6–18–03 Wednesday
Vol. 68 No. 117 June 18, 2003

Pages 36445–36742

Federal Register

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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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Presidential Documents

Title 3—

The President

Proclamation 7685 of June 13, 2003

National Homeownership Month, 2003

By the President of the United States of America

A Proclamation

Homeownership is more than just a symbol of the American Dream; it is an important part of our way of life. Core American values of individuality, thrift, responsibility, and self-reliance are embodied in homeownership. I am committed to helping more families know the security and sense of pride that comes with owning a home.

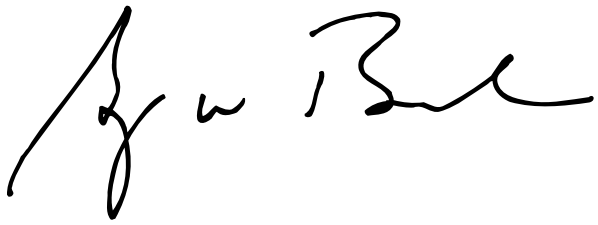
The Department of Housing and Urban Development is leading an Administration-wide effort to bring new tools and resources to would-be homeowners. We are providing financial assistance to qualified families through the American Dream Downpayment Fund, funding educational programs that stress financial literacy, and offering a compassionate hand to those who dream of moving from subsidized housing into homeownership. And through the Self-Help Homeownership Opportunity Program, my Administration partners with nonprofit organizations that offer homeownership opportunities to families willing to contribute their skills and labor to help build a home of their own. We are also proposing ways to make it easier to shop for a mortgage and to make mortgages available to more families through the Federal Housing Administration.

Today, the United States is fortunate in that our homeownership rate is at an all-time high, and low interest rates continue to encourage millions of Americans to become first-time homeowners. Although a record number of Americans own their own homes, we continue to see a gap between the homeownership rates of minorities and nonminorities. By a significant margin, minority families are less likely to own their own homes. Therefore, I have called upon the entire housing industry to join with my Administration to expand minority homeownership across the Nation. Our goal is to help at least 5.5 million minority families become homeowners by the end of this decade, and our Blueprint for the American Dream Partnership is taking bold steps to make this a reality.

Across our Nation, every citizen, regardless of race, creed, color, or place of birth, should have the opportunity to become a homeowner. Homeownership represents a pathway to pride and prosperity for many families, encourages values of responsibility and sacrifice, creates stability for neighborhoods and communities, and generates economic growth that helps strengthen the entire Nation.

NOW, THEREFORE, I, GEORGE W. BUSH, 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 2003 as National Homeownership Month. I call upon the people of the United States to join me in recognizing the importance of offering every American the opportunity to realize their dream of homeownership and to help work towards making that dream a reality.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of June, in the year of our Lord two thousand three, and of the Independence of the United States of America the two hundred and twenty-seventh.



[FR Doc. 03–15539
Filed 6–17–03; 8:45 am]
Billing code 3195–01–P

Presidential Documents

Proclamation 7686 of June 13, 2003

Father's Day, 2003

By the President of the United States of America

A Proclamation

Fatherhood is one of life's most challenging yet fulfilling endeavors. On Father's Day, we honor America's fathers and express our appreciation for all they do to help build a strong foundation for our children and our Nation. We also reaffirm our commitment to supporting fathers and encouraging responsible fatherhood in our society.

Fathers have indispensable roles to play in the lives of their children: provider, protector, nurturer, teacher, and friend. Every caring father unconditionally loves his sons and daughters and strives for the best for his children in the future. In seeking to give their children the opportunity to succeed, fathers offer needed strength, guidance, and discipline.

Fathers teach their children many basic things in life: how to read a book, throw a ball, tie a necktie, ride a bike, or drive a car. More importantly, they also help instill time- honored values in their children, such as hard work, respect, honesty, and good citizenship. Through their words, actions, and sacrifices, fathers play an important role in shaping the characters of their sons and daughters.

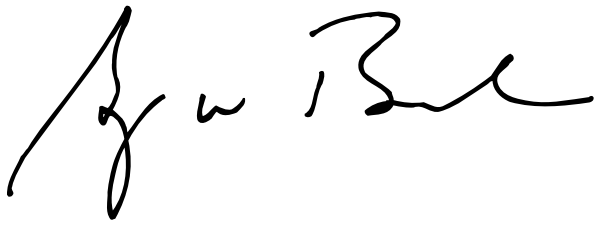
The time and attention that a father gives to a child is irreplaceable—there is no substitute for the involvement and commitment of a responsible father. Not only are fathers essential to the healthy development of children, they also influence the strength of families and the stability of communities.

For this reason, our Government is working to help fathers succeed in this challenging, but life-affirming, role. Over the last 2 years, my Administration has taken important steps to promote responsible fatherhood and encourage community-based initiatives that help them fulfill their important roles. We are working to provide funds for healthy marriage and parenting education and for community mentoring programs to help fathers become more engaged and involved in their children's lives.

This Father's Day, we recognize the many fathers who are heroes and role models for their children, and we encourage more men to fulfill this responsibility by loving their sons and daughters with all their heart and demonstrating this love daily. By working together to encourage America's fathers, we can strengthen our society and help ensure the well-being of all our children.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, in accordance with a joint resolution of the Congress approved April 24, 1972, as amended (36 U.S.C. 109), do hereby proclaim June 15, 2003, as Father's Day. I encourage all Americans to express love, admiration, and thanks to their fathers for their contributions to our lives and to society. I direct the appropriate officials of the Government to display the flag of the United States on all Government buildings on this day. I also call upon State and local governments and citizens to observe this day with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of June, in the year of our Lord two thousand three, and of the Independence of the United States of America the two hundred and twenty-seventh.



[FR Doc. 03–15540
Filed 6–17–03; 8:45 am]
Billing code 3195–01–P

Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM257; Special Conditions No. 25–238–SC]

Special Conditions: Boeing Model 747SP Series; 747–100 Series; and 747–200B, –200C, and –200F Series Airplanes; High-Intensity Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments

SUMMARY: These special conditions are issued for Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The airplane modification includes the installation of an Electronic Flight Instrument System (EFIS), which performs critical functions. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for the protection of this system from the effects of high-intensity-radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

EFFECTIVE DATE: The effective date of these special conditions is June 10, 2003. Comments must be received on or before July 18, 2003.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attention: Rules Docket (ANM–113), Docket No. NM257, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. All comments must be marked: Docket No. NM257.

FOR FURTHER INFORMATION CONTACT: Greg Dunn, FAA, Airplane and Flight Crew Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2799; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that notice and opportunity for public comment in accordance with 14 CFR 11.38 are unnecessary, because the FAA has provided previous opportunities to comment on substantially identical special conditions and has fully considered and addressed all the substantive comments received. Based on a review of the comment history and the comment resolution, the FAA is satisfied that new comments are unlikely. The FAA, therefore, finds that good cause exists for making these special conditions effective upon issuance.

However, the FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On May 1, 2002, J.R.G Design submitted an application to the New York Aircraft Certification Office for a Supplemental Type Certificate (STC). The Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes are being modified for use by a head of state; they are non N-registered airplanes operating under part 91. This project involves replacing round dial displays in the cockpit with four EFIS displays. The EFIS upgrade is for multiple airplane installations. These systems may be vulnerable to HIRF external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR 21.17, J.R.G Design, Inc. must show that Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes meet the applicable provisions in effect on the date of application for the supplemental type certificate or applicable provisions of 14 CFR part 25, as amended by Amendments 21–1 through 25–106, for areas affected by the change to the greatest extent feasible. If the Administrator finds that the applicable airworthiness regulations (*i.e.,* part 25 as amended) do not contain adequate or appropriate safety standards for Boeing Model 747SP series; 747–100 series; and 747–200 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with § 11.38 and become part of the type

certification basis in accordance with § 21.101(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, these special conditions would also apply to the other model under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Novel or Unusual Design Features

As noted earlier, Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes will incorporate four EFIS displays (two for each pilot) that will perform critical functions. These systems may be vulnerable to HIRF external to the airplane. The current airworthiness standards of part 25 do not contain adequate or appropriate safety standards for the protection of this equipment from the adverse effects of HIRF. Accordingly, these systems are considered to be novel or unusual designs.

Discussion

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

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes. These special conditions require that avionic/electronic and electrical systems that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters and the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical avionic/electronic and electrical systems to HIRF must be established.

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

1. A minimum threat of 100 volts rms (root-mean-square) per meter electric field strength from 10 KHz to 18 GHz.

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

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

2. A threat external to the airframe of the field strengths identified in the table below for the frequency ranges indicated. Both peak and average field strength components from the table are to be demonstrated.

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz–100 kHz	50	50
100 kHz–500 kHz	50	50
500 kHz–2 MHz	50	50
2 MHz–30 MHz	100	100
30 MHzs–70 MHz	50	50
70 MHz–100 MHz	50	50
100 MHz–200 MHz ...	100	100
200 MHz–400 MHz ...	100	100
400 MHz–700 MHz ...	700	50
700 MHz–1 GHz	700	100
1 GHz–2 GHz	2000	200
2 GHz–4 GHz	3000	200
4 GHz–6GHz	3000	200
6 GHz–8 GHz	1000	200
8 GHz–12 GHz	3000	300
12 GHz–18 GHz	2000	200
18 GHz–40 GHz	600	200

Note.—The field strengths are expressed in terms of peak of the root-mean-square (rms) over the complete modulation period.

The threat levels identified above are the result of an FAA review of existing studies on the subject of HIRF, in light of the ongoing work of the Electromagnetic Effects Harmonization Working Group of the Aviation Rulemaking Advisory Committee.

Applicability

As discussed above, these special conditions are applicable to Boeing Model 747SP series; 747–110 series; and 747–200B, –200C, and –200F series airplanes. Should J.R.G. Design apply at a later date for a type certificate change for these airplane models incorporating the same novel or unusual design feature, these special conditions would apply to those airplanes as well, under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Conclusion

This action affects only certain novel or unusual design features on Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes. It is not a rule of general applicability and affects only the applicant which applied to the FAA for approval of these features on the airplane. The FAA has determined that notice and opportunity for public comment are unnecessary, because the FAA has provided previous opportunities to comment on substantially identical special conditions and has fully considered and addressed all the substantive comments received. The FAA is satisfied that new comments are unlikely and finds, therefore, that good cause exists for making these special conditions effective upon issuance.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 747SP series; 747–100 series; and 747–200B, –200C, and –200F series airplanes.

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

2. For the purpose of these special conditions, the following definition applies: *Critical Functions*: Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington on June 10, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15401 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–331–AD; Amendment 39–13195; AD 2003–12–10]

RIN 2120–AA64

Airworthiness Directives; Aerospatiale Model ATR42–200, –300, –320, and –500 Series Airplanes; and Model ATR72–102, –202, –212, and 212A Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Aerospatiale Model ATR42–200, –300, –320, and –500 series airplanes; and Model ATR72–102, –202, –212, and 212A series airplanes; that requires modification of the flight attendant's seat located in the front of the cabin, and follow-on actions. This action is necessary to prevent release of the forward flight attendant's shoulder restraint harness, which could result in injury to the flight attendant in case of turbulence. This action is intended to address the identified unsafe condition.

DATES: Effective July 23, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 23, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Aerospatiale Model ATR42–200, –300, –320, and –500 series airplanes; and Model ATR72–102, –202, –212, and 212A series airplanes was published in the **Federal Register** on February 21, 2003 (68 FR 8477). That action proposed to require modification of the flight attendant's seat located in the front of the cabin, and follow-on actions.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Clarification of Applicability

We have revised the applicability listed in Table 1 in this final rule to more clearly identify those airplanes affected by this AD.

Conclusion

After careful review of the available data, we have determined that air safety and the public interest require the adoption of the rule with the change described previously. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the NPRM regarding that material.

Cost Impact

The FAA estimates that approximately 80 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $1,786 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $147,680, or $1,846 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect 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, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it 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:

2003–12–10 Aerospatiale: Amendment 39–13195. Docket 2002–NM–331–AD.

Applicability: Airplanes listed in the following table, certificated in any category:

TABLE 1.—APPLICABILITY

Airplane models—	On which these modifications have been installed—	On which these modifications have not been installed—
ATR42–200, –300, and -–320 series airplanes	0384, 1685, or 1991; or modifications per Avions de Transport Regional (ATR) Service Bulletins ATR42–25–0082, ATR42–98–331A, or ATR42–98–409C.	5328 per ATR Service Bulletin ATR42–25–0141, 0619, or 8023 per ATR Service Bulletin ATR42–98–025A
ATR42–500 series airplanes	4181 or 5042	5301 per ATR Service Bulletin ATR42–98–524D, or 5328 per ATR Service Bulletin ATR42–25–0141
ATR72–102, –202, –212, and –212A series airplanes.	(No applicable modification)	5328 (replacement of the inertia-reel harness with a fixed harness) per ATR Service Bulletin ATR72–25–1082

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 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 (c) 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 release of the forward flight attendant's shoulder restraint harness, which could result in injury to the flight attendant in case of turbulence; accomplish the following:

Modification

(a) Within 18 months after the effective date of this AD: Modify the forward flight attendant's seat located in the front of the cabin (including replacing the inertia-reel harness with a new fixed harness, and replace the backrest cover and backrest cushion with new components), per ATR Service Bulletin ATR42–25–0141, dated October 15, 2002 (for Model ATR42–200, –300, –320, and –500 series airplanes); or Service Bulletin ATR72–25–1082, dated October 15, 2002 (for Model ATR72–102, –202, –212, and 212A series airplanes); as applicable.

Follow-on Actions

(b) Before further flight following accomplishment of the modification required by paragraph (a) of this AD: Accomplish paragraphs (b)(1) and (b)(2) of this AD per ATR Service Bulletin ATR42–25–0141, dated October 15, 2002; or ATR Service Bulletin ATR72–25–1082, dated October 15, 2002; as applicable.

(1) Replace the seat identification placard with a new placard having a new part number (P/N).

(2) Install a new modification placard to indicate accomplishment of the SICMA Service Bulletin 138–25–008, dated September 18, 2002.

Note 2: ATR Service Bulletins ATR42–25–0141 and ATR72–25–1082 reference SICMA Service Bulletin 138–25–008 as an additional source of service information for procedures to modify the forward flight attendant's seat, and to perform follow-on actions (including replacing the seat identification placard with a new placard, and installing a new modification placard).

Alternative Methods of Compliance

(c) 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, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(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.

Incorporation by Reference

(e) The actions shall be done in accordance with Avions de Transport Regional Service Bulletin ATR42–25–0141, dated October 15, 2002; or Avions de Transport Regional Service Bulletin ATR72–25–1082, dated October 15, 2002; as applicable. 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 Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in French airworthiness directive 2002–539(B), dated October 30, 2002.

Effective Date

(f) This amendment becomes effective on July 23, 2003.

Issued in Renton, Washington, on June 10, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15220 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–271–AD; Amendment 39–13194; AD 2003–12–09]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Model BAe 146 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain BAE Systems (Operations) Limited Model BAe 146 series airplanes, that requires modification of the flight annunciator box. This action is necessary to prevent traffic collision avoidance system (TCAS) aural messages and resolution advisories of the TCAS from being inhibited following a ground proximity warning system alert or test message, which could prevent the TCAS from providing attention-getting alerts, and could result in the consequent possibility of a mid-air collision or near mid-air collision. This action is

intended to address the identified unsafe condition.

DATES: Effective July 23, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 23, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain BAE Systems (Operations) Limited Model BAe 146 series airplanes was published in the **Federal Register** on March 12, 2003 (68 FR 11760). That action proposed to require modification of the flight annunciator box.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency, this final rule retains the language of the NPRM regarding that material.

Cost Impact

The FAA estimates that 20 airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 work hours per airplane to accomplish the modification, and that the average labor rate is $60 per work hour. Required parts will cost approximately $250 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $7,400, or $370 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect 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, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it 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:

2003–12–09 BAE Systems (Operations) Limited (Formerly British Aerospace Regional Aircraft): Amendment 39–13194. Docket 2001–NM–271–AD.

Applicability: Model BAe 146 series airplanes on which Modifications HCM50261X; HCM01077L or HCM50273B; and HCM50040E or HCM50040N; have been installed; 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 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 aural messages and resolution advisories of the traffic collision avoidance system (TCAS) from being inhibited following a ground proximity warning system alert or test message, which could prevent the TCAS from providing attention-getting alerts, and could result in the consequent possibility of a mid-air collision or near mid-air collision, accomplish the following:

Modification

(a) Within 1 year after the effective date of this AD: Modify the flight annunciator box (including installing 2 diode modules with associated wiring, and re-routing existing wiring), per the Accomplishment Instructions of BAE Systems (Operations) Limited Modification Service Bulletin SB.34–339–50261Y, dated April 11, 2001. Although paragraph 2.F.(2) of the Accomplishment Instructions references a reporting requirement, such reporting is not required by this AD.

Alternative Methods of Compliance

(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, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Avionics Inspector, who may

add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(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.

Incorporation by Reference

(d) The actions must be done in accordance with BAE Systems (Operations) Limited Modification Service Bulletin SB.34–339–50261Y, dated April 11, 2001. 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 British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in British airworthiness directive 003–04–2001.

Effective Date

(e) This amendment becomes effective on July 23, 2003.

Issued in Renton, Washington, on July 10, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15221 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–98–AD; Amendment 39–13196; AD 2003–12–11]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–145 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain EMBRAER Model EMB–145 series airplanes, that requires a one-time ultrasonic inspection of the maneuvering actuator piston rod of the main landing gear (MLG) to ensure adequate wall thickness of the piston rods, and replacement of any discrepant piston rod with a new piston rod. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent failure of the maneuvering actuator piston rod of the MLG, which would impede retraction of the MLG, and consequent reduced controllability of the airplane.

DATES: Effective July 23, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 23, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain EMBRAER Model EMB–145 series airplanes was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on June 5, 2000 (65 FR 35590). That action proposed to require a one-time ultrasonic inspection of the maneuvering actuator piston rod of the main landing gear (MLG) to ensure adequate wall thickness of the piston rods, and replacement of any discrepant piston rod with a new piston rod.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request to Credit Work Done Per Earlier Service Bulletin Versions

Several commenters request that the supplemental NPRM be revised to allow credit for work accomplished in accordance with the original version of EMBRAER Service Bulletin 145–32–0031, dated July 3, 1998; and Change 01, dated December 8, 1998. The commenters note that, if the inspection and related actions have been accomplished in accordance with either of those service bulletin versions, no additional work would be necessary to accomplish the actions specified in Change 02 of the service bulletin. The commenters suggest that failure to include this credit provision in the AD could unnecessarily require operators to request an alternative method of compliance to demonstrate compliance with the requirements of the AD.

The FAA agrees. The procedures described in the original issue and Change 01 of EMBRAER Service Bulletin 145–32–0031 are essentially the same as those described in Change 02. Therefore, the original issue and Change 01 of the service bulletin are also acceptable for compliance with this AD. Paragraph (a) of this final rule has been revised accordingly.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the NPRM regarding that material.

Cost Impact

The FAA estimates that 33 airplanes of U.S. registry will be affected by this proposed AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of this AD on U.S. operators

is estimated to be $1,980, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect 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, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it 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:

2003–12–11 Empresa Brasileira de Aeronautica S.A. (Embraer): Amendment 39–13196. Docket 99–NM–98–AD.

Applicability: Model EMB–145 series airplanes, equipped with main landing gear maneuvering actuators, part and serial numbers as listed in EMBRAER Service Bulletin 145–32–0031, Change No. 02, dated February 12, 1999; certificated in any category.

Note 1: This AD applies to each airplane identified in thepreceding 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 failure of the maneuvering actuator piston rod of the main landing gear (MLG), which would impede retraction of the MLG, and consequent reduced controllability of the airplane, accomplish the following:

Ultrasonic Inspection and Replacement, If Necessary

(a) Within the next 100 landings after the effective date of this AD, perform an ultrasonic inspection of the maneuvering actuator piston rods of the MLG to ensure adequate wall thickness of the piston rods, in accordance with EMBRAER Service Bulletin 145–32–0031, Change No. 02, dated February 12, 1999. An inspection is also acceptable for compliance with the requirements of this AD if done in accordance with EMBRAER Service Bulletin 145–32–0031, dated July 3, 1998; or Change 01, dated December 8, 1999.

(1) If the thickness of any measurement point in any piston rod is greater than 2.0 mm (.079 inch), no further action is required by this AD.

(2) If the thickness of any measurement point in any piston rod is from 1.5 mm (.059 inch) to 2.0 mm (.079 inch): Within 500 landings after the effective date of this AD, replace the piston rod with a new rod having the correct part number as specified in the service bulletin.

(3) If the thickness of any measurement point in any piston rod is less than 1.5 mm (.059 inch): Within 50 landings after the effective date of this AD, replace the piston rod with a new rod having the correct part number as specified in the service bulletin.

Alternative Methods of Compliance

(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, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(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.

Incorporation by Reference

(d) Unless otherwise specified in this AD, the actions must be done in accordance with EMBRAER Service Bulletin 145–32–0031, Change No. 02, dated February 12, 1999. 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 Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Brazilian airworthiness directive 98–09–01 R1, dated March 15, 1999.

Effective Date

(e) This amendment becomes effective on July 23, 2003.

Issued in Renton, Washington, on June 10, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15222 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NE–09–AD; Amendment 39–13193; AD 2003–12–08]

RIN 2120–AA64

Airworthiness Directives; General Electric Company CF6–80A1/A3 and CF6–80C2A PMC Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), that is applicable to General Electric Company (GE) CF6–80A1/A3 and CF6–80C2A PMC series turbofan engines. This amendment requires performing either a directional pilot valve (DPV) pressure switch moisture purge procedure and an operational check of the fan reverser or replacing the DPV assembly with a serviceable assembly and performing an operational check of the fan reverser. Thereafter, this AD requires one of these actions on a repetitive basis. This amendment is prompted by a review of fan reverser safety analyses resulting from the discovery of an undetectable failure mode of the DPV pressure switch on certain GE CF6–80C2A and CF6–80A1/A3 engine models. The actions specified by this AD are intended to prevent inadvertent fan reverser deployment, which, if it occurred in-flight, could result in loss of control of the airplane.

DATES: Effective July 23, 2003. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 23, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Middle River Aircraft Systems, Mail Point 46, 103 Chesapeake Park Plaza, Baltimore, MD, 21220–4295, telephone: (410) 682–0094; fax: (410) 682–0100. This information may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Karen Curtis, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7192; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to General Electric Company (GE) CF6–80A1/A3 and CF6–80C2A PMC series turbofan engines was published in the **Federal Register** on June 21, 2002 (67 FR 42202). That action proposed to require performing either a directional pilot valve (DPV) pressure switch moisture purge procedure and an operational check of the fan reverser, or replacing the DPV assembly with a serviceable assembly and performing an operational check of the fan reverser. Thereafter, that action proposed to require one of these actions on a repetitive basis in accordance with Middle River Aircraft Systems Alert Service Bulletins (ASBs) CF6–80A1/A3 SB 78A4030, dated April 4, 2002 or CF6–80C2A PMC SB 78A1118, dated April 4, 2002.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request to Revise Applicability Statement

One commenter requests that the applicability statement be revised to reference the left-hand fan reverser halves associated with the engines instead of the engine models themselves. The commenter believes that the DPV assembly is not a part of the engine, but is instead a part of the left-hand fan reverser half. The commenter notes the fact that the reverser halves and engines can be removed or installed separately.

The FAA does not agree. The FAA acknowledges that in service the engines and fan reversers can be separated, with the possibility of reversers remaining installed on-wing, while different engines are installed. However, the fan reverser assembly and, therefore, the DPV are part of the engine (14 CFR part 33) type design. The applicability to the engine model is, therefore, appropriate. No changes will be made to the AD as a result of this comment.

Request to Add Isopropyl Alcohol as an Alternate to Acetone

One commenter requests that isopropyl alcohol be allowed as an acceptable alternate to the acetone solvent listed in the consumables of the ASBs as the fluid used for purging moisture from the DPV pressure switch assemblies. The commenter notes that some airports may restrict the use of acetone. The commenter also notes that the DPV assembly manufacturer has agreed that alcohol is an acceptable alternate for acetone for the purposes of accomplishing the moisture purge service bulletins.

The FAA agrees that isopropyl alcohol is an acceptable alternate for acetone for this application. The FAA, GE, and the component manufacturer, previously identified this issue and the ASBs were revised on August 23, 2002, to allow the use of isopropyl alcohol. The compliance section of this final rule AD has been revised to add Revision 1 to each of the ASBs.

Alternative for Replacement of Serviceable DPV

One commenter requests that deactivation of the fan reverser be allowed as an alternative to replacement with a serviceable DPV. The commenter sites a previous AD (99–18–19) that allowed deactivation instead of a DPV leak check inspection.

The FAA agrees and the final rule is revised to allow deactivation. Limitations for operation with one or more reversers deactivated have also been added and are consistent with the previous AD.

Request to Rewrite Description of the Failure Sequence

One commenter requests that the description of the failure sequence in the discussion section of the NPRM preamble be reworded to clarify that an additional failure is required in order for the undetectable DPV pressure switch freezing failure to result in an inadvertent deployment (IAD). The commenter believes that the current statement is misleading. The commenter believes that in addition to the pressurization failure, a directional failure is required before an IAD can occur.

The FAA does not agree. While the FAA agrees that the wording could have been clearer, the requested change does not affect the conclusion that an unsafe condition has been identified. In addition, the Discussion section details are not repeated in the final rule after an NPRM, and therefore, the AD remains unchanged as a result of this comment.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Regulatory Analysis

This final rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this final rule.

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 the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 final evaluation has been prepared for this action and it 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, 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 a new airworthiness directive to read as follows:

2003–12–08 General Electric Company: Amendment 39–13193. Docket No. 2002–NE–09–AD.

Applicability: This airworthiness directive (AD) is applicable to General Electric Company (GE) CF6–80A1/A3 and CF6–80C2A PMC series turbofan engines. These engines are installed on, but not limited to Airbus Industrie A300–600 and A310 series airplanes.

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

Compliance: Compliance with this AD is required as indicated, unless already done. To prevent inadvertent fan reverser deployment, which, if it occurred in-flight, could result in loss of control of the airplane, do the following:

GE CF6–80A1/A3 Series Engines

(a) For GE CF6–80A1/A3 series engines, perform one of the following no later than 1,400 flight hours time-since-new (TSN) or 600 flight hours time-in-service (TIS) after the effective date of this AD, whichever occurs later:

(1) Perform the directional pilot valve (DPV) pressure switch moisture purge, in accordance with Paragraph 3.C. of the Accomplishment Instructions of Middle River Aircraft Systems Alert Service Bulletins (ASBs) CF6–80A1/A3 SB 78A4030, dated April 4, 2002, or CF6–80A1/A3 SB 78A4030, Revision 1, dated August 23, 2002, or

(2) Replace the DPV assembly with a serviceable assembly, or

(3) Deactivate the thrust reverser. The DPV must be replaced with a serviceable assembly within 10 days after deactivation. Information on deactivating the thrust reverser can be found in the applicable Aircraft Maintenance Manual (AMM).

(b) After each purge or replacement done in accordance with paragraph (a)(1), (a)(2), or (a)(3) of this AD, perform an operational check of the fan reverser in accordance with Paragraph 3.E. of the Accomplishment Instructions of ASBs CF6–80A1/A3 SB 78A4030, dated April 4, 2002, or CF6–80A1/A3 SB 78A4030, Revision 1, dated August 23, 2002.

(c) Thereafter, for GE CF6–80A1/A3 series engines, at intervals not to exceed 1,400 hours TIS since the last pressure switch purge or replacement of the DPV assembly, perform one of the following:

(1) Perform the DPV pressure switch moisture purge, in accordance with Paragraph 3.C. of the Accomplishment Instructions of Middle River Aircraft Systems ASBs CF6–80A1/A3 SB 78A4030, dated April 4, 2002, or CF6–80A1/A3 SB 78A4030, Revision 1, dated August 23, 2002, or

(2) Replace the DPV assembly with a serviceable assembly, or

(3) Deactivate the thrust reverser. The DPV must be replaced with a serviceable assembly within 10 days after deactivation. Information on deactivating the thrust reverser can be found in the applicable AMM.

(d) After each purge or replacement done in accordance with paragraph (c)(1), (c)(2), or (c)(3) of this AD, perform an operational check of the fan reverser in accordance with Paragraph 3.E. of the Accomplishment Instructions of ASBs CF6–80A1/A3 SB 78A4030, dated April 4, 2002, or CF6–80A1/A3 SB 78A4030, Revision 1, dated August 23, 2002.

GE CF6–80C2A Series Engines

(e) For GE CF6–80C2A1/A2/A3/A5/A8 series engines, perform one of the following no later than 1,400 flight hours TSN or 600 flight hours TIS after the effective date of this AD, whichever occurs later:

(1) Perform the DPV pressure switch moisture purge, in accordance with Paragraph 3.C. of the Accomplishment Instructions of Middle River Aircraft Systems ASBs CF6–80C2A PMC SB 78A1118, dated April 4, 2002, or CF6–80C2A PMC SB 78A1118, Revision 1, dated August 23, 2002, or

(2) Replace the DPV assembly with a serviceable assembly, or

(3) Deactivate the thrust reverser. The DPV must be replaced with a serviceable assembly within 10 days after deactivation. Information on deactivating the thrust reverser can be found in the applicable AMM.

(f) After each purge or replacement done in accordance with paragraphs (e)(1), (e)(2), or (e)(3) of this AD, perform an operational check of the fan reverser, in accordance with Paragraph 3.E. of the Accomplishment Instructions ASBs CF6–80C2A PMC SB 78A1118, dated April 4, 2002, or CF6–80C2A PMC SB 78A1118, Revision 1, dated August 23, 2002.

(g) Thereafter, for GE CF6–80C2A1/A2/A3/A5/A8 series engines, perform one of the following at intervals not to exceed 1,400 hours TIS since the last pressure switch purge or replacement of the DPV assembly:

(1) Perform the DPV pressure switch moisture purge, in accordance with Paragraph 3.C. of the Accomplishment Instructions of Middle River Aircraft Systems ASBs CF6–80C2A PMC SB 78A1118, dated April 4, 2002, or CF6–80C2A PMC SB 78A1118, Revision 1, dated August 23, 2002, or

(2) Replace the DPV assembly with a serviceable assembly, or

(3) Deactivate the thrust reverser. The DPV must be replaced with a serviceable assembly within 10 days after deactivation. Information on deactivating the thrust reverser can be found in the applicable AMM.

(h) After each purge or replacement done in accordance with paragraphs (g)(1), (g)(2), or (g)(3) of this AD, perform an operational check of the fan reverser, in accordance with Paragraph 3.E. of the Accomplishment Instructions of ASBs CF6–80C2A PMC SB 78A1118, dated April 4, 2002, or CF6–80C2A PMC SB 78A1118, Revision 1, dated August 23, 2002.

Serviceable DPV Assembly

(i) For the purpose of this AD, a serviceable DPV assembly is an assembly that has:

(1) Accumulated zero time since new, or

(2) Passed the tests in the Middle River Aircraft Systems Component Maintenance Manual GEK 85007 (78–31–51), Revision No. 7 or later, Directional Pilot Solenoid Valve, Page Block 101, Testing and Troubleshooting, and that has zero flight hours TIS since passing the tests, or

(3) Been successfully purged according to paragraphs (a)(1), (c) (1), (e)(1) or (g)(1) of this AD immediately before installation on the fan reverser.

Deactivation Requirements

(j) If one or both thrust reversers are deactivated, then prior to further flight, revise the Limitations Section of the FAA-approved AFM to include the following:

''The takeoff performance on wet and contaminated runways with a thrust

reverser(s) deactivated shall be determined in accordance with Airbus Flight Operations Telex (FOT) 999.0066/99, dated June 9, 1999, as follows:

For takeoff on wet runways, use performance data in accordance with paragraph 4.1.1 of the FOT.

For takeoff on contaminated runways, use performance data in accordance with paragraph 4.1.2 of the FOT.''

(1) Notwithstanding the provisions of the FAA approved A300–600 and A310 Master Minimum Equipment List (MMEL), dispatch with both thrust reversers deactivated, for the purposes of complying with this AD, is approved.

(2) Notwithstanding the provisions of the FAA Approved A300–600 and A310 MMEL, airplanes which have deactivated one or both thrust reversers in compliance with this AD, may not conduct operation on contaminated runways, as defined in Airbus Flight Crew Operating Manual Section 2.18.50, unless all components of the Main Wheel Brakes, Green and Yellow Brake Systems, Antiskid System, Ground Spoiler System, and all Spoiler and Speed Brake Surfaces, operate normally.

Note 2: The ''FCOM'' referenced in Airbus FOT 999.0066/99, dated June 9, 1999, is Airbus Industrie Flight Crew Operating Manual (FCOM), Revision 27 for Airbus Model A310 series airplanes and Revision 22 for A300–600 series airplanes. [The revision number is indicated on the List of Effective Pages (LEP) of the FCOM.]

Alternative Methods of Compliance

(k) 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, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(l) Special flight permits may be issued in accordance with §§ 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 done.

Documents That Have Been Incorporated By Reference

(m) The actions must be done in accordance with the following Middle River Aircraft Systems Alert Service Bulletins:

Document no.	Pages	Revision	Date
CF6–80C2A, PMC SB 78A1118	All	Original	April 4, 2002
Total Pages: 18.			
CF6–80C2A, PMC SB 78A1118	1	1	August 23, 2002
	2–4	Original	April 4, 2002
	5	1	August 23, 2002
	6–8	Original	April 4, 2002
	9–10	1	August 23, 2002
	11–18	Original	April 4, 2002
Total Pages: 18.			
CF6–80A1/A3, SB 78A4030	All	Original	April 4, 2002
Total Pages: 18.			
CF6–80A1/A3, SB 78A4030	1	1	August 23, 2002
	2–4	Original	April 4, 2002
	5	1	August 23, 2002
	6–8	Original	April 4, 2002
	9–10	1	August 23, 2002
	11–18	Original	April 4, 2002
Total Pages: 18.			

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 Middle River Aircraft Systems, Mail Point 46, 103 Chesapeake Park Plaza, Baltimore, MD, 21220–4295, telephone: (410) 682–0094; fax: (410) 682–0100. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(n) This amendment becomes effective on July 23, 2003.

Issued in Burlington, Massachusetts, on June 9, 2003.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03–15223 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 305

Rule Concerning Disclosures Regarding Energy Consumption and Water Use of Certain Home Appliances and Other Products Required Under the Energy Policy and Conservation Act (''Appliance Labeling Rule'')

AGENCY: Federal Trade Commission.

ACTION: Final rule and conditional exemption.

SUMMARY: The Federal Trade Commission (''Commission'') announces amendments to the Appliance Labeling Rule and the issuance of a conditional exemption in response to a request from the Association of Home Appliance Manufacturers (''AHAM'') related to certain labeling requirements for clothes washers.

DATES: The effective date of the amendments to 16 CFR part 305 is January 1, 2004. The effective date of the conditional exemption described herein is June 11, 2003.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, Attorney, Division of Enforcement, Federal Trade Commission, Washington, DC 20580, (202) 326–2889.

SUPPLEMENTARY INFORMATION:

I. Background

A. FTC Requirements

The Commission issued the Appliance Labeling Rule in 1979, 44 FR 66466 (Nov. 19, 1979) (''Rule''), in response to a directive in the Energy Policy and Conservation Act of 1975 (''EPCA'') (42 U.S.C. 6294). EPCA also requires the Department of Energy (''DOE'') to develop test procedures that measure how much energy certain appliances use, and to determine the representative average cost a consumer pays for the different types of available energy.

The rule covers, among other things, eight categories of major household appliances: refrigerators and

refrigerator-freezers, freezers, dishwashers, clothes washers, water heaters, room air conditioners, furnaces, and central air conditioners. The rule requires manufacturers of all covered appliances to disclose specific energy consumption or efficiency information (derived from the DOE test procedures) at the point of sale in the form of an ''EnergyGuide'' label and in catalogs. The rule requires manufacturers to include, on labels, an energy consumption or efficiency figure and a ''range of comparability.'' This range shows the highest and lowest energy consumption or efficiencies for all comparable appliance models so consumers can compare the energy consumption or efficiency of other models similar to the labeled model.

