance under this Program, including financial ability or inability to otherwise pursue the proposed program.

(ii) *Innovation.* Describe the innovative application of distance education/learning identified in the project. Examples of innovation may include, but are not limited to, approaches in reaching audiences, methods of connectivity and/or interaction, use of existing resources with innovations in the teaching/learning transaction, and entrepreneurial approaches to distance education.

(b) Strategy.

(i) *Instructional Methodology/Strategies.* Explain the instructional/educational method or strategy to be implemented including appropriateness for audience and learning environment. Explanation should demonstrate knowledge of how people learn and/or interact in a mediated environment.

(ii) *Evaluation Plan.* Describe both formative and summative design for evaluating specific aspects of the project. These designs may include methods for evaluating the overall effectiveness of the Program in terms of teaching and learning, behavior change/problem-solving, immediate application, meeting learner needs, and/or potential for replication.

(iii) *Outreach Plan.* Describe a plan for informing others about positive and negative outcomes, results, lessons learned, innovative ideas, and research findings from the project.

(iv) *Partnerships and Collaboration.* Describe partnerships and

collaborations fostered through this project including expected impact and benefit to those involved such as the learner, institution, agency, state, and nation. Partners are defined as all those who will collaborate on the project. Submit evidence that partnerships are in place, and that those partners have a substantial role and interest in the project. Examples of role and interest might include joint risk taking and shared benefits. Include information about any current affiliations with established agricultural telecommunications networks that distribute programs to a wide geographical area.

(c) *Sustainability.* Include strong evidence of the project's ability to continue and grow after receiving the funding. Examples may include replication by others; continued funding other than from this Program, or opportunities for sale of products; and/or use of ideas and results of project by others.

C. Capacity Building

1. Description

Applicants submitting proposals in the Capacity Building area should target the development of capacity in the area of distance education at the university, state, regional, national or international level. Proposals must include a detailed plan for assessing capacity or a plan for targeting need based on a completed needs assessment.

Each proposal will be evaluated based on three broad principles: (1) Is there a real need for the project; (2) will the strategy identified meet the need; and (3) is the project sustainable?

Each proposal must document the need for the project, based on literature review, case studies, audience analysis and needs assessment.

The project strategy should reflect an integrated approach to instructional design including subject-matter content, educational methodology and compatible production and delivery techniques. The approach described must meet the identified need.

Evidence must be given that the project will be supported by the institution or by other groups or institutions who may wish to continue the project.

2. Project Narrative

The narrative portion of the proposal must describe how the project meets the three broad principles identified above. It must not exceed 15 pages in length and no additional material or appendix will be considered. The narrative should contain the following sections:

(a) Project Need. Describe the background and situation leading to the need for the project. The project must be based on a need articulated by an audience or on a needs assessment. Describe the targeted audience(s) for whom the project will be designed including pertinent history identified in need, demographics, and expected impact on the targeted audience(s). If appropriate, describe the methodology and results of the needs assessment. Applicants should describe how the capacity built will improve program production or program delivery. Demonstrate the need for assistance under this Program, including financial ability or inability to otherwise pursue the proposed program.

(b) Strategy.

(i) *Capacity Assessment.* Include a detailed assessment of capacity or a fully developed plan for assessing capacity. Areas of consideration include, but are not limited to: faculty/staff development; support resources; production/technical capability; delivery capability; building learner capacity.

(ii) *Evaluation Plan.* Describe both formative and summative design for evaluating specific aspects of the project. These designs may include methods for evaluating the overall effectiveness of program in terms of teaching and learning, behavior change/problem-solving, immediate application, meeting learner need, and/or potential for replication.

(iii) *Outreach Plan.* Describe a plan for informing others about positive and negative outcomes, results, lessons learned, innovative ideas, research findings from the project.

(c) Sustainability.

(i) *Sustainability.* Include strong evidence of the project's ability to continue and grow after receiving the funding. Examples may include replication by others; continued funding other than from this Program, or opportunities for sale of products; and/or use of ideas and results of project by others.

(ii) *Institutional Commitment.* Discuss institutional commitment to the project. For example, substantiate that the institution(s) attributes a priority to the project; discuss how the project will contribute to the achievement of the institution's(s') long-term (five- to ten-year) goals; explain how the project will help satisfy the institution's(s') high priority objectives; or show how this project is linked to and supported by the institution's(s') strategic plan.

(iii) *Partnerships and Collaboration.* Describe partnerships and collaborations fostered through this project including expected impact and benefit to those involved such as the learner, institution, agency, state, and nation. Partners are defined as all those who will collaborate on the project. Submit evidence that partnerships are in place, and that those partners have a substantial role and interest in the project. Examples of role and interest might include joint risk taking and shared benefits. Include information about any current affiliations with established agricultural telecommunications networks that distribute programs to a wide geographical area.

Part III.—Preparation of a Proposal

A. Program Application Materials

Copies of this solicitation and the Application Submission Package, which contains required forms, certifications, and instructions for preparing and submitting project applications, may be obtained by contacting:

Proposal Services Unit, Grants Management Branch, Office of Extramural Programs, Cooperative State Research, Education, and Extension Service

U.S. Department of Agriculture, Stop 2245, 1400 Independence Avenue, SW.,Washington, DC 20250–2245, Telephone: (202) 401–5048.

Application materials may also be requested via Internet by sending a message with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov that states that you wish to receive a copy of the application materials for the FY 1997 Agricultural Telecommunications Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

B. Content of a Proposal

1. Cover Page. Complete the ''Project Application'' form, Form CFD–2101, in its entirety.

a. One copy of the ''Project Application'' form must contain the pen-and-ink signatures of the project director and authorized organizational representative for the applicant organization.

b. Note that by signing the ''Project Application'' form the applicant is providing the required certifications set forth in 7 CFR part 3017, as amended by 61 FR 250, January 4, 1996, regarding Debarment and Suspension and Drug-Free Workplace, and 7 CFR part 3018, regarding Lobbying. The certification forms are included in the application package for informational purposes only. It is not necessary to submit the forms to USDA.

2. Table of Contents. For ease in locating information, each proposal must contain a detailed table of contents just after the proposal cover page. The Table of Contents should include page numbers for each component of the proposal. Pagination should begin immediately following the Table of Contents.

3. Project Summary. The proposal must contain a project summary of 200 words or less on a separate page. This page must include the title of the project and the names of the project director and the applicant organization, followed by the summary. The summary should be self-contained, and should describe the situation, targeted audience, purpose of the project, program goal, methodology, and expected outcomes of the project.

4. Program Areas. Each proposal must identify the area under which funds are requested and contain the required information for that area. Note that the project narrative should be limited to 20 pages in length.

5. Staffing Pattern and Procedure. Each proposal must describe the staff needed for project administration, instructional design/curriculum development, production, evaluation, and marketing/promotion. The narrative should demonstrate that the staffing and implementation procedure will result in an integrated approach involving content specialists, instructional designers, and quality production resources, and that the individual staff members proposed are qualified to perform these roles. The emphasis of the narrative should be placed on the relationship of the staff expertise to the proposed effort.

6. Personnel Support. To assist peer reviewers in assessing the competence and experience of the proposed project staff, key personnel who will be involved in the proposed project must be identified clearly. For each project director involved, and for all senior associates and other professional personnel who are expected to work on the project, whether or not funds are sought for their support, the following should be included:

(a) An estimate of the time commitments necessary;

(b) A curriculum vitae limited to the presentation of academic, research and extension credentials, e.g., educational, employment and professional history, and honors and awards, with emphasis on their relationship to the effort being proposed. Unless pertinent to the project, to personal status, or the status of the organization—meetings attended, seminars given, or personal data such as birth date, marital status, or community activities should not be included. The vitae shall be no more than two pages in length, excluding the publication list(s); and

(c) Publication List(s). A chronological list of the most representative publications during the past five years as it relates to the proposed effort, including those in press, must be provided for each professional project member for whom a curriculum vitae is provided. Authors should be listed in the same order as they appear on each paper cited, along with the title and complete reference as these items usually appear in journals.

7. A. Budget.

A detailed budget is required for each year of funding requested. In addition, a summary budget is required detailing requested support for the overall project period. The budget form may be reproduced as needed by applicants. Funds may be requested under any of the categories listed on the form, provided that the item or service for which support is requested is allowable under the authorizing legislation, the applicable Federal cost principles, and this solicitation, and can be justified as necessary for the successful conduct of the proposed project.