The rule requires manufacturers, after filing an initial report, to report annually the estimated annual energy consumption or energy efficiency ratings for the appliances derived from tests performed pursuant to the DOE test procedures. 16 CFR 305.8(b). Because manufacturers regularly add new models to their lines, improve existing models, and drop others, the database from which the ranges of comparability are calculated is constantly changing. Under section 305.10 of the rule, to keep the required information on labels consistent with these changes, the Commission publishes new ranges (but not more often than annually) if an analysis of the new information indicates that the upper or lower limits of the ranges have changed by more than 15%. Otherwise, the Commission publishes a statement that the prior ranges remain in effect for the next year.

B. New DOE Test Procedure and Energy Standards for Clothes Washers

New energy conservation standards and a new DOE test procedure for clothes washers will become effective on January 1, 2004. The new energy conservation standard requires that all new residential clothes washers manufactured after January 1, 2004, be 22% more efficient than today's minimally compliant clothes washer.[1] Accordingly, the 2004 energy standard will render a substantial portion of the existing clothes washer market obsolete.

The new DOE test procedure for clothes washers, which also will become effective on January 1, 2004, is found at 10 CFR part 430, subpart B, Appendix J1.[2] Application of the new test procedure (sometimes referred to as the ''J1'' test or the ''Modified Energy Factor'' test) will likely produce energy consumption figures different from those yielded by the old (''J'') test procedure (10 CFR part 430, subpart B, Appendix J).[3] Because these test results are used to determine energy use information that appears on the FTC EnergyGuide label, consumers may not be able effectively to compare the energy performance of clothes washers if the labels are based on the two different test procedures.

II. AHAM's Request

To ease the transition to the new energy efficiency standard and new (J1) test procedure, AHAM[4] wrote to FTC staff on February 7, 2003, requesting permission to begin using that test for labeling clothes washers during 2003, before the test becomes effective. In addition, AHAM's letter requests that the Commission allow its members to provide special wording on the EnergyGuide labels for these models to help consumers in distinguishing washers tested under the new (J1) procedure from those tested under the old (J) procedure (*see* Prototype Label 2 at the end of this document). AHAM proposed a modified label that would display a banner across the top stating: ''This Model has been Tested to the 2004 Test Procedure. Compare only with Models with this Notice.'' AHAM requested that the Commission allow its members to begin using the new (J1) test and modified labels on May 1, 2003, and that the labeling changes be made ''permanent.''[5] To grant AHAM's request, the Commission would have to grant an exemption from certain EnergyGuide testing and labeling requirements for the remainder of this year and issue rule amendments to make the requested labeling changes a permanent requirement for all manufacturers after January 1, 2004.

AHAM submitted its request because it asserts that the transition to clothes washers compliant with the new 2004 energy efficiency standard and new test procedure, with respect to testing and labeling, could be unduly burdensome to manufacturers and confusing to consumers. According to AHAM, there will be hundreds of new energy efficient models introduced throughout the course of 2003. Under current requirements, manufacturers will have to test and rate these new models first under the old (J) procedure for 2003, and then again under the new (J1) procedure in order to distribute them in 2004. AHAM stated that, since several samples of each basic model need to be tested to determine statistically valid ratings, such duplicative testing would result in tremendous laboratory and manufacturer staff resources for hundreds of new models. Also, AHAM states that retail floor models are not changed frequently. Thus, without action by the FTC, retail display units for new models introduced this year will have energy labels based on the old (J) test well into 2004 and beyond. AHAM is concerned that these display units could be very confusing and misleading as consumers seek to compare units tested under different procedures in a single showroom without any notice that differences exist.

III. Proposed Exemption and Proposed Rulemaking

In an April 3, 2003, document (68 FR 16231), the Commission sought comments on AHAM's proposal. The proposal raised two procedural matters: (1) A request for an exemption from certain testing and labeling requirements for clothes washers from May through December 31, 2003 (to permit testing and labeling pursuant to the new (J1) test); and (2) a proposed ''permanent'' rule change, effective January 1, 2004, to conform existing label content and format requirements to label changes permitted by the 2003 exemption.

A. Proposed Conditional Exemption for 2003

The proposed exemption implicated several provisions of the Appliance Labeling rule. The rule requires that, for purposes of the EnergyGuide label, manufacturers use the estimated annual energy consumption as derived from the DOE clothes washer test procedures in 10 CFR part 430 (*see* 16 CFR 305.5(a)

[1] 66 FR 3314, 3315 (Jan. 12, 2001). A second amended energy efficiency standard, slated to take effect on January 1, 2007, requires that all new residential clothes washers manufactured after that date be 35% more efficient than today's minimally compliant clothes washer.

[2] The EnergyStar program, run by DOE and the U.S. Environmental Protection Agency, already requires use of the new (J1) test to certify clothes washers under that program.

[3] According to AHAM, the clothes washer test procedures were revised to better reflect current usage habits by incorporating updated temperature utilization factors that are more appropriate for today's designs.

[4] The manufacturers identified in AHAM's request are Alliance Laundry Systems, Electrolux Home Products, Fisher & Paykel Ltd., GE Appliances, Maytag Appliances, Miele Corp., and Whirlpool Corp. Subsequently, AHAM informed Commission staff that BSH, Gonrenje, and Asko also are participating in AHAM's request. According to AHAM, these manufacturers produce over 95% of the clothes washers sold in the United States.

[5] AHAM also requested that the Commission change the reporting date for clothes washer data in the rule from March 1 to October 1 for each year. The Commission addressed the requested date change for data submission in an earlier **Federal Register** document (*see* 68 FR 8448 (Feb. 21, 2003)).

and 305.11(a)(5)(i)(E)). Because the new (J1) test for clothes washers will not become effective until January 1, 2004, the current rule does not authorize the use of that test for energy consumption information on EnergyGuide labels until that date. By granting the requested exemption, the Commission would allow manufacturers to begin using the new test results on EnergyGuide labels before 2004. In addition, the rule does not allow any marks or identification other than those specified in the rule to appear on the label except for some limited exceptions not applicable here (*see* 16 CFR 305.11(a)(5)(i)(K)). Accordingly, absent an exemption, the rule does not allow the kind of explanatory information proposed by AHAM.

B. Proposed Rule Change for EnergyGuide Labels for 2004 and Beyond

In the April 3, 2003, document, the Commission indicated that, by granting the exemption, it is probable that many new clothes washers distributed for sale in the United States for the remainder of 2003 would have labels containing the proposed advisory language that: ''This Model has been Tested to the 2004 Test Procedure. Compare only with Models with this Notice.'' Once this change is made to EnergyGuide labels on units distributed in 2003, a return to the conventional label in the future may cause consumer confusion because the units with the modified label will stay on showroom floors into 2004 and beyond. Given these considerations, AHAM asked the Commission to make its proposed label changes permanent. The Commission proposed that the advisory language required by the rule after January 1, 2004, should be identical to that on the label during the exemption period. The Commission sought public comment on a proposed rule change that would incorporate AHAM's suggested label changes and require these changes for all clothes washers distributed for sale in the United States beginning January 1, 2004.

IV. Comment Analysis

The Commission received four comments in response to the April 3, 2003, document.[6] The three industry comments (from Alliance, Whirlpool, and AHAM) supported the proposed conditional exemption and rule change. AHAM stated that, ''early compliance with J1 labeling requirements in 2003 is critical to the efficiency of testing and production as the industry transitions to new washer standards by the end of 2003.''[7] Whirlpool echoed AHAM's comment, adding that, without the conditional exemption, it would be not be able ''to meet existing commitments to trade partners.''[8] These three commenters also supported the proposal to make the changes to the EnergyGuide label permanent. The fourth commenter, NRCan (the agency responsible for appliance labeling in Canada), raised concerns about the impact of the proposal on adjoining labels bearing both the U.S. EnergyGuide and the Canadian ''EnerGuide'' label (as allowed by the Commission's rule). An analysis of specific issues raised by the comments follows:

A. Differences Between the J and J1 Tests

Comments

The Commission requested comments on whether the differences between the results yielded by the new (J1) and old (J) tests are significant enough to warrant special advisory language on the EnergyGuide labels. The Commission also asked whether one test yields significantly higher or lower results than the other. The three industry comments indicated that the differences were significant enough to warrant the change. Alliance stated that the tests yielded a 25% difference for one of its models.[9] Whirlpool and AHAM commented that the new (J1) test results are generally lower than the older (J) test results and the differences could be as much as 40%.[10]

Discussion

According to the commenters, the differences in energy use results yielded by the two tests can be significant. Given this information, we believe the explanatory text on the labels is appropriate to aid consumers in distinguishing models tested under the two procedures. The Commission notes that DOE periodically modifies the test procedure for covered products and such changes can yield different test results for the same model. In the past, the Commission has not required additional information on the EnergyGuide label in response to test procedure changes. In this case, however, there are special circumstances that, in the Commission's view, warrant the explanatory language as requested by AHAM. First, because the new conservation standard will become effective on the same date as the new test procedure, a large number of new models will appear on the market over a short period of time in response to the more stringent efficiency standards. In addition, the differences between the results of the old and new test procedures could be quite substantial in this case, up to 40% as indicated by the industry comments. Finally, because the exemption will allow manufacturers to begin using the new (J1) test results for labeling early, manufacturers will distribute new products with labels based on the new test while they will continue to distribute older products with labels reflecting the old test. Accordingly, the transition between the old and new labels in showrooms will likely be longer than is usually the case when DOE amends a test procedure. Considering all these factors, the Commission believes that explanatory language as suggested by AHAM is appropriate.

B. Content, Size, and Placement of the Modified Language

Comments

The Commission solicited comments on the proposed changes to the label, such as the content, size, and placement of the modified language on the EnergyGuide. The Commission asked whether the proposed language on the EnergyGuide label will help consumers in their purchasing decisions, or cause undue confusion. In addition, commenters were asked whether the reference to the year ''2004'' on the label will create confusion in subsequent years if the proposed change becomes a permanent fixture on the label and whether the explanatory language should be required on both the top and the bottom of the label. The Commission sought comment on alternatives to the proposed advisory language, such as using the term ''J1'' or ''Modified Energy Factor'' in lieu of ''2004'' in describing the test.

The three industry comments stated that the proposed changes are appropriate and that the changes to the EnergyGuide label will help consumers. Whirlpool stated that there will be less need for dealers to ''refloor'' model units and less confusion for ''energy conscientious consumers when selecting new appliances.''[11] The industry commenters also preferred the reference to ''the 2004 procedure'' over other descriptors such as ''J1'' or

[6] The Commission received comments from Alliance Laundry Systems (''Alliance'') (1), Whirlpool Corporation (''Whirlpool'') (2), AHAM (3), and Natural Resources Canada (''NRCan'') (4).

[7] AHAM (3) p. 1.

[8] Whirlpool (2) p. 3.

[9] Alliance (1) p. 1 (attachment).

[10] AHAM (3) p. 2; Whirlpool (2) p. 4.

[11] Whirlpool (2) p. 4

''Modified Energy Factor'' because consumers would have ''no clue'' as to the meaning of these latter terms.[12] They did not believe it was necessary to place the explanatory language on the bottom of the label (in addition to the statements proposed for the top and middle of the label). Whirlpool wrote that such information would be redundant for consumers.[13] Finally, AHAM and Alliance requested that the size of the new label be 7⅜ inch (18.73 cm.) as currently required by the Rule and not 8 inches (20.32 cm.) as proposed by the Commission.[14] Alliance suggested that the use of a 7⅜ inch (18.73 cm.) label can be accomplished by not incorporating the proposed text in the middle of the label.[15]

Discussion

The Commission agrees with the commenters that the ''2004'' language is preferable to alternatives such as ''J1'' and ''Modified Energy Factor.'' It is possible that, in later years, the reference to ''2004'' on the label may raise questions for consumers. Ultimately, however, we do not believe that this reference will have a significant impact on consumers' ability to compare clothes washer energy use because the relevant energy use and operating cost information will be clearly marked on the label. Accordingly, we have retained the reference to ''2004'' in the explanatory language for the final rule.

The Commission recognizes that it may not be desirable to retain this ''2004'' reference on the clothes washer labels indefinitely. Although the explanatory language will aid consumers during the upcoming transition period, the language will eventually become unnecessary because all models will carry the same label. The Commission may consider eliminating the special advisory language from the rule in the future. Each year, the Commission analyzes energy use information submitted for all clothes washers sold in the United States to determine whether the ranges of comparability for the EnergyGuide labels should change. If the Commission determines to amend the ranges in a given year, new labels printed as a result will display different ranges and use updated information to calculate operating costs. Accordingly, if there is perceived need to discontinue the explanatory statements on the labels in the future, the issuance of new ranges could provide the Commission with the opportunity to consider eliminating the advisory language published here.

The Commission has decided to make minor revisions to the proposed wording of the explanatory language. Instead of stating in the banner on top of the label that, ''This Model has been Tested to the 2004 Test Procedure. Compare only with Models with this Notice,'' the Commission believes that it is preferable to state, ''This model has been tested using the 2004 test procedure. Compare only with models displaying this statement.'' Similarly, the Commission has changed the explanatory text in the middle of the label to read: ''Compare the energy use of this clothes washer only with models tested using the 2004 test procedure.'' These modifications replace the phrase ''Tested to the'' with ''tested *using* the'' (emphasis added). In addition, the phrase ''with this Notice'' in the top banner has been changed to ''displaying this statement.'' The final language also eliminates stray capitalization that appeared in the proposed language. The Commission believes these minor changes will make it easier for consumers to understand the intended message.

Finally, some commenters stated that the conventional size label (7⅜ inches; 18.73 cm.) should be used for the exemption and final rule instead of an 8 inch (20.32 cm.) label as proposed. Upon further review, the existing label size (7⅜ inch; 18.73 cm.) will accommodate the additional banner. We see no significant benefit to requiring the proposed 8 inch (20.32 cm.) label instead of the conventional 7⅜ inch (18.73 cm.) label. The Commission, however, does not agree with Alliance that the modified language in the middle of the label should be removed. This language in the middle of the label reinforces the message provided by the explanatory information in the top banner. Using existing font and format requirements for the EnergyGuide label, the conventional (7⅜ inch; 18.73 cm.) label can accommodate the explanatory language at the top and in the middle of the label (as shown in Prototype Label 2).

C. Impact on Canadian and Mexican Labels

Comments

The Commission asked whether the implementation of AHAM's proposal would cause consumer confusion for those units with EnergyGuide labels adjoining energy labels required by Mexico or Canada. Manufacturers using such joint labels generally print them on hang tags with the U.S. label on one side and the Canadian label on the other. NRCan raised concerns about the impact of the proposal for consumers examining these adjoining labels. Beginning in 2004, NRCan will require an equivalent of the J1 test for labeling purposes. That agency, however, may not have time to harmonize fully with the FTC's exemption and rule if the changes are implemented as proposed before then. Therefore, NRCan is concerned that there may be confusion if both labels do not report the same information on both sides. NRCan indicated, however, that it has discussed options with the Canadian Appliance Manufacturers Association and is willing to work to identify non-regulatory approaches to this issue.[16] Without such a resolution, manufacturers would continue to use the Canadian equivalent of the old (J) test for new models sold in Canada until the end of this year.

The other commenters believed that the proposal would not cause confusion where adjoining labels are used. AHAM stated that the EnergyGuide label is discernable from that of Mexico or Canada because it is entirely in English, has a unique format, and clearly states that the results are based on U.S. government tests. In addition, AHAM suggested that the proposed J1 label would make it clear that the label should only be compared with other labels bearing the same message.[17] Alliance asserted that, ''[t]he Commission's first priority is to provide accurate information to U.S. consumers, not withhold action or information because of potential impacts to consumers in neighboring countries.'' In its view, any confusion resulting from the change would be far less than the confusion that would result if the Commission does not issue the proposed exemption and amendment.[18]

Discussion

The Commission understands NRCan's concerns about the use of new (J1) test data on labels and the advisory language related to that test on adjoining U.S.-Canadian labels. We do not, however, believe that these concerns warrant a change to the proposed conditional exemption and rule amendments. Beginning January 1, 2004, all models distributed in the U.S. and Canada will display labels based on the same test. Before that time, it is

[12] AHAM (3) p. 2; Alliance (1) p. 2; and Whirlpool (2) p. 4.

[13] Whirlpool (2) p. 4.

[14] AHAM (3) p. 2; Alliance (1) p. 2.

[15] Alliance (1) p. 2.

[16] NRCan (4) pp. 1–2.

[17] AHAM (3) p. 2; *see also* Whirlpool (2) p. 4.

[18] Alliance (1) p. 2.

unclear whether manufacturers will distribute new models in Canada if, in doing so, they will have to conduct the same double testing they have sought to avoid through their petition to the Commission. In addition, NRCan, as suggested in its comment, may identify a ''non-regulatory'' solution that allows manufacturers to use the J1 test for labels on products sold in Canada and thus eliminate these concerns altogether.

Even assuming some new models are distributed this year bearing the joint label, the Commission does not expect that differences between the Canadian and U.S. labels will significantly impede consumers' ability to compare the energy use of competing products. Since 1996, the Commission's rule has allowed manufacturers to print the EnergyGuide label directly adjoining the Canadian EnerGuide. *See* 16 CFR 305.11(5)(i)(I). The U.S. EnergyGuide label contains operating cost information not found on the Canadian EnerGuide label. In addition, range of comparability information on the FTC EnergyGuide label may not be the same as that on the Canadian EnerGuide labels. We have no evidence that these differences have caused confusion. As Alliance suggests in its comments, the EnergyGuide's reference to U.S. government tests alerts consumers that the label is intended for U.S. consumers.[19] In the long term, the Commission believes it is important to harmonize the U.S. label with the Canadian label as much as possible. Given the relatively short duration of the exemption period and for the other reasons discussed above, however, the Commission is not requiring any specific conditions for the exemption with regard to adjoining labels.

D. Benefits and Costs of the Conditional Exemption and Amendments

Comments

The Commission asked for comments on the economic impact of the proposed rule and conditional exemption, including impacts on small business. AHAM stated that the proposals would impose no additional burdens on manufacturers and would assist manufacturers in meeting DOE efficiency standards by January 1, 2004.[20] Whirlpool added that it would suffer serious consequences if the FTC failed to implement these changes by early May.[21] Alliance indicated that the proposal would reduce a significant burden on manufacturers. It estimated that the proposal would save that company 35 working days of one laboratory technician dedicated to DOE energy testing.[22]

Discussion

The manufacturers have described the burdens they are seeking to avoid through the requested exemption. The Commission believes that issuance of the exemption and final rule will help to avoid those burdens while, at the same time, minimizing any consumer confusion associated with the transition from the old Appendix J test procedure to the new Appendix J1 procedure.

V. Final Conditional Exemption and Amendments

The Commission has considered the comments received and has decided to issue the conditional exemption and amendments as detailed in this section. The Commission believes that there are benefits to allowing manufacturers to begin changing over to the new labels and test results at this time. The exemption and rule change will allow manufacturers to avoid testing their new products multiple times pursuant to two test procedures for the purposes of FTC labeling.[23] In addition, consumers will obtain information based on the new test sooner. The Commission also believes that the changes to the label will minimize consumer confusion resulting from the exemption and transition to the new test by alerting consumers that the energy use information on some labels is derived from a new test procedure.

A. Final Conditional Exemption

The Commission grants AHAM's request for an exemption from the requirements in 16 CFR 305.5(a) and 305.11(a) only to the extent required to allow manufacturers to:

(1) Use the test procedure in 10 CFR part 430, subpart B, Appendix J1 for determining the energy use figure printed on EnergyGuide labels of clothes washers distributed between June 11, 2003, and December 31, 2003;[24] and

(2) For such models, use EnergyGuide labels that contain the following modifications to the format and content requirements in 16 CFR 305.11, as illustrated in Prototype Label 2 at the end of this document:

(a) The use of the statement ''Compare the energy use of this clothes washer only with other models tested using the 2004 test procedure'' in lieu of the statement ''Compare the Energy Use of this Clothes Washer with Others Before You Buy''; and

(b) The use of the statement ''This model has been tested using the 2004 test procedure. Compare only with models displaying this statement.'' in a 10/16 inch (1.59 cm.) in height, process black bar across the top of the label.

The Commission grants the exemption with the following conditions: (1) That any manufacturers using this exemption must use it for all clothes washer models introduced between June 11, 2003, and December 31, 2003 (they may also use it for existing models that meet the new conservation standard), and (2) the modified EnergyGuide label must be used if the new (J1) test is used to derive energy use information on the EnergyGuide label for clothes washers. The manufacturers remain obliged to comply with all other Rule requirements. Manufacturers not specifically named in AHAM's request may use this exemption as long as they follow the conditions specified by the Commission.[25]

B. Final Amendments

After considering the comments, the Commission has determined to issue the final rule as described in this section. To avoid confusion that may result from switching back to the conventional label after the exemption period, the Commission believes that is preferable to amend the Rule to require the explanatory language on EnergyGuide labels for all models beginning January 1, 2004. These label changes are identical to those allowed by the conditional exemption. The final amendments published here will minimize consumer confusion that could result from a return to the conventional label at the end of the exemption period.

[19] Alliance (1) p. 2.

[20] AHAM (3) p. 3.

[21] Whirlpool (2) p. 5.

[22] Alliance (1) p. 2.

[23] As stated in the proposal, it is the Commission's understanding that AHAM's members intend to test new models under the new (J1) test procedure and use limited testing under the old (J) procedure to develop data for the purposes of DOE and FTC reporting requirements during the remainder of 2003. 64 FR at 16232. The final conditional exemption and rule amendments announced in this document apply only to FTC labeling requirements and do not change existing DOE requirements or otherwise relieve manufacturers from complying with DOE requirements.

[24] The April 3, 2003, **Federal Register** document proposed that the exemption period begin May 1, 2003 (*see* 68 FR at 16233). This date is now infeasible given the timing of the April 3 document's publication.

[25] Given the limited duration of this conditional exemption, the Commission is not incorporating the exemption into the text of the rule (see 16 CFR 305.19).

Consistent with the conditional exemption, the final rule does not require an 8 inch label as proposed but instead retains the 7⅜ inch (18.73 cm.) length currently required by the Rule. In addition, the final rule incorporates the minor wording and format changes to the explanatory statements described in the comment analysis and in the description of the conditional exemption. The final rule changes are printed at the end of this document. All manufacturers must follow these requirements beginning January 1, 2004.[26]

VI. Regulatory Analysis and Regulatory Flexibility Act Requirements

Under section 22 of the FTC Act, 15 U.S.C. 57b, the Commission must issue a regulatory analysis for a proceeding to amend a rule only when it: (1) Estimates that the amendment will have an annual effect on the national economy of $100,000,000 or more; (2) estimates that the amendment will cause a substantial change in the cost or price of certain categories of goods or services; or (3) otherwise determines that the amendment will have a significant effect upon covered entities or upon consumers. The Commission has determined that the exemption and amendments to the rule will not have such effects on the national economy, on the cost of covered products, or on covered parties or consumers.

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–612, requires that agencies conduct analyses of the anticipated economic impact of proposed amendments on small businesses. The purpose of a regulatory flexibility analysis is to ensure that the agency considers impact on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA, 5 U.S.C. 605, provides that such an analysis is not required if the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.

There are approximately 20 manufacturers of clothes washers sold in the United States. Most of these manufacturers are relatively large.[27] Because the clothes washer requirements of the Appliance Labeling rule cover a limited number of manufacturers, most of which are large, the Commission does not believe the proposed amendments or exemption will affect a substantial number of small businesses. In any event, the proposed amendments and exemptions are unlikely to have a significant economic impact upon such entities, if any. Specifically, the proposed rule and exemption involve minor text changes to labels already required by the rule. The content of these labels must be changed in response to new ranges of comparability published by the Commission from time to time. Moreover, for the reasons explained earlier, the final rule amendments and exemption are expected to lessen the compliance burdens that would be imposed on regulated entities if they were not permitted to label their products in accordance with the 2004 test procedures before those procedures officially take effect. In the Commission's view, the amendments and exemption should not have a significant or disproportionate impact on the costs of small manufacturers and retailers.

Based on available information, therefore, the Commission certifies that these amendments to the Appliance Labeling rule and the issuance of the requested exemption will not have a significant economic impact on a substantial number of small businesses.

VII. Paperwork Reduction Act

In a 1988 notice (53 FR 22113), the Commission stated that the Rule contains disclosure and reporting requirements that constitute ''information collection requirements'' as defined by 5 CFR 1320.7(c), the regulation that implements the Paperwork Reduction Act.[28] The Commission noted that the rule had been reviewed and approved by the Office of Management and Budget (''OMB'') and has been assigned OMB Control No. 3084–0068 with respect to the rule's recordkeeping and reporting requirements until September 30, 2004, subject to further renewal. The exemption and amendments issued in this document do not change the substance, frequency of the recordkeeping, disclosure, or reporting requirements and, therefore, do not require further OMB clearance.[29]

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

VIII. Final Rule Amendments

■ For the reasons set out in the preamble, the Federal Trade Commission amends 16 CFR part 305 as follows:

PART 305—[AMENDED]

■ 1. The authority citation for part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

■ 2. Amend § 305.11 by revising paragraph (a)(5)(i)(A) and adding new paragraph (a)(5)(i)(L) to read as follows:

§ 305.11 Labeling for covered products.

(a) * * *

(5) * * *

(i) * * *

(A) Headlines and texts, as illustrated in the Prototype Labels in Appendix L to this Part, are standard for all labels except clothes washer labels, which must have the text and features described in 305.11(a)(5)(i)(L) of this part.

* * * * *

(L) Clothes washer labels must have the headlines and texts as illustrated in Prototype Label 2 of Appendix L of this Part. In particular, clothes washer labels must have the following headline as illustrated in Prototype Label 2: ''Compare the energy use of this clothes washer only with other models tested using the 2004 test procedure.'' In addition to the requirements for other labels, clothes washer labels must have a 10/16 inch (1.59 cm.) in height, process black bar across the top that contains the following text in process yellow as illustrated in Prototype Label 2: ''This model has been tested using the 2004 test procedure. Compare only with models displaying this statement.''

* * * * *

■ 3. Appendix L to part 305 is amended by revising Prototype Label 2 and Sample Label 3 to read as follows:

Appendix L to Part 305—Sample Labels

* * * * *

BILLING CODE 6750–01–C

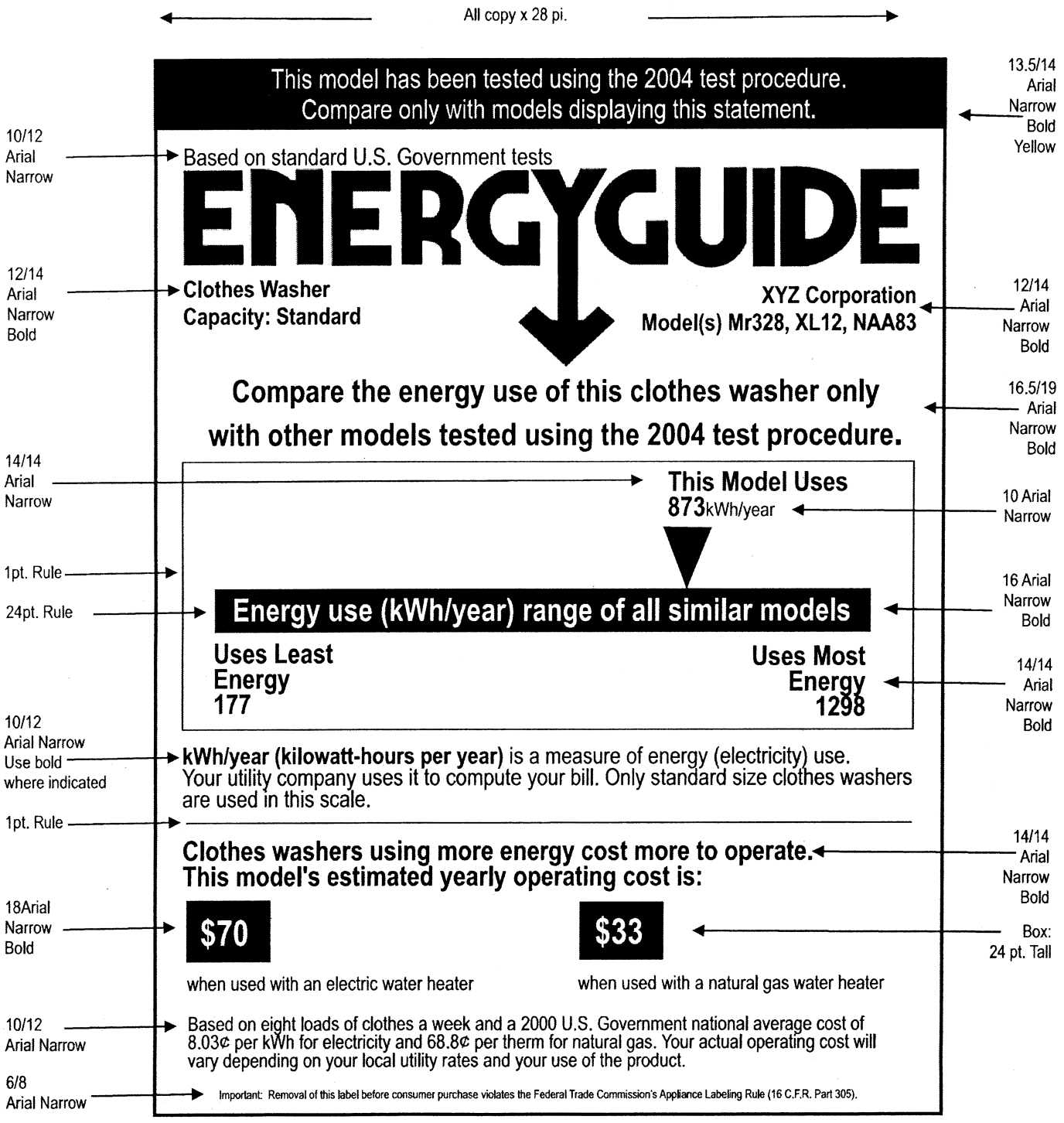
[26] Prototype Label 2 in the final rule does not contain a specific reference to the 10/16 inch height for the black bar across the top of the label. Because the final graphic may not be to scale as it appears in the **Federal Register** or the Code, specific references to dimensions on the prototype label may be confusing. The text of the rule clearly states the 10/16 (1.59 cm.) inch requirement.

[27] Although no comments were received regarding the size of manufacturers subject to the Rule, the Commission believes that few would qualify as a small business under the relevant threshold (*i.e.*, 1000 employees). *See http://www.sba.gov/size/sizetable2002.html* (Small Business Standards Matched To North American Industry Classification System, Code 335224, Household Laundry Equipment Manufacturing).

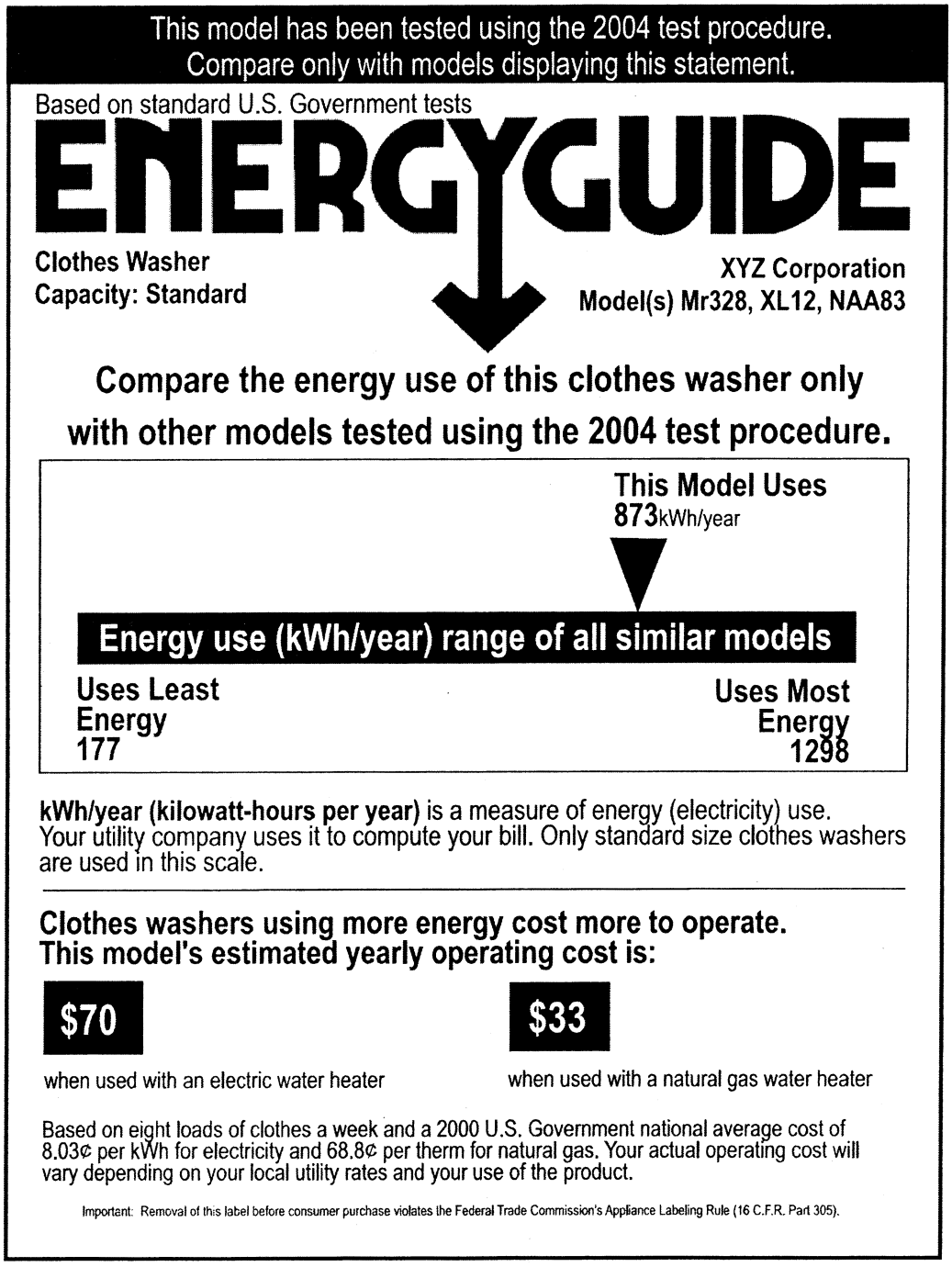
[28] 44 U.S.C. 3501–20.

[29] The exemption and final rule amendments may modify the existing burden slightly by requiring additional information on the labels. However, because the labels are already required and their content changes from time to time when ranges of comparability are amended, we believe that the overall impact of this final rule and exemption is negligible and does not significantly alter the rule's overall burden.

All copy Arial Narrow Regular or Bold as below.
Helvetica Condensed series typeface or other equivalent also acceptable.



Prototype Label 2



Sample Label 3

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–15369 Filed 6–17–03; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Diego 03–023]

RIN 1625–AA00

Safety Zone; Colorado River, Laughlin, NV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone near Laughlin, NV on the navigable waters of the Colorado River in support of the Laughlin 4th of July fireworks show. This temporary safety zone is necessary to provide for the safety of the crew, spectators, participants of the event, participating vessels and other vessels and users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 8:30 p.m. (PDT) on July 4, 2003 through 9:30 p.m. (PDT) on July 6, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket [COTP San Diego 03–023] and are available for inspection or copying at Marine Safety Office San Diego, 2716 N. Harbor Drive, San Diego, CA 92101–1064 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer Austin Murai, USCG, c/o U.S Coast Guard Captain of the Port, telephone (619) 683–6495.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. In keeping with the requirements of 5 U.S.C. 553(d)(3), the Coast Guard also finds that good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register**. The precise location of the event necessitating promulgation of this safety zone and other logistical details surrounding the event were not finalized until a date fewer than 30 days prior to the event. Delaying the effective date of this rule would be contrary to the public interest because doing such would prevent the Coast Guard from maintaining the safety of the participants of the event and users of the waterway.

Background and Purpose

The Coast Guard is establishing a temporary safety zone on the navigable waters of the Colorado River in Laughlin, Nevada in support of the Laughlin 4th of July fireworks show. The fireworks will be launched from an area on land, however, the fallout area will be over a section of the Colorado River and a safety zone is necessary to provide for the safety of the spectators and users of this waterway.