The following guidelines should be used in developing your proposal budget(s):

(a) *Salaries and Wages.* Salaries and wages are allowable charges and may be requested for personnel who will be working on the project in proportion to the time such personnel will devote to the project. If salary funds are requested, the number of Professionals and Other Personnel and the number of full-time equivalents (FTE) must be shown in the spaces provided. Grant funds may not be used to augment the total salary or rate of salary of project personnel or to reimburse them for time in addition to a regular full-time salary covering the same general period of employment. Salary funds requested must be consistent with the normal policies of the institution and with OMB Circular No. A–21, Cost Principles for Educational Institutions. Administrative and Clerical salaries are normally classified as indirect costs. However, if requested under A., they must be fully justified.

(b) *Fringe Benefits.* Funds may be requested for fringe benefit costs if the usual accounting practices of the institution provide that institutional contributions to employee benefits (social security, retirement, etc.) be treated as direct costs. Fringe benefit costs may be included only for those personnel whose salaries are charged as a direct cost to the project. See OMB Circular No. A–21, Cost Principles for Educational Institutions, for further guidance in this area.

(c) *Nonexpendable Equipment.* Nonexpendable equipment means tangible nonexpendable personal property including exempt property charged directly to the award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. As such, items of necessary instrumentation or other nonexpendable equipment should be listed individually by description and estimated cost. This applies to revised budgets, as the equipment item(s) and amount(s) may change. Each applicant also must attach to its budget an analysis of the costs and benefits of purchasing (or leasing) different types of facilities, equipment, components, hardware and software, and other items.

In addition, pursuant to section 716(b) of Pub. L. No. 104–180, (the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1997) in the case of any equipment or product that may be authorized to be purchased with funds provided under this program, entities receiving such funds are encouraged to use such funds to purchase only American-made equipment or products.

Note: Sec. 1673(g)(2) of Pub. L. No. 101–624 identifies that not more than 10% of the funds appropriated for this program may be applied to the acquisition and installation of nonexpendable equipment.

(d) *Materials and Supplies.* The types of expendable materials and supplies which are required to carry out the project should be indicated in general terms with estimated costs.

(e) *Travel.* The type and extent of travel and its relationship to project objectives should be described briefly and justified.

(f) *Publication Costs/Page Charges.* Anticipated costs of preparing and publishing results of the project being proposed (including page charges, necessary illustrations, and the cost of a reasonable number of coverless reprints) may be estimated and charged against the grant.

(g) *Computer (ADPE) Costs.* Reimbursement for the costs of using specialized facilities (such as a university- or department-controlled computer mainframe or data processing center) may be requested if such services are required for completion of the work.

(h) *All Other Direct Costs.* Anticipated direct project charges not included in other budget categories must be itemized with estimated costs and justified on a separate sheet of paper

attached to the budget. This applies to revised budgets, as the item(s) and dollar amount(s) may change. Examples may include space rental at remote locations, subcontractual costs, and charges for consulting services. Applicants are encouraged to consult the ''Instructions for Completing the Agricultural Telecommunications Program Budget,'' for detailed guidance relating to this budget category.

(i) *Indirect Costs.* If requested, the current rate negotiated with the cognizant Federal negotiating agency should be used. Indirect costs may not exceed the negotiated rate. If no rate has been negotiated, a reasonable dollar amount in lieu of indirect costs may be requested, which will be subject to approval by USDA.

B. Matching Funds

(1) Proposals must include written verification of commitments of matching support (including both cash and in-kind contributions) from third parties. Written verification means:

(a) For any third party cash contributions, a separate pledge agreement for each donation, signed by the authorized organizational representatives of the donor organization and the applicant organization, which must include: (1) The name, address, and telephone number of the donor; (2) the name of the applicant organization; (3) the title of the project for which the donation is made; (4) the dollar amount of the cash donation; and (5) a statement that the donor will pay the cash contribution during the project period; and

(b) For any third party in-kind contributions, a separate pledge agreement for each contribution, signed by the authorized organizational representatives of the donor organization and the applicant organization, which must include: (1) The name, address, and telephone number of the donor; (2) the name of the applicant organization; (3) the title of the project for which the donation is made; (4) a good faith estimate of the current fair market value of the in-kind contribution; and (5) a statement that the donor will make the contribution during the grant period.

(2) The sources and amount of all matching support from outside the applicant institution should be summarized on a separate page and placed in the proposal immediately following the budget form and any attachment thereto. All pledge agreements must be placed in the proposal immediately following the summary of matching support.

(3) Applicants should refer to OMB Circulars A–110, ''Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals and Other Non-Profit Organizations,'' and A–122, ''Cost Principles for Non-Profit Organizations,'' for further guidance and other requirements relating to matching and allowable costs.

8. Current and Pending Support. All proposals must list any other current public or private support (including in-house support) to which key personnel identified in the proposal have committed portions of their time, whether or not salary support for person(s) involved is included in the budget. Analogous information must be provided for any pending proposals that are being considered by, or that will be submitted in the near future to, other possible sponsors, including other USDA programs or agencies. Concurrent submission of identical or similar proposals to the possible sponsors will not prejudice proposal review or evaluation by the Administrator for this purpose. However, a proposal that duplicates or overlaps substantially with a proposal already reviewed and funded (or that will be funded) by another organization or agency will not be funded under this program.

9. Compliance with the National Environmental Policy Act (NEPA). As outlined in 7 CFR part 3407 (the CSREES regulations implementing NEPA), the environmental data or documentation for any proposed project is to be provided to CSREES in order to assist CSREES in carrying out its responsibilities under NEPA. In some cases, however, the preparation of environmental data may not be required. Certain categories of actions are excluded from the requirements of NEPA.

In order for CSREES to determine whether any further action is needed with respect to NEPA (e.g., preparation of an environmental assessment (EA) or environmental impact statement (EIS)), pertinent information regarding the possible environmental impacts of a proposed project is necessary; therefore, the National Environmental Policy Act Exclusions Form (Form CSREES–1234) provided must be included in the proposal indicating whether the applicant is of the opinion that the project falls within one or more of the categorical exclusions. Form CSREES–1234 should be included at the end of the proposal.

Even though a project may fall within the categorical exclusions, CSREES may determine that an EA or an EIS is necessary for an activity, if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect.

Part IV.—Submission of a Proposal

A. What to Submit

An original and eight copies of the proposal must be submitted. Each copy of each proposal must be stapled securely in the upper left hand corner (Do Not Bind). All copies of the proposal must be submitted in one package.

B. Where and When to Submit

Proposals must be received on or before August 4, 1997.

Proposals sent by First Class mail must be sent to the following address:

Proposal Services Unit, Grants Management Branch, Office of Extramural Programs, Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture, STOP 2245, 1400 Independence Avenue, S.W., Washington, D.C. 20250–2245, Telephone: (202) 401–5048.

Proposals that are delivered by Express mail, courier service, or by hand must be submitted to the following address (note that the zip code differs from that shown above): Proposal Services Unit, Grants Management Branch; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 303; Aerospace Center; 901 D Street SW.; Washington, DC 20024. Telephone: (202) 401–5048.

Part V.—Selection Process and Evaluation Criteria

A. Selection Process

1. All proposals will be acknowledged.

2. Each proposal will be evaluated in a two-part process. First, each proposal will be screened to ensure it meets the requirements as set forth in this solicitation. Proposals that meet these requirements will be technically evaluated by a peer review panel using the criteria identified in the annual solicitation, as appropriate. Each proposal will be judged on its own merits.

3. Final decisions will be made by USDA based upon the individual views of the panel members and consideration of other factors, including the budget limitation.

B. Evaluation Criteria

The maximum score a proposal can receive is 100 points. The peer review

panel will be selected and organized to provide maximum expertise and objective judgment in the evaluation of proposals. In the event the number of proposals accepted exceed dollars available, proposals will be ranked and support levels will be recommended by the panel(s) within the limitation of total funding available in FY 1997. The projects will be judged based on the following criteria.

1. Program Delivery

(a) Project Need—40 points.