Discussion of Rule

The Coast Guard proposes to establish this temporary rule to provide for the safety of the participants, spectators and other users of the waterways. The temporary safety zone is specifically defined as 600 yards around the point 35°09.270″ N, 114°34.222″ W. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

Due to the temporary safety zone's short duration of one hour for two days, its limited scope of implementation, and because vessels will have an opportunity to request authorization to transit, the Coast Guard expects the economic impact of this rule to be so minimal that full regulatory evaluation under the regulatory policies and procedures of the DHS is unnecessary.

Small Entities

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

For the same reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule is not expected to have a significant economic impact on any substantial number of entities, regardless of size.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), the Coast Guard wants to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If your small business or organization is affected by this rule and you have questions concerning its provisions or options for compliance, please contact Lieutenant Commander Rick Sorrell, U.S. Coast Guard Marine Safety Office San Diego at (619) 683–6495.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

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

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of

their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that Order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

Under figure 2–1, paragraph (34)(g), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; and 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.

■ 2. From 8:30 p.m. on July 4, 2003 through 9:30 p.m. on July 6, 2003 add a new § 165.T11–042 to read as follows:

§ 165.T11–042 Safety Zone; Colorado River, Laughlin, Nevada.

(a) *Location.* The temporary safety zone is specifically defined as 600 yards around the point 35°09.270′ N, 114°34.222′ W.

(b) *Enforcement period.* This section will be enforced from 8:30 p.m. to 9:30 p.m. (PDT) on July 4, 2003 and from 8:30 p.m. through 9:30 p.m. on July 6, 2003. If the event concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this zone by all vessels is prohibited, unless authorized by the Captain of the Port, or his designated representative. Mariners requesting permission to transit through the safety zone may request authorization to do so from the designated representative. The designated representative may be contacted via VHF–FM channel 16.

Dated: June 6, 2003.

Robert E. McFarland,

Lieutenant Commander, U.S. Coast Guard, Acting Captain of the Port, San Diego.

[FR Doc. 03–15302 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

33 CFR Part 203

RIN 0710–AA47

Natural Disaster Procedures: Preparedness, Response, and Recovery Activities of the Corps of Engineers; Correction

AGENCY: Army Corps of Engineers, DoD.

ACTION: Final rule; correction.

SUMMARY: The Corps promulgated a final rule to revise 33 CFR part 203. This file rule was published in the **Federal Register** on April 21, 2003, with inadvertent errors in section 203.62. The final rule completes the rulemaking process initiated on February 26, 2002, with publication of the proposed rule to revise 33 CFR part 203, which implements Pub. L. 84–99. The revisions are necessary to reflect current policy, add features required by the Water Resources Development Act of 1996 (WRDA 96), and streamline certain procedures concerning Corps authority addressing disaster preparedness, response, and recovery activities. WRDA 96 additions include the option to provide nonstructural alternatives in lieu of structural repairs to levees damaged by flood events, and the provision of a levee owner's manual. Other significant changes include expansion of investigation ability for potential Advance Measures work, and a streamlined approach for requests for assistance from Native American tribes and Alaska Native Corporations.

DATES: This rule became effective on May 21, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey D. Jensen, Headquarters, U.S. Army Corps of Engineers, Civil Emergency Management Branch, CECW–HS–E, at (202) 761–4561.

SUPPLEMENTARY INFORMATION:

I. Background. Section 203.62 is corrected by redesignation of the second paragraph (d) ''Guidance'' as paragraph (e) and paragraph (e) ''Guidance-transport of water'' as paragraph (f) and

paragraph (f) ''Request for assistance'' as paragraph (g).

Dated: June 2, 2003.

Lawrence A. Lang,

Acting Chief, Operations Division, Directorate of Civil Works.

■ Accordingly, 33 CFR part 203 section 203.62 is correctly revised as follows:

PART 203—EMERGENCY EMPLOYMENT OF ARMY AND OTHER RESOURCES, NATURAL DISASTER PROCEDURES

§ 203.62 Drought assistance.

(a) *Authority.* The Chief of Engineers, acting for the Secretary of the Army, has the authority under certain statutory conditions to construct wells for farmers, ranchers, political subdivisions, and to transport water to political subdivisions, within areas determined to be drought-distressed.

(b) *General policy.* (1) It is a non-Federal responsibility for providing an adequate supply of water to local inhabitants. Corps assistance to provide emergency water supplies will only be considered when non-Federal interests have exhausted reasonable means for securing necessary water supplies, including assistance and support from other Federal agencies.

(2) Before Corps assistance is considered under this authority, the applicability of other Federal assistance authorities must be evaluated. If these programs cannot provide the needed assistance, then maximum coordination should be made with appropriate agencies in implementing Corps assistance.

(c) *Governor's request.* A letter signed by the Governor, requesting Corps assistance and addressing the State's commitments and capabilities with response to the emergency situation, is required. All requests should identify the following information:

(1) A description of local and State efforts undertaken. A verification that all available resources have been committed, to include National Guard assets.

(2) Identification of the specific needs of the State, and the required Corps assistance.

(3) Identification of the additional commitments to be accomplished by the State.

(4) Identification of the project sponsor(s).

(d) *Definitions applicable to this section.*

(1) *Construction.* This term includes initial construction, reconstruction, or repair.

(2) *Drought-distressed area.* An area that the Secretary of the Army determines, due to drought conditions, has an inadequate water supply that is causing, or is likely to cause, a substantial threat to the health and welfare of the inhabitants of the impacted area, including the threat of damage or loss of property.

(3) *Eligible applicant.* Any rancher, farmer or political subdivision within a designated drought-distressed area that is experiencing an inadequate supply of water due to drought.

(4) *Farmer or rancher.* An individual who realizes at least one-third of his or her gross annual income from agricultural sources, and is recognized in the community as a farmer or rancher. A farming partnership, corporation, or similar entity engaged in farming or ranching, which receives its majority income from such activity, is also considered to be a farmer or rancher, and thus an eligible applicant.

(5) *Political subdivision.* A city, town, borough, county, parish, district, association, or other public body created by, or pursuant to, Federal or State law, having jurisdiction over the water supply of such public body.

(6) *Reasonable cost.* In connection with the Corps construction of a well, means the lesser of:

(i) The cost of the Chief of Engineers to construct a well in accordance with these regulations, exclusive of:

(A) The cost of transporting equipment used in the construction of wells, and

(B) The cost of investigation and report preparation to determine the suitability to construct a well, or,

(ii) The cost to a private business of constructing such a well.

(7) *State.* Any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, Northern Marianas Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(e) *Guidance—construction of wells.* (1) Assistance to an eligible applicant for the construction of a well may be provided on a cost-reimbursable basis if:

(i) It is in response to a written request by a farmer, rancher, or political subdivision for construction of a well under Public Law 84–99.

(ii) The applicant is located within an area that the Secretary of the Army has determined to be drought-distressed.

(iii) The Secretary of the Army has made a determination that:

(A) The applicant, as a result of the drought, has an inadequate supply of water.

(B) An adequate supply of water can be made available to the applicant through the construction of a well.

(C) As a result of the drought, a private business could not construct the well within a reasonable time.

(iv) The applicant has secured the necessary funding for well construction from commercial or other sources, or has entered into a contract to pay to the United States the reasonable cost of such construction with interest over a period of years, not to exceed 30, as the Secretary of the Army deems appropriate.

(v) The applicant has obtained all necessary Federal, State and local permits.

(2) The financing of the cost of construction of a well by the Corps under this authority should be secured by the project applicant.

(3) The project applicant will provide the necessary assurances of local cooperation by signing a Cooperation Agreement (subpart G of this part) prior to the start of Corps work under this authority.

(4) Equipment owned by the United States will be utilized to the maximum extent possible in exercising the authority to drill wells, but can only be used when commercial firms cannot provide comparable service within the time needed to prevent the applicant from suffering significantly increased hardships from the effects of an inadequate water supply.

(f) *Guidance-transport of water.* (1) Assistance to an applicant in the transportation of water may be provided if:

(i) It is in response to a written request by a political subdivision for transportation of water.

(ii) The applicant is located within an area that the Secretary of the Army has determined to be drought-distressed.

(iii) The Secretary of the Army has made a determination that, as a result of the drought, the applicant has an inadequate supply of water for human consumption, and the applicant cannot obtain water.

(2) Transportation of water by vehicles, small diameter pipe line, or other means will be at 100 percent Federal cost.

(3) Corps assistance in the transportation of emergency water supplies will be provided only in connection with water needed for human consumption. Assistance will not be provided in connection with water needed for irrigation, recreation, or other non-life supporting purposes, or livestock consumption.

(4) Corps assistance will not include the purchase of water, nor the cost of loading or discharging the water into or from any Government conveyance, to include Government-leased conveyance.

(5) Equipment owned by the United States will be utilized to the maximum extent possible in exercising the authority to transport water, consistent with lowest total Federal cost.

(g) *Request for assistance.* A written request must be made to the district commander with Civil Works responsibility for the affected area. Upon receipt of a written request, the appropriate State and Federal agencies will be notified, and coordination will continue as appropriate throughout the assistance.

[FR Doc. 03–15305 Filed 6–17–03; 8:45 am]

BILLING CODE 3710–92–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 260

[Docket No. 96–5 CARP DSTRA]

Determination of Reasonable Rates and Terms for the Digital Performance of Sound Recordings

AGENCY: Copyright Office, Library of Congress.

ACTION: Final regulation.

SUMMARY: The Copyright Office is announcing the final regulations that will govern SoundExchange, an unincorporated division of the Recording Industry Association of America, Inc., when it functions as the designated agent for the purpose of receiving royalty payments and statements of accounts from nonexempt subscription digital transmission services which make digital transmissions of sound recordings under a statutory license.

DATES: *Effective Date:* July 18, 2003.

Applicability Date: The regulations apply to the license period which began on November 1, 1995.

FOR FURTHER INFORMATION CONTACT: David O. Carson, General Counsel, or Tanya M. Sandros, Senior Attorney, Copyright Arbitration Royalty Panel, P.O. Box 70977, Southwest Station, Washington, DC 20024. Telephone: (202) 707–8380. Telefax: (202) 252–3423.

SUPPLEMENTARY INFORMATION:

Background

Section 106(6) of the Copyright Act, title 17 of the United States Code, gives copyright owners of sound recordings an exclusive right to perform their copyrighted work publicly by means of a digital audio transmission. This right is limited by section 114(d), which allows certain noninteractive digital audio services to transmit sound recordings under a compulsory license, provided that the services pay a reasonable royalty fee and comply with the terms of the statutory license. Among the categories of services that may use the section 114 license are preexisting subscription services [1] of which there are only three: Digital Cable Radio Associates, now known as Music Choice; DMX Music, Inc. (''DMX''); and Muzak, L.P. (''Muzak'').

In 1998, the Librarian of Congress adopted final rates and terms applicable to the preexisting services after a hearing before a copyright arbitration royalty panel (''CARP''). *See* 63 FR 25394 (May 8, 1998). In that proceeding, the parties proposed a term which gave the RIAA the responsibility for collecting and distributing the royalty fees to all copyright owners. *Id.* at 25397. The Librarian adopted this term, then crafted additional regulations that afforded copyright owners a means to verify the accuracy of the royalty payments made by the RIAA collective,[2] established the value of each performance, specified the nature of the costs that RIAA may deduct from the royalty fees prior to distribution, and set forth a procedure for handling royalty fees in the case where the collective is unable to identify or locate a copyright owner who is entitled to receive royalties collected under the statutory license.

RIAA appealed both the rate and the additional terms announced in the Librarian's determination and final order. *See, Recording Industry Ass'n* v. *Librarian of Congress,* 176 F.3d 528 (D.C. Cir. 1999). The United States Court of Appeals for the District of Columbia Circuit upheld the rate and found that the Librarian had the authority to impose additional terms on copyright owners or their agents. However, it remanded for further consideration certain terms imposed on RIAA under 37 CFR 260.2(d), 260.3(d), 260.6(b), and 260.7, because the CARP had not considered these issues, leaving the record devoid of any evidence upon which to fashion any terms concerning the collection and distribution of the royalty fees. *Id.* at 536.

In 2001, RIAA petitioned the Copyright Office to adopt new terms that would govern the RIAA collective. These terms were to be adopted pursuant to § 251.63(b) which allows the Librarian of Congress to adopt proposed terms that are the result of settlement negotiations, provided that no person with a substantial interest and an intent to participate in a CARP proceeding files an objection.

Accordingly, the Copyright Office published the proposed terms in the **Federal Register** and requested public comment. 66 FR 38226 (July 23, 2001). In response to this notice, the American Federation of Musicians (''AFM'') and the American Federation of Television and Radio Artists (''AFTRA'') filed a Notice of Intent to Participate and objections to certain of the proposed terms. Shortly thereafter, RIAA began discussions with AFTRA and AFM regarding their objections, and the matter was held in abeyance, pending the outcome of those discussions.

In the meantime, Congress passed the Small Webcaster Settlement Act of 2002 (''SWSA''), Public Law 107–321, 116 Stat. 2780, which, among other things, amended 17 U.S.C. 114(g) in two important ways that bear directly on two key issues raised in this proceeding. First, the SWSA provides for direct payment to featured recording artists and to the administrators of the escrow accounts provided for in 17 U.S.C. 114(g)(2)(B)&(C). Second, the act allows a designated agent, prior to the distribution of the royalty receipts, to deduct reasonable costs incurred by that agent in the administration of those receipts, including, but not limited to, costs associated with the collection and distribution of the royalty fees and the costs incurred in participating in negotiations or arbitration proceedings under sections 112 and 114.

Because of these changes in the law, RIAA revised its proposed amendments to 37 CFR part 260 to conform the terms in question to the new law and, in doing so, it addressed the concerns of AFM and AFTRA. However, the proposed rules could not be adopted until all interested parties had an opportunity to comment. Therefore, pursuant to § 251.63(b) of the CARP rules, the Library published in the **Federal Register** the proposed terms and sought comment from any party with a substantial interest in this proceeding. 68 FR 19482 (April 21, 2003).

[1] A ''preexisting subscription service'' is defined as:

a service that performs sound recordings by means of noninteractive audio-only subscription digital audio transmissions, which was in existence and was making such transmissions to the public for a fee on or before July 31, 1998, and may include a number of limited number of sample channels representative of the subscription service that are made available on a nonsubscription basis in order to promote the subscription service.

17 U.S.C. 114(j)(11).

[2] In November 2000, RIAA formed ''SoundExchange,'' an unincorporated division of RIAA, to administer statutory licenses, including its responsibilities under the Librarian's May 8 Order. See, Revised RIAA petition to Establish Terms Governing SoundExchange at 1 n.1 (March 12, 2003).

Having received no objections to the recently proposed terms, the Librarian is adopting the proposed amendments as final regulations. The proposed terms shall govern SoundExchange, the collecting rights entity that was formed from the designated RIAA collective, in its capacity as the sole agent designated to receive royalty payments from the three subscription services that were parties to this proceeding. Terms governing the administrative functions of any future collective or the designation of alternative agents shall be decided in future rate adjustment proceedings either through negotiations or after a hearing before a CARP based upon a fully developed written record. *See, e.g.*, 67 FR 45239 (July 8, 2002).

List of Subjects in 37 CFR Part 260

Copyright, Digital audio transmissions, Performance right, Sound recordings.

Final Regulation

■ For the foregoing reasons, the Library amends part 260 of 37 CFR as follows:

PART 260—USE OF SOUND RECORDINGS IN A DIGITAL PERFORMANCE

■ 1. The authority citation for part 260 continues to read as follows:

Authority: 17 U.S.C. 114, 801(b)(1).

§ 260.2 [Amended]

■ 2. In § 260.2, remove paragraph (d).

■ 3. Section 260.3 is amended by revising paragraphs (c), (d), and (e) to read as follows:

§ 260.3 Terms for making payments of royalty fees.

* * * * *

(c) The agent designated to receive the royalty payments and the statements of account shall have the responsibility of making further distribution of these payments to those parties entitled to receive such payments according to the provisions set forth at 17 U.S.C. 114(g)(2); Provided that the designated agent shall only be responsible for making distributions to those parties who provide the designated agent with such information as is necessary to identify and pay the correct recipient for such payments. The agent shall distribute royalty payments on a reasonable basis that values all performances by a Licensee equally based upon the information provided by the Licensee pursuant to the regulations governing records of use of performances by Licensees; Provided, however, that parties who have designated the agent may agree to allocate their shares of the royalty payments made by any Licensee among themselves on an alternative basis. Parties entitled to receive payments under 17 U.S.C. 114(g)(2) may agree with the designated agent upon payment protocols to be used by the designated agent that provide for alternative arrangements for the payment of royalties consistent with the percentages in 17 U.S.C. 114(g)(2).

(d) The designated agent may deduct from the payments made by Licensees under § 260.2, prior to the distribution of such payments to any person or entity entitled thereto, all incurred costs permitted to be deducted under 17 U.S.C. 114(g)(3); Provided, however, that any party entitled to receive royalty payments according to 17 U.S.C. 114(g)(2) may agree to permit the designated agent to deduct any additional costs.

(e) Commencing June 1, 1998, and until such time as a new designation is made, SoundExchange, which currently is an unincorporated division of the Recording Industry Association of America, Inc., shall be the agent that receives royalty payments and statements of account under this part 260 and shall continue to be designated as such if it should be separately incorporated.

■ 4. Section 260.6 is revised to read as follows:

§ 260.6 Verification of royalty payments.

(a) *General.* This section prescribes general rules pertaining to the method of verification of the payment of royalty fees by the designated agent to interested parties; Provided, however, that the designated agent and any interested person may agree as to an alternative method of verification.

(b) *Frequency of verification.* Interested parties may conduct a single audit of the designated agent during any given calendar year and no calendar year shall be subject to audit more than once.

(c) *Notice of intent to audit.* Interested parties must file with the Copyright Office a notice of intent to audit the designated agent. Such notice of intent shall also be served at the same time on the designated agent to be audited. Within 30 days of the filing of the notice of intent, the Copyright Office shall publish in the **Federal Register** a notice announcing such filing.

(d) *Retention of records.* The interested party requesting the verification procedure shall retain the report of the verification for a period of three years.

(e) *Acceptable verification procedure.* An audit, including underlying paperwork, which was performed in the ordinary course of business according to generally accepted auditing standards by an independent auditor, shall serve as an acceptable verification procedure for all interested parties.

(f) *Costs of the verification procedure.* The interested parties requesting the verification procedure shall pay for the cost of the verification procedure, unless an independent auditor concludes that there was an underpayment of five (5) percent or more, in which case, the designated agent shall bear the costs of the verification procedure.

(g) *Interested parties.* For purposes of this section, interested parties are those individuals or entities who are entitled to receive royalty payments pursuant to 17 U.S.C. 114(g)(2), or their designated agents.

§ 260.7 [Amended]

■ 5. Section 260.7 is amended by removing the word ''collecting'' after the phrase ''If the designated'; by removing the word ''collecting'' each place it appears and adding the word ''designated '' in its place; and in the last sentence, by removing the word ''fees'' and adding the word ''payments'' in its place.

Dated: May 27, 2003.

Marybeth Peters,

Register of Copyrights.

Approved by:

James H. Billington,

The Librarian of Congress.

[FR Doc. 03–15384 Filed 6–17–03; 8:45 am]

BILLING CODE 1410–33–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO 180–1180a; FRL–7513–9]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is announcing it is approving a revision to the Missouri State Implementation Plan (SIP) which pertains to the rescission of two rules which control the emissions of Perchloroethylene Dry Cleaning Installations in the Kansas City and St. Louis areas. This revision will rescind two rules that have been superseded by the statewide Maximum Achievable Control Technology rule. There is no

relaxation of controls by rescinding these rules. Approval of this revision will eliminate redundancy and conflicting requirements.

DATES: This direct final rule will be effective August 18, 2003, unless EPA receives adverse comments by July 18, 2003. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101, or E-mail her at *algoe-eakin.amy@epa.gov.*

Copies of documents relative to this action are available for public inspection during normal business hours at the above-listed Region 7 location. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Amy Algoe-Eakin at (913) 551–7942.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This section provides additional information by addressing the following questions:

What is a SIP?
What is the Federal approval process for a SIP?
What does Federal approval of a state regulation mean to me?
What is being addressed in this document?
Have the requirements for approval of a SIP revision been met?
What action is EPA taking?

What Is a SIP?

Section 110 of the Clean Air Act (CAA) requires states to develop air pollution regulations and control strategies to ensure that state air quality meets the national ambient air quality standards established by EPA. These ambient standards are established under section 109 of the CAA, and they currently address six criteria pollutants. These pollutants are: carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

Each state must submit these regulations and control strategies to us for approval and incorporation into the Federally-enforceable SIP.

Each Federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin. These SIPs can be extensive, containing state regulations or other enforceable documents and supporting information such as emission inventories, monitoring networks, and modeling demonstrations.

What Is the Federal Approval Process for a SIP?

In order for state regulations to be incorporated into the Federally-enforceable SIP, states must formally adopt the regulations and control strategies consistent with state and Federal requirements. This process generally includes a public notice, public hearing, public comment period, and a formal adoption by a state-authorized rulemaking body.

Once a state rule, regulation, or control strategy is adopted, the state submits it to us for inclusion into the SIP. We must provide public notice and seek additional public comment regarding the proposed Federal action on the state submission. If adverse comments are received, they must be addressed prior to any final Federal action by us.

All state regulations and supporting information approved by EPA under section 110 of the CAA are incorporated into the Federally-approved SIP. Records of such SIP actions are maintained in the Code of Federal Regulations (CFR) at Title 40, Part 52, entitled ''Approval and Promulgation of Implementation Plans.'' The actual state regulations which are approved are not reproduced in their entirety in the CFR outright but are ''incorporated by reference,'' which means that we have approved a given state regulation with a specific effective date.

What Does Federal Approval of a State Regulation Mean to Me?

Enforcement of the state regulation before and after it is incorporated into the Federally-approved SIP is primarily a state responsibility. However, after the regulation is Federally approved, we are authorized to take enforcement action against violators. Citizens are also offered legal recourse to address violations as described in section 304 of the CAA.

What Is Being Addressed in This Document?

Missouri rule 10 CSR 10–2.280 and Missouri rule 10 CSR 10–5.320 relate to the control of emissions from Perchloroethylene Dry Cleaning Installations for the Kansas City and St. Louis areas, respectively. These rules had been approved by EPA as representing Reasonably Available Control Technology (RACT) in the Kansas City and St. Louis areas.

This revision to Missouri's SIP will rescind rules 10 CSR 10–2.280 and 10 CSR 10–5.320, which have been superseded by the state-adopted Maximum Achievable Control Technology (MACT) rule 10 CSR 10–6.075. The latter rule incorporates by reference the EPA rule, 40 CFR part 63, subpart M. As such, prior to this action, there were three Federally enforceable regulations for the Perchloroethylene Dry Cleaning Installations.

An EPA review concluded that the rescission of these two Missouri rules does not result in any increase in emissions. There is no relaxation of controls by rescinding rules 10 CSR 10–2.280 and 10 CSR 10–5.320. Sources subject to the rule must still meet a control technology at least as stringent as RACT. Therefore, there are no adverse impacts on the ability of the Kansas City and St. Louis areas to maintain the 1-hour ozone standard. The controls on subject dry cleaning installations will remain enforceable by the state under 10 CSR 10–6.075, and by EPA, under 40 CFR part 63, subpart M. Approval of this revision will eliminate redundancy and conflicting requirements.

The state submittal has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submittal also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the technical support document which is part of this document, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

What Action Is EPA Taking?

We are approving the revision to rescind Missouri rule 10 CSRS 10–2.280, Control of Emissions from Perchloroethylene Dry Cleaning Installations and Missouri rule 10 CSR 10–5.320, Control of Emissions from Perchloroethylene Dry Cleaning Installations from the Missouri SIP.

We are processing this action as a final action because the revisions make routine changes to the existing rules which are noncontroversial. Therefore, we do not anticipate any adverse comments. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For

this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies 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.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 *note*) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 18, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Ozone, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Dated: June 8, 2003.

James B. Gulliford,

Regional Administrator, Region 7.

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart AA—Missouri

■ 2. Section 52.1320 is amended by:
■ a. Revising paragraph (b)(3); and
■ b. In the table to paragraph (c) by removing the entries under Chapter 2 for 10–2.280 and under Chapter 5 for 10–5.320.

The revision reads as follows:

§ 52.1320 Identification of plan.

* * * * *

(b) * * *

(3) Copies of the materials incorporated by reference may be inspected at the Environmental Protection Agency, Region VII, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101; the Office of Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC; or at the EPA Air and Radiation Docket and Information Center, Room B–108, 1301 Constitution Avenue, NW. (Mail Code 6102T), Washington, DC 20460.

* * * * *

[FR Doc. 03–15251 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0155; FRL–7308–8]

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of glyphosate in or on corn, field, forage at 6.0 parts per million (ppm) and reduces the tolerance on grain, aspirated fractions from 200 ppm to 100 ppm. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective June 18, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0155, must be received on or before August 18, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: Tompkins.Jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAIC 111)
- Animal production (NAIC 112)
- Food manufacturing (NAIC 311)
- Pesticide manufacturing (NAIC 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0155. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of April 17, 2002 (67 FR 18894) (FRL–6830–5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a number of pesticide petitions by Monsanto, 600 13th St., NW., Suite 660, Washington, DC 20005. The notice included a summary of the petition prepared by Monsanto, the registrant. Comments received in the public docket with respect to the Notice of Filing were addressed in the final rule publication in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2), and will not be presented again here in this final rule.

The petitions requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate in or on corn, field, forage at 6 ppm; by reducing the tolerance on aspirated grain fractions from 200 ppm to 100 ppm. In addition, the Agency is taking this opportunity to change the commodity definition from aspirated grain fractions to grain, aspirated fractions; deleting the existing tolerance for soybean, aspirated grain fractions at 50.0 ppm since these soybean fractions are included in the ''grain, aspirated fractions'' tolerance described above; and by deleting the existing tolerance for animal, feeds, nongrass group, except alfalfa at 200 ppm, which is now included in the established tolerance for animal feed, nongrass, group at 400 ppm.

Section 408(b)(2)(A)(i) of the FFDCA 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) of the FFDCA 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 and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA 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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of glyphosate on grain, aspirated fractions at 100 ppm and corn, field, forage at 6.0 ppm. EPA's assessment of exposures and risks associated with establishing glyphosate tolerances for a number of feed commodities was performed previously and was presented in detail in the final rule on Glyphosate Pesticide Tolerances (67 FR 60934, September 27, 2002) (FRL–7200–2). Given that higher tolerances for glyphosate are currently established for other significant animal feed commodities, the dietary burden for cattle, poultry, and hogs will be unaffected by a glyphosate tolerance for aspirated grain fractions at 100 ppm and corn, field, forage at 6.0 ppm. EPA estimates a worst-case dietary burden for livestock animals by assuming an animal consumes dietary feeds bearing the highest permitted residues. In the case of glyphosate, the dietary feed bearing the highest permitted residue is alfalfa hay as the roughage component of the diet with a tolerance of 400 ppm whereas only 6 ppm of glyphosate is permitted in corn forage and 100 ppm in grain, aspirated fractions.

Accordingly EPA's previous assessment of exposures and risks will not change. Based on these prior risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to glyphosate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant and livestock commodities. These methods include gas liquid chromatography (GLC) (Method I in Pesticides Analytical Manual (PAM) II; the limit of detection is 0.05 ppm) and high performance liquid chromatography (HPLC) with fluorometric detection. Use of the GLC method is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion in PAM II. A gas chromatography mass spectrometry (GC/MS) method for glyphosate in crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL). Thus, adequate analytical methods are available for residue data collection and enforcement of the tolerances of glyphosate in/on aspirated grain, aspirated fractions and corn, field, forage. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

Codex and Mexican maximum residue limits (MRLs) are established for residues of glyphosate (glifosato) *per se* and Canadian MRLs are established for combined residues of glyphosate and AMPA in a variety of raw agricultural, processed, and animal commodities. Currently a relevant Codex MRL for maize forage is established at 1.0 ppm. No Canadian MRL is established for aspirated grain fractions or corn forage. The U.S. tolerance corn, field, forage at 6.0 ppm, cannot be harmonized with the Codex MRL for maize, forage at 1 ppm because the U.S. tolerance is based on higher application rates than those used in the residue studies previously considered by Codex.

V. Conclusion

Therefore, the tolerance is established for residues of glyphosate, in or on grain, aspirated fractions at 100 ppm and corn, field, forage at 6.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0155 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 18, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0155, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and

hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 2, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.364 is amended by removing the entire entries for ''Animal feed, nongrass, group, except alfalfa,'' ''Aspirated grain fractions,'' and ''Soybean, aspirated grain fractions'' and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows.

§ 180.364 Glyphosate; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Corn, field, forage	6.0
* * * * *	*
Grain, aspirated fractions	100.0
* * * * *	*

* * * * *

[FR Doc. 03–15128 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0113; FRL–7301–1]

Bacillus Pumilus Strain QST2808; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the *Bacillus pumilus* strain QST2808 in or on all agricultural commodities when applied/used in accordance with label directions. AgraQuest, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus pumilus* strain QST2808. The temporary tolerance exemption will expire on June 30, 2006.

DATES: This regulation is effective June 18, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0113, must be received by EPA on or before August 18, 2003.

ADDRESSES: Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8077 ; e-mail address: *cerrelli.susanne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production/Agriculture (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0113. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 3, 2001 (66 FR 22225) (FRL–6773–9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 1G6240), submitted by AgraQuest, Inc., 1530 Drew Avenue, Davis, CA 95616. This notice included a summary of the petition prepared by the petitioner AgraQuest, Inc. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Bacillus pumilus* strain QST2808. Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA

determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA 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 and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA 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. . . .'' Additionally, section 408(b)(2)(D) of the FFDCA requires that 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.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Bacillus pumilus is a ubiquitous and naturally occurring bacteria found in soil. The results of the acute toxicology and pathogenicity studies required of the petitioner under section 408(d)(2)(A) of the FFDCA in support of its petition for a temporary exemption from the requirement of a tolerance for *Bacillus pumilus* strain QST2808 indicate negligible to no mammalian toxicity. In addition, no pathogenicity was observed in any of the tests conducted with the *Bacillus pumilus* strain QST2808 Technical product.

The toxicology and pathogenicity data generated by AgraQuest, Inc in support of this temporary exemption from the requirement of a tolerance are summarized below.

1. *Acute oral toxicity and pathogenicity rats (OPPTS Harmonized Guideline 885.3050; Master Record Identification Number (MRID) 451366–04).* Fifteen male and fifteen female rats each were administered 4.1 x 10^9 cfu of *Bacillus pumilus* strain QST2808 Technical and observed for 14 days. Based on the data, *Bacillus pumilus* strain QST2808 does not appear to be toxic, infective, and/or pathogenic in rats, when dosed at 4.1 x 10^9 cfu/animal. Classification: Acceptable; Toxicity Category IV. (C. Etsitty's Memorandum to John L. Kough, dated 1/7/02 (hereinafter referred to as ''BPPD Review - 1/7/02'')).

2. *Acute dermal toxicity (OPPTS Harmonized Guideline 885.3100; MRID 451366–05).* Five male and five female rabbits were dermally treated with 2g/kg body weight *Bacillus pumilus* strain QST2808 Technical for 24 hours and observed for the following 14 days. The acute lethal dose (LD_{50}) is greater than 2,000 mg/kg. Classification: Acceptable; Toxicity Category III. (BPPD Review - 1/7/02).

3. *Primary eye irritation (OPPTS Harmonized Guideline 870.2400; MRID 452679–01).* Three male rabbits each were administered 0.1 mL of QST2808 Technical in the everted lower lid of one eye and then observed for 72 hours. Based on the data, QST2808 Technical showed minimal effects to the eye. Classification: Acceptable; Toxicity Category IV. (BPPD Review - 1/7/02).

4. *Acute injection toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3200; MRID 451366–07).* Eighteen male and eighteen female rats each were dosed at 1.6 x 10^8 cfu *Bacillus pumilus* strain QST2808 Technical intravenously and monitored over a period of 28 days. A gross necropsy was performed on all rats. Based on the data, the test organism was not toxic, infective, or pathogenic to rats. Classification: Acceptable. (BPPD Review - 1/7/02).

5. *Acute pulmonary toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3150; MRID 451366–06).* Eighteen male and eighteen female rats each were administered 1.6 x 10^8 cfu *Bacillus pumilus* strain QST2808 Technical by a single intratracheal dosage and monitored over a period of 35 days for clinical signs of toxicity. Necropsy studies showed no significant signs of abnormalities due to the test organism. Based on the data, *Bacillus pumilus* strain QST2808 was not toxic, infective, and/or pathogenic to rats when dosed at 1.6 x 10^8 cfu/animal. Classification: Acceptable. (BPPD Review - 1/7/02).

6. *Acute Inhalation toxicity (OPPTS Harmonized Guideline 870.1300).* Results of the acute pulmonary toxicity/pathogenicity (MRID 451366–06) performed with *Bacillus pumilus* strain QST2808 Technical indicate that it is not toxic, infective, and/or pathogenic to rats when dosed at 1.6 x 10^8 cfu/animal. For the purposes of this specific action, the Agency has determined that the acute pulmonary toxicity/pathogenicity data are adequate to support and/or fulfill this particular data requirement.

7. *Primary dermal irritation (OPPTS Harmonized Guideline 870.2500; MRID 452679–02).* Each of three male adult rabbits were treated dermally with 0.5 mL QST2808 Technical for 4 hours and observed for the following 72 hours. Based on the data, no abnormal clinical signs were noted. Approximately 60 minutes after patch removal, very slight erythema was noted on one of the three rabbits with resolution by 24 hours. When dosed with QST2808 Technical at 0.5 mL/animal, QST2808 Technical was essentially non-irritating. Classification: Acceptable; Toxicity Category IV. (BPPD Review - 1/7/02).

8. *Hypersensitivity incidents (OPPTS Harmonized Guideline 885.3400).* The registrant reported (November 1, 2000) no incidents to date.

9. *Immune response.* There is no information to suggest that *Bacillus pumilus* strain QST2808 has an effect on the immune system. The submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient (MRID 451366–04; 451366–06, and 451366–07).

Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR § 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR § 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or

buildings (residential and other indoor uses).

A. Dietary Exposure

Humans and animals are commonly exposed to *Bacillus pumilus*, a ubiquitous microorganism that inhabits soil. No toxicological endpoints were identified for *Bacillus pumilus* strain QST2808. The low toxicity and non-pathogenicity/infectivity of *Bacillus pumilus* strain QST2808 is demonstrated by the data summarized in Unit III of this action.

1. *Food*. While the proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities, negligible to no risk is expected for the general population, including infants and children, or animals because *Bacillus pumilus* strain QST2808 technical demonstrated no pathogenicity or oral toxicity at the maximum doses tested, as noted above in (Unit III).

2. *Drinking water exposure*. Most importantly, there is no evidence of adverse effects from oral, dermal, or inhalation exposure to this microbial agent. (See ''Unit III. Toxicological Profile'' above.) In addition, the potential for transfer of *Bacillus pumilus* strain QST2808 to surface or ground water during run-off associated with intended use applications is considered minimal to non-existent, due in part to its percolation through and resulting capture in soil. Accordingly, the use of this microbial pest control agent on terrestrial plants is not anticipated to negatively impact the quality of drinking water.

B. Other Non-Occupational Exposure

Based on the proposed use patterns, the potential of non-dietary exposures to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children, is unlikely. Accordingly, the Agency believes that the potential aggregate non-occupational exposure, derived from dermal and inhalation exposure through the application of *Bacillus pumilus* strain QST2808, should fall well below the currently tested microbial safety levels.

1. *Dermal exposure*. The potential for dermal exposure to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children, is unlikely because potential use sites are agricultural and horticultural. However, since *Bacillus pumilus* strain QST2808 is a naturally occurring bacteria in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to this proposed product would be negligible. Furthermore, and as demonstrated in Unit III of this action, the organism is of low dermal toxicity, the acute lethal dose (LD_{50}) is greater than 2,000 mg/kg, and the QST2808 Technical was essentially non-irritating (Toxicity Category IV). Accordingly, the risks anticipated for this route of exposure are considered minimal.