Did the proposal describe the background and situation leading to the need for the project? Is the project based on a need articulated by an audience, or on a needs assessment? Are the targeted audience(s) for whom the project will be designed described, including pertinent history identified in need, demographics, and expected impact on audience? If appropriate, are methodology and results of needs assessment described? Did the proposal demonstrate the need for assistance under this Program, including a statement of financial ability or inability to otherwise pursue the proposed program and the impact of participation in this Program on this ability?

(b) Strategy—40 points.

(i) *Partnerships and Collaboration.* Are partnerships and collaborations fostered through this project described, including expected impact and benefit to those involved such as learner, institution, agency, state, and nation? Is there evidence that partnerships are in place, and that those partners have a substantial role and interest in the project and are examples of role and interest given, including joint risk taking and shared benefits? Is evidence provided of any current affiliations with established agricultural telecommunications networks that distribute programs to a wide geographical area?

(ii) *Alternative Distance Learning Technologies.* Does the proposal include a plan for the development and employment of alternative distance learning technologies including, but not limited to, internet, multimedia, audio/visual, and other telecommunications technologies?

(iii) *Infrastructure.* Does the proposal include a framework representing both the technological and human infrastructure including, but not limited to, technical trouble-shooting, scheduling and operation management, and learner and program support? Is there evidence of learner support including, but not limited to, facilitation of access, accommodation for diversity in special needs and learning styles, and recognition of need for alternative modes of program design and delivery?

(iv) *Innovation.* Does the proposal describe how the application of distance education/learning delivery identified in the project is innovative? Are examples provided that may include, but are not limited to, approaches in reaching audiences; methods of connectivity and/or interaction; use of existing resources with innovations in the teaching/learning transaction; entrepreneurial approaches to distance education delivery.

(v) *Outreach Plan.* Is there an outreach plan articulating an approach for informing others about positive and negative outcomes, results, lessons learned, innovative ideas, and findings from the project?

(vi) *Evaluation Plan.* Are both formative and summative design for evaluating specific aspects of the project described? Do they include evaluating the overall effectiveness of program in terms of teaching and learning, behavior change/problem-solving, immediate application, meeting learner needs, and/or potential for replication?

(c) Sustainability—20 points.

(i) *Project Sustainability.* Does the proposal present strong evidence of the project's ability to continue and grow after receiving the funding? Does this evidence include replication by others; continued funding other than from this program, or opportunities for sale of products; and/or use of ideas and results of project by others?

(ii) *Cost/Benefit.* Does the proposal include a cost-benefit analysis of the proposed project, including comparison to other delivery methods, relative benefit to learner, and staffing costs versus benefits?

2. Innovative Program Development/Production

(a) Project Need—30 points.

(i) *Project Need.* Does the proposal describe the background and situation leading to the need for the project? Is the project based on a need articulated by an audience, or on a needs assessment? Are the targeted audience(s) for whom the project will be designed described, including pertinent history identified in need, demographics, and expected impact on audience? If appropriate, are methodology and results of needs assessment described? Did the proposal demonstrate the need for assistance under this program, including a statement of financial ability or inability to otherwise pursue the proposed program and the impact of participation in this Program on this ability?

(ii) *Innovation.* Does the proposal describe how the application of distance education/learning is innovative? Are examples provided that may include, but are not limited to, approaches in reaching audiences; methods of connectivity and/or interaction; use of existing resources with innovations in the teaching/learning transaction; entrepreneurial approaches to distance education?

(b) Strategy—50 points.

(i) *Strategy.* Does the proposal make the case that the strategy outlined will accomplish the goals and meet the need(s) identified in part one?

(ii) *Instructional Methodology/Strategies.* Is the instructional/educational method or strategy to be implemented explained, including its appropriateness for the audience and learning environment? Does the explanation demonstrate knowledge of how people learn and/or interact in a mediated environment?

(iii) *Evaluation Plan.* Are both formative and summative design for evaluating specific aspects of the project described? Do they include evaluating the overall effectiveness of the Program in terms of teaching and learning, behavior change/problem-solving, immediate application, meeting learner needs, and/or potential for replication?

(iv) *Outreach Plan.* Does the outreach plan articulate an approach for informing others about positive and negative outcomes, results, lessons learned, innovative ideas, and findings from the project?