2. *Inhalation exposure*. The potential for inhalation exposure to *Bacillus pumilus* strain QST2808 pesticide residues for the general population, including infants and children is unlikely because potential use sites are agricultural and horticultural. However, since *Bacillus pumilus* is a natural occurring bacteria in soil, there is a great likelihood of prior exposure for most, if not all individuals. Accordingly, the increase in exposure due to this proposed product would be negligible. Furthermore, and as demonstrated in Unit III of this action, the acute pulmonary toxicity/pathogenicity testing performed on the technical formulation did not demonstrate pathogenicity or toxicity of *Bacillus pumilus* strain QST2808. (See Unit III above.) Accordingly, the risks anticipated for this route of exposure are considered minimal.

V. Cumulative Effects

The Agency has considered the potential for cumulative effects of *Bacillus pumilus* strain QST2808 and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Bacillus pumilus* strain QST2808 is practically non-toxic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism (see Unit III above), no cumulative effects from the residues of this product with other related microbial pesticides is anticipated.

VI. Determination of Safety for U.S. Population, Infants and Children

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of *Bacillus pumilus* strain QST2808 due to its use as a microbial pest control agent. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, *Bacillus pumilus* strain QST2808 is not pathogenic or infective and is practically non-toxic to mammals. (See Unit III above.) Accordingly, exempting *Bacillus pumilus* strain QST 2808 from the requirement of a tolerance should be considered safe and pose no significant risk.

FFDCA section 408(b)(2)(C) 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are incorporated into EPA risk assessments either directly through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. Due to the ubiquitous nature of *Bacillus pumilus*, residues of this microbial pesticide in or on agricultural commodities are not expected to significantly increase exposure to the U.S. population, including infants and children. Here, EPA concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *Bacillus pumilus* strain QST2808 and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *Bacillus pumilus* strain QST2808 residues.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone

systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, *Bacillus pumilus* strain QST2808 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

To date, the Agency has no information to suggest that *Bacillus pumilus* strain QST2808 has an effect on the endocrine systems. Moreover, as is expected from a non-pathogenic microorganism that is practically non-toxic to mammals, the submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. (BPPD Review - 1/7/02).

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including *Bacillus pumilus* strain QST2808's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purpose for *Bacillus pumilus* strain QST2808.

C. Codex Maximum Residue Level

There is no Codex Alimentarius Commission Maximum Residue Level for *Bacillus pumilus* strain QST2808.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0113 in the subject line on the first page of your submission. All objections and requests for hearings must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 18, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0113, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes a temporary exemption from the tolerance requirement for *Bacillus pumilus* strain QST2808 under section 408(d) of the FFDCA in response to a petition submitted to the Agency. 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 3, 2003.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.1226 is added to subpart D to read as follows:

§ 180.1226 Bacillus pumilus strain QST2808; temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* strain QST2808 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 03–15129 Filed 6–17 –03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0196; FRL–7311–2]

Azoxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of azoxystrobin, methyl (E)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝-(methoxymethylene)-benzeneacetate, and its Z isomer, methyl (Z)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝(methoxymethylene)-benzeneacetate, in or on artichoke, globe; asparagus; brassica, head and stem, subgroup 5A; herb subgroup 19A, (dried) except chive; and herb subgroup 19A, (fresh) except chive. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective June 18, 2003. Objections and requests for hearings, identified by docket identification (ID) number OPP–2003–0196, must be received on or before August 18, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, and pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0196. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of March 26, 2003 (68 FR 14622) (FRL–7299–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 2E6375, 2E6488, 2E6489, and 2E6495) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Syngenta, the registrant.

The petitions requested that 40 CFR 180.507 be amended by establishing tolerances for combined residues of the fungicide azoxystrobin, methyl (*E*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝-(methoxymethylene) benzeneacetate and its Z isomer methyl (Z)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝-(methoxymethylene) benzeneacetate, in or on artichoke, globe at 4.0 parts per million (ppm); asparagus at 0.02 ppm; brassica, head and stem, subgroup 5A at 3.0 ppm; herb subgroup 19A, dried, except chive at 260 ppm; and herb subgroup 19A, fresh, except chive at 50 ppm.

Section 408(b)(2)(A)(i) of the FFDCA 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) of the FFDCA 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 and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA 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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for combined residues of azoxystrobin on artichoke, globe at 4.0 ppm; asparagus at 0.04 ppm; brassica, head and stem, subgroup 5A at 3.0 ppm; herb subgroup 19A, dried, except chive at 260 ppm; and herb subgroup 19A, fresh, except chive at 50 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including

infants and children. The nature of the toxic effects caused by azoxystrobin are discussed in Unit III.A of the Final Rule on Azoxystrobin Pesticide Tolerance published in the **Federal Register** on September 20, 2002 (67 FR 59169)(FRL–7198–9).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for azoxystrobin used for human risk assessment is discussed in Unit III.B. of the Final Rule on Azoxystrobin Pesticide Tolerance published in the **Federal Register** on September 20, 2002 (67 FR 59169)(FRL–7198–9).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.507) for the combined residues of azoxystrobin, in or on a variety of raw agricultural commodities. Tolerances have been established for residues of azoxystrobin in or on a variety of raw agricultural commodities at levels ranging from 0.01 ppm (pecans) to 55 ppm (soybean hay), and on meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at levels ranging from 0.01 to 0.07 ppm, and on milk at 0.006 ppm. A time-limited tolerance (to expire on 12/31/2003) is currently established at 30 ppm for the head and stem Brassica vegetables, subgroup 5A. Risk assessments were conducted by EPA to assess dietary exposures from azoxystrobin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. In conducting this acute risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumption was made for the acute exposure assessment: A Tier 1 acute dietary exposure analysis was performed for azoxystrobin.

ii. *Chronic exposure.* In conducting this chronic risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analysis was performed for the general U.S. Population and all population subgroups using tolerance level residues (livestock) and total residues of concern (plants; parent and metabolites) and 100% crop treated data for the proposed commodities and all registered uses.

iii. *Cancer.* EPA's Cancer Assessment Review Committee (CARC) evaluated the carcinogenic potential of azoxystrobin and classified azoxystrobin as ''not likely to be a human carcinogen'' based on the revised Cancer Guidelines.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for azoxystrobin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of azoxystrobin.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to azoxystrobin they are further discussed in the aggregate risk section in Unit III.E.

Although moderately persistent in soils and stable to hydrolysis, the likelihood of azoxystrobin moving into ground and surface water is low due to high soil/water partitioning coefficients and low single application rates. However, with multiple applications and repeated usage, azoxystrobin and especially its degradate (''compound 2'', (*E*)-2-2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]-3-methoxyacrylic acid) may eventually build up in environmental compartments and move into drinking water resources.

Based on the Tier I modeling results using the FQPA Index Reservoir Screening Tool (FIRST) model, azoxystrobin EECs in surface water are not likely to exceed 170 parts per billion (ppb) for the acute (peak) concentration or 33 ppb for the chronic (365–day) concentration. These values represent upper-bound estimates of the concentrations that might be found in surface water which result from the use of azoxystrobin on turf.

The SCI-GROW screening model developed in the Agency estimates potential ground water concentrations under hydrologically vulnerable conditions. Based on the highest use rate (turf use, nine applications per year, 10–day interval, and 0.55 lb ai/A/application), the upper-bound concentration of azoxystrobin was estimated at 3.1 ppb. This value was used for both acute and chronic risk assessments. This value represents upper-bound estimates of the concentrations that might be found in ground water which result from the use of azoxystrobin on turf.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Azoxystrobin is currently registered for use on residential non-dietary sites (turf and ornamentals). The risk assessment was conducted using the following residential exposure assumptions: There is a potential for short-term dermal and inhalation exposures to homeowners who apply products containing azoxystrobin; however, EPA did not identify dermal endpoints for azoxystrobin. Because no dermal endpoints could be indentified, EPA expects no risk from dermal exposure to azoxystrobin. There is also potential for non-dietary, oral exposure following lawn treatment. Short- and intermediate-term non-dietary, oral exposure assessments were included for toddlers, since EPA selected toxicology endpoints for these exposures and there is a potential for hand-to-mouth and object-to mouth transfer of residues from treated turfgrass and incidential ingestion of soil from treated turfgrass.

Postapplication exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. The exposure via incidental ingestion of other plant material may occur but is considered negligible. The residential exposure and risk assessment was conducted using the application for turf because it is the highest single use rate. Azoxystrobin may be applied to turf at rates of up to 0.9516 active ingredient (a.i.) per acre five times per year (i.e., not to exceed 5 lb/ai/acre/year).

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA 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.''

EPA does not have, at this time, available data to determine whether azoxystrobin has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to azoxystrobin and any other substances and azoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that azoxystrobin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. Azoxystrobin studies have indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to azoxystrobin.

3. *Conclusion*. There is a complete toxicity data base for azoxystrobin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10–fold safety factor for increased susceptibility of infants and children be removed (i.e., reduced to 1X). The FQPA factor is removed because:

- The toxicology data base is complete
- The developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure
- Unrefined chronic dietary exposure estimates (assuming all commodities contain tolerance level residues) will overestimate dietary exposure
- Modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a

point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to azoxystrobin will occupy 10% of the aPAD for the U.S. population, 17% of the aPAD for children 1–2 years old, 9% of the aPAD for females 13 years and older, and 10% of the aPAD for adults 50+ years old. In addition, there is potential for acute dietary exposure to azoxystrobin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AZOXYSTROBIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.67	10	170	3.1	21,000
Children 1–2 years old	0.67	17	170	3.1	5,600
Females 13–49 years	0.67	9	170	3.1	18,000
Adults (50+ years)	0.67	10	170	3.1	21,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to azoxystrobin from food will utilize 12% of the cPAD for the U.S. population, 22% of the cPAD for children 1–2 years old, 11% of the cPAD for females 13–49 years old, and 11% for adults 50+ years old. Based on the use pattern, chronic residential exposure to residues of azoxystrobin is not expected. In addition, there is potential for chronic dietary exposure to azoxystrobin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO AZOXYSTROBIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.18	12	33	3.1	5,500
Children 1–2 years	0.18	22	33	3.1	1,400
Females 13–49 years	0.18	11	33	3.1	4,800
Adults 50+ years	0.18	11	33	3.1	5,600

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Azoxystrobin is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for azoxystrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,200 for adults, and 430 for children 1–2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of azoxystrobin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. Population	1,200	100	33	3.1	8,000
Children 1–2 years old	430	100	33	3.1	1,900

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Azoxystrobin is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for azoxystrobin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 420 for children 1–2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of azoxystrobin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Inter-mediate-Term DWLOC (ppb)
Children 1–2 years old	420	100	33	3.1	1,600

5. *Aggregate cancer risk for U.S. population.* There is no evidence for mutagenicity or carcinogenicity. Azoxystrobin has been classified as ''not likely to be carcinogenic in humans'' by EPA; therefore, azoxystrobin is not expected to pose a carcinogenic risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to azoxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methodology is available for enforcement of these tolerances. The gas chromatography/nitrogen phosphorous detector (GC/NPD) method (RAM 243/04) has undergone a method validation by the EPA analytical laboratory. EPA comments have been incorporated and the revised method (designated RAM 243) will be submitted to FDA for inclusion in PAM, Volume II as an enforcement method.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Codex, Canadian, or Mexican Maximum Residue Levels (MRLs) have been established for residues of azoxystrobin. Therefore, no tolerance discrepancies exist between countries for this chemical.

V. Conclusion

Therefore, the tolerances are established for combined residues of azoxystrobin, methyl (*E*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝-(methoxymethylene)-benzeneacetate, and its Z isomer, methyl (Z)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∝-(methoxymethylene)-benzeneacetate, in or on artichoke, globe at 4.0 ppm; asparagus at 0.04 ppm; brassica, head and stem, subgroup 5A at 3.0 ppm; herb subgroup 19A, dried, except chive at 260 ppm; and herb subgroup 19A, fresh, except chive at 50 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0196 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 18, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions

on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0196, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop

an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 6, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.507 is amended by adding alphabetically commodities to the table in paragraph (a)(1) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Artichoke, globe	4.0
Asparagus	0.04
* * *	* *
Brassica, head and stem, subgroup 5A	3.0
* * *	* *
Herb subgroup 19A, dried, except chive	260
Herb subgroup 19A, fresh, except chive	50
* * *	* *

* * * * *

[FR Doc. 03–15261 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 257 and 258

[FRL–7514–7]

RIN 2050–AE86

Criteria for Classification of Solid Waste Disposal Facilities and Practices and Criteria for Municipal Solid Waste Landfills: Disposal of Residential Lead-Based Paint Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: To help accelerate the pace of lead-based paint removal from residences, and thereby reduce exposure to children and adults from the health risks associated with lead, EPA is promulgating a change to its definition of ''municipal solid waste landfill unit'' in both the Criteria for Classification of Solid Waste Disposal Facilities and Practices and the Criteria for Municipal Solid Waste Landfills. In addition, EPA is promulgating two new definitions for ''construction and demolition (C&D) landfill'' and ''residential lead-based paint waste.'' This final rule will expressly allow residential lead-based paint waste that is exempted from the hazardous waste management requirements as household waste to be disposed of in construction and demolition landfills by stating that a construction and demolition landfill accepting residential lead-based paint waste, and no other household waste, is not a municipal solid waste landfill unit. Today's action would not prevent a municipal solid waste landfill unit from continuing to receive residential lead-based paint waste.

DATES: This final rule will become effective on June 18, 2003. The Agency finds good cause to make this rule effective immediately because today's final rule provides an additional disposal option for residential lead-based paint waste.

ADDRESSES: Copies of the documents relevant to this action (Docket No. RCRA–2001–0017) are available for public inspection during normal business hours from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays, at the RCRA Information Center (RIC), located at EPA West, Room B–102, 1301 Constitution Ave., NW. Washington, DC.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at (800) 424–9346 or TDD (800) 553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call (703) 412–9810 or TDD (703) 412–3323.

For information on specific aspects of this rule, contact Paul Cassidy, Municipal and Industrial Solid Waste Division, Office of Solid Waste (mail code 5306W), U.S. Environmental Protection Agency (EPA, HQ), 1200 Pennsylvania Avenue, NW, Washington, DC 20460; (703) 308–7281, *cassidy.paul@epa.gov*. The index and some supporting materials are available on the Internet. You can find these materials at *http://www.epa.gov/epaoswer/non-hw/muncpl/landfill/pb-paint.htm.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Regulated Entities

Entities potentially covered by this regulation are public or private individuals or groups that generate residential lead-based paint (LBP) waste as a result of abatement, rehabilitation, renovation and remodeling in homes, residences, and other households. By ''households,'' we mean single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreation areas. Affected categories and entities include:

Category	Examples of affected entities
Individuals and firms who generate residential LBP wastes.	Contractors and do-it-yourselfers who generate and dispose of residential LBP waste as a result of abatement, rehabilitation, renovation and remodeling in homes, residences, and other households.
Construction and demolition waste disposal firms.	Owners or operators of construction and demolition landfills that accept residential LBP waste for disposal.

The table above is not intended to be exhaustive but, rather, is intended to provide examples of entities likely to be regulated by this action. To determine whether your facility would be impacted by this action, you should carefully examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular facility, please contact Paul Cassidy, U.S. EPA, Office of Solid Waste (5306W), 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone 703–308–7281; e-mail: *cassidy.paul@epa.gov*.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. RCRA–2001–0017. The official public docket consists of the documents specifically referenced in this action, any public comments received and other information related to this action. The official public docket is the collection of materials that is available for public viewing at the RCRA Information Center (RIC), located at EPA West, Room B–102, 1301 Constitution Ave. NW., Washington DC. The Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744. In the Washington, DC, metropolitan area, call 202–566–0270 or TDD 703–412–3323 (hearing impaired). To review the docket materials in person, we recommend that the public make an appointment by calling 202–566–0270. The public can copy a maximum of 100 pages from the docket at no charge. Additional copies cost $0.15/page. If you access the information electronically, you can download or print copies free of charge.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http.www.epa.gov/fedrgstr*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified above in Unit I.B.

C. Acronyms

Acronym	Definition
CDC	Centers of Disease Control and Prevention.
C&D	Construction and Demolition.
CFR	Code of Federal Regulations.
EA	Economic Analysis.
EPA	Environmental Protection Agency.
FR	Federal Register.
HUD	U.S. Department of Housing and Urban Development.
IQ	Intelligence Quotient.
LBP	Lead-Based Paint.
MSWLF	Municipal Solid Waste Landfill.
OMB	Office of Management and Budget.
OPPTS	Office of Prevention, Pesticides, and Toxic Substances.
OSWER	Office of Solid Waste and Emergency Response.
RCRA	Resource Conservation and Recovery Act.
RIC	RCRA Docket Information Center.
TC	Toxicity Characteristic.
TCLP	Toxicity Characteristic Leaching Procedure.
TSCA	Toxic Substances Control Act.
USEPA	United States Environmental Protection Agency.

Outline

I. Legal Authority

EPA is promulgating this rule pursuant to section 1008(a)(3), 2002(a), 4004(a) and 4010(c) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. Secs. 6907(a), 6912(a), 6944(a), 6949a(c). We are also correcting a typographical error in the existing statement of authority in part 257 by amending the citation to 42 U.S.C. 6949(c) to read ''6949a(c).''

II. Summary of Proposed Lead-Based Paint Rule

A. Proposed Change to the Definition of ''Municipal Solid Waste Landfill (MSWLF) Unit''

In its October 23, 2001, proposal (see 66 FR 53566–53573) regarding the disposal of residential lead-based paint waste, the Agency proposed to expressly allow construction and demolition landfills to receive residential lead-based paint (LBP) waste.[1] This was to be accomplished in part by adding a sentence to the definition of municipal solid waste landfill (MSWLF) unit in 40 CFR 257.2 and 258.2, as follows: ''A

[1] EPA published a direct final rule at 66 FR 53535 (Oct. 23, 2001) together with the proposed rule. EPA withdrew the direct final rule after receiving adverse comments. 66 FR 67108 (Dec. 28, 2001). Today's rule is final action on the proposed rule.

construction and demolition landfill that receives residential lead-based paint waste and does not receive any other household waste is not a MSWLF unit.'' The Agency explained in the preamble to the proposal that the existing definition of a MSWLF unit includes language which states that a disposal unit ''that receives household waste'' is a municipal solid waste landfill unit. This language can be construed to prohibit the disposal of any household waste into a facility that is not designed and operated in conformance with 40 CFR part 258 regulations. As a result the Agency proposed to amend the definition of MSWLF unit, to distinguish residential lead-based paint waste, which has been determined to be a household waste, from other types of household waste, for purposes of disposal.

The definition as proposed is as follows: ''Municipal solid waste landfill (MSWLF) unit means a discrete area of land or an excavation that receives household waste, and that is not a land application unit, surface impoundment, injection well, or waste pile, as those terms are defined in this section. A MSWLF unit also may continue to receive other types of RCRA Subtitle D wastes, such as commercial solid waste, nonhazardous sludge, and industrial solid waste. Such a landfill may be publicly or privately-owned. A MSWLF unit may be a new MSWLF unit, an existing MSWLF unit or a lateral expansion. A construction and demolition landfill that receives residential lead-based paint waste and does not receive any other household waste is not a MSWLF unit.''

The proposed change was designed to simply distinguish residential LBP waste from other household wastes. The proposal would not alter what a MSWLF could or could not receive. MSWLFs would be allowed to continue to receive residential LBP waste as household waste. The proposed rule expressly provided an additional land-based waste disposal option for residential LBP waste.

B. Proposed Definition of ''Construction and Demolition Landfill''

The October 23, 2001 notice also proposed to add a definition of a construction and demolition (C&D) waste landfill, which would expressly allow only C&D landfills, and no other types of land disposal units that meet the criteria of 40 CFR part 257, to receive residential LBP waste. The Agency proposed to define a C&D landfill as follows: ''Construction and demolition (C&D) landfill means a solid waste disposal facility subject to the requirements of subparts A or B of this part that receives construction and demolition waste and does not receive hazardous waste (defined in Sec. 261.3 of this chapter) other than conditionally exempt small quantity generator waste (defined in Sec. 261.5 of this chapter), or industrial solid waste (defined in Sec. 258.2 of this chapter). A C&D landfill typically receives any one or more of the following types of solid wastes: roadwork material, excavated material, demolition waste, construction/renovation waste, and site clearance waste.'' The proposed rule would add this definition to 40 CFR parts 257 and 258.

C. Proposed Definition of ''Residential Lead-Based Paint Waste''

Finally, EPA proposed to define ''residential lead-based paint waste'' to clarify the scope of the waste stream addressed by the proposed rule. The proposed definition of residential lead-based paint waste is as follows: ''Residential lead-based paint waste means waste generated as a result of lead-based paint activities (including abatement, rehabilitation, renovation and remodeling) in homes and other residences. The term residential lead-based paint waste includes, but is not limited to, lead-based paint debris, chips, dust, and sludges.'' Not included in the proposed definition of residential LBP waste were residential LBP demolition and deconstruction waste, and LBP waste from nonresidential structures such as public and commercial buildings, warehouses, bridges, water towers, and transmission towers.

In proposing the definition of residential lead-based paint waste, the Agency included these particular LBP activities because they were limited to residences and would pose lead hazards to occupants, especially to children. We included the particular waste types (*i.e.*, debris, chips, dust, and sludges) because they are typically generated during the named LBP activities.

D. Rationale for Proposed Rule

In the preamble to the proposal, EPA explained the Agency's rationale and justification of the proposed changes, as well as the analytical basis for the proposal. The proposal provided a specific discussion of: (1) The reasons that residential lead-based paint is a concern to children; (2) the Congressional enactment of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (hereinafter referred to as Title X of the Housing and Community Development Act of 1992, or Title X); (3) the concerns of stakeholders who have seen the application of RCRA's hazardous waste regulations as a barrier to the cost-effective abatement of lead hazards; (4) the 1988 proposed rule under the Toxic Substances Control Act (TSCA) which proposed new TSCA management and disposal standards for LBP debris generated by contractors from pre-1978 homes and public and commercial buildings; (5) the 1988 temporary suspension of the toxicity characteristic for specified lead-based paint debris under RCRA; and (6) the July 31, 2000 memorandum clarifying the regulatory status under RCRA Subtitle C of wastes generated as a result of LBP activities, including abatements, renovation and remodeling, and rehabilitations in homes and other residences. In the July 31, 2000 memorandum, the Agency interpreted residential LBP waste as a household waste excluded from the hazardous waste management requirements pursuant to the household waste exclusion in 40 CFR 261.4(b)(1), thus giving rise to the proposed amendments to parts 257 and 258 to expand disposal options for residential LBP waste to include C&D landfills, as well as MSWLF units.

III. Summary of Public Comments and the Agency's Response to Those Comments

The Agency received a total of eight comments on the proposed residential LBP waste rule: four from construction and/or demolition trade associations, and one each from a state, an association of state agencies, an environmental organization, and an individual. In general, commenters supported the proposal to allow residential LBP waste to be disposed of in C&D landfills. However, some commenters requested clarifications of the rule or preamble language or suggested additions to the rule language.

Definition of Residential Lead-Based Paint Waste

The state commenter argued that the proposed rule contained a significant flaw by including chips, dust and sludges in the definition of ''residential lead-based paint waste,'' because EPA failed to take into account the potential for sleet, surface-water or wind-borne movement of lead paint chips, dust, and sludges off-site from a C&D landfill. The commenter stated that the placement of LBP dust, chips and sludges in an open environment (*i.e.*, a landfill that does not provide for daily cover) over an extended period of time, *e.g.*, 30 days, may allow a significant rain or wind event to transport lead-containing materials off-site. The commenter

further stated that sudden intense rain events or winds above 20 to 25 miles per hour can transport lead-containing wastes off-site by surface water or air currents. The commenter suggested that requiring daily cover or special packaging at C&D landfills for the above-mentioned wastes would mitigate the potential for adverse impact from surface water or air transport.

Because other features of C&D landfills and LBP waste handling practices serve to mitigate potential impacts from surface water or air transport, the Agency does not believe that requirements for daily cover or special packaging are needed on the federal level. Surface water transport off-site by sudden intense rain events would constitute ''non-point source'' pollution under the Clean Water Act. To mitigate potential surface water impacts, C&D landfills must comply with 40 CFR 257.3–3(c), which requires that a facility or practice shall not cause non-point source pollution that violates legal requirements implementing an areawide or statewide water quality management plan approved by EPA under the Clean Water Act.

To further mitigate potential water or air transport, both EPA and the U.S. Department of Housing and Urban Development (HUD) have issued guidance for LBP waste management calling for the containment of LBP wastes in plastic with sealed seams. EPA's ''Reducing Lead Hazards When Remodeling Your Home'' EPA 747–K–97–001 *(http://www.epa.gov/lead/rrpamph.pdf)* and EPA's Model Renovation Training Course EPA 747–B–00–005/6 (*http://www.epa.gov/opptintr/lead/rrmodel.htm*) both call for safe and secure disposal. Safe and secure disposal involves placing the LBP wastes in plastic (4–6 mil poly) bags that are sealed closed. HUD modified the EPA training course and developed their own training program to serve the specific needs of HUD's constituents. The HUD training course entitled ''Addressing Lead-Based Paint Hazards During Renovation, Remodeling and Rehabilitation in Federally Owned and Assisted Housing'' (also referred to as ''The 3R Course'') *(http://www.hud.gov/offices/lead/training/3r/3r_course.cfm)* was first delivered to remodeling and rehabilitation workers during HUD's nationwide training initiative in 2001–2002. HUD's training recommends that safe disposal of LBP wastes be accomplished by means of plastic bags. Other HUD brochures and documents also recommend that LBP wastes be placed in plastic bags for safe disposal. These brochures include:

''Lead Paint Can Poison: Is Your Family at Risk?'' (*http://www.hud.gov/offices/lead/outreach/parents.pdf*).

''Lead Paint Safety—A Field Guide for Painting, Home Maintenance, and Renovation Work'' (*http://www.hud.gov/offices/lead/training/LBPguide.pdf*).

''Caution: Lead Paint Handle With Care'' (*http://www.hud.gov/offices/lead/outreach/tradesOKAYTOPRINT.pdf*).

''Lead Paint Can Poison: Protect Your Family When You Repaint or Remodel''. (*http://www.hud.gov/offices/lead/outreach/remodel.pdf*)

HUD also operates the Lead-Based Paint Hazard Control Grant Program that has as its primary purpose to reduce the exposure of young children to lead-based paint hazards in their homes. The program provides grants to State and local governments for control of lead-based paint hazards in privately owned, low income owner-occupied and rental housing. These grants are designed to stimulate the development of a trained and certified hazard evaluation and control industry. Evaluation and hazard control work under the program must be conducted by either contractors who are certified and workers who are trained through a State-accredited program or by contractors trained in lead-safe work practices in the case of interim controls.

Moreover, as of March 1, 2000, lead service providers within the United States must be certified (or licensed) under an EPA authorized lead program. Most of the States have developed and are administering such a program and EPA certifies lead service providers in states that do not have their own programs. As of January 2003, 38 States had EPA-approved state lead programs that actively certify (license) lead service providers.

EPA has also discussed this issue with the National Association of Demolition Contractors (NADC). NADC re-confirmed EPA's understanding that paint chips and dust are managed in plastic bags. NADC stated that lead-based dust is removed with vacuums with HEPA filters and that the vacuum bags are removed and then tied closed prior to disposal. Paint chips that may fall on a plastic sheet are collected in the plastic sheet which is then placed in a tied plastic bag.

As stated above, the EPA believes that sufficient guidance, literature, training programs, EPA-approved state lead programs, and current practices exist so that whether the LBP waste is in the form of chips, dust, or sludge it will be managed appropriately (*i.e.*, containment in plastic bags on site prior to transport to disposal). At the disposal facility, the containment plastic serves to mitigate against potential impacts of water or wind transport.

Additionally, where water or wind transport are problematic, States have demonstrated their ability, even in the absence of a federal requirement, to impose additional requirements for weekly, monthly, or daily cover as necessary to control particulate releases. According to the 1995 report, ''Construction and Demolition Waste Landfills,'' 14 States require on-site C&D units to provide daily cover, while 19 States require daily cover at off-site C&D units. Based on these C&D landfill features and LBP waste handling practices, the Agency does not believe it is necessary to impose on the federal level a requirement for daily cover at C&D landfills receiving LBP waste.

Two industry association commenters stated that lead-based paint architectural debris generated from all structures, commercial and industrial, as well as, residential, can safely be disposed of in C&D landfills (*i.e.*, Subtitle D facilities). The commenters disagreed with the Agency's statement in the preamble that demolition and deconstruction waste was not similar to household waste. The commenters believe that LBP material handled by the demolition industry in commercial and industrial structures is no more dangerous to public health and the environment than when LBP appears in a residential structure.

The Agency wishes to clarify that today's rule is an outgrowth of the July 31, 2000 Memorandum stating that waste generated as a result of LBP activities in homes and other residences falls within the exclusion for ''household waste'' in 40 CFR 261.4(b)(1). (See 66 FR 53569.) The scope of this rulemaking concerns only residential lead-based paint wastes and not lead-based paint wastes from commercial and industrial structures because lead-based paint waste from commercial and industrial structures does not fall within the exclusion for ''household waste'' in 40 CFR 261.4(b)(1) or the definition of ''household waste'' in 40 CFR 258.2. Thus, *residential* LBP waste that would otherwise be hazardous waste subject to the hazardous waste management requirements of Subtitle C of RCRA can be managed under Subtitle D of RCRA. The purpose of this rulemaking is to expand Subtitle D disposal options for this particular household waste, which, without today's rule could only be disposed of in municipal solid waste landfills pursuant to 40 CFR part 258.

The July 31, 2000 Memorandum did not affect the regulatory status of

nonresidential LBP waste, such as that generated during the abatement or renovation and remodeling of a commercial building. ''Household waste'' is defined as ''any material (including garbage, trash and sanitary waste in septic tanks) *derived from households* (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas).'' (Emphasis added.)

The Agency recognizes that not all lead-based paint waste, whether from residential, commercial, or industrial sources, is ''hazardous waste'' which must be managed under RCRA Subtitle C. Any LBP waste that is not hazardous waste can be safely disposed of in a Subtitle D landfill, including a C&D waste landfill.

Several commenters stated that the proposed rule was not sufficiently clear as to the distinctions between those LBP activities that generate waste that would qualify as ''residential LBP waste'' (*e.g.* abatement, rehabilitation, renovation, and remodeling'') and those that would not fall within the scope of the rule (*e.g.*, ''demolition and deconstruction''). One of these commenters stated that the regulated community might believe that there is some deconstruction or demolition occurring whenever you perform rehabilitation, renovation, remodeling, and perhaps to some extent abatement. The commenter suggested that the focus of the final rule be on waste type and not on waste activity.

The Agency distinguishes demolition and deconstruction activities from abatement, rehabilitation, renovation, and remodeling on the basis that demolition and deconstruction result in the elimination of the residential structure, while the residential structure remains where the other listed activities are conducted. The proposed definition of residential lead based paint waste does not include residential demolition and deconstruction activities. The proposed definition was limited to LBP waste that would be subject to Subtitle C of RCRA, except that it is included within the household waste exclusion in 40 CFR 261.4(b)(1). The Agency has applied two criteria to define the scope of the exclusion: (1) The waste must be generated by individuals on the premises of a household, and (2) the waste must be composed primarily of materials found in the wastes generated by consumers in their homes (49 FR 44978 and 63 FR 70241). In the case of LBP wastes, we have determined that demolition and deconstruction, which result in the elimination of the household structure, are outside the scope of the household waste exclusion and therefore are not included in the definition of ''residential LBP waste.'' Although demolition activities and renovation activities may produce some of the same types of waste, the waste type is not a factor for consideration under 40 CFR 261.4(b)(1), and therefore, today's final rule continues to read as proposed. The Agency wants to make it clear that deconstruction and demolition wastes can continue to be placed in construction and demolition waste landfills provided that these types of wastes do not exhibit the toxicity or any other characteristic (*i.e.*, are not a hazardous waste).

One commenter was specifically concerned that the proposed definition of residential lead-based paint waste could create confusion about the scope of activities that are considered ''lead-based paint activities'' under the Toxic Substances Control Act (TSCA). The proposed residential LBP definition states that LBP activities include abatement, rehabilitation, renovation, and remodeling. Regulations promulgated under TSCA define ''lead-based paint activities'' to mean lead inspection, risk assessment, and abatement in the case of target (most pre-1978) housing (see 40 CFR 745.223). Renovation, remodeling, and rehabilitation are not considered lead-based paint activities under Title X. The commenter was concerned that the Agency was trying to change the scope of the TSCA regulation under the proposed RCRA regulation. The commenter suggested that the term lead-based paint activities be deleted and replaced with the phrase ''activities that disturb lead-based paint.''

The Agency did not intend or propose to change the scope of the TSCA regulation in the October 2001 proposal. However, to eliminate any potential confusion, the Agency has decided to change the definition of residential LBP wastes to eliminate the words ''lead-based paint activities.'' The definition of residential LBP wastes included in today's final rule does not use the term ''lead-based paint activities.'' This definition is as follows: ''Residential lead-based paint waste means waste containing lead-based paint, which is generated as a result of activities such as abatement, rehabilitation, renovation and remodeling in homes and other residences. The term residential lead-based paint waste includes, but is not limited to, lead-based paint debris, chips, dust, and sludges.''

Definition of Construction and Demolition Waste Landfill

A trade association commenter objected to the proposed definition of ''construction and demolition waste landfill'' because the proposed rule would define a C&D waste landfill as one that does not receive ''industrial wastes,'' as defined in section 258.2. The commenter objected because the definition as proposed would preclude a C&D landfill that receives industrial waste in the form of manufacturer's ''off-spec,'' rejected, or damaged construction materials from accepting residential lead-based paint waste. Thus C&D landfills in that state would have to choose between residential LBP waste or off spec., damaged, or rejected construction materials, but not both.

In the proposed definition of construction and demolition waste landfill, the Agency stated that C&D waste landfills were not eligible to receive ''industrial solid wastes as defined in 40 CFR 258.2.'' The definition of ''industrial solid waste'' in section 258.2 covers ''wastes resulting from'' particular manufacturing or industrial processes. In defining C&D landfills, the Agency was concerned about C&D waste landfills receiving wastes generated by manufacturing or industrial processes and, as such, wrote the definition to exclude such wastes. In practice, industrial process wastes are typically managed on-site, or in limited cases, sent off-site to private/commercial industrial waste facilities. Industrial process wastes should not be received for disposal at a C&D waste landfill. The commenter was concerned that off-spec construction products (*e.g.*, toilets or shingles) would not be allowed in a C&D waste landfill because of the proposed definition. However, the Agency views ''off-spec,'' rejected, or damaged construction materials as virtually identical in nature to the type of waste that is appropriately received at a C&D waste landfill and are not ''industrial solid waste'' as defined at 40 CFR 258.2. Because the definition of industrial solid waste does not explicitly include materials that do not meet manufactures' specifications, are damaged or rejected for use, EPA believes that industrial waste in the form of manufacturer's ''off-spec,'' rejected, or damaged construction materials can be appropriately placed in a C&D landfill. In addition, the Agency expects that States would exercise judgment in what is considered industrial wastes. Thus, EPA believes that the definition in today's final rule accommodates disposal of unused construction materials that do not meet

manufacturers' specifications, are damaged or rejected for use.

Another commenter stated that the definition of C&D landfill as proposed could be interpreted to mean that conditionally exempt small quantity generator waste could be accepted in a 40 CFR part 257 Subpart A facility. The commenter suggested a wording change to eliminate this possible misinterpretation.

EPA does not intend that a C&D landfill be allowed to receive conditionally exempt small quantity generator wastes if the C&D landfill meets the requirements of 40 CFR part 257 Subpart A, but does not meet the requirements of part 257, subpart B. Therefore, the Agency has changed the definition of C&D waste landfill to eliminate any potential confusion. The definition has been changed to clarify that conditionally exempt small quantity generator wastes can only be disposed of in a C&D landfill that meets the requirements of 40 CFR part 257, Subpart B.

Effect on State Programs

The state association commenter indicated that it is important that EPA be explicit that states are not required to amend their programs to incorporate today's rule; however the commenter also suggested language to assure States that their prior approved programs will not be reopened regardless of whether they adopt today's rule or not. EPA agrees with the comment and has revised the language in Section V. of today's preamble to make this clear.

Lead-Contaminated Soils

Lastly, a commenter stated that EPA had missed a golden opportunity to allow lead-contaminated soils to be managed similarly and requested that EPA move expeditiously to craft a rule to allow lead-contaminated soils to be disposed of in C&D and municipal solid waste landfills. The commenter claimed that the disposal of lead-contaminated soils in C&D landfills and municipal solid waste landfills is environmentally safer than is the disposal of lead-based paint debris. The commenter also argued that the cost of managing those soils that fail the TCLP under the RCRA hazardous waste requirements discourages soil lead abatement from residences. As discussed previously, today's rulemaking is limited to providing the C&D landfill disposal option for residential lead-based paint waste addressed in the July 31, 2000 Memorandum. Lead-contaminated soils were not included in the July 31, 2000 Memorandum, thus EPA is not addressing disposal of lead-contaminated soils at this time.

Summary of Final Rule Changes

This final rule will expressly allow residential lead-based paint waste to be disposed of in construction and demolition waste landfills by clearly stating that a construction and demolition landfill accepting residential lead-based paint waste, and no other household waste, is not a municipal solid waste landfill unit. Today's action does not prevent a municipal solid waste landfill from continuing to receive residential lead-based paint waste. Two minor changes were made to the final regulatory language based on comments received on the proposal. Today's final rule was modified to remove ''LBP activities'' to one that includes ''activities that disturb LBP.'' The definition of construction and demolition waste landfill was changed to eliminate any confusion so that small quantity generator waste can only be disposed of in a facility that meets the requirements of 40 CFR part 257, subpart B.

IV. Other Applicable Federal, State, Tribal, and Local Requirements

Today's final rule would not alter the authority of State, local and Tribal governments to regulate LBP waste more stringently than does EPA. Generators of residential LBP waste should contact the appropriate State environmental agencies to determine if there are additional or more stringent disposal requirements for residential LBP waste. Also, generators are subject to applicable HUD and/or TSCA regulations when addressing residential LBP hazards.

V. How Will States and Tribes Implement This Final Rule?

Because today's final rule is less stringent than existing federal criteria, States are not required to amend their permit programs which have been determined to be adequate under 40 CFR part 239. States have the option of amending statutory or regulatory definitions pursuant to today's final rule. If a state chooses to amend its permit program pursuant to today's action, the State would be required to notify the Regional Administrator of the modification as provided by 40 CFR 239.12. Whether a State chooses to incorporate today's rule into its solid waste program has Statutory and Executive Order Reviews no effect on its existing status with respect to EPA approval, *i.e.*, State revisions will not open previously approved solid waste programs for Federal review.

Today's amendments are directly applicable to landfills in States without an approved permit program under part 239 and in Indian Country. We encourage Tribes to adopt today's rule into their programs to promote lead-based paint abatement activities in homes and other residences in Indian Country.

VI. How Does This Final Rule Comply With Applicable Statutes and Executive Orders?

Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

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

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

EPA has performed a full economic analysis, ''Economic Analysis of EPA's Final Rule Amending 40 CFR parts 257 and 258,'' which is available in the docket for today's rule. The Economic Analysis concludes that this rule will impose no additional costs to parties, but may result in cost savings and incremental public health benefits. The rule authorizes the disposal of residential LBP waste in C&D landfills, where previously, as ''household waste'' under the July 31, 2000 policy memorandum, disposal was authorized only in MSWLFs. Therefore, EPA believes that, in those parts of the country where costs associated with transport to and disposal in C&D landfills is less expensive than costs associated with MSWLF disposal, some

residential LBP waste will be diverted from MSWLFs to C&D landfills. Where this occurs, generators will benefit from lower waste management and disposal costs.

EPA believes that only residential LBP waste generators in the Midwest, Northeast, and South regions will shift disposal from MSWLFs to C&D landfills, based on an analysis of the relative costs of MSWLF and C&D landfill disposal by region. EPA further believes that the percentage of residential LBP waste that is affected is proportional to the share of these three regions in the number of housing units with LBP, which is 84.4 percent. Under these assumptions, an estimated 0.87 million tons of residential LBP waste may be diverted from MSWLFs to C&D landfills annually. This represents 0.73 percent of the total volume of all waste disposed of in MSWLFs annually. This shift in disposal would save residential LBP waste generators in the Midwest, Northeast, and South regions up to an estimated $16.76 million annually. The savings accruing to generators of residential LBP abatement waste is estimated at $0.79 million per year, while the savings accruing to generators of residential renovation and remodeling waste is $15.98 million per year.

EPA estimates that of the $0.79 million in savings that could accrue to generators of residential LBP abatement waste, an estimated 39.7 percent, or $0.31 million, will be generated annually in the public housing sector. EPA assumes that in the public sector, any savings in residential LBP waste management and disposal costs will be used to conduct additional LBP abatements. Given an average cost for LBP abatement in public housing units of $3,650, the $0.31 million in annual savings would fund an additional 86 abatements each year. This ensuing increase in LBP abatement projects would result in a more rapid reduction in the potential for exposure to the hazards of LBP, especially for children. These hazards include decreased intelligence (*i.e.*, lower IQ), behavioral problems, reduced physical stature and growth, and impaired hearing.

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2050–0154. Copies of the ICR document(s) may be obtained from Susan Auby, by mail at the Office of Environmental Information, Collection Strategies Division, U.S. Environmental Protection Agency (2822), 1200 Pennsylvania Ave., NW., Washington, DC 20460, by email at *auby.susan@epa.gov,* or by calling (202) 260–2740. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr.*

Today's action does not impose any new information collection burden. The previously approved information collection requirements are contained in the existing regulations at 40 CFR 257.30. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's final rule on small entities, a small entity is defined as: (1) A small business that is primarily engaged in lead paint removal as described in the North American Industry Classification System (see *http://www.sba.gov/size/SIC2NAICSmain.html);* (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule does not impose any new requirements on small entities. In fact, the rule will provide an additional non-mandatory option for the disposal of residential LBP waste, which could result in less cost in managing residential LBP waste.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of regulatory actions on State, local, and Tribal governments, and the private sector. Under Section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, Section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objective of the rule. The provisions of Section 205 do not apply when they are inconsistent with applicable law. Moreover, Section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under Section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. This final rule does not impose any enforceable duty on any State, local or tribal governments or the private sector. Thus, today's final rule is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' Policies that have federalism implications' is defined in the Executive Order to include regulations that 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.''

This final rule does not have federalism implications. It 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, as specified in Executive Order 13132. As explained in Section V. of this preamble, none of today's proposed revisions are more stringent or broaden the scope of the existing Federal requirements. Therefore, States are not required to adopt the revision to the definition of MSWLF unit nor the additional definitions of construction and demolition (C&D) landfill and residential lead-based paint waste in today's rule. Thus, Executive Order 13132 does not apply to this final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Today's final rule would expressly provide an additional option for disposal of certain waste applicable in Indian Country, but would not create any mandate on Indian tribal governments. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Risks and Safety Risks

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

This final rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866. However, this rule will affect decisions involving the environmental health or safety risks to children. In fact, it will benefit children by allowing environmentally protective disposal of residential lead-based paint waste in C&D landfills, which is less costly than disposal in MSWLFs in certain areas of the U.S., therefore reducing the cost of lead abatements. Reducing the cost of LBP abatements will also reduce the amount of time needed to complete abatements in public housing. Lower abatement costs may increase the amount of private homes undergoing abatements. By reducing costs associated with the disposal of LBP waste, the Agency believes that the number of abatements may marginally increase, thus resulting in a reduction of the number of children exposed to LBP.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it will not have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub L. 104–113, Sec. 12(d) (15 U.S.C. 272 note) directs us to use voluntary consensus standards in our regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards. Today's final rule does not involve technical standards, voluntary or otherwise. Therefore, the NTTAA does not apply to today's final rule.

J. Executive Order 12898: Federal Action To Address Justice in Minority Populations and Low-Income Populations

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' as well as through EPA's April 1995, ''Environmental Justice Strategy, OSWER Environmental Justice Task Force Action Agenda Report,'' and the National Environmental Justice Advisory Council, EPA has undertaken to incorporate environmental justice into its policies and programs. EPA is committed to addressing environmental justice concerns, and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income, bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities.

Today's final rule is not expected to negatively impact any community, and therefore is not expected to cause any disproportionately high and adverse impacts to minority or low-income communities versus non-minority or affluent communities. On the contrary, since the rule will reduce the cost of performing LBP abatements in certain regions of the U.S., EPA believes that the savings will afford public housing authorities, in particular, the opportunity to conduct additional abatements of LBP hazards in affected

housing units. Tenants of public housing units are possibly more likely to be minority and lower-income households, and the rule should have the effect of providing a differential benefit to such populations.

K. Congressional Review Act

The Congressional review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that, before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C., 804(2). This rule will be effective on June 18, 2003.

List of Subjects

40 CFR Part 257

Environmental protection, Waste treatment and disposal.

40 CFR Part 258

Environmental protection, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: June 12, 2003.

Christine Todd Whitman,

Administrator.

■ For reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 257—[AMENDED]

■ 1. The authority citation for part 257 is revised to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a)(1), 6944(a), and 6949a(c); 33 U.S.C. 1345(d) and (e).

■ 2. Section 257.2 is amended:
■ a. By adding in alphabetical order the definitions for ''Construction and demolition (C&D) landfill'' and ''Residential lead-based paint waste,'' and
■ b. By revising the definition of ''Municipal solid waste landfill (MSWLF) unit.''

The revision and additions read as follows:

§ 257.2 Definitions.

* * * * *

Construction and demolition (C&D) landfill means a solid waste disposal facility subject to the requirements of subparts A or B of this part that receives construction and demolition waste and does not receive hazardous waste (defined in § 261.3 of this chapter) or industrial solid waste (defined in § 258.2 of this chapter). Only a C&D landfill that meets the requirements of subpart B of this part may receive conditionally exempt small quantity generator waste (defined in § 261.5 of this chapter). A C&D landfill typically receives any one or more of the following types of solid wastes: roadwork material, excavated material, demolition waste, construction/renovation waste, and site clearance waste.

* * * * *

Municipal solid waste landfill (MSWLF) unit means a discrete area of land or an excavation that receives household waste, and that is not a land application unit, surface impoundment, injection well, or waste pile, as those terms are defined in this section. A MSWLF unit also may receive other types of RCRA Subtitle D wastes, such as commercial solid waste, nonhazardous sludge, and industrial solid waste. Such a landfill may be publicly or privately owned. A MSWLF unit may be a new MSWLF unit, an existing MSWLF unit or a lateral expansion. A construction and demolition landfill that receives residential lead-based paint waste and does not receive any other household waste is not a MSWLF unit.

* * * * *

Residential lead-based paint waste means waste containing lead-based paint, which is generated as a result of activities such as abatement, rehabilitation, renovation and remodeling in homes and other residences. The term residential lead-based paint waste includes, but is not limited to, lead-based paint debris, chips, dust, and sludges.

* * * * *

PART 258—[AMENDED]

■ 1. The authority citation for part 258 continues to read as follows:

Authority: 33 U.S.C. 1345(d) and (e); 42 U.S.C. 6902(a), 6907, 6912(a), 6944, 6945(c) and 6949a(c).

■ 2. Section 258.2 is amended:
■ a. By adding in alphabetical order the definitions for ''Construction and demolition (C&D) landfill'' and ''Residential lead-based paint waste,'' and
■ b. By revising the definition of ''Municipal solid waste landfill (MSWLF) unit.''

The revision and additions read as follows:

§ 258.2 Definitions.

* * * * *

Construction and demolition (C&D) landfill means a solid waste disposal facility subject to the requirements in part 257, subparts A or B of this chapter that receives construction and demolition waste and does not receive hazardous waste (defined in § 261.3 of this chapter) or industrial solid waste (defined in § 258.2 of this chapter). Only a C&D landfill that meets the requirements of 40 CFR part 257, subpart B may receive conditionally exempt small quantity generator waste (defined in § 261.5 of this chapter). A C&D landfill typically receives any one or more of the following types of solid wastes: roadwork material, excavated material, demolition waste, construction/renovation waste, and site clearance waste.

* * * * *

Municipal solid waste landfill (MSWLF) unit means a discrete area of land or an excavation that receives household waste, and that is not a land application unit, surface impoundment, injection well, or waste pile, as those terms are defined under § 257.2 of this chapter. A MSWLF unit also may receive other types of RCRA Subtitle D wastes, such as commercial solid waste, nonhazardous sludge, conditionally exempt small quantity generator waste and industrial solid waste. Such a landfill may be publicly or privately owned. A MSWLF unit may be a new MSWLF unit, an existing MSWLF unit or a lateral expansion. A construction and demolition landfill that receives residential lead-based paint waste and does not receive any other household waste is not a MSWLF unit.

* * * * *

Residential lead-based paint waste means waste containing lead-based paint, which is generated as a result of activities such as abatement, rehabilitation, renovation and remodeling in homes and other residences. The term residential lead-based paint waste includes, but is not limited to, lead-based paint debris, chips, dust, and sludges.

* * * * *

[FR Doc. 03–15363 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[Docket No. OST 1999–6189]

RIN 9991–AA37

Organization and Delegation of Powers and Duties, Update of Secretarial Delegations

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Final rule.

SUMMARY: The Secretary of Transportation (Secretary) is delegating to the Maritime Administrator his authority to issue, transfer, amend, or reinstate a license for the construction and operation of a deepwater port as provided for in the Deepwater Port Act, of 1974, as amended. Section 106 of the Maritime Transportation Security Act of 2002 amended the Deepwater Port Act to include facilities that transport natural gas from the United States outer continental shelf. This rule does not change the previous delegation of license processing functions to the United States Coast Guard, now part of the Department of Homeland Security, and to the Maritime Administration. The two agencies will continue to coordinate their processing of the license applications. The rule also does not change the previous delegation of Deepwater Port Act authority to the Administrator of the Research and Special Programs Administration.

EFFECTIVE DATE: June 18, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Kessler, Senior Attorney-Advisor, Office of the Assistant General Counsel for Environmental, Civil Rights, and General Law, Department of Transportation, Room 10102, 400 Seventh Street, SW., Washington, DC 20590, Phone: (202) 366–9154.

SUPPLEMENTARY INFORMATION: This rule revises the Secretary's reservation of authority under the Deepwater Port Act, as amended. The Secretary is delegating to the Maritime Administrator his authority to issue, transfer, amend, or reinstate a license for the construction and operation of a deepwater oil or natural gas port as provided for in the Deepwater Port Act of 1974, as amended, 33 U.S.C. 1501–1524 (DWPA). The DWPA, as amended by section 106 of the Maritime Transportation Security Act of 2002, Pub. L. 107–295, 116 STAT. 2064 at 286 (MTSA), governs the licensing of any offshore facility used to handle and transport petroleum and natural gas, pursuant to the amendment of the DWPA. A deepwater port must be licensed by the Secretary. To date, LOOP LLC is the only offshore deepwater port facility licensed by the Secretary under the DWPA. LOOP LLC's License was issued on January 17, 1977, and was amended and updated on June 1, 2000.

The Commandant of the United States Coast Guard (USCG) and the Administrator of the Maritime Administration (MARAD) have operated under delegated authority to coordinate the processing of applications for the issuance, transfer, amendment, or reinstatement of a license for the construction and operation of a deepwater port. 62 FR 11382 (March 12, 1997); 49 CFR 1.46(s) and 1.66(aa). The USCG has the additional statutory responsibility to approve an operations manual for a deepwater port. 33 U.S.C. 1503(e)(1). The USCG retained the statutory and delegated authorities upon its transfer to the Department of Homeland Security (Department of Homeland Security Delegation Number: 0170, § 2. (75), March 3, 2003; Pub. L. 107–296, section 888.). This rule does not change the authorities delegated to USCG and to MARAD nor does it change the coordination between the USCG and MARAD for processing license applications. The rule clarifies that the authorities of USCG and MARAD for processing license applications include the authorities to process an application for a license reinstatement. 33 U.S.C. 1503(b) and (f) (as amended by Pub. L. 98–419, Sept. 25, 1984).

This rule does not change the Secretary's previous delegation of DWPA authority to the Administrator of the Research and Special Programs Administration (RSPA) in 49 CFR 1.53(a)(3) for the establishment, enforcement, and review of regulations concerning the safe construction, operation or maintenance of pipelines on Federal lands and the Outer Continental Shelf (33 U.S.C. 1520).

By **Federal Register** notices dated, respectively, December 27, 2002 (67 FR 79234), and January 23, 2003 (68 FR 3299), the Department of Transportation through the USCG and MARAD gave notice, as required by the DWPA, of applications filed by Port Pelican LLC and El Paso Energy Bridge Gulf of Mexico, LLC for licenses to own, construct, and operate deepwater natural gas port facilities. Since then, MARAD and the USCG have been coordinating the processing of these applications. By this rule, MARAD has the authority over the issuance of the licenses for the respective applicants and for any future applicants.

This amendment to 49 CFR part 1 to reflect the Secretary's delegation of his authority to issue, transfer, amend or reinstate a license for the construction and operation of a deepwater port to the Maritime Administrator relates solely to departmental organization, procedure, and practice. Therefore, notice and comment are unnecessary under 5 U.S.C. 553(b). Further, since the amendment expedites the MARAD's ability to meet the statutory intent of the applicable laws and regulations covered by this delegation, the Secretary finds good cause under 5 U.S.C. 553(d)(3) for the final rule to be effective on the date of publication in the **Federal Register**.

Regulatory Process Matters

Regulatory Assessment

This rulemaking is a nonsignificant regulatory action under section 3(f) of Executive Order 12866 and has not been reviewed by the Office of Management and Budget under that Order. This rule is also not significant under the regulatory policies and procedures of the Department of Transportation, 44 FR 11034.

This rule does not impose unfunded mandates or requirements that will have any impact on the quality of the human environment.

Small Business Impact

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601 *et seq.*, (Act) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by government regulations. The Act requires agencies to review proposed regulations that may have a significant economic impact on a substantial number of small entities. For purposes of this rule, small entities include all small businesses that are potential offerors and contractors bidding on Department of Transportation proposed acquisitions. The Act does not apply to this rulemaking, since a notice of proposed rulemaking was not required. However, the Department certifies that this rule does not have a significant economic impact on a substantial number of small entities. The rule makes administrative changes to 49 CFR Part 1; therefore, a Regulatory Flexibility Analysis has not been performed.

Collection of Information

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

Federalism Assessment

This proposed rule has been reviewed in accordance with the principles and

criteria contained in Executive Order 13132 dated August 4, 1999, and it is determined that this action does not have a substantial direct effect on the States, or the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule will not limit the policymaking discretion of the State nor preempt any State law or regulation.

List of Subjects in 49 CFR Part 1

Authority delegations (Government agencies), Organizations and functions (Government agencies).

■ In consideration of the foregoing, Part 1 of Title 49, Code of Federal Regulations, is amended as follows:

PART 1—[AMENDED]

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

Authority: 49 U.S.C. 322; 46 U.S.C. 2104(a); 28 U.S.C. 2672; 31 U.S.C. 3711(a)(2); Pub. L. 101–552, 104 Stat. 2736; Pub. L. 106–159, 113 Stat. 1748; Pub. L. 107–71, 115 Stat. 597; Pub. L. 107–295.

■ 2. In § 1.44, revise paragraph (o) to read as follows:

§ 1.44 Reservation of authority.

* * * (o) Deepwater ports. Repealed.

* * * * *

■ 3. In § 1.66, redesignate paragraphs (aa)(1) through (6) as paragraphs (aa)(2) through (7). Add a new paragraph (aa)(1) and revise newly designated (aa)(2) to read as follows:

§ 1.66 Delegations to the Maritime Administrator.

* * * * *

(aa) * * *

(1) The authority to issue, transfer, amend, or reinstate a license for the construction and operation of a deepwater port (33 U.S.C. 1503(b)).

(2) The authority to process applications for the issuance, transfer, amendment, or reinstatement of a license for the construction and operation of a deepwater port (33 U.S.C. 1503(b)), as amended, in coordination with the Commandant of the Coast Guard.

* * * * *

Issued in Washington, DC on this 4th day of June, 2003.

Norman Y. Mineta,

Secretary of Transportation.

[FR Doc. 03–15400 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–62–P

Proposed Rules

Federal Register
Vol. 68, No. 117
Wednesday, June 18, 2003

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 Part 1220

[No. LS–02–14]

Amendment to the Soybean Promotion and Research Rules and Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Soybean Promotion and Research Rules and Regulations (Rules and Regulations) established under the Soybean Promotion, Research, and Consumer Information Act (Act) by requiring first purchasers of soybeans and producers marketing processed soybeans or soybean products of a producer's own production in the States or regions of Delaware, Louisiana, South Carolina, Texas, Eastern Region, and the Western Region, to remit and report assessments on a quarterly basis rather than a monthly basis. This proposed change would reduce the administrative costs of monthly reporting imposed on these smaller soybean producing States and regions.

DATES: Written comments must be received by July 18, 2003.

ADDRESSES: Send a copy of your comments to Kenneth R. Payne, Chief; Marketing Programs Branch; Livestock and Seed Program; Agricultural Marketing Service (AMS), USDA, Room 2638–S; STOP 0251; 1400 Independence Avenue, SW.; Washington, DC 20250–0251. Comments may also be sent electronically to *SoybeanComments@usda.gov* or by facsimile at 202/720–1125. All comments should reference the docket number LS–02–14, the date, and the page number of this issue of the **Federal Register**. Comments will be available for public inspection via the Internet at *http://www.ams.usda.gov/lsg/mpb/rp-soy.htm* or between 8 a.m. and 4:30 p.m. Eastern Time, Monday through Friday, except holidays at the above address.

FOR FURTHER INFORMATION CONTACT: Marlene M. Betts, Agricultural Marketing Specialist, Marketing Programs Branch, 202/720–1115.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Office of Management and Budget (OMB) has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposal is not intended to have a retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under § 1971 of the Act, a person subject to the Soybean Promotion and Research Order (Order) may file a petition with the Department of Agriculture (Department) 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 requesting a modification of the Order or an exemption from the Order. The petitioner is afforded the opportunity for a hearing on the petition. After a hearing, the Department would rule on the petition. The Act provides that the district courts of the United States in any district in which such person is an inhabitant, or has their principal place of business, has jurisdiction to review the Department's ruling on the petition, if a complaint for this purpose is filed within 20 days after the date of the entry of the ruling. Further, § 1974 of the Act provides, with certain exceptions, that nothing in the Act may be construed to preempt or supersede any other program relating to soybean promotion, research, consumer information, or industry information organized and operated under the laws of the United States or any State. One exception in the Act concerns assessments collected by Qualified State Soybean Boards (QSSBs). The exception provides that to ensure adequate funding of the operations of QSSBs under the Act, no State law or regulation may limit or have the effect of limiting the full amount of assessments that a QSSB in that State may collect, and which is authorized to be credited under the Act. Another exception concerns certain referenda conducted during specified periods by a State relating to the continuation or termination of a QSSB or State soybean assessment.

Regulatory Flexibility Act

AMS has determined that this proposed rule will not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), because it only revises the remittance of assessments and reports from a monthly basis to a quarterly basis for certain States or regions. The States or regions of Delaware, Louisiana, South Carolina, Texas, Eastern Region, and the Western Region will be changed from monthly remitting States or regions to quarterly remitting States or regions to reduce administrative costs. Because of the minimal number of first purchasers, producers, and total remittances from these States and regions, allowing the States or regions to remit and report assessments on a quarterly basis would benefit QSSBs, the States and regions, and the United Soybean Board (Board) by reducing the administrative costs of remitting and reporting assessments on a monthly basis. The proposed action would likely reduce administrative costs by approximately $10,000. As such, these changes will not have a significant impact on a substantial number of small entities. There are an estimated 30,000 soybean producers who pay assessments and an estimated 150 first purchasers who collect assessments in the four affected States and two regions. There are six QSSBs that would be affected under this proposed rule. Most of these entities would be considered small entities under the criteria established by the Small Business Administration (13 CFR 121.201).

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1990 (44 U.S.C. Chapter 35), the reporting and recordkeeping requirements included in 7 CFR part 1220 were previously approved by OMB and were assigned OMB control number 0581–0093. The purpose of this proposed rule is to change the remitting and reporting of assessments to a quarterly basis from a monthly basis in four soybean producing States and two regions. There

are a minimal number of first purchasers and producers in these four States and two regions. This change would not substantially impact the overall total burden hours. As a result, no change to the previously submitted burden estimate is necessary.

Background and Proposed Changes

The Act (7 U.S.C. 6301–6311) provides for the establishment of a coordinated program of promotion and research designed to strengthen the soybean industry's position in the marketplace, and to maintain and expand domestic and foreign markets and uses for soybeans and soybean products. The program is financed by an assessment of 0.5 of 1 percent of the net market price of soybeans sold by producers. The final Order establishing a soybean promotion, research, and consumer information program was published in the July 9, 1991, issue of the **Federal Register** (56 FR 31043) and assessments began on September 1, 1991.

The Soybean Promotion and Research Rules and Regulations, 7 CFR part 1220, published in the **Federal Register** on July 2, 1992 (57 FR 29436), specify in § 1220.312(b) that first purchasers and producers responsible for remitting assessments shall remit assessments and reports on a monthly or quarterly basis depending upon the State or region in which they are located. This proposed rule would change the States or regions of Delaware, Louisiana, South Carolina, Texas, Eastern Region, and the Western Region from remitting and reporting assessments on a monthly basis to a quarterly basis. Currently, 15 States and 2 regions report on a monthly basis and 14 States report on a quarterly basis.

The Board, in conjunction with the affected States and regions, recommended to AMS to change the period for remitting and reporting assessments for the following States or regions from a monthly basis to quarterly basis: Delaware, Louisiana, South Carolina, Texas, Eastern Region, and the Western Region.

This proposed rule would assist these smaller soybean producing States and regions (listed above) in reporting and remitting their assessments to the Board. The Board has decided that the current requirement to remit and report assessments on a monthly basis is no longer necessary given the minimal number of first purchasers and total remitters from these smaller soybean producing States and regions. Allowing these States and regions to become quarterly remitters would reduce their administrative costs. It is estimated that administrative costs would be reduced by approximately $10,000 if first purchasers of soybeans and producers marketing processed soybeans and soybean products of a producer's own production in the States and regions of Delaware, Louisiana, South Carolina, Texas, the Eastern Region, and the Western Region could remit and report assessments on a quarterly basis. Producers that market soybeans to first purchasers would continue to pay the assessment at the time of settlement. Due to the minimal number of first purchasers and total remittances in these States and regions, allowing the States or regions to remit quarterly would be beneficial to the States, regions, and the Board by reducing the administrative costs of collecting assessments.

A 30-day comment period is provided for interested persons. For the aforementioned reasons, a 30-day comment period is deemed appropriate so that the proposed change, if adopted, can be implemented as soon as possible.

List of Subjects in 7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Soybeans and soybean products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, it is proposed that Title 7, part 1220 be amended as follows:

PART 1220—SOYBEAN PROMOTION, RESEARCH, AND CONSUMER INFORMATION

1. The authority citation for 7 CFR part 1220 continues to read as follows:

Authority: 7 U.S.C. 6301–6311.

2. In § 1220.312, the table in paragraph (b) is revised to read as follows:

* * * * *

(b) * * *

Monthly	Quarterly
Arkansas	Alabama
Iowa	Delaware
Kansas	Florida
Kentucky	Georgia
Michigan	Illinois
Minnesota	Indiana
Missouri	Louisiana
Mississippi	Maryland
North Carolina	North Dakota
Tennessee	Nebraska
Wisconsin	New Jersey
	Ohio
	Oklahoma
	Pennsylvania
	South Carolina
	South Dakota
	Texas
	Virginia
	Eastern Region
	Western Region

* * * * *

Dated: June 12, 2003.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 03–15318 Filed 6–17–03; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–370–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757 Series Airplanes Powered by Pratt & Whitney Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Boeing Model 757 series airplanes, that currently requires modification of the nacelle strut and wing structure. This action would reduce a certain compliance time in the existing AD. The actions specified by the proposed AD are intended to prevent fatigue cracking in primary strut structure and consequent reduced structural integrity of the strut. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–370–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–370–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the

Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, PO Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dennis Stremick, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6450; fax (425) 917–6590.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–370–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–114, Attention: Rules Docket No. 2001–NM–370–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On September 28, 2000, the FAA issued AD 2000–20–09, amendment 39–11920 (65 FR 59703, October 6, 2000), applicable to certain Boeing Model 757 series airplanes, that requires modification of the nacelle strut and wing structure. The requirements of that AD are intended to prevent fatigue cracking in primary strut structure and consequent reduced structural integrity of the strut.

Actions Since Issuance of Previous Rule

Since the issuance of AD 2000–20–09, the airplane manufacturer has done a new structural reassessment of the upper link of the strut of Boeing Model 757 series airplanes powered by Pratt & Whitney engines. This reassessment indicates that certain design changes are needed on the upper link to ensure that fatigue cracking does not occur on the primary strut structure before an airplane reaches its design service objective of 20 years, or 50,000 flight cycles. Analysis indicates that such cracking, if it were to occur, would grow at a much greater rate than originally expected. Fatigue cracking in primary strut structure would result in reduced structural integrity of the strut.

The compliance time for the modification of the upper link (Boeing Service Bulletin 757–54–0036, dated May 14, 1998) required by paragraph (b) of AD 2000–20–09, has been reduced due to this new structural assessment.

Explanation of New Relevant Service Information

We have reviewed and approved Boeing Service Bulletin 757–54–0034, Revision 1, dated October 11, 2001. (Boeing Service Bulletin 757–54–0034, dated May 14, 1998, was referenced as the appropriate source of service information for the actions required by paragraph (a) of AD 2000–20–09.) We find that the changes incorporated in Revision 1 of the service bulletin are not substantive, meaning that airplanes modified per the original issue of the service bulletin are not subject to any additional work under Revision 1 of the service bulletin. Therefore, we have added Revision 1 of the service bulletin as another source of service information for the accomplishment of the modification required by paragraph (a) of this AD.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 2000–20–09 to continue to require modification of the nacelle strut and wing structure. This new action proposes to reduce a certain compliance time in the existing AD. The actions would be required to be accomplished in accordance with the service bulletins described previously, and as discussed below.

Difference Between This Proposed AD and Service Bulletin 757–54–0036

This proposed AD would add a grace period of 2 years to the thresholds recommended in the service bulletin for accomplishment of the modification of the upper link and wire support bracket of the strut, as specified in paragraph (d) of this AD, as follows: Prior to the accumulation of 27,000 total flight cycles (for Model 757–200 series airplanes) or 29,000 total flight cycles (for Model 757–200PF series airplanes), or within 2 years after the effective date of this AD, whichever is later.

Cost Impact

There are approximately 317 airplanes of the affected design in the worldwide fleet. The FAA estimates that 278 airplanes of U.S. registry would be affected by this proposed AD. Since this proposed AD would merely reduce the compliance time for certain actions required by AD 2000–20–09 (Service Bulletin 757–54–0036), it would add no additional costs, and would require no additional work to be performed by affected operators. The current costs associated with AD 2000–20–09 are reiterated in their entirety (as follows) for the convenience of affected operators:

It will take approximately 800 work hours per airplane to accomplish the required modification of the nacelle strut and wing structure described in Boeing Service Bulletin 757–54–0034, at an average labor rate of $60 per work hour. Required parts will be provided at no cost by the airplane manufacturer. Based on these figures, the cost impact of this required modification on U.S. operators is estimated to be $13,344,000, or $48,000 per airplane.

It will take approximately 26 work hours per airplane to accomplish the actions described in Boeing Service Bulletin 757–54–0027, Revision 1, at an average labor rate of $60 per work hour. Required parts will be provided at no cost by the airplane manufacturer.

Based on these figures, the cost impact of these required actions on U.S. operators is estimated to be $433,680, or $1,560 per airplane.

It will take approximately 90 work hours per airplane to accomplish the actions described in Boeing Service Bulletin 757–54–0036, at an average labor rate of $60 per work hour. Required parts will be provided at no cost by the airplane manufacturer. Based on these figures, the cost impact of these required actions on U.S. operators is estimated to be $1,501,200, or $5,400 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 removing amendment 39–11920 (65 FR 59703, October 6, 2000), and by adding a new airworthiness directive (AD), to read as follows:

Boeing: Docket 2001–NM–370–AD. Supersedes AD 2000–20–09, Amendment 39–11920.

Applicability: Model 757 series airplanes powered by Pratt & Whitney engines, line numbers 1 through 735 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 (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, unless accomplished previously.

To prevent fatigue cracking in primary strut structure and consequent reduced structural integrity of the strut, accomplish the following:

Restatement of Requirements of AD 2000–20–09:

Modifications

(a) Modify the nacelle strut and wing structure on both the left and right sides of the airplane, in accordance with Boeing Service Bulletin 757–54–0034, dated May 14, 1998; or Revision 1, dated October 11, 2001; at the later of the times specified in paragraph (a)(1) or (a)(2) of this AD.

(1) Prior to the accumulation of 37,500 total flight cycles, or within 20 years since the date of manufacture, whichever occurs first. Use of the optional threshold formula described in paragraph I.D. of the service bulletin is an acceptable alternative to the 20-year threshold.

(2) Within 3,000 flight cycles after November 13, 2000 (the effective date of AD 2000–20–09, amendment 39–11920).

(b) Except as provided by paragraph (d) of this AD: Prior to or concurrently with the accomplishment of the modification of the nacelle strut and wing structure required by paragraph (a) of this AD; as specified in paragraph I.D., Table I, ''Strut Improvement Bulletins,'' on page 5 of Boeing Service Bulletin 757–54–0034, dated May 14, 1998; accomplish the actions specified in Boeing Service Bulletin 757–54–0027, Revision 1, dated October 27, 1994; and Boeing Service Bulletin 757–54–0036, dated May 14, 1998, as applicable, in accordance with those service bulletins.

Repair

(c) If any damage to airplane structure is found during the accomplishment of the modification required by paragraph (a) of this AD; and the service bulletin specifies to contact Boeing for appropriate action: Prior to further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

New Requirements of this AD:

Modification

(d) Modify the nacelle strut (includes replacing the upper link with a new, improved part and modifying the wire support bracket attached to the upper link) in accordance with Boeing Service Bulletin 757–54–0036, dated May 14, 1998, at the earlier of the times specified in paragraph (d)(1) or (d)(2) of this AD.

(1) Prior to or concurrently with accomplishment of the modification of the nacelle strut and wing structure required by paragraph (a) of this AD.

(2) Prior to the accumulation of 27,000 total flight cycles (for Model 757–200 series airplanes) or 29,000 total flight cycles (for Model 757–200PF series airplanes), or within 2 years after the effective date of this AD, whichever is later.

Alternative Methods of Compliance

(e) 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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

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

Special Flight Permits

(f) 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 June 12, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15336 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–408–AD]

RIN 2120–AA64

Airworthiness Directives; Learjet Model 60 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Learjet Model 60 airplanes, that currently requires inspection to detect bends in or damage to the fuel crossflow tube; inspection to determine clearance between the fuel crossflow tube and the flight control cables; and replacement or repair of the tube, if necessary. This action would require a review of airplane maintenance records or an inspection to determine if a fuel crossflow tube having a certain part number is installed; and follow-on/corrective actions, as applicable. This action also would expand the applicability of the existing AD to include additional airplanes. The actions specified by the proposed AD are intended to prevent chafing and consequent failure of the fuel crossflow tube due to inadequate clearance between the tube and the flight control cables, which could result in loss of fuel from one fuel tank during normal operating conditions or loss of fuel from both main fuel tanks during fuel cross-feeding operations. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–408–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–408–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Learjet, Inc., One Learjet Way, Wichita, Kansas 67209–2942. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Jeffrey Janusz, Aerospace Engineer, Systems and Propulsion Branch, ACE–116W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4148; fax (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications 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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–408–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–114, Attention: Rules Docket No. 2000–NM–408–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On June 28, 1995, the FAA issued airworthiness directive (AD) 95–14–09, amendment 39–9303 (60 FR 36984, July 19, 1995), applicable to certain Learjet 60 airplanes, to require inspection to detect bends in or damage to the fuel crossflow tube; inspection to determine clearance between the fuel crossflow tube and the flight control cables; and replacement or repair of the tube, if necessary. That action was prompted by reports of chafing of the fuel crossflow tube by flight control cables. The requirements of that AD are intended to prevent chafing and consequent failure of the fuel crossflow tube due to inadequate clearance between the tube and the flight control cables, which could result in loss of fuel from one fuel tank during normal operating conditions or loss of fuel from both main fuel tanks during fuel cross-feeding operations.