(v) *Partnerships and Collaboration.* Are partnerships and collaborations fostered through this project described, including expected impact and benefit to those involved such as learner, institution, agency, state, and nation? Is there evidence that partnerships are in place, and that those partners have a substantial role and interest in the project? Are examples of role and interest given such as joint risk taking and shared benefits? Is evidence provided of any current affiliations with established agricultural telecommunications networks that distribute programs to a wide geographical area?

(c) Sustainability—20 points.

Does the proposal present strong evidence of the project's ability to continue and grow after receiving the funding. Does this evidence include replication by others; continued funding other than from this Program, or opportunities for sale of products; and/or use of ideas and results of project by others?

3. Capacity Building

(a) Project Need—20 points.

Did the proposal describe the background and situation leading to the need for the project? Is the project based on a need articulated by an audience, or on a needs assessment? Are the targeted audience(s) for whom the project will be designed described, including pertinent history identified in terms of need, demographics, and expected impact on an audience? If appropriate, are the methodology and results of needs assessment described? Did the applicant describe how the capacity built will improve program production or program delivery? Did the proposal demonstrate the need for assistance under this Program, including a statement of financial ability or inability to otherwise pursue the proposed program and the impact of participation in this Program on this ability?

(b) Strategy—30 points.

(i) *Capacity Assessment.* Is a detailed assessment of capacity or a fully developed plan for assessing capacity included? Does the assessment include faculty/staff development; support resources; production/technical capability; delivery capability; building learner capacity?

(ii) *Evaluation Plan.* Are both formative and summative design for evaluating specific aspects of the project described? Do they include evaluating the overall effectiveness of the Program in terms of teaching and learning, behavior change/problem-solving, immediate application, meeting learner needs, and/or potential for replication?

(iii) *Outreach.* Does the outreach plan articulate an approach for informing others about positive and negative outcomes, results, lessons learned, innovative ideas, and findings from the project?

(c) Sustainability—50 points.

(i) *Sustainability.* Does the proposal present strong evidence of the project's ability to continue and grow after receiving the funding? Does this evidence include replication by others; continued funding other than from this Program, or opportunities for sale of products; and/or use of ideas and results of project by others?

(ii) *Institutional Commitment.* Does the proposal discuss the institutional commitment to the project? Does the proposal substantiate that the institution(s) attributes a priority to the project; discuss how the project will contribute to the achievement of the institution's(s') long-term (five- to ten-year) goals; explain how the project will help satisfy the institution's(s') high priority objectives; or show how this project is linked to and supported by the institution's(s') strategic plan?

(iii) *Partnerships and Collaboration.* Are partnerships and collaborations fostered through this project described, including expected impact and benefit to those involved such as learner, institution, agency, state, and nation? Is there evidence that partnerships are in place, and that those partners have a substantial role and interest in the project? Are examples of role and interest given including joint risk taking and shared benefits? Is evidence provided of any current affiliations with established agricultural telecommunications networks that distribute programs to a wide geographical area?

Part VI.—Supplementary Information:

A. Access to Peer Review Information

Information regarding the peer review process will be made available to the extent permitted under the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), and implementing Departmental and other Federal regulations. Implementing Departmental regulations are found at 7 CFR part 1.

B. Grant Awards

1. General

Within the limit of funds available for such purpose, the awarding official of CSREES shall make grants to those responsible, eligible applicants whose proposals are judged most meritorious in the announced program area and under the procedures set forth in this solicitation. The date specified by the Administrator as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practicable so that project goals may be attained within the funded project period. All funds granted by CSREES under this solicitation shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (parts 3015, 3016, and 3019 of 7 CFR).

2. Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one-time basis as part of the responsibility determination prior to the award of a grant identified under this part if such information has not been provided previously under this or another program for which the sponsoring agency is responsible. Copies of forms recommended for use in fulfilling the requirements contained in this section will be provided by the sponsoring agency as part of the preaward process.

3. Grant Award Document and Notice of Grant Award

(a) The grant award document shall include, at a minimum, the following:

(1) Legal name and address of performing organization.

(2) Title of project.

(3) Name(s) and address(es) of Project Director(s).

(4) Identifying grant number assigned by the Department.