Actions Since Issuance of Previous Rule

Since the issuance of that AD, the manufacturer has implemented a design change to adequately preclude chafing or bending of the fuel crossflow tube. Although the minimum clearance required by AD 95–14–09 was adequate, there was a possibility that the fuel crossflow tube could be installed incorrectly due to installation variables, including rotation of the fuel crossflow tube. The design change calls for an increased minimum clearance and the installation of a specific part number for the fuel crossflow tube, which can be installed in only one way.

Explanation of New Service Information

The FAA has reviewed and approved Bombardier Learjet 60 Alert Service Bulletin SB A60–28–3, Revision 2, dated October 26, 1998. This service bulletin describes procedures for inspecting the fuel crossflow tube for damage (*e.g.*, chafing and/or bends), measuring the clearance between the

crossflow tube and flight control cables, and correcting incorrect clearance. For certain airplanes, this service bulletin also describes procedures for replacing existing fuel crossflow tubes with new fuel crossflow tubes. This service bulletin also adds certain airplanes to the effectivity listing.

We also have reviewed and approved Bombardier Learjet 60 Service Bulletin SB 60–28–4, Revision 2, dated August 22, 2001. For certain airplanes, this service bulletin describes procedures for replacing existing fuel crossflow tubes with new fuel crossflow tubes, and measuring the clearance between the crossflow tube and flight control cables.

Accomplishment of the actions specified in these service bulletins is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 95–14–09 to require a review of maintenance records or an inspection to determine if a fuel crossflow tube having a certain part number is installed; and follow-on/corrective actions, as applicable. Certain actions would be required to be accomplished in accordance with the service bulletins described previously, except as discussed below.

Differences Between Proposed Rule and Service Bulletins

Operators should note the following differences between the proposed AD and the service bulletins:

- Bombardier Learjet 60 Alert Service Bulletin SB A60–28–3, Revision 2, recommends that the fuel crossflow tube be inspected for bends and evidence of damage (*e.g.*, contact with the flight control cables). It also recommends that the clearance between the fuel crossflow tube and flight control cables be measured to ensure that it is at least 0.150 inch. This proposed AD would not require those inspections because they pertain to the previous airplane design. In lieu of the previously described inspections for bends and evidence of damage, this proposed AD would require a review of the airplane maintenance records or an inspection to determine if a certain part number for the fuel crossflow tube is installed. In addition, the proposed AD would require measurement of the clearance between the fuel crossflow tube and flight control cables to ensure that it is at least 0.35 inch. We have determined that an interval of 25 flight hours (after the effective date of this proposed AD) for accomplishment of the review of the airplane maintenance records/inspection would address the identified unsafe condition in a timely manner.
- Alert Service Bulletin A60–28–3, Revision 2, also recommends a compliance time of 600 flight hours to replace the fuel crossflow tube, if necessary. This proposed AD would extend the compliance time to require replacement of any fuel crossflow tube not having the correct part number, with a new tube having the correct part number, within 90 days after the proposed inspection. In developing an appropriate compliance time for this proposed AD, we considered not only the manufacturer's recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to perform the inspection. In light of all of these factors, the FAA finds a longer compliance time for completing the proposed actions to be warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.
- Bombardier Learjet 60 Service Bulletins SB A60–28–3, Revision 2, and SB 60–28–4, Revision 2, specify that if the correct fuel crossflow tube part number is installed and if the specified minimum clearance does not exist between the fuel crossflow tube and the flight control cables, the manufacturer may be contacted for disposition. This proposed AD would require that correction of any incorrect clearances be accomplished per a method approved by the FAA.

Clarification of Part Number for Installation

Operators should note that, in Bombardier Learjet 60 Alert Service Bulletin SB A60–28–3, Revision 2, the fuel crossflow tube to be installed in the airplane is incorrectly identified as part number (P/N) 6026020–001 in Figure 1, detail D; the correct P/N is 6026020–005. The FAA has been advised that the manufacturer will issue a revision to this alert service bulletin to correct the error.

Changes to the Applicability of the Existing AD

This proposed AD would expand the applicability to include affected airplanes having serial numbers 60–056 through 60–145 inclusive, in addition to serial numbers 60–001 through 60–055 inclusive identified in the existing AD. All of these airplanes are subject to the identified unsafe condition of this AD.

Changes to 14 CFR Part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directive system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance (AMOC). Because we have now included this material in part 39, only the office authorized to approve AMOCs is identified in each individual AD. Therefore paragraph (d) and Note 1 of AD 95–14–09 have not been included in this proposed AD. Paragraph (c) of AD 95–14–09 has been revised to only identify the office authorized to approve AMOCs, and is identified as paragraph (f) in this proposed AD.

Cost Impact

There are approximately 145 Model 60 airplanes of the affected design in the worldwide fleet. The FAA estimates that 109 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 2 work hours per airplane to accomplish the review of airplane maintenance records/inspection proposed in this AD action, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed requirements of this AD on U.S. operators is estimated to be $13,080, or $120 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 removing amendment 39–9303 (60 FR 36984, July 19, 1995), and by adding a new airworthiness directive (AD), to read as follows:

Learjet: Docket 2000–NM–408–AD. Supersedes AD 95–14–09, Amendment 39–9303.

Applicability: Model 60 airplanes, serial numbers 60–001 through 60–145 inclusive, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent chafing and consequent failure of the fuel crossflow tube due to inadequate clearance between the tube and the flight control cables, which could result in loss of fuel from one fuel tank during normal operating conditions or loss of fuel from both main fuel tanks during fuel cross-feeding operations, accomplish the following:

Part Identification

(a) Within 25 flight hours after the effective date of this AD, inspect the fuel crossflow tube to determine whether part number (P/N) 5026020–005 is installed. Instead of inspecting the tube, a review of airplane maintenance records is acceptable if the P/N of the tube can be positively determined from that review.

Clearance Measurement and Corrective Action

(b) For all airplanes: If P/N 6026020–005 is found installed during the review or inspection required by paragraph (a) of this AD, before further flight, measure the clearance between the fuel crossflow tube and the flight control cables to determine if it is at least 0.35 inch, per paragraph 2.B.(8) of the Accomplishment Instructions of Bombardier Learjet 60 Alert Service Bulletin SB A60–28–3, Revision 2, dated October 26, 1998.

(1) If the clearance is 0.35 inch or more, no further action is required by this paragraph.

(2) If the clearance is less than 0.35 inch, before further flight, repair per a method approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA.

Part Replacement, Measurement, and Repair

(c) For airplanes having serial numbers 60–001 through 60–055: If P/N 6026020–005 is not found installed during the review or inspection required by paragraph (a) of this AD, within 90 days after accomplishing the review or inspection, replace the existing fuel crossflow tube with a new fuel crossflow tube having P/N 6026020–005, and measure the clearance between the newly installed fuel crossflow tube and the flight control cables, per paragraph 2.A. of the Accomplishment Instructions of Bombardier Learjet 60 Service Bulletin SB 60–28–4, Revision 2, dated August 22, 2001.

(1) If the clearance is 0.35 inch or more, no further action is required by this paragraph.

(2) If the clearance is less than 0.35 inch, before further flight, repair per a method approved by the Manager, Wichita ACO, FAA.

(d) For airplanes having serial numbers 60–056 through 60–145: If P/N 6026020–005 is not found installed during the review or inspection required by paragraph (a) of this AD, within 90 days after accomplishing the review or inspection, replace the existing fuel crossflow tube with a new fuel crossflow tube having P/N 6026020–005, and measure the clearance between the newly installed fuel crossflow tube and the flight control cables to determine if the clearance is at least 0.35 inch, per paragraph 2.B. of the Accomplishment Instructions of Bombardier Learjet 60 Alert Service Bulletin SB 60–28–3, Revision 2, dated October 26, 1998.

(1) If the clearance is 0.35 inch or more, no further action is required by this paragraph.

(2) If the clearance is less than 0.35 inch, before further flight, repair per a method approved by the Manager, Wichita ACO, FAA.

Note 1: Alert Service Bulletin SB A60–28–3, Revision 2, Figure 1, detail D., incorrectly identifies the fuel crossflow tube to be installed as P/N 6026020–001. The manufacturer is aware of this error and plans to correct the part number in the next revision of the alert service bulletin.

Part Installation

(e) As of the effective date of this AD, only fuel crossflow tubes having P/N 6026020–005 shall be installed on any airplane.

Alternative Methods of Compliance

(f) In accordance with 14 CFR 39.19, the Manager, Wichita ACO, FAA, is authorized to approve alternative methods of compliance for this AD.

Issued in Renton, Washington, on June 12, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15339 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–179–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310 Series 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 all Airbus Model A310 series airplanes. This proposal would require electrical conductivity testing to verify the correct heat treatment of the two half fittings holding the ejection jack for the ram air turbine (RAT). This action is necessary to prevent decreased structural integrity of the two half fittings and loss of the RAT during extension, which could lead to reduced controllability of the airplane in the event of a dual engine failure, or in the event of loss of two or all hydraulic systems. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by July 18, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–179–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2002–NM–179–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tom Groves, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1503; fax (425) 227–1149.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2002–NM–179–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–114, Attention: Rules Docket No. 2002–NM–179–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on all Airbus Model A310 series airplanes. The DGAC advises that an operator reported that the two half fittings holding the ejection jack for the ram air turbine (RAT) were found cracked. Investigation showed that the cracks were due to stress corrosion. Conductivity testing revealed that the heat treatment of the half fittings aluminum alloy was incorrect. Incorrect heat treatment of the half fittings decreased the material behavior against stress corrosion, and was identified as the cause of the cracking. This condition, if not corrected, could result in decreased structural integrity of the half fittings and loss of the RAT during extension, which could lead to reduced controllability of the airplane in the event of a dual engine failure, or in the event of loss of two or all hydraulic systems.

Explanation of Relevant Service Information

Airbus has issued Service Bulletin A310–57A2084, including Appendix 01, dated May 3, 2002, which describes procedures for a one-time electrical conductivity test of the half fittings, to check for the heat treatment status. The service bulletin also describes procedures for a detailed inspection of the half fittings for cracks or corrosion, if necessary. The service bulletin also describes procedures for replacement of the half fittings. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The DGAC classified this service bulletin as mandatory and issued French airworthiness directive 2002–263(B), dated May 15, 2002, in order to ensure the continued airworthiness of these airplanes in France.

FAA's Conclusions

This airplane model is manufactured in France 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, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, 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 accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Differences Between Proposed Rule, the Foreign Airworthiness Directive, and the Service Bulletin

The proposed AD would differ from the parallel French airworthiness directive in that it would require all replacement half fittings to have successfully passed the electrical conductivity test per Airbus Service Bulletin A310–57A2084, including Appendix 01, dated May 3, 2002. Operators should note that the parallel French airworthiness directive requires that replacement half fittings have a certain part number and should either have been ordered after November 2001, or have successfully passed the electrical conductivity test. The FAA does not consider the ''order date'' as sufficient assurance that the replacement half fittings have the correct heat treatment.

Operators should also note that, although the service bulletin specifies reporting to Airbus the result of the inspections and any corrective actions, the proposed AD does not include such a requirement.

Cost Impact

The FAA estimates that 48 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed actions, 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 $2,880, or $60 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. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include

incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Changes to 14 CFR Part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. Because we have now included this material in part 39, only the office authorized to approve AMOCs is identified in each individual AD.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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:

Airbus: Docket 2002–NM–179–AD.

Applicability: All Model A310 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent decreased structural integrity of the two half fittings and loss of the ram air turbine (RAT) during extension, which could lead to reduced controllability of the airplane in the event of a dual engine failure, or in the event of loss of two or all hydraulic systems, accomplish the following:

Service Bulletin References

(a) The following information pertains to the service bulletin referenced in this AD:

(1) The term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of Airbus Service Bulletin A310–57A2084, including Appendix 01, dated May 3, 2002.

(2) Although the service bulletin referenced in this AD specifies to submit information to the manufacturer, this AD does not include such a requirement.

Conductivity Test

(b) Within 600 flight hours after the effective date of this AD, perform a one-time electrical conductivity test of the two half fittings holding the RAT ejection jack, to verify correct heat treatment of the half fittings, per the service bulletin.

(1) If correct heat treatment of the two half fittings is verified, no further action is required by this paragraph.

(2) If incorrect heat treatment of any half fitting is found by the test performed in paragraph (b) of this AD, perform a detailed inspection of the two half fittings for any cracking or corrosion, per the service bulletin.

Note 1: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Corrective Action

(c) For any half fittings that require a detailed inspection per paragraph (b)(2) of this AD: Do the actions specified in paragraph (c)(1) or (c)(2) of this AD, as applicable, per the service bulletin.

(1) If no cracking or corrosion is found: Within one year after the effective date of this AD, replace the two half fittings with half fittings having part number A5721023800000 that have successfully passed the electrical conductivity test, per the service bulletin.

(2) If any cracking or corrosion is found: Before further flight, replace the two half fittings with half fittings having part number A5721023800000 that have successfully passed the electrical conductivity test, per the service bulletin.

Parts Installation

(d) As of the effective date of this AD, no person shall install a half fitting having part number A5721023800000 that has not successfully passed the electrical conductivity test per the service bulletin, on any airplane.

Alternative Methods of Compliance

(e) In accordance with 14 CFR 39.19, the Manager, ANM–116, FAA, is authorized to approve alternative methods of compliance for this AD.

Note 2: The subject of this AD is addressed in French airworthiness directive 2002–263(B), dated May 15, 2002.

Issued in Renton, Washington, on June 12, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15335 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–238–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200F, 747–200C, 747–300, 747SR, and 747SP Series 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 all Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200F, 747–200C, 747–300, 747SR, and 747SP series airplanes. This proposal would require repetitive inspections for discrepancies of the structure near and common to the upper chord and splice fittings of the rear spar of the wing, and repair if necessary. This proposal also would provide for an optional modification that, if accomplished, would terminate the repetitive inspection requirement, but would necessitate eventual post-modification inspections. This action is necessary to find and fix fatigue cracking of structure near and common to the upper chord and splice fittings of the rear spar of the wing, which could result in loss of structural integrity of

the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–238–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–238–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, PO Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tamara Anderson, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6421; fax (425) 917–6590.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–238–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–114, Attention: Rules Docket No. 2001–NM–238–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports indicating that fatigue cracking has been found on the wing on several Boeing Model 747–100 and 747–200B series airplanes. The cracking is adjacent and common to the upper chord and splice fittings of the rear spar of the wing. Such cracking, if not corrected, could result in loss of structural integrity of the airplane.

The subject area on Model 747–100B, 747–100B SUD, 747–200F, 747–200C, 747–300, 747SR, and 747SP series airplanes is similar to that on the affected Model 747–100 and 747–200B series airplanes. Therefore, all of these airplanes may be subject to the same unsafe condition.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, which describes procedures for repetitive inspections for discrepancies of the structure near and common to the upper chord and splice fittings of the rear spar of the wing, and repair if necessary. The inspection procedures include removing existing bolts; performing an ultrasonic or magnetic particle inspection for cracking of removed H–11 bolts; performing a detailed inspection of all other removed bolts for cracking, corrosion, or damage; replacing cracked, corroded, or damaged bolts with new improved bolts; removing any installed repair bushings; performing an open-hole high frequency eddy current (HFEC) inspection for cracking of the bolt holes; installing new bushings if necessary; reinstalling bolts that are not cracked, corroded, or damaged; torquing the nuts; performing a detailed inspection of the shim between the kick fitting and bulkhead strap for cracking or migration; and replacing the shim with a new shim if necessary. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

The service bulletin also describes procedures for an optional modification, which involves removing installed repair bushings, performing an open-hole HFEC inspection for cracking of the bolt holes, repairing any cracking that is found, oversizing bolt holes, and installing new improved bolts. Accomplishment of the optional modification eliminates the need for the repetitive inspections described previously, but necessitates eventual post-modification inspections. The post-modification inspections involve procedures similar to those for the pre-modification inspections, which were described previously.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below under the heading ''Differences Between Proposed Rule and Service Bulletin.''

Clarification of Credit for Actions Accomplished Previously

Flag Note 1 of the logic diagram in Figure 1 of Boeing Alert Service Bulletin 747–57A2314, Revision 1, specifies that, for certain fastener holes on certain airplanes, an inspection per Figure 4, Step 14, of Boeing Service Bulletin 747–57–2110 is considered acceptable for compliance with the initial inspection specified in paragraph (a) of this proposed AD. We have reviewed and approved Boeing Service Bulletin 747–57–2110, Revision 6, dated November 21, 1991; and Revision 7, dated April 23, 1998; and have determined that accomplishment of an initial inspection before the effective date of this AD per Figure 4, Step 14, of one of those revisions of the service bulletin would provide an acceptable level of safety.

We have also reviewed Boeing Service Bulletin 747–57–2110, Revision 3, dated February 19, 1987; Revision 4, dated May 26, 1988; and Revision 5, dated October 26, 1989. We have determined that accomplishment of an initial inspection before the effective date of this AD per Figure 4, Step 9, of one of those revisions of the service bulletin would provide an acceptable level of safety. The first repeat inspection per paragraph (b) of this proposed AD would be required to be accomplished at the applicable interval established in paragraph (b) of this proposed AD after the most recent inspection per Figure 4, Step 14, of Boeing Service Bulletin 747–57–2110, Revision 6 or 7; or Figure 4, Step 9, of Boeing Service Bulletin 747–57–2110, Revision 3, 4, or 5.

Differences Between Proposed Rule and Service Bulletin

Operators should note that, although the service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions, this proposal would require the repair of those conditions to be accomplished per a method approved by the FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

Operators should also note that, although Appendix B of Boeing Alert Service Bulletin 747–57A2314, Revision 1, describes procedures for reporting discrepancies found during an inspection, this proposed AD would not require those actions.

Cost Impact

There are approximately 593 airplanes of the affected design in the worldwide fleet. The FAA estimates that 176 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 8 work hours per airplane to accomplish the proposed inspection, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed inspection on U.S. operators is estimated to be $84,480, or $480 per airplane, per inspection cycle.

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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Should an operator elect to accomplish the optional terminating action that would be provided by this AD action, it would take approximately 22 work hours to accomplish it, at an average labor rate of $60 per work hour. The cost of required parts would be approximately $10,700 per airplane. Based on these figures, the cost impact of the optional terminating action would be approximately $12,020 per airplane.

If the optional terminating action provided by this AD action is accomplished, an eventual post-modification inspection would be necessary. That inspection would take approximately 8 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the post modification inspections would be approximately $480 per airplane, per inspection cycle.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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:

Boeing: Docket 2001–NM–238–AD.

Applicability: All Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200F, 747–200C, 747–300, 747SR, and 747SP series airplanes; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To find and fix fatigue cracking of structure near and common to the upper chord and splice fittings of the rear spar of the wing, which could result in loss of structural integrity of the airplane, accomplish the following:

Initial Inspections

(a) Perform inspections for discrepancies of the structure near and common to the upper chord and splice fittings of the rear spar of the wing, per Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003. The inspection procedures include removing existing bolts; performing an ultrasonic or magnetic particle inspection for cracking of removed H–11 bolts; performing a detailed inspection of all other removed bolts for cracking, corrosion, or damage; replacing cracked, corroded, or damaged bolts with new improved bolts; removing any installed repair bushings; performing an open-hole high frequency eddy current (HFEC) inspection for cracking of the bolt holes; installing new bushings, if necessary; reinstalling bolts that are not cracked, corroded, or damaged; torquing the nuts; performing a detailed inspection of the shim between the kick fitting and bulkhead strap for cracking or migration; and replacing the shim with a new shim if necessary, except as provided by paragraph (h) of this AD. Do the initial inspection at the time specified in paragraph (a)(1) or (a)(2) of this AD, whichever is later.

(1) Inspect at the earlier of the applicable times specified in the ''Flights'' and ''Hours'' columns under the heading ''Initial

Inspection Threshold'' in Table 1 of Figure 1 of the service bulletin. Where the ''Initial Inspection Threshold'' column of Table 1 of Figure 1 of the service bulletin specifies ''flights'' and ''hours,'' for the purposes of this paragraph the numbers in that column are considered to be the airplane's total flight cycles and total flight hours.

(2) Inspect within 18 months after the effective date of this AD.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Repetitive Inspections

(b) Repeat the inspection required by paragraph (a) of this AD at intervals not to exceed the earlier of the times specified in the ''Flights'' and ''Hours'' columns under the heading ''Repeat Inspection Intervals'' in Table 1 of Figure 1 of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, until paragraph (d) of this AD is accomplished. Where the ''Repeat Inspection Intervals'' column of Table 1 of Figure 1 of the service bulletin specifies ''flights'' and ''hours,'' for the purposes of this paragraph, the figures in that column are considered to be the number of flight cycles and flight hours from the time of the most recent inspection per paragraph (a) or (b) of this AD, except as provided by paragraph (g) of this AD.

Repair

(c) If any cracking is found during any inspection required by paragraph (a) or (b) of this AD, before further flight, repair per the Accomplishment Instructions of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, except as provided by paragraph (h) of this AD.

Optional Modification

(d) Accomplishment of the modification specified in Part 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, constitutes terminating action for the initial inspections required by paragraph (a) of this AD and the repetitive inspections required by paragraph (b) of this AD, provided that the repetitive post-modification inspections required by paragraph (e) of this AD are initiated at the applicable time. The modification procedures include removing installed repair bushings, performing an open-hole HFEC inspection for cracking of the bolt holes, repairing any cracking that is found, oversizing bolt holes, and installing new improved bolts.

Post-Modification Inspections

(e) For airplanes on which the optional modification specified in paragraph (d) of this AD is accomplished: At the earlier of the times specified in the ''Flights'' and ''Hours'' columns under the heading ''Post Modification Threshold'' in Table 2 of Figure 1 of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, perform a post-modification inspection per Part 5 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003. The inspection procedures include removing existing bolts; performing a detailed inspection of removed bolts for cracking, corrosion, or damage; replacing cracked, corroded, or damaged bolts with new bolts; removing any installed repair bushings; performing an open-hole HFEC inspection for cracking of the bolt holes; installing new bushings if necessary; reinstalling bolts that are not cracked, corroded, or damaged; torquing the nuts; performing a detailed inspection of the shim between the kick fitting and bulkhead strap for cracking or migration; and replacing the shim with a new shim if necessary; except as provided by paragraph (h) of this AD. Where the ''Post Modification Inspection Threshold'' column of Table 2 of Figure 1 of the service bulletin specifies ''flights'' and ''hours,'' for the purposes of this paragraph, the numbers in that column are considered to be the flight cycles and flight hours after accomplishment of the modification specified in paragraph (d) of this AD.

(1) Repeat the inspection at intervals not to exceed the earlier of the times specified in the ''Flights'' and ''Hours'' columns under the heading ''Post Modification Repeat Inspection Intervals'' in Table 2 of Figure 1 of the service bulletin. Where the ''Post Modification Repeat Inspection Intervals'' column of Table 2 of Figure 1 of the service bulletin specifies ''flights'' and ''hours,'' for the purposes of this paragraph, the numbers in that column are considered to be the flight cycles and flight hours since the most recent inspection per paragraph (e) or (e)(1) of this AD.

(2) If any cracking is found during any inspection required by paragraph (e) or (e)(1) of this AD, before further flight, repair per the Accomplishment Instructions of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, except as provided by paragraph (h) of this AD.

Actions Accomplished Per Previous Issue of Service Bulletin

(f) Inspections, repairs, or modifications accomplished before the effective date of this AD per Boeing Alert Service Bulletin 747–57A2314, including Appendix A and B, dated June 28, 2001, are considered acceptable for compliance with the corresponding action specified in this AD, except as provided by paragraph (h) of this AD.

(g) As specified in Flag Note 1 of the logic diagram in Figure 1 of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003: An inspection accomplished before the effective date of this AD per Figure 4, Step 14, of Boeing Service Bulletin 747–57–2110, Revision 6, dated November 21, 1991; or Revision 7, dated April 23, 1998; is considered acceptable, as applicable, for compliance with the initial inspection required by paragraph (a) of this AD. An inspection accomplished before the effective date of this AD per Figure 4, Step 9, of Boeing Service Bulletin 747–57–2110, Revision 3, dated February 19, 1987; Revision 4, dated May 26, 1988; and Revision 5, dated October 26, 1989; is also considered acceptable, as applicable, for compliance with the initial inspection required by paragraph (a) of this AD. The first repeat inspection per paragraph (b) of this AD must be accomplished at the applicable interval established in paragraph (b) of this AD after the most recent inspection per Figure 4, Step 14, of Boeing Service Bulletin 747–57–2110, Revision 6 or 7; or Figure 4, Step 9, of Boeing Service Bulletin 747–57–2110, Revision 3, 4, or 5.

Exception to Instructions in Service Bulletin

(h) Where Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, specifies to contact Boeing for appropriate action, before further flight, repair per a method approved by the Manager, Seattle ACO, or per data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

(i) Although Appendix B of Boeing Alert Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, refers to a reporting requirement, such reporting is not required by this AD.

Parts Installation

(j) Except as provided by paragraphs (a) and (b) of this AD, as of the effective date of this AD, no person may install any alloy steel bolt in any location specified in this AD on any airplane listed in the applicability of this AD.

Alternative Methods of Compliance

(k) 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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(l) 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 June 11, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15324 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–181–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–200F and –200C Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to all Boeing Model 747–200F and –200C series airplanes, that currently requires repetitive detailed inspections or a one-time open-hole high frequency eddy current inspection to detect cracking of certain areas of the upper deck floor beams, and corrective actions if necessary. This action would add new one-time inspections for cracking of the web, upper chord, and strap of the upper deck floor beams. This action also would add a requirement to modify or repair the upper deck floor beams, as applicable, which would eventually necessitate accomplishment of new repetitive inspections for cracking of the upper deck floor beams. This action is necessary to prevent fatigue cracks in the upper chord and web of upper deck floor beams and the resultant failure of such floor beams. Failure of a floor beam could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of the airplane. This action is intended to address the identified unsafe conditions.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–181–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–181–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, PO Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Rick Kawaguchi, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6434; fax (425) 917–6590.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–181–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–114, Attention: Rules Docket No. 2001–NM–181–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On April 20, 1998, the FAA issued AD 98–09–17, amendment 39–10498 (63 FR 20311, April 24, 1998), applicable to all Boeing Model 747–200F and –200C series airplanes, to require repetitive inspections or a one-time inspection to detect cracking of certain areas of the upper deck floor beams, and corrective actions if necessary. That action was prompted by reports indicating that fatigue cracks were found in the upper chord and web of upper deck floor beams. The requirements of that AD are intended to prevent such fatigue cracking and the resultant failure of such floor beams. Failure of the floor beam could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of the airplane.

In the preamble to AD 98–09–17, we specify that the actions required by that AD are considered ''interim action'' and that the manufacturer was developing a preventive modification to address the unsafe condition. We indicated that we might consider further rulemaking action once the modification was developed, approved, and available. Though the manufacturer now has developed such a modification, we have determined that it does not provide an adequate level of safety, as explained below under the heading ''Differences Between Proposed AD and Service Bulletins.'' However, considering the nature of the identified unsafe condition, we have determined that it is necessary to proceed with rulemaking action at this time to ensure the continued operating safety of the affected airplane fleet. This proposed AD follows from that determination.

Explanation of Relevant Service Information

We have reviewed and approved Boeing Alert Service Bulletin 747–53A2429, dated March 22, 2001. That

service bulletin describes procedures for a one-time detailed inspection for cracking of the web, upper chord, and strap of certain upper deck floor beams; and an open-hole high frequency eddy current (HFEC) inspection for cracking of the fastener holes of the web and upper chord. The service bulletin also describes procedures for modifying the upper chord of the upper deck floor beams, if no cracking is found, and for installing a permanent repair if cracking is found. The service bulletin recommends new repetitive open-hole HFEC or surface HFEC inspections of the upper deck floor beams following such modification or permanent repair. However, the service bulletin does not contain instructions for such inspections.

We also have reviewed and approved Boeing Service Bulletin 747–53A2420, Revision 1, dated January 7, 1999. (AD 98–09–17 refers to Boeing Alert Service Bulletin 747–53A2420, dated March 26, 1998, as the appropriate source of service information for the inspections required by that AD.) In addition to procedures for inspections of the entire area subject to inspections per AD 98–09–17, Boeing Service Bulletin 747–53A2420, Revision 1, describes procedures for time-limited repairs of certain crack configurations in the upper deck floor beams. These time-limited repairs involve removing the existing strap; performing HFEC inspections of the chord, web, and angle, as applicable; stop-drilling cracks; trimming the angle and machining the vertical leg of the chord, if necessary; and installing a new strap.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 98–09–17 to continue to require repetitive detailed inspections or a one-time open-hole HFEC inspection to detect cracking of certain areas of the upper deck floor beams, and corrective actions if necessary. The proposed AD would add a requirement for new one-time detailed and open-hole HFEC inspections for cracking of the web, upper chord, and strap of upper deck floor beams. The proposed AD also would require modification or permanent repair of the upper deck floor beams, as applicable, which would eventually necessitate new repetitive open-hole HFEC or surface HFEC inspections for cracking of the upper deck floor beams. The actions would be required to be accomplished in accordance with Boeing Alert Service Bulletin 747–53A2429 and Boeing Service Bulletin 747–53A2420, Revision 1, except as discussed below.

Differences Between Proposed AD and Service Bulletins

Operators should note that, although Boeing Service Bulletin 747–53A2420, Revision 1, specifies that the manufacturer may be contacted for disposition of certain repair conditions, this proposed AD would require the repair of those conditions to be accomplished in accordance with a method that we have approved, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who we have authorized to make such findings.

Operators should note that, although Boeing Alert Service Bulletin 747–53A2429 provides specific instructions for modifying the upper chord of the upper deck floor beams or installing a permanent repair, this proposed AD would require a modification or permanent repair be accomplished in accordance with a method that we have approved, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who we have authorized to make such findings. We have determined that the modification and permanent repair procedures specified in Boeing Alert Service Bulletin 747–53A2429 do not provide an adequate level of safety. This determination is based on two reports that we recently received, which indicate that cracks have been found on airplanes that had a modification similar to that specified in Boeing Alert Service Bulletin 747–53A2429. Boeing concurs with our determination and intends to revise that service bulletin in the future to include new modification and permanent repair procedures. Once we have reviewed the revised service bulletin, we may consider approving it as an alternative method of compliance to allow the modification or permanent repair to be accomplished per that service bulletin.

Explanation of Change Made To Existing Requirements

We have changed all references to a ''detailed visual inspection'' in the existing AD to ''detailed inspection'' in this action. Note 3 of this proposed AD defines such an inspection.

Cost Impact

There are approximately 81 airplanes of the affected design in the worldwide fleet. We estimate that 23 airplanes of U.S. registry would be affected by this proposed AD.

For airplanes on which the repetitive detailed inspection that is currently required by AD 98–09–17 is accomplished, that inspection takes approximately 1 work hour per airplane, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required detailed inspection is estimated to be $60 per airplane, per inspection cycle.

The HFEC inspection that is currently required by AD 98–09–17 takes approximately 6 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $8,280, or $360 per airplane.

The new one-time detailed and HFEC inspections that are proposed in this AD action would take approximately 7 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the new proposed inspection on U.S. operators is estimated to be $9,660, or $420 per airplane.

For airplanes subject to the modification that is proposed in this AD action, it would take approximately 172 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $4,959 per airplane. Based on these figures, the cost impact of the proposed modification is estimated to be $15,279 per airplane.

For airplanes subject to the repair that is proposed in this AD action, it would take approximately 172 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $21,646 to $21,857 per airplane. Based on these figures, the cost impact of the proposed repair is estimated to be $31,966 to $32,177 per airplane.

The follow-on repetitive inspections that are proposed in this AD action would take approximately 6 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the new proposed follow-on inspections on U.S. operators is estimated to be $8,280, or $360 per airplane, per inspection cycle.

The cost impact figures discussed above are 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 proposed AD were not adopted. The cost impact figures discussed in AD

rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 removing amendment 39–10498 (63 FR 20311, April 24, 1998), and by adding a new airworthiness directive (AD), to read as follows:

Boeing: Docket 2001–NM–181–AD. Supersedes AD 98–09–17, Amendment 39–10498.

Applicability: All Model 747–200F and –200C series airplanes, 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 (l)(1) 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 reduced controllability of the airplane and/or rapid decompression of the airplane due to fatigue cracking in the upper deck floor beams, accomplish the following:

Requirements of AD 98–09–17

Note 2: For the purposes of calculating the compliance threshold and repetitive interval for the actions required by paragraphs (a) and (b) of this AD, ''flight cycles'' are considered to be flight cycles with a cabin pressure differential greater than 2.0 pounds per square inch (psi).

Repetitive Inspections of Certain Upper Deck Floor Beams

(a) For airplanes that have accumulated less than 18,000 total flight cycles as of May 11, 1998 (the effective date of AD 98–09–17, amendment 39–10498): Prior to the accumulation of 15,000 total flight cycles, or within 250 flight cycles after May 11, 1998, whichever occurs later, inspect the upper chord, web, and strap of the upper deck floor beams at body station (BS) 340 through BS 440 inclusive, and the upper deck floor beams at BS 500 and BS 520, on the right and left sides of the airplane, in accordance with paragraph (a)(1) or (a)(2) of this AD. The inspections shall be accomplished in accordance with Boeing Alert Service Bulletin 747–53A2420, dated March 26, 1998; or Boeing Service Bulletin 747–53A2420, Revision 1, dated January 7, 1999.

(1) Perform a detailed inspection to detect cracks in accordance with Figure 2 of the service bulletin.

(i) Repeat the detailed inspection thereafter at intervals not to exceed 25 flight cycles, until the requirements of paragraph (a)(1)(ii) or (e) of this AD are accomplished.

(ii) Within 500 flight cycles after accomplishment of the initial detailed inspection, accomplish paragraph (a)(2) of this AD.

(2) Perform a one-time open hole high frequency eddy current (HFEC) inspection to detect cracks in accordance with Figure 3 of the service bulletin. Accomplishment of this action constitutes terminating action for the repetitive inspection requirements of paragraph (a)(1)(i) of this AD.

(b) For airplanes that have accumulated 18,000 or more total flight cycles as of May 11, 1998: Within 25 flight cycles after May 11, 1998, inspect the upper chord, web, and strap of the upper deck floor beams at BS 340 through BS 440 inclusive, and the upper deck floor beams at BS 500 and BS 520, on the right and left sides of the airplane, in accordance with paragraph (b)(1) or (b)(2) of this AD. The inspections shall be accomplished in accordance with Boeing Alert Service Bulletin 747–53A2420, dated March 26, 1998; or Boeing Service Bulletin 747–53A2420, Revision 1, dated January 7, 1999.

(1) Perform a detailed inspection to detect cracks in accordance with Figure 2 of the service bulletin.

(i) Repeat the detailed inspection thereafter at intervals not to exceed 25 flight cycles, until the requirements of paragraph (b)(1)(ii) or (e) of this AD are accomplished.

(ii) Within 250 flight cycles after accomplishment of the initial detailed inspection, accomplish paragraph (b)(2) of this AD.

(2) Perform a one-time open hole HFEC inspection to detect cracks in accordance with Figure 3 of the service bulletin. Accomplishment of this action constitutes terminating action for the repetitive inspection requirements of paragraph (b)(1)(i) of this AD.

Repair

(c) If any cracking is found during any inspection required by paragraphs (a) or (b) of this AD, prior to further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA.

New Requirements of this AD

Note 3: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Adjustments to Compliance Time: Cabin Differential Pressure

(d) For the purposes of calculating the compliance threshold and repetitive interval for the actions required by paragraphs (e), (h), (i), and (j) of this AD: The number of flight cycles in which cabin differential pressure is at 2.0 psi or less need not be counted when determining the number of flight cycles that have occurred on the airplane, provided that flight cycles with momentary spikes in cabin differential pressure above 2.0 psi are included as full pressure cycles. For this provision to apply, all cabin pressure records must be maintained for each airplane: No fleet-averaging of cabin pressure is allowed.

Detailed and Eddy Current Inspections of Certain Upper Deck Floor Beams

(e) Within 5,000 flight cycles after accomplishing the most recent inspection required by paragraph (a) or (b) of this AD, or within 1,000 flight cycles after the effective date of this AD, whichever is later: Do paragraphs (e)(1) and (e)(2) of this AD, in

accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2429, dated March 22, 2001. Accomplishment of both paragraphs (e)(1) and (e)(2) of this AD constitutes terminating action for the repetitive inspection requirement of paragraph (a)(1)(i) or (b)(1)(i) of this AD, as applicable.

(1) Do a one-time detailed inspection for cracking of the web, upper chord, and strap of the upper deck floor beams at BS 340 through BS 440 inclusive, BS 500, and BS 520, on the right and left sides of the airplane, as specified in Figure 1 of the service bulletin.

(2) Do an open-hole high frequency eddy current inspection for cracking of the fastener holes of the web and upper chord of the upper deck floor beams at BS 340 through BS 440 inclusive, BS 500, and BS 520, on the right and left sides of the airplane, as specified in Figure 2 of the service bulletin.

Compliance With Paragraphs (a) or (b) and (e)

(f) Airplanes on which the inspections required by paragraph (e) of this AD are accomplished within the compliance time specified in paragraph (a) or (b) of this AD, as applicable, are not required to be inspected in accordance with paragraph (a) or (b) of this AD, as applicable.

Modification of Upper Deck Floor Beams

Note 4: The modification procedures specified in Boeing Alert Service Bulletin 747–53A2429, dated March 22, 2001, do not provide an adequate level of safety and are not acceptable for compliance with paragraph (g) of this AD. Figure 3 of the service bulletin is used only for identifying the floor beams.

(g) If no cracking is found during the inspections required by paragraph (e) of this AD, before further flight, except as provided by paragraph (i) of this AD, modify the upper chord of the upper deck floor beams at the locations in Figure 3 of Boeing Alert Service Bulletin 747–53A2429, dated March 22, 2001, in accordance with a method approved by the Manager, Seattle ACO, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a modification method to be approved, the approval must specifically reference this AD.

Repair of Upper Deck Floor Beams

(h) If any crack is found during either inspection required by paragraph (e) of this AD: Before further flight, except as provided by paragraph (i) of this AD, do paragraph (h)(1) or (h)(2) of this AD.

(1) Accomplish all actions associated with the time-limited repair, including removing the existing strap; performing HFEC inspections of the chord, web, and angle, as applicable; stop-drilling cracks; trimming the angle and machining the vertical leg of the chord, as applicable; and installing a new strap. Do these actions in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–53A2420, Revision 1, dated January 7, 1999; except, where the service bulletin specifies to contact Boeing for appropriate action, before further flight, repair in accordance with a method approved by the Manager, Seattle ACO, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD. Within 1,500 flight cycles or 18 months after the installation of the time-limited repair, whichever is first, do paragraph (h)(2) of this AD.

(2) Accomplish the permanent repair of the upper deck floor beams at the locations shown in Figures 4 and 5, as applicable, of Boeing Alert Service Bulletin 747–53A2429, dated March 22, 2001, in accordance with a method approved by the Manager, Seattle ACO, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically refer to this AD.

Note 5: The permanent repair procedures specified in Boeing Alert Service Bulletin 747–53A2429, dated March 22, 2001, do not provide an adequate level of safety and are not acceptable for compliance with paragraph (h)(2) of this AD.

Airplanes Modified or Repaired Previously

(i) For airplanes on which a repair per paragraph (c) of this AD or the modification or permanent repair specified in Boeing Alert Service Bulletin 747–53A2429, dated March 22, 2001, was accomplished before the effective date of this AD: Within 5,000 flight cycles after installation of such modification or repair, as applicable, inspect per paragraph (e) of this AD, then do paragraph (g) or (h) of this AD, as applicable.

Repetitive Inspections After Modification or Permanent Repair

(j) Within 15,000 flight cycles after installation of the modification or permanent repair in accordance with paragraph (g) or (h) of this AD, as applicable, do paragraph (j)(1) or (j)(2) of this AD, in accordance with a method approved by the Manager, Seattle ACO. For an inspection method to be approved, the approval letter must specifically reference this AD.

(1) *Option 1*: Do surface HFEC inspections along the lower edge of the upper chord of the upper deck floor beams at BS 340 through BS 440 inclusive, BS 500, and BS 520, on the right and left sides of the airplane. Repeat the surface HFEC inspections at intervals not to exceed 1,000 flight cycles.

(2) *Option 2*: Do open-hole HFEC inspections for cracking at fasteners common to the upper chord, reinforcement straps, and body frame of the upper deck floor beams at BS 340 through BS 440 inclusive, BS 500, and BS 520, on the right and left sides of the airplane. Repeat the open-hole HFEC inspections at intervals not to exceed 3,000 flight cycles.

Repair

(k) If any cracking is found during any inspection required by paragraph (j)(1) or (j)(2) of this AD: Before further flight, repair in accordance with a method approved by the Manager, Seattle ACO, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically refer to this AD.

Alternative Methods of Compliance

(l)(1) 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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

(2) Alternative methods of compliance, approved previously in accordance with AD 98–09–17, amendment 39–10498, are approved as alternative methods of compliance with paragraphs (a), (b), and (c) of this AD.

Note 6: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(m) 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 June 11, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15325 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–328–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) 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 & 440) airplanes. This proposal would require installing new vent tube assemblies for the main fuel tanks; and, on certain airplanes, inspecting to measure the clearance between the vent system tubing and the applicable wing ribs, and corrective action if necessary. This action is necessary to prevent a fire hazard due to fuel spillage. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by July 18, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–328–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9–anm–nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–328–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, 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, 10 Fifth Street, Third Floor, Valley Stream, New York.

FOR FURTHER INFORMATION CONTACT: James Delisio, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7521; 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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–328–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–114, Attention: Rules Docket No. 2001–NM–328–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

Transport Canada Civil Aviation (TCCA), 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 & 440) series airplanes. TCCA advises that fuel can enter the vent line system of the main tank and get trapped. During refueling, or ground and flight maneuvers, the fuel may spill from certain scoops onto the ground, run along the lower wing skin, accumulate in the dry bay, and possibly drip onto the main landing gear and brakes. This fuel spillage, if not corrected, could result in a fire hazard.

Explanation of Relevant Service Information

Bombardier has issued Service Bulletin 601R–28–024, Revision 'A', dated November 11, 1998, which describes procedures for installing new vent tube assemblies for the main fuel tanks to prevent fuel escaping from the tank vent lines and spilling. The service bulletin also describes procedures for inspecting certain airplanes to measure the clearance between the vent system tubing and the applicable wing ribs, and installing bracket assemblies on those airplanes to provide the proper clearance, if necessary. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. TCCA classified this service bulletin as mandatory and issued Canadian airworthiness directive CF–2001–31, dated August 7, 2001, to ensure 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, TCCA has kept the FAA informed of the situation described above. The FAA has examined the findings of TCCA, 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 accomplishment of the actions specified in the service bulletin described previously.

Changes to 14 CFR part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. Because we have now included this material in part 39, only the office authorized to approve AMOCs is identified in each individual AD.

Cost Impact

The FAA estimates that the proposed installation would be required to be accomplished on 45 Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes of U.S. registry, that it would take approximately 15 work hours per airplane to accomplish the proposed installation, and that the average labor rate is $60 per work hour. Required parts would cost approximately $10,273 per airplane. Based on these figures, the cost impact of the proposed installation on U.S. operators is estimated to be $502,785, or $11,173 per airplane.

The FAA estimates that the proposed inspection would be required to be accomplished on 43 Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes of U.S. registry, that it would take approximately 1 work hour 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 inspection on U.S. operators is estimated to be $2,580, or $60 per airplane.

The cost impact figures discussed above are 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. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 2001–NM–328–AD.

Applicability: Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes having serial numbers 7003 through 7067 inclusive and 7069 through 7109 inclusive, certificated in any category; excluding those airplanes on which the actions specified in Bombardier Service Bulletin 601R–28–024, dated May 21,1996, have been accomplished. (This applicability includes airplanes informally identified as ''Series 200.'')

Compliance: Required as indicated, unless accomplished previously.

To prevent a fire hazard due to fuel spillage, accomplish the following:

Installation

(a) Within 180 days after the effective date of this AD, install new vent tube assemblies for the main fuel tanks, per Part A of paragraph 2.B. of the Accomplishment Instructions of Bombardier Service Bulletin 601R–28–024, Revision 'A', dated November 11, 1998.

Inspection and Corrective Action

(b) For airplanes having serial numbers 7003 through 7035 inclusive, and 7048 through 7057 inclusive: Before further flight after installing the vent tube assemblies as required by paragraph (a) of this AD, perform a general visual inspection to measure the clearance between the vent system tubing and the applicable wing rib, per Part B of paragraph 2.B. of the Accomplishment Instructions of Bombardier Service Bulletin 601R–28–024, Revision 'A', dated November 11, 1998.

Note 1: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(1) If the clearance between the vent system tubing and the applicable wing rib is 0.125 inch or more, no further action is required by this paragraph.

(2) If the clearance between the vent system tubing and the applicable wing rib is less than 0.125 inch, prior to further flight, install the bracket assemblies in accordance with paragraphs B.(8) through B.(10) of the Accomplishment Instructions of the service bulletin.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, New York Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

Note 2: The subject of this AD is addressed in Canadian airworthiness directive CF–2001–31, dated August 7, 2001.

Issued in Renton, Washington, on June 11, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15326 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–246–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–200, –200C, –300, –400, and –500 Series 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 Boeing Model 737–200, –200C, –300, –400, and –500 series airplanes. This proposal would require repetitive inspections to find fatigue cracking of certain upper and lower skin panels of the fuselage, and follow-on and corrective actions, if necessary. This proposal also includes terminating action for the repetitive inspections of

certain modified or repaired areas only. This action is necessary to find and fix fatigue cracking of the skin panels, which could result in sudden fracture and failure of the skin panels of the fuselage, and consequent rapid decompression of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–246–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–246–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, PO Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Duong Tran, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6452; fax (425) 917–6590.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–246–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–114, Attention: Rules Docket No. 2001–NM–246–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports indicating that cracks were found along the edges of the chem-milled pockets in the upper skin at stringer S–12, and above the S–4, S–10, and S–14 lap joints, on several Boeing Model 737 series airplanes. The cracks were up to 6 inches long and multiple adjacent bays were found to be cracked along the same stringers on three of the airplanes. The airplanes had accumulated between 34,574 and 56,949 total flight cycles. Additionally, skin cracks up to 4 inches long located below the S–14 lap joint along the bonded skin doublers were reported on 25 other airplanes which had accumulated between 22,786 and 80,113 total flight cycles.

Analysis by the manufacturer revealed that these cracks are caused by fatigue due to high bending stresses at the edge of chem-milled pockets or bonded skin doublers. Such fatigue cracking could result in sudden fracture and failure of the skin panels of the fuselage, and consequent rapid decompression of the airplane.

Related Rulemaking

This proposed AD is related to AD 2002–07–08, amendment 39–12702 (67 FR 17917, April 12, 2002). That AD references Boeing Service Bulletin 737–53A1177, Revision 6, dated May 31, 2001, as the appropriate source of service information for accomplishment of the specified actions. (The AD also referenced, for accomplishment of certain actions, Boeing Alert Service Bulletin 737–53A1177, Revision 1, dated September 19, 1996; Revision 2, dated July 24, 1997; Revision 3, dated September 18, 1997; Revision 4, dated September 2, 1999; and Revision 5, dated February 15, 2001.) That AD is applicable to certain Boeing Model 737 series airplanes and requires repetitive inspections to find cracking of the lower skin at the lower row of fasteners in the lap joints of the fuselage, and repair of any cracking found. That AD also requires modification of the fuselage lap joints at certain locations, which constitutes terminating action for repetitive inspections of the modified areas. Additionally, that AD requires replacement of a preventive modification with an improved modification.

Explanation of Relevant Service Information

We have reviewed and approved Boeing Alert Service Bulletin 737–53A1210, Revision 1, including Appendix A and Evaluation Form, dated October 25, 2001. The service bulletin describes procedures for repetitive external detailed and eddy current inspections to find fatigue cracking of the upper and lower skin panels of the fuselage (crown area and lower lobe area) at stringer S–12, and above the S–4, S–10, and S–14 lap joints, and repair of any cracking with either a permanent or time-limited repair.

For airplanes on which a time-limited repair is done, Part 4 of the service bulletin describes procedures for a subsequent permanent repair within 10,000 flight cycles after installation of the time-limited repair. Doing a permanent repair eliminates the need for the repetitive inspections for the repaired area only.

For Group 3, 5, 6, and 8 airplanes only, on which no cracking is found, Part 5 of the service bulletin provides procedures for a preventive modification of the chem-milled pockets in the upper skins at stringer S–12, between body station (BS) 500D and BS 520, which would end the repetitive inspections for the modified area only.

The service bulletin also describes procedures for repetitive follow-on visual inspections for cracking of the lower lobe skins from S–15L to S–15R between stations 360 and 1016 and in section 41; replacement of any loose fasteners with new fasteners; an internal eddy current inspection of the skin, tear straps, and lap joint in each adjacent bay for cracking; and repair of any cracking found.

Accomplishment of the actions specified in Service Bulletin 737–53A1210, Revision 1, is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Differences Between Proposed AD and Service Bulletin 737–53A1210, Revision 1

The service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions, but this proposed AD would require the repair of those conditions to be done per a method approved by the FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

The service bulletin recommends that, after installation of a time-limited repair, an internal eddy current inspection should be done at the first ''C–check'' or within 4,000 flight cycles, whichever is last. Because ''C–check'' schedules vary among operators, such a nonspecific interval would provide no assurance that operators would do the inspection within the prescribed schedule. This proposed AD would require that the inspection be done within 4,000 flight cycles after the repair installation. We find that a 4,000-flight-cycle interval is appropriate for affected airplanes to continue to operate without compromising safety.

Although the service bulletin recommends that operators report inspection results to the manufacturer, this proposed AD does not contain such a reporting requirement.

Interim Action

This is considered to be interim action for Group 7 airplanes. Although the service bulletin described previously does not include the inspection of the crown area (upper lobe) for Group 7 airplanes, as specified in paragraph (a) of this proposed AD, the manufacturer has advised that it currently is developing a new service bulletin to address those airplanes. Once the FAA has reviewed and approved the service bulletin, we may consider additional rulemaking to mandate those inspections.

Cost Impact

There are approximately 2,200 airplanes of the affected design in the worldwide fleet. The FAA estimates that 903 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 94 work hours per airplane to accomplish the proposed inspections of the crown area, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of these proposed inspections on U.S. operators is estimated to be $5,092,920, or $5,640 per airplane, per inspection cycle.

It would take approximately 96 work hours per airplane to accomplish the proposed inspections of the lower lobe area, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of these proposed inspections on U.S. operators is estimated to be $5,201,280, or $5,760 per airplane, per inspection cycle.

The cost impact figures discussed above are 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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Should an operator elect to install the preventive modification, it would take approximately 108 work hours to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the preventive modification is estimated to be $6,480 per airplane.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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:

Boeing: Docket 2001–NM–246–AD.

Applicability: Model 737–200, –200C, –300, –400, and –500 series airplanes, as listed in Boeing Alert Service Bulletin 737–53A1210, Revision 1, dated October 25, 2001; 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 (g) 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 find and fix fatigue cracking of certain upper and lower skin panels of the fuselage, which could result in sudden fracture and failure of the skin panels and consequent rapid decompression of the airplane, accomplish the following:

External Detailed and Eddy Current Inspections

(a) For Groups 1 through 6 and Group 8 airplanes: Before the accumulation of 35,000 total flight cycles, or within 4,500 flight cycles after the effective date of this AD, whichever is later, do external detailed and eddy current inspections of the crown area skin panels of the fuselage for cracking, per Part 1 and Figure 1 of the Work Instructions of Boeing Alert Service Bulletin 737–53A1210, Revision 1, including Appendix A and excluding Evaluation Form, dated October 25, 2001. Repeat the inspections at least every 4,500 flight cycles until paragraph (c) or (d)(1)(ii) of this AD has been done, as applicable. Although paragraph 1.D. of the service bulletin references a reporting requirement, such reporting is not required by this AD.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

(b) For all airplanes: Before the accumulation of 40,000 total flight cycles, or within 4,500 flight cycles after the effective date of this AD, whichever is later, do an external detailed inspection of the lower lobe area and section 41 of the fuselage for cracking, per Part 2 and Figure 2 of the Work Instructions of Boeing Alert Service Bulletin 737–53A1210, Revision 1, including Appendix A and excluding Evaluation Form, dated October 25, 2001. Repeat the inspection at least every 9,000 flight cycles until paragraph (d)(2) of this AD has been done, as applicable.

Preventive Modification

(c) For Groups 3, 5, 6, and 8 airplanes: If no cracking is found during any inspection required by paragraph (a) of this AD, doing the preventive modification of the chem-milled pockets in the upper skin as specified in Part 5 of the Work Instructions of Boeing Alert Service Bulletin 737–53A1210, Revision 1, including Appendix A and excluding Evaluation Form, dated October 25, 2001, ends the repetitive inspections for the modified area only.

Corrective Actions

(d) If any cracking is found during any inspection required by paragraph (a) or (b) of this AD, before further flight, do the actions specified in paragraphs (d)(1) and (d)(2) of this AD, as applicable, per the Work Instructions of Boeing Alert Service Bulletin 737–53A1210, Revision 1, including Appendix A and excluding Evaluation Form, dated October 25, 2001. Where the service bulletin specifies to contact Boeing for repair instructions, before further flight, repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

(1) For cracking of the crown area, do the repair specified in either paragraph (d)(1)(i) or (d)(1)(ii) of this AD. Installation of the lap joint repair specified in paragraph (g) of AD 2002–07–08, amendment 39–12702, is considered acceptable for compliance with the corresponding action specified in this paragraph for the lap joint areas only.

(i) Do a time-limited repair per Part 4 of the Work Instructions of the service bulletin, then do the actions required by paragraph (e) of this AD at the times specified in that paragraph.

(ii) Do a permanent repair per Part 3 of the Work Instructions of the service bulletin. Installation of a permanent repair ends the repetitive inspections required by paragraph (a) of this AD for the repaired area only.

(2) For cracking of the lower lobe area and Section 41, repair per Part 2 of the Work Instructions of the service bulletin. Accomplishment of this repair ends the repetitive inspections required by paragraph (b) of this AD for the repaired area only.

Follow-on and Corrective Actions

(e) If a time-limited repair is done, as specified in paragraph (d)(1)(i) of this AD: Do the actions specified in paragraphs (e)(1), (e)(2), and (e)(3) of this AD, at the times specified, per the Work Instructions of Boeing Alert Service Bulletin 737–53A1210, Revision 1, including Appendix A and excluding Evaluation Form, dated October 25, 2001.

(1) Within 3,000 flight cycles after doing the repair: Do a general visual inspection of the repaired area for loose fasteners per Part 4 of the Work Instructions of the service bulletin. If any loose fastener is found, before further flight, replace with a new fastener per the service bulletin. Then repeat the inspection at least every 3,000 flight cycles until permanent rivets are installed in the repaired area, which ends the repetitive inspections for this paragraph.

(2) Within 4,000 flight cycles after doing the repair: Do an internal eddy current inspection of the skin, tear straps, and lap joint in each adjacent bay of the repaired area for cracking, per Part 4 of the Work Instructions of the service bulletin. If any cracking is found, before further flight, repair per a method approved by the Manager, Seattle ACO, or per data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the FAA to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

(3) Within 10,000 flight cycles after doing the repair: Make the repair permanent per Part 4 and Figure 20 of the Work Instructions of the service bulletin, which ends the repetitive inspections for the repaired area only.

Credit for Actions Done per Previous Service Bulletin

(f) Inspections, repairs, and preventive modifications done before the effective date of this AD per Boeing Alert Service Bulletin 737–53A1210, dated December 14, 2000, are acceptable for compliance with the corresponding actions required by this AD.

Alternative Methods of Compliance

(g) 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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permit

(h) 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 June 11, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15327 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–169–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and Model MD–88 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas airplanes. This proposal would require reversing the ground stud installation of the main

battery, and installing a new nameplate on the cover of the battery. This action is necessary to prevent damage to equipment or possible fire in the electrical/electronics equipment compartment due to electrical arcing between the ground stud of the main battery and adjacent structure. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–169–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–169–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: Elvin Wheeler, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5344; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received. Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–169–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–114, Attention: Rules Docket No. 2000–NM–169–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

As part of its practice of re-examining all aspects of the service experience of a particular aircraft whenever an accident occurs, the FAA has become aware of a report indicating that heat damage had been detected on the ground stud of the main battery and on adjacent structure of a Model DC–9–82 (MD–82) airplane. The heat damage has been attributed to a loose or inadequately tightened ground stud of the main battery, which resulted in electrical arcing. Such electrical arcing could result in damage to equipment or possible fire in the electrical/electronics equipment compartment.

The ground stud of the main battery on McDonnell Douglas Model DC–9–81 (MD–81), DC–9–83 (MD–83), DC–9–87 (MD–87), and MD–88 airplanes is identical to that on the affected Model. Therefore, all of these models may be subject to the same unsafe condition.

Other Related Rulemaking

The FAA, in conjunction with Boeing and operators of Model Douglas DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and Model MD–88 airplanes, has reviewed all aspects of the service history of those airplanes to identify potential unsafe conditions and to take appropriate corrective actions. This proposed airworthiness directive (AD) is one of a series of corrective actions identified during that process. We have previously issued several other ADs and may consider further rulemaking actions to address the remaining identified unsafe conditions.

Explanation of Relevant Service Information

The FAA has reviewed and approved McDonnell Douglas Alert Service Bulletin MD–80–24A159, Revision 01, dated January 24, 2000, which describes procedures for reversing the ground stud of the main battery and installing a nameplate at stations Y=110.000 and Z=39.000 in the lower nose frame area. The manufacturer advises that reversing the ground stud installation will allow easier access to tighten the ground stud nut to proper torque, which will minimize the possibility of the ground stud coming loose and causing arcing or further damage. Installation of the nameplate will clarify installation and torque requirements for future maintenance. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Changes to 14 CFR Part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance (AMOC). Because we have now included this material in part 39, we no longer need to include it in each individual AD; however, this

proposed AD identifies the office authorized to approve AMOCs.

Cost Impact

There are approximately 1,224 Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and Model MD–88 airplanes of the affected design in the worldwide fleet. The FAA estimates that 600 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $38, per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $94,800, or $158 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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions. The manufacturer may cover the cost of parts associated with this proposed AD, subject to warranty conditions. Manufacturer warranty remedies also may be available for labor costs associated with this proposed AD. As a result, the costs attributable to the proposed AD may be less than stated above.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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:

McDonnell Douglas: Docket 2000–NM–169–AD.

Applicability: Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87), and Model MD–88 airplanes, as listed in McDonnell Douglas Alert Service Bulletin MD80–24A159, Revision 01, dated January 24, 2000; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent damage to equipment or possible fire in the electrical/electronics equipment compartment due to electrical arcing between the ground stud of the main battery and adjacent structure; accomplish the following:

(a) Within 1 year after the effective date of this AD, reverse the installation of the ground stud for the main battery, and install a new nameplate on the cover of the battery; per McDonnell Douglas Alert Service Bulletin MD80–24A159, Revision 01, dated January 24, 2000.

(b) Accomplishment of the actions specified in paragraph (a) of this AD before the effective date of this AD, in accordance with McDonnell Douglas Service Bulletin MD80–24A159, dated March 15, 1996, is considered to be an acceptable method of compliance with paragraph (a) of this AD.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California, is authorized to approve alternative methods of compliance for this AD.

Issued in Renton, Washington, on June 12, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15333 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–164–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–11 and –11F Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model MD–11 and –11F airplanes. This proposal would require an initial general visual inspection of the power feeder cables of the integrated drive generator (IDG) and the fuel feed lines of engine plyons No. 1 and No. 3 on the wings for proper clearance and damage; corrective actions if necessary; and repetitive general visual inspections and a terminating action for the repetitive inspections. This action is necessary to prevent potential chafing of the power feeder cables of the IDG in engine pylons No. 1 and No. 3 on the wings, and consequent arcing on the fuel lines in the engine pylons and possible fuel fire. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–164–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–16–4AD'' in the subject line and need not be submitted

in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (562) 627–5350; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–164–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–114, Attention: Rules Docket No. 2001–NM–164–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

As part of its practice of re-examining all aspects of the service experience of a particular aircraft whenever an accident occurs, the FAA has become aware of reports indicating that the power feeder cables of the integrated drive generator (IDG) are riding against structure and fuel lines in engine pylons No. 1 and No. 3 on the wings of certain McDonnell Douglas Model MD–11 and –11F airplanes. The cables are routed too closely to the components. This condition, if not corrected, could result in potential chafing of the power feeder cables of the IDG in engine pylons No. 1 and No. 3 on the wings, and consequent arcing on the fuel lines in the engine pylons and possible fuel fire.

Other Related Rulemaking

The FAA, in conjunction with Boeing and operators of Model MD–11 and –11F airplanes, has reviewed all aspects of the service history of those airplanes to identify potential unsafe conditions and to take appropriate corrective actions. This proposed airworthiness directive (AD) is one of a series of corrective actions identified during that process. We have previously issued several other ADs and may consider further rulemaking actions to address the remaining identified unsafe conditions.

Explanation of Relevant Service Information

We have reviewed and approved Boeing Alert Service Bulletin MD11–54A011, Revision 02, dated May 31, 2002. The service bulletin describes procedures for an initial general visual inspection of the power feeder cables of the IDG and the fuel feed lines of engine plyons No. 1 and 3 on the wings for proper clearance and damage; corrective action if necessary; and repetitive general visual inspections and a terminating action for the repetitive inspections. The corrective actions include:

- Repositioning cables with improper clearance; and
- Repairing damage or replacing damaged cables or fuel feed lines with new or serviceable cables or fuel feed lines.

The terminating action involves:

- Installing brackets to support the IDG harness;
- Installing new clamps on the power feeder cables of the IDG of engine pylons No. 1 and No. 3; and
- Replacing the existing fairlead with a new clamp, and installing new tape; as applicable.

Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Boeing also has issued Information Notice MD11–54A011 R02 IN 02, dated July 11, 2002. The information notice informs operators of a typographical error for the string tie part number (P/N) specified in the Boeing Alert Service Bulletin MD11–54A011, Revision 02. The service bulletin specifies string tie P/N 190L0F21G/A; the correct P/N is 109 LOF 21G/A.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Clarification of Procedures in Service Bulletin

Boeing has informed us that, although the service bulletin specifies two options (*i.e.*, ''Option 1'' and ''Option 2'') for Conditions 1 through 3 findings, these actions are not optional. The intent is that the actions specified in Option 1 be accomplished until the actions specified in Option 2 are accomplished at a later time. If an operator elects to accomplish the actions specified in Option 2 before the actions specified in Option 1, the actions specified in Option 1 do not need to be accomplished.

Changes to 14 CFR part 39/Effect on the Proposed AD

On July 10, 2002, we issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance (AMOCs). Because we have now included this material in part 39, only the office authorized to approve

AMOCs is identified in each individual AD.

Cost Impact

There are approximately 195 Model MD–11 and –11F airplanes of the affected design in the worldwide fleet. The FAA estimates that 74 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour 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 $4,440, or $60 per airplane, per inspection cycle.

It would take approximately 4 work hours per airplane to accomplish the terminating action, at an average labor rate of $60 per work hour. Required parts would cost approximately $91 per airplane. Based on these figures, the cost impact of this terminating action is estimated to be $24,494, or $331 per airplane.

The cost impact figures discussed above are 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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions. Manufacturer warranty remedies may be available for labor costs associated with this proposed AD. As a result, the costs attributable to the proposed AD may be less than stated above.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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:

McDonnell Douglas: Docket 2001–NM–164–AD.

Applicability: Model MD–11 and –11F airplanes, as listed in Boeing Alert Service Bulletin MD11–54A011, Revision 02, dated May 31, 2002; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent potential chafing of the power feeder cables of the integrated drive generator (IDG) in engine pylons No. 1 and No. 3 on the wings, and consequent arcing on the fuel lines in the engine pylons and possible fuel fire, accomplish the following:

Note 1: Boeing has issued Information Notice MD11–54A011 R02 IN 02, dated July 11, 2002. The information notice informs operators of a typographical error for the string tie part number (P/N) specified in the Boeing Alert Service Bulletin MD11–54A011, Revision 02. The service bulletin specifies string tie P/N 190L0F21G/A; the correct P/N is 109 LOF 21G/A.

Initial Inspection

(a) Within 30 days after the effective date of this AD, do a general visual inspection of the power feeder cables of the IDG and the fuel feed lines of engine pylons No. 1 and 3 on the wings for proper clearance and damage, per Boeing Alert Service Bulletin MD11–54A011, Revision 02, dated May 31, 2002.

Note 2: For the purposes of this AD, a general visual inspection is defined as ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

Condition 1: Proper Clearance and No Damage

(b) If proper clearance exists and no damage is detected during any inspection required by paragraph (a) of this AD, do the action(s) specified in paragraphs (b)(1), (b)(2), and (b)(3) of this AD, as applicable, per Boeing Alert Service Bulletin MD11–54A011, Revision 02, dated May 31, 2002.

(1) For Group 1 and Group 2 airplanes identified in the service bulletin: Repeat the inspection required by paragraph (a) of this AD every 6 months until the modification required by paragraph (b)(2) or (b)(3) of this AD, as applicable, has been done.

(2) For Group 1 airplanes identified in the service bulletin: Within 18 months after the effective date of this AD, install the brackets to support the IDG harness, and install new clamps on the power feeder cables of the IDG of the No. 1 and No. 3 pylons.

(3) For Group 2 airplanes identified in the service bulletin: Within 18 months after the effective date of this AD, replace the existing fairlead with a new clamp, and install new tape.

Condition 2: Improper Clearance and No Damage

(c) If improper clearance exists and no damage is detected during any inspection required by paragraph (a) of this AD, do the action(s) specified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, as applicable, per Boeing Alert Service Bulletin MD11–54A011, Revision 02, dated May 31, 2002.

(1) For Group 1 and Group 2 airplanes identified in the service bulletin: Before further flight, reposition cables, and repeat the inspection required by paragraph (a) of this AD every 6 months until the modification required by paragraph (c)(2) or (c)(3) of this AD, as applicable, has been done.

(2) For Group 1 airplanes identified in the service bulletin: Within 18 months after the effective date of this AD, install the brackets to support the IDG harness, and install new clamps on the power feeder cables of the IDG of engine pylons No. 1 and No. 3.

(3) For Group 2 airplanes identified in the service bulletin: Within 18 months after the effective date of this AD, replace the existing fairlead with a new clamp, and install new tape.

Condition 3: Improper Clearance and Damage Detected

(d) If improper clearance exists and any damage is detected during any inspection required by paragraph (a) of this AD, do the action(s) specified in paragraphs (d)(1), (d)(2), and (d)(3) of this AD, as applicable, per Boeing Alert Service Bulletin MD11–54A011, Revision 02, dated May 31, 2002.

(1) For Group 1 and Group 2 airplanes identified in the service bulletin: Before further flight, reposition cables; repair damage or replace damaged cables or fuel feed lines with new or serviceable cables or

fuel feed lines; and repeat the inspection required by paragraph (a) of this AD every 6 months until the modification required by paragraph (d)(2) or (d)(3) of this AD, as applicable, has been done.

(2) For Group 1 airplanes identified in the service bulletin: Within 18 months after the effective date of this AD, install the brackets to support the IDG harness, and install new clamps on the power feeder cables of the IDG of engine pylons No. 1 and No. 3.

(3) For Group 2 airplanes identified in the service bulletin: Within 18 months after the effective date of this AD, replace the existing fairlead with a new clamp, and install new tape.

Credit for Earlier Service Bulletin

(e) Accomplishment of the actions specified in this AD before the effective date of this AD per Boeing Alert Service Bulletin MD11–54A011, Revision 01, dated August 22, 2002, is acceptable for compliance with the requirements of this AD.

Alternative Methods of Compliance

(f) In accordance with 14 CFR 39.19, the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

Issued in Renton, Washington, on June 12, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15334 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–171–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) Airplanes and Model MD–88 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) airplanes and Model MD–88 airplanes. This proposal would require a general visual inspection for chafing of the power feeder cables of the auxiliary power unit (APU), and repair if necessary. This proposal also would require replacement of a support bracket located on the left side of the lower cargo compartment with a new ''U'' shaped bracket. This action is necessary to prevent chafing of the power feeder cables of the APU, which could result in electrical arcing to adjacent structure and consequent fire in the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–171–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–171–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: Elvin Wheeler, Aerospace Engineer; Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5344; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–171–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–114, Attention: Rules Docket No. 2000–NM–171–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received a report indicating that the power feeder cables of the auxiliary power unit (APU) had chafed against a support bracket located in the forward lower cargo compartment of a Model MD–88 airplane. Investigation revealed that a spacer that separates the cable from the bracket might have been inadvertently omitted during maintenance. This condition, if not corrected, could cause chafing of the power feeder cables of the APU, which could result in electrical arcing to adjacent structure and consequent fire in the airplane.

Other Related Rulemaking

The FAA, in conjunction with Boeing and operators of Model MD–11 and –11F airplanes, has reviewed all aspects of the service history of those airplanes

to identify potential unsafe conditions and to take appropriate corrective actions. This proposed airworthiness directive (AD) is one of a series of corrective actions identified during that process. We have previously issued several other ADs and may consider further rulemaking actions to address the remaining identified unsafe conditions.

Explanation of Relevant Service Information

The FAA has reviewed and approved McDonnell Douglas Alert Service Bulletin MD80–24A105, Revision 02, dated January 24, 2000, which describes procedures for inspecting for any chafed power feeder cables of the APU, and repairing if necessary. The alert service bulletin also describes procedures for replacing a support bracket for the power feeder cable on the left side of the lower cargo compartment between fuselage stations Y=218.000 and Y=237.000 with a new ''U'' shaped bracket. The new bracket will eliminate the need for a spacer and minimize the possibility of cable chafing and arcing.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the alert service bulletin described previously.

Changes to 14 CFR Part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance (AMOC). Because we have now included this material in part 39, only the office authorized to approve AMOCs is identified in each individual AD.

Cost Impact

There are approximately 634 airplanes of the affected design in the worldwide fleet. The FAA estimates that 438 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the inspection and replacement of the bracket, and that the average labor rate is $60 per work hour. Required parts would cost approximately $147 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $90,666, or $207 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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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:

McDonnell Douglas: Docket 2000–NM–171–AD.

Applicability: Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) airplanes, and Model MD–88 airplanes, as listed in McDonnell Douglas Alert Service Bulletin MD80–24A105, Revision 02, dated January 24, 2000; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent chafing of the power feeder cables of the auxiliary power unit (APU), which could result in electrical arcing to adjacent structure and consequent fire in the airplane; accomplish the following:

No Reporting Requirement

(a) Although the alert service bulletin referenced in this AD specifies to submit information to the manufacturer, this AD does not include such a requirement.

Inspection for Chafing

(b) Within 1 year after the effective date of this AD, perform a general visual inspection for chafing of the power feeder cables of the auxiliary power unit, per McDonnell Douglas Alert Service Bulletin MD80–24A105, Revision 02, dated January 24, 2000.

(1) If no chafing is detected, no further action is required by this paragraph.

(2) If any chafing is detected, before further flight, repair the cable(s) per the alert service bulletin.

Note 1: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

Replacement of a Support Bracket

(c) Within 1 year after the effective date of this AD, replace the support bracket for the power feeder cable located on the left side of the lower cargo compartment between fuselage stations Y=218.000 and Y=237.000 with a new ''U'' shaped bracket.