(5) Project period, which specifies how long the Department intends to support the effort.

(6) Total amount of Departmental financial assistance approved during the project period.

(7) Legal authority under which the grant is awarded.

(8) Approved budget plan for categorizing project funds to accomplish the stated purpose of the grant award.

(9) Other information or provisions deemed necessary by the Department to carry out its granting activities or to accomplish the purpose of a particular grant.

(b) The notice of grant award, in the form of a letter, will provide pertinent instructions and information to the grantee which are not included in the grant award document described above.

C. Use of Funds; Changes

1. Delegation of Fiscal Responsibility

The grantee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of grant funds.

2. Change in Project Plans

(a) The permissible changes by the grantee, project director(s), or other key project personnel in the approved project grant shall be limited to changes in methodology, techniques, or other aspects of the project to expedite achievement of the project's approved goals. If the grantee and/or the project director(s) are uncertain as to whether a change complies with this provision, the question must be referred to the Authorized Departmental Officer (ADO) for a final determination.

(b) Changes in approved goals, or objectives, shall be requested by the grantee and approved in writing by the ADO prior to effecting such changes. In no event shall requests for such changes be approved which are outside the scope of the original approved project.

(c) Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the grantee and approved in writing by the ADO prior to effecting such changes.

(d) Transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not Federal funds are involved, shall be requested by the grantee and approved in writing by the ADO prior to effecting such transfers.

3. Changes in Project Period

The project period may be extended by CSREES without additional financial support, for such additional period(s) as the ADO determines may be necessary to complete or fulfill the purposes of an approved project. Any extension of time shall be conditioned upon prior request by the grantee and approval in writing by the ADO, unless prescribed otherwise in the terms and conditions of a grant.

4. Changes in Approved Budget

Changes in an approved budget must be requested by the grantee and approved in writing by the ADO prior to instituting such changes if the revision will result in a need or claim for the award of additional funds or involve transfers or expenditures of amounts requiring prior approval as set forth in the applicable Federal cost principles, Departmental regulations, or in the grant award.

D. Other Federal Statutes and Regulations That Apply

Several other Federal statutes and/or regulations apply to grant proposals considered for review and to project grants awarded under this part. These include but are not limited to:

7 CFR part 1—USDA implementation of the Freedom of Information Act.

7 CFR part 3—USDA implementation of OMB Circular A–129, regarding debt collection.

7 CFR part 15, subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

7 CFR part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., Circular Nos. A–21, and A–122) and incorporating provisions of 31 U.S.C. 6301–6308 (formerly the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95–224), as well as general policy requirements applicable to recipients of Departmental financial assistance.

7 CFR part 3017, as amended by 61 **Federal Register** 250, January 4, 1996—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants).

7 CFR part 3018—USDA implementation of New Restrictions on Lobbying. Imposes new prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans.

7 CFR part 3019—USDA implementation of OMB Circular A–110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

7 CFR part 3051—USDA implementation of OMB Circular No. A–133, Audits of Institutions of Higher Education and Other Nonprofit Institutions.

7 CFR part 3407—CSREES procedures to implement the National Environmental Policy Act of 1969, as amended.

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR Part 15B (USDA implementation of statute), prohibiting discrimination based upon physical or mental handicap in Federally assisted programs.

35 U.S.C. 200 et seq.—Bayh-Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR part 401).

E. Other Conditions

The Department may, with respect to any grant, impose additional conditions prior to or at the time of any award when, in the Department's judgment, such conditions are necessary to assure or protect advancement of the approved project, the interests of the public, or the conservation of grant funds.

Done at Washington, DC., on this 29th day of May, 1997.

George Cooper,

Deputy Administrator, Partnerships, Cooperative State Research, Education, and Extension Service.