Alternative Methods of Compliance

(d) In accordance with 14 CFR 39.19, the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

Issued in Renton, Washington, on June 12, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15337 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–169–AD]

RIN 2120–AA64

Airworthiness Directives; Aerospatiale Model ATR42–500 and ATR72 Series 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 Aerospatiale Model ATR42–500 and ATR72 series airplanes. This proposal would require inspecting the wire bundle in the area of electrical rack 90VU to detect damage, verifying that the conduit around the wire bundle is in the proper position, and installing a clamp between the wire bundles and the carbon shelves structure. This action is necessary to prevent chafing of a wire bundle, which could result in an electrical short and potential loss of several functions essential for safe flight. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by July 18, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–169–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain ''Docket No. 2002–NM–169–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer; International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2002–NM–169–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–114, Attention: Rules Docket No. 2002–NM–169–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Aerospatiale Model ATR42–500 and ATR72 series airplanes. The DGAC advises that, after parking a Model ATR42–500 series airplane with the right-hand engine on, the flightcrew tried unsuccessfully to start the left-hand engine. Investigation revealed wire chafing on electrical rack 90VU between the carbon structure of the 95VU shelf and the main wire bundle. This chafing led to a short circuit, which burned several wires of the bundle (including the left-hand engine ignition circuits) and the protective sheath (conduit). It was determined that the chafing and subsequent electrical short circuit probably occurred when the wire bundle on the shelf was mispositioned during maintenance, and that this wire bundle is susceptible to such mispositioning. This created a direct contact between the wire bundle and the carbon shelf (an abrasive structure). This condition could also exist on shelves 93VU and 94VU and, if not corrected, could result in the loss of several functions essential for safe flight.

The design of the wire bundle routing is the same on Model ATR42–500 and ATR72 series airplanes; therefore, these airplane models are subject to the identified unsafe condition.

Explanation of Relevant Service Information

The manufacturer has issued Avions de Transport Regional Service Bulletins ATR42–92–0007 (for Model ATR42–500 series airplanes) and ATR72–92–1007 (for Model ATR72 series airplanes), both dated January 25, 2002. These service bulletins describe procedures for inspecting the wire bundles in the area of electrical rack 90VU to detect damage, verifying that the conduit around the wire bundles is in the proper position, and installing a clamp between the wire bundles and the carbon shelves structure (93VU, 94VU, 95VU). Accomplishment of the actions specified in the applicable service bulletins is intended to adequately address the identified unsafe condition. The DGAC classified these service bulletins as mandatory and issued French airworthiness directives 2002–090–092(B) and 2002–091–066(B), both

dated February 20, 2002, to ensure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of §21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, 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 accomplishment of the actions specified in the service bulletin described previously. The actions would be required to be accomplished in accordance with the service bulletins described previously, except as discussed below.

Difference Between Proposed AD and Service Bulletins

The service bulletins do not provide procedures to repair damaged wiring. This proposed AD would require that damaged wiring be repaired in accordance with the applicable ATR Aircraft Schematic Manual, Chapter 20–27–17, dated October 1, 1995.

Changes to 14 CFR Part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance (AMOCs). It is not necessary to include this material in each individual AD; however, the office authorized to approve AMOCs is identified in paragraph (b) of this proposed AD.

Cost Impact

The FAA estimates that 86 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $259 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $42,914, or $499 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. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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:

Aerospatiale: Docket 2002–NM–169–AD.

Applicability: Model ATR42–500 and ATR72 series airplanes, certificated in any category, on which ATR Modification 1447 has been incorporated and ATR Modification 4840 has not been incorporated.

Compliance: Required as indicated, unless accomplished previously.

To prevent chafing of a wire bundle in the area of electrical rack 90VU, which could result in an electrical short and potential loss of several functions essential for safe flight, accomplish the following:

Modification

(a) Within 500 flight hours or 6 months after the effective date of this AD, whichever occurs first: Do a detailed inspection to detect damage of the wire bundles in the area of electrical rack 90VU, ensure that the conduit around the wire bundles is in the proper position, and install a clamp between the wire bundles and the carbon shelves structure (94VU, 94VU, 95VU); in accordance with Avions de Transport Regional Service Bulletin ATR42–92–0007 (for Model ATR42–500 series airplanes) or ATR72–92–1007 (for Model ATR72 series airplanes), both dated January 25, 2002, as applicable. Repair any damaged wiring before further flight in accordance with Chapter 20–27–17 of the applicable ATR Aircraft Schematic Manual, dated October 1, 1995.

Note 1: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, is authorized to approve alternative methods of compliance for this AD.

Note 2: The subject of this AD is addressed in French airworthiness directives 2002–090–092(B) and 2002–091–066(B), both dated February 20, 2002.

Issued in Renton, Washington, on June 12, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15338 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 312, 314, 320, 600, 601, and 606

[Docket No. 2000N–1484]

RIN 0910–AA97

Safety Reporting Requirements for Human Drug and Biological Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 14, 2003, the comment period for a proposed rule published in the **Federal Register** of March 14, 2003 (68 FR 12406). The proposed rule would amend the agency's pre- and postmarketing safety reporting regulations for human drug and biological products. The agency is taking this action in response to a request for more time to submit comments to FDA.

DATES: Submit written or electronic comments on the proposed rule by October 14, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *FDADockets@oc.fda.gov* or on the Internet at *http://accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm.*

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Audrey A. Thomas, Center for Drug Evaluation and Research (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5626.

For information concerning human biological products: Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6079.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 14, 2003 (68 FR 12406), FDA published a proposed rule that, if finalized, would amend its pre-and postmarketing safety reporting regulations for human drug and biological products to:

- Implement definitions and reporting formats and standards recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and by the World Health Organization's Council for International Organizations of Medical Sciences;
- Codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed drugs and licensed biological products;
- Require that certain information, such as domestic reports of medication errors, be submitted to the agency in an expedited manner; and
- Clarify certain requirements and make other minor revisions.

FDA also proposed to amend its postmarketing annual reporting regulations for human drug and licensed biological products by revising the content for these reports.

Interested persons were given until July 14, 2003, to submit written or electronic comments to the agency on the proposal. On May 7, 2003, FDA received a written request to allow an additional 90 days for interested persons to comment. FDA believes that an extension of 90 days to the comment period is appropriate, given the length and complexity of the proposed rule. Therefore, FDA is extending the comment period until October 14, 2003. This extension will provide the public with a total of 210 days to submit comments.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the proposal. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 11, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15341 Filed 6–17–03; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO 180–1180; FRL–7514–1]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve a revision to the Missouri State Implementation Plan (SIP) which pertains to the control of emissions from Perchloroethylene Dry Cleaning Installations in Kansas City and St. Louis areas, respectively. This revision will rescind two rules that have been superseded by the statewide Maximum Achievable Control Technology rule. There is no relaxation of controls by rescinding these rules. Approval of this revision will eliminate redundancy and conflicting requirements. In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

DATES: Comments on this proposed action must be received in writing by July 18, 2003.

ADDRESSES: Comments may be mailed to Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101, or E-mail her at *algoe-eakin.amy@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Amy Algoe-Eakin at (913) 551–7942.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final

rule which is located in the rules section of the **Federal Register**.

Dated: June 8, 2003.

James B. Gulliford,

Regional Administrator, Region 7.

[FR Doc. 03–15252 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–7514–5]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule and request for comment.

SUMMARY: The Environmental Protection Agency (EPA, also the Agency or we in this preamble) is proposing to grant a petition submitted by the Southeastern Public Service Authority (SPSA) and Onyx Environmental Services (Onyx), to exclude (or delist) on a one-time basis certain solid wastes generated at the SPSA Power Plant in Portsmouth, Virginia, from the lists of hazardous waste. This waste is currently located at the SPSA Regional Landfill in Suffolk, Virginia.

The Agency has tentatively decided to grant the petition based on an evaluation of specific information provided by the petitioners. This tentative decision, if finalized, would conditionally exclude the petitioned waste from the requirements of the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

The Agency is requesting comments on this proposed decision.

DATES: To make sure we consider your comments on this proposed exclusion, they must be postmarked by August 4, 2003. Comments received after the close of the comment period will be designated as late. EPA is not required to consider late comments.

Any person may request a hearing on this tentative decision to grant the petition by filing a request by July 3, 2003. The request must contain the information prescribed in 40 CFR 260.20(d).

ADDRESSES: Please send two copies of your comments to David M. Friedman, Technical Support Branch (3WC11), Waste and Chemicals Management Division, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103–2029.

Your request for a hearing should be addressed to James J. Burke, Director, Waste and Chemicals Management Division (3WC00), U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103–2029.

FOR FURTHER INFORMATION CONTACT: For technical information concerning this document, please contact David M. Friedman at the address above, at (215) 814–3395, or via e-mail at *friedman.davidm@epa.gov.*

SUPPLEMENTARY INFORMATION:

Docket

EPA has established an official docket for this action. The official docket consists of the petition submitted by SPSA/Onyx, the results of a risk assessment which evaluates the potential impact of the petitioned waste on human health and the environment, any public comments received, and other information related to this action. The official docket for this proposed rule is located at the offices of U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103–2029, and is available for you to view from 8:30 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays. Please call David M. Friedman at (215) 814–3395 for appointments. The public may copy material from the docket at $0.15 per page.

Outline

The information in this preamble is organized as follows:

I. Background

A. What Laws and Regulations Give EPA the Authority To Delist Waste?

EPA published amended lists of hazardous wastes from non-specific and specific sources on January 16, 1981, as part of its final and interim final regulations implementing Section 3001 of RCRA. These lists have been amended several times, and are found at 40 CFR 261.31 and 261.32.

We list these wastes as hazardous because: (1) they typically and frequently exhibit one or more of the characteristics of hazardous wastes identified in subpart C of 40 CFR part 261 (*i.e.*, ignitability, corrosivity, reactivity, and toxicity), or (2) they meet the criteria for listing contained in 40 CFR 261.11(a)(2) or (a)(3).

We also define residues from the treatment, storage, or disposal of listed hazardous wastes and mixtures containing listed hazardous wastes as hazardous wastes. (*See* 40 CFR 261.3(a)(2)(iv) and (c)(2)(i), referred to as the ''mixture'' and ''derived-from'' rules, respectively.)

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste that is described in these regulations generally is hazardous, a specific waste from an individual facility that would otherwise meet the listing description may not be.

For this reason, 40 CFR 260.20 and 260.22 provide an exclusion procedure which allows a person to demonstrate that a specific listed waste from a particular generating facility should not be regulated as a hazardous waste, and should, therefore, be delisted.

According to 40 CFR 260.22(a)(1), in order to have a waste excluded, a petitioner must first show that the waste generated at its facility does not meet any of the criteria for which the waste was listed. The criteria which we use to list wastes are found in 40 CFR 261.11. An explanation of how these criteria apply to a particular waste is contained in the background document for that listed waste.

In addition to the criteria that we considered when we originally listed the waste, we are also required by the provisions of 40 CFR 260.22(a)(2) to consider any other factors (including additional constituents), if there is a reasonable basis to believe that these factors could cause the waste to be hazardous.

In a delisting petition, the petitioner must demonstrate that the waste does not exhibit any of the hazardous waste characteristics defined in subpart C of 40 CFR part 261 (*i.e.*, ignitability, corrosivity, reactivity, and toxicity), and must present sufficient information for EPA to determine whether the waste contains any other constituents at hazardous levels.

A generator remains obligated under RCRA to confirm that its waste remains non-hazardous based on the hazardous waste characteristics defined in subpart C of 40 CFR part 261, even if EPA has delisted its waste.

B. What Does SPSA/Onyx Request in Their Petition?

On April 7, 2003, SPSA/Onyx petitioned EPA to exclude on a one-time basis a combustion ash generated at SPSA's waste-to-energy facility in Portsmouth, Virginia. The ash which is the subject of this petition is currently located at SPSA's Regional Landfill in Suffolk, Virginia. The total volume of the subject combustion ash at the SPSA Landfill was determined by SPSA/Onyx to be 1410 cubic yards.

The ash was produced by the routine combustion of a batch of municipal and commercial solid waste which was processed in SPSA's Refuse Derived Fuel (RDF) plant and burned in SPSA's Power Plant in Portsmouth, Virginia. A small amount of this waste consisted of materials containing the spent non-halogenated solvent, methyl ethyl ketone (EPA Hazardous Waste Number F005).

II. Waste-Specific Information

A. How Was the Waste Generated?

In January, 2002, Logan Aluminum, Inc. (Logan) sent a routine shipment of fourteen drums of hazardous waste generated at the Logan plant in Russellville, Kentucky, to Onyx's facility in West Carrollton, Ohio. Logan manufactures aluminum sheet used in making beverage cans. Its process includes application of an FDA-approved, food-safe coating by passing sheet aluminum through rollers. The rollers are cleaned periodically by wiping them with cloth strips using virgin methyl ethyl ketone (MEK) as the cleaning agent. MEK is the only solvent used by Logan in this process.

The used wipes are collected in drums along with other materials including personal protective equipment, excess coating, paper, cardboard and packing materials. These wipes are classified by the Kentucky Department for Environmental Protection as spent solvent wastes.

Onyx Environmental Services is a company that provides a wide range of environmental services to other companies. These services include hazardous and non-hazardous waste management.

Logan has a contractual arrangement with Onyx for the transportation and disposal of hazardous and non-hazardous wastes. Every two months, Logan ships its wastes to Onyx in 55-gallon drums.

On January 30, 2002, Onyx picked up a shipment of eighty-two drums from Logan. Fourteen of the drums contained MEK rags used in the roller cleaning process, and these drums were shipped with a Uniform Hazardous Waste Manifest. Sixty drums in this shipment contained only non-hazardous waste and eight others, which were not further involved in this incident, were also designated as hazardous. All the drums in this shipment were received at Onyx's West Carrollton facility on February 9, 2002.

In the petition, Onyx asserts that on February 16, 2002, the fourteen drums containing the used wipes were inadvertently included in a shipment of eighty-three drums sent under a non-hazardous waste manifest to Eagle Environmental Services, Inc.'s (Eagle) waste processing facility in Dorchester, South Carolina. Eagle operates a facility that processes non-hazardous industrial waste for recycling and disposal, and is permitted for such activities by the South Carolina Department of Health and Environmental Control.

Eagle emptied the fourteen drums containing the used wipes and processed their contents, along with approximately twenty-three drums of non-hazardous industrial waste, by shredding the combined material and mixing it with sawdust to absorb any free liquids that may have been present. On February 22, 2002, the processed material, totaling 47,380 pounds, was shipped in a single container under a non-hazardous waste manifest to SPSA's RDF plant in Portsmouth, Virginia. Here, this material was mixed with other non-hazardous solid waste and then burned in SPSA's Power Plant.

The ash resulting from combustion of this batch of RDF was delivered to the SPSA Regional Landfill in Suffolk, Virginia, on February 23, 2002. Following standard procedure, the ash was stockpiled there for use as daily cover in the Landfill.

According to Onyx, on February 26, 2002, it discovered its error and notified the Ohio Environmental Protection Agency and Eagle that the drums had been shipped to Eagle without the required hazardous waste manifest. On February 27, 2002, Eagle notified Chesapeake Waste Solutions, the waste broker that had arranged the shipment from Eagle to SPSA, and Chesapeake Waste Solutions notified SPSA. SPSA then notified the Virginia Department of Environmental Quality.

Approximately 510 tons (835 cubic yards) of this ash had been used as daily cover at the SPSA Regional Landfill before SPSA received notification on February 27, 2002, that the ash was subject to regulation as a hazardous waste. The remaining ash (about 250 tons or 575 cubic yards) has been segregated and stored on a liner under a water- and wind-tight cover on an adjacent area of the Landfill. The area of the Landfill where the material was used as cover is cordoned off and operations remain suspended in this area.

B. What Information Did SPSA/Onyx Submit To Support Their Petition?

In order to support their petition, SPSA/Onyx submitted detailed descriptions of the chemicals used and the wastes generated by Logan, detailed information related to the material shipments received for destruction at SPSA's Power Plant during the period of time between receipt of the shipment of material from Eagle and notification of the shipping error, and validated analytical results from representative samples of the ash obtained by SPSA/Onyx on October 15, 2002 and January 28, 2003.

Because of the number and variety of waste streams that were processed at the SPSA waste-to-energy facility, we requested that SPSA/Onyx analyze the ash for the entire list of constituents found in Appendix IX to 40 CFR part 264.

On October 15, 2002, SPSA/Onyx collected eight samples and one duplicate sample from ash being stored in a segregated waste pile at the SPSA Regional Landfill. The ash that was used for daily cover in the Landfill was not sampled. The ash has been homogenized by several processes such as loading out at the power plant, transportation and stockpiling, and, therefore, the ash currently stored in the waste pile (which is lined with a geosynthetic liner and covered with a high-density polyethylene cap) was determined to be representative of that portion of the ash which was used as daily cover.

Total analysis was performed on all samples for the entire list of Appendix IX constituents, which include volatiles, semi-volatiles, pesticides, herbicides, PCBs, polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) metals, cyanide, and sulfide. Toxicity Characteristic Leaching Procedure (TCLP) leachate analysis was performed on all Appendix IX metals. TCLP leachate analysis was not performed on the organic constituents or cyanide, since allowable holding times were exceeded, and any results obtained from such samples may not be reliable. Holding time requirements

were met, however, for total constituent analysis of the organic constituents and cyanide. Therefore, in our evaluation of the organic constituents (except for the PCDDs and PCDFs) and cyanide, we have calculated the theoretical maximum leachate concentrations by applying the most conservative assumption.

Analyzing a waste for TCLP constituent concentrations involves application of the TCLP followed by analysis of the TCLP leachate for the constituents of concern. For a waste that is a physical solid (*i.e.*, a waste that does not contain a liquid phase), the maximum theoretical leachate concentration can be calculated by dividing the total concentration of the constituent by twenty. This twenty-fold dilution is part of the TCLP protocol and represents the liquid to solid ratio employed in the test procedure.

If the TCLP were performed on the actual waste, the concentration of this constituent in the TCLP leachate could not exceed the calculated value derived from the procedure described above. The actual TCLP concentration, if determined, may be substantially less than the calculated value because the calculated value assumes that 100 percent of the constituent leaches from the waste.

PCDD and PCDF analysis of the samples collected during the October 15, 2002 sampling event were inadvertently analyzed by SPSA/Onyx's laboratory using SW–846 Method 8280 rather than the specified method, SW–846 Method 8290. Method 8280 did not yield results that were sufficiently sensitive for this evaluation. On January 28, 2003, four additional composite ash samples were collected and analyzed for total and leachable PCDDs and PCDFs concentrations using Method 8290.

The maximum total constituent and maximum leachate concentrations for all detected inorganic constituents in SPSA/Onyx's waste samples are presented in Table 1.

The detection limits presented in Table 1 represent the lowest concentrations quantifiable by SPSA/Onyx using appropriate methods to analyze the waste.

TABLE 1.—MAXIMUM TOTAL CONSTITUENT AND LEACHATE CONCENTRATIONS [1] IN ASH

Inorganic constituents	Total constituent concentration (mg/kg)	TCLP leachate concentration (mg/1)
Antimony	125	0.54
Arsenic	45.9	0.18
Barium	375	0.21
Beryllium	1.7	<0.005
Cadmium	34.9	0.11
Chromium	808	<0.5
Cobalt	27.3	<0.05
Copper	2830	1.8
Lead	1650	<0.5
Mercury	6.8	0.003
Nickel	449	0.065
Selenium	4.6	<0.25
Silver	9.5	<0.5
Thallium	1.2	<2.0
Tin	149	<0.1
Vanadium	29.6	0.012
Zinc	9810	8.5
Cyanide (total	0.28	0.014 [2]

[1] These levels represent the highest concentration of each constituent found in any sample. These levels do not necessarily represent the specific levels found in any one sample.
[2] This value is the calculated theoretical maximum leachate concentration based on the maximum total constituent concentration.
< Denotes that the constituent was not detected at the concentration specified in the table.

The maximum total constituent and maximum leachate concentrations for all detected organic constituents in SPSA/Onyx's waste samples are presented in Table 2.

TABLE 2.—MAXIMUM TOTAL CONSTITUENT AND LEACHATE CONCENTRATIONS [1] IN ASH

Organic constituents	Total constituent concentration (mg/kg)	TCLP leachate concentration (mg/1)
Actone	0.058	0.0029 [3]
Aceonitrile	<0.31	<0.0155 [3]
Bis(2-ethylhexyl)phthlate	2.6	0.13 [3]
Butylbenzylphthalate	<2.0	<0.1 [3]
DDD	<0.0022	<0.00011 [3]
Endrin aldehyde	<0.0022	<0.00011 [3]
Heptachlor	<0.002	<0.0001 [3]
Methyl ethyl ketone (2-butanone)	<0.049	<0.00245 [3]
Methylene chloride	0.0082	0.00014 [3]

TABLE 2.—MAXIMUM TOTAL CONSTITUENT AND LEACHATE CONCENTRATIONS [1] IN ASH—Continued

Organic constituents	Total constituent concentration (mg/kg)	TCLP leachate concentration (mg/1)
2,3,7,8-TCDD [2]	0.0175	0.00000000017

[1] These levels represent the highest concentration of each constituent found in any sample. These levels do not necessarily represent the specific levels found in any one sample.
[2] For risk assessment of PCDDs and PCDFs compounds, toxicity values are expressed as 2,3,7,8-TCDD equivalents (TEQs).
[3] This value is the calculated theoretical maximum leachate concentration based on the maximum total constituent concentration.
< Denotes that the constituent was not detected at the concentration specified in the table.

EPA requires that petitioners submit signed certifications affirming the truthfulness, accuracy and completeness of the information in their delisting petitions (See 40 CFR 260.22(i)(12)). SPSA and Onyx each submitted signed certifications stating that all submitted information is true, accurate and complete.

III. EPA's Evaluation of the Petition

A.What Method Did EPA Use To Evaluate Risk?

For this delisting determination, we used information gathered by SPSA/Onyx to identify plausible exposure routes (*i.e.*, groundwater, surface water, and air) for hazardous constituents present in the petitioned waste. Because of its physical form, we determined that disposal in a RCRA Subtitle D landfill was the most reasonable, worst-case (least protective) disposal scenario for SPSA/Onyx's petitioned waste. We then used a fate and transport model to predict the release of hazardous constituents from the petitioned waste once it is disposed of, in order to evaluate the potential impact on human health and the environment. To perform this evaluation, we used a Windows-based software tool, the Delisting Risk Assessment Software Program (DRAS), to estimate the potential releases of waste constituents and to predict the risk associated with those releases. DRAS accomplishes this using several EPA models including the EPA Composite Model for Leachate Migration with Transformation Products (EPACMTP) fate and transport model for estimating groundwater releases. For a detailed description of the DRAS program and the EPACMPT model, *See* 65 FR 58015, September 27, 2000. Subsequent revisions to the DRAS program are described in 65 FR 75637 (December 4, 2000). The DRAS program is available on the World Wide Web at *http://www.epa.gov/earth1r6/6pd/rcra_c/pd-o/dras.htm.* The technical support document for the DRAS program is also available on the World Wide Web at *http://www.epa.gov/earth1r6/6pd/rcra_c/pd-o/dtsd.htm* as well as in the public docket for this proposed rule.

The Agency believes that the EPACMTP fate and transport model represents a reasonable worst-case scenario for possible groundwater contamination resulting from disposal of the petitioned waste in a landfill, and that a reasonable worst-case scenario is appropriate when evaluating whether a waste should be relieved of the protective management constraints of the RCRA Subtitle C program. The use of a reasonable worst-case scenario results in conservative values for the compliance-point concentrations and insures that the waste, once removed from hazardous waste regulation, will not pose a significant threat to human health or the environment.

In assessing potential risks to groundwater, we use the estimated waste volume and the maximum measured or calculated leachate concentrations as inputs to the DRAS program to estimate the constituent concentrations in the groundwater at a hypothetical receptor well downgradient from the disposal site. Using an established risk level, the DRAS program can back-calculate receptor well concentrations (referred to as a compliance-point concentration) using standard risk assessment algorithms and Agency health-based numbers.

For constituents which are not detected in leachate analysis, the DRAS requires that the detection limit be entered along with the other data. In these circumstances, the DRAS uses one-half the detection limit to calculate risk. We believe it is inappropriate to evaluate constituents which are not detected in any sample analyzed, if an appropriate analytical method was used.

Similarly, the DRAS also predicts possible risks associated with releases of waste constituents through surface pathways (*e.g.*, volatilization or wind-blown particulate from the landfill). As in the groundwater analyses, the DRAS uses the established acceptable risk level, the health-based data, and standard risk assessment and exposure algorithms to perform this assessment.

In most cases, because a delisted waste is no longer subject to hazardous waste regulation, the Agency is generally unable to predict, and does not presently control, how a petitioner will manage a waste after it is excluded. Therefore, we believe that it is inappropriate to consider extensive site-specific factors when applying the fate and transport model.

The back-calculation procedure contrasts with the method used to compute the cumulative risk for a one-time delisting petition. To determine cumulative risk, the calculations proceed in a forward direction. Beginning with the leachate and total waste concentrations for each constituent in the waste (source concentrations), the waste volume and exposure parameters are used to estimate the upper-bound excess lifetime cancer risks(risk) and noncarcinogenic hazards (hazard). The risk is said to be cumulative because risks and hazards are summed separately for receptors (resident adults and children) across all applicable waste constituents and exposure pathways to obtain an estimate of the total individual risk and hazard for each receptor. Risk is the probability that a receptor will develop cancer. Risk is estimated based on a unique set of exposure, model, and toxicity assumptions.

Hazard is defined as the potential for noncarcinogenic health effects as a result of exposure to constituents of concern, averaged over an exposure period of less than an entire lifetime. A hazard is not a probability but rather a measure (expressed as a ratio) of the magnitude of a receptor's potential exposure relative to a standard exposure level. The standard exposure level is calculated over an exposure period such that there is no likelihood of adverse health effects to potential receptors, including sensitive populations.

If a delisting evaluation is performed for a one-time exclusion, the DRAS computes the cumulative carcinogenic

risk by summing the carcinogenic risks for all waste constituents for a given exposure pathway and then summing the carcinogenic risks for each pathway analyzed in the delisting risk assessment. The DRAS also computes the cumulative noncarcinogenic risk by summing the Hazard Quotients for all waste constituents for a given exposure pathway to obtain exposure pathway-specific Hazard Indexes (HIs), and then summing the HIs associated with each exposure pathway analyzed. For a one-time exclusion, the results of the cumulative risk assessment may be used in lieu of the calculated delisting levels. Since this is a one-time delisting, we do not need to establish monitoring concentrations for each batch of waste that is subsequently managed under the exclusion. Therefore, we set the evaluation levels in the cumulative risk process at the established target risk range (1×10^{-4} to 1×10^{-6} for carcinogenic waste constituents and a HI of 1.0 to 0.1 for noncarcinogenic waste constituents). Use of the cumulative risk analysis allows the risk associated with an individual waste constituent to extend to a less conservative risk level as long as the cumulative risk for the entire petitioned waste lies below or within EPA's target risk range.

For calculation of delisting levels for multi-year (batch) waste generation, EPA Region III generally defines acceptable risk levels as wastes with an excess cancer risk of no more than 1×10^{-6} and a hazard quotient of no more than 0.1 for individual constituents. For a one-time delisting, EPA Region III evaluates the cumulative cancer risk and cumulative hazard index of the petitioned waste. A cumulative cancer risk less than 1×10^{-4} and a cumulative hazard index less than or equal to 1 are considered to be protective of human health and will be considered acceptable for this type of delisting determination.

B. What Other Factors Did EPA Consider in Its Evaluation?

We also consider the applicability of groundwater monitoring data during the evaluation of delisting petitions where the petitioned waste is currently managed or was once managed in a land-based unit (*e.g.,* a landfill or surface impoundment).

We use the results of groundwater monitoring data evaluations as a check on the reasonable worst case evaluations performed, in order to provide an additional level of confidence in our delisting decisions. Because groundwater monitoring data are descriptive of the impact of the petitioned waste under actual conditions, and not reasonable worst case assumptions, we believe that evidence of groundwater contamination originating from a land-based waste management unit may be sufficient basis for petition denial.

In this case, SPSA/Onyx has not generated the subject ash until this recent incident (described earlier in this preamble) which resulted in a small amount of the ash being used as daily cover in the SPSA Regional Landfill. We have determined that it would not be helpful to request groundwater monitoring data since the small amount of ash used as daily cover would not have a detectable impact on the groundwater at this Regional Landfill.

C. What Conclusion Did EPA Reach?

EPA believes that the information provided by SPSA/Onyx provides a reasonable basis to grant SPSA/Onyx's petition. We, therefore, propose to grant SPSA/Onyx a one-time delisting for the 1410 cubic yards of petitioned ash currently located at the SPSA Regional Landfill. This includes both the ash which has been segregated in a waste pile at the site as well as the ash that has been used as cover material in the Landfill. The data submitted to support the petition and the Agency's evaluation show that the constituents in the SPSA/Onyx ash are below health-based levels used by the Agency for delisting decision-making, and that the ash does not exhibit any of the characteristics of a hazardous waste.

For this delisting determination, we used information gathered to identify plausible exposure routes (*i.e.,* groundwater, surface water, air) for hazardous constituents present in the petitioned waste. We determined that disposal in a RCRA Subtitle D landfill is the most reasonable, worst-case disposal scenario for SPSA/Onyx's petitioned waste. We applied the DRAS described above to predict the maximum allowable concentrations of hazardous constituents that may be released from the petitioned waste after disposal, and we determined the potential impact of the disposal of SPSA/Onyx's petitioned waste on human health and the environment.

The estimated total cumulative risk posed by the waste, as calculated using the DRAS, is 4.1×10^{-5}. We believe that this risk is acceptable both because the value is within the generally acceptable range of 1×10^{-4} to 1×10^{-6} and, as stated above, for a one-time delisting, EPA Region III considers a cumulative cancer risk less than 1×10^{-4} to be protective of human health.

The estimated cumulative hazard index for this waste is calculated by DRAS to be 3.2×10^{-1}. We likewise believe that this risk is acceptable both because the value is within the generally acceptable range of 1.0 to 0.1 and, for a one-time delisting, EPA Region III considers a cumulative hazard index less than or equal to 1 to be protective of human health.

We believe the data submitted in support of the petition show that the waste will not pose a threat when disposed of in a RCRA Subtitle D landfill. We, therefore, propose to grant SPSA/Onyx's request for a one-time delisting for the 1410 cubic yards of ash currently located at the SPSA Regional Landfill.

IV. Conditions for Exclusion

A. What Conditions Are Associated With This Exclusion?

The proposed exclusion would apply only to the estimated 1410 cubic yards of ash currently located at the SPSA Regional Landfill as described in SPSA/Onyx's petition. No ash other than the ash described in this petition could be managed as nonhazardous waste under this exclusion.

If SPSA and/or Onyx discovers that a condition or assumption related to the characterization of this waste that was used in the evaluation of this petition is not as reported in the petition, SPSA and/or Onyx will be required to report any information relevant to that condition or assumption in writing to the Regional Administrator and the Virginia Department of Environmental Quality within 10 calendar days of discovering that condition.

The purpose of this condition is to require SPSA and/or Onyx to disclose new or different information that may be pertinent to the delisting. This provision will allow us to reevaluate the exclusion based on this new information in order to determine if our original decision was correct. If we discover such information from any source, we will act on it as appropriate. Further action may include repealing the exclusion, modifying the exclusion, or other appropriate action deemed necessary to protect human health or the environment. EPA has the authority under RCRA and the Administrative Procedures Act, 5 U.S.C. 551 *et seq.* (1978), (APA), to reopen the delisting under the conditions described above.

SPSA/Onyx state in their petition that the waste, if delisted, will remain at the SPSA Regional Landfill. However, in order to adequately track wastes that have been delisted, in the event that a decision is made to dispose of all or part

of the ash off-site, we will require that SPSA/Onyx provide a one-time notification to any State regulatory agency to which or through which the delisted waste will be transported for disposal. SPSA/Onyx will be required to provide this notification at least 60 calendar days prior to commencing these activities. Failure to provide such notification will be a violation of the delisting, and may be grounds for revocation of the exclusion.

B. What Happens if SPSA or Onyx Fails To Meet the Conditions of This Exclusion?

If SPSA or Onyx violates the terms and conditions established in the exclusion, the Agency may start procedures to withdraw the exclusion, and may initiate enforcement actions.

V. Effect on State Authorizations

This proposed exclusion, if promulgated, would be issued under the Federal RCRA delisting program. States, however, may impose more stringent regulatory requirements than EPA pursuant to Section 3009 of RCRA. These more stringent requirements may include a provision which prohibits a Federally-issued exclusion from taking effect in the State. Because a petitioner's waste may be regulated under a dual system (*i.e.*, both Federal (RCRA) and State (RCRA) or State (non-RCRA) programs), petitioners are urged to contact State regulatory authorities to determine the current status of their wastes under the State laws.

Furthermore, some States are authorized to administer a delisting program in lieu of the Federal program (*i.e.*, to make their own delisting decisions). Therefore, this proposed exclusion, if promulgated, may not apply in those authorized States, unless it is adopted by the State. If the petitioned waste is managed in any State with delisting authorization, SPSA/Onyx must obtain delisting authorization from that State before the waste may be managed as nonhazardous in that State.

VI. Effective Date

EPA is today making a tentative decision to grant SPSA/Onyx's petition. This proposed rule, if made final, will become effective immediately upon such final publication. The Hazardous and Solid Waste Amendments of 1984 amended Section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here, because this rule, if finalized, would reduce the existing requirements for a facility generating hazardous wastes. In light of the unnecessary hardship and expense that would be imposed on this petitioner by an effective date six months after publication and the fact that a six-month deadline is not necessary to achieve the purpose of RCRA Section 3010, EPA believes that this exclusion should be effective immediately upon final publication. These reasons also provide a basis for making this rule effective immediately, upon final publication, under the Administrative Procedures Act, 5 U.S.C. 553(d).

VII. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a rule of general applicability and therefore is not a ''regulatory action'' subject to review by the Office of Management and Budget. Because this action is a rule of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Because the rule will affect only one facility, it will not significantly or uniquely affect small governments, as specified in section 203 of UMRA, or communities of Indian tribal governments, as specified in Executive Order 13175 (65 FR 67249, November 6, 2000). For the same reason, this rule 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This rule does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: June 10, 2003.

Donald S. Welsh,

Regional Administrator, Region III.

For the reasons set forth in the preamble, 40 CFR Part 261 is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for Part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

Appendix IX of Part 261—[Amended]

2. Table 1 of Appendix IX of Part 261 is amended to add the following waste stream in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22.

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * * * *
Southeastern Public Service Authority (SPSA) and Onyx Environmental Services (Onyx).	Suffolk, Virginia	Combustion ash generated from the burning of the spent solvent methyl ethyl ketone (Hazardous Waste Number F005) and disposed of in a Subtitle D landfill. This is a one-time exclusion for 1410 cubic yards of ash and is effective after (insert publication date of the final rule). *(1) Reopener language*

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(a) If SPSA and/or Onyx discovers that any condition or assumption related to the characterization of the excluded waste which was used in the evaluation of the petition or that was predicted through modeling is not as reported in the petition, then SPSA and/or Onyx must report any information relevant to that condition or assumption, in writing, to the Regional Administrator and the Virginia Department of Environmental Quality within 10 calendar days of discovering that information. (b) Upon receiving information described in paragraph (a) of this section, regardless of its source, the Regional Administrator will determine whether the reported condition requires further action. Further action may include repealing the exclusion, modifying the exclusion, or other appropriate action deemed necessary to protect human health or the environment. *(2) Notification Requirements* In the event that the delisted waste is transported off-site for disposal, SPSA/Onyx must provide a one-time written notification to any State Regulatory Agency to which or through which the delisted waste described above will be transported at least 60 calendar days prior to the commencement of such activities. Failure to provide such notification will be deemed to be a violation of this exclusion and may result in revocation of the decision and other enforcement action.
*	*	* * * * *

[FR Doc. 03–15361 Filed 6–17–03; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Vehicle Compatibility, Docket No. NHTSA–2003–14623; Rollover Mitigation, Docket No. NHTSA–2003–14622]

Vehicle Compatibility and Rollover Mitigation Integrated Project Team (IPT) Plans

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

ACTION: Notice of availability of documents.

SUMMARY: This notice