[FR Doc. 97–14586 Filed 6–3–97; 8:45 am]

BILLING CODE 3410–22–P

federal register

Wednesday
June 4, 1997

Part IV

The President

Presidential Determination No. 97–24 of May 23, 1997—Waiver of Statutory Restrictions To Permit Assistance to Turkey

Federal Register
Vol. 62, No. 107
Wednesday, June 4, 1997

Presidential Documents

Title 3—

The President

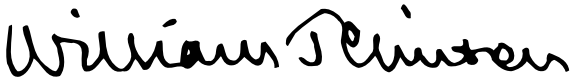
Presidential Determination No. 97–24 of May 23, 1997

Waiver of Statutory Restrictions To Permit Assistance to Turkey

Memorandum for the Secretary of State

Pursuant to subsection (b) of section 620I of the Foreign Assistance Act of 1961, as amended, I hereby determine that it is in the national security interest of the United States that assistance be furnished to Turkey without regard to the restriction in subsection (a) of section 620I.

You are authorized and directed to transmit this determination and justification to the Congress and to arrange for its publication in the **Federal Register**.



THE WHITE HOUSE,
Washington, May 23, 1997.

Memorandum of Justification Regarding Determination Under Section 620I of the Foreign Assistance Act of 1961, as Amended

The Administration fully supports the goal of maintaining open humanitarian aid corridors and has actively worked through diplomatic channels to encourage the speedy and efficient flow of humanitarian goods. The application of section 620I requires a careful consideration of the circumstances in each case. This is particularly true with respect to Turkey.

Strong feelings of ethnic kinship exist between the Turks and Azerbaijanis, and the Turkish government has resisted public pressures to become directly involved in the Nagorno-Karabakh conflict. Until March, 1993, Turkey permitted U.S. humanitarian and other non-military shipments destined for Yerevan to transit Turkish territory in response to the grave situation in Armenia. However, Turkey closed its land borders to Armenia in 1993 when local Armenian forces seized large areas of Azerbaijan despite UN Security Council resolutions calling for the withdrawal of all occupying forces and cessation of hostilities.

Since 1994, Turkey has taken several unilateral steps to improve its bilateral ties with Armenia while balancing its relations with Azerbaijan and supporting the OSCE's Minsk Group talks on resolving the Nagorno-Karabakh conflict. Most notably, Turkey reopened an air corridor to Armenia in 1995. In another positive step, in March, 1996 Turkish Prime Minister Yilmaz publicly expressed willingness to reopen the land border with Armenia once Armenia and Azerbaijan agree upon a statement of principles for a settlement of the conflict. Turkey's land border with Armenia, however, remains closed for the present. A large volume of assistance—mostly food and oil—as well as an increasing volume of commercial traffic flow by ship through the Turkish Straits to Georgian ports for shipment by rail to Armenia. Should the border be reopened, we are likely to continue to ship most assistance to Armenia through Georgia to take advantage of its more developed rail network.

It is very much in our national security interests not to terminate U.S. assistance programs for Turkey. Such a termination would create significant difficulties in our bilateral relations, affecting a broad range of national security interests. Such a termination would also reduce prospects for the successful resolution of the Nagorno-Karabakh conflict.

Turkey is at the nexus of a number of issues that are critical for the U.S. on the Eurasian continent: securing peace in the Balkans, advancing a settlement in Cyprus and resolution of Aegean issues, containing Iraq and Iran, bringing stability to the Caucasus, implementing the CFE treaty, addressing the future of NATO and bringing Caspian Basin oil to the West. Turkey hosts the continuing U.S.-led coalition effort to protect the Kurdish populations of northern Iraq, and has increasingly important and useful relationships with Israel and the moderate Arab states of the Middle East. Finally, Turkey is important for U.S. trade and investment, and has been designated as one of the ten big emerging markets for U.S. companies by the Department of Commerce.

There are over 3,000 uniformed military and civilian DoD personnel (excluding dependents) stationed in Turkey, a democratic, secular nation in a region with weak democratic traditions, and widespread political instability. Incirlik, the easternmost NATO Air Base, and other NATO-dedicated bases in Turkey are essential for the projection of U.S./NATO power into an unstable region having critical oil resources. Some 2,700 sorties were flown out of Incirlik during the Gulf War.

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The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–2470). The text will also be made available on the Internet from GPO Access at http://www.access.gpo.gov/su_docs/. Some laws may not yet be available.

H.R. 1650/P.L. 105–16

To authorize the President to award a gold medal on behalf of the Congress to Mother Teresa of Calcutta in recognition of her outstanding and enduring contributions through humanitarian and charitable activities, and for other purposes. (June 2, 1997; 111 Stat. 35)

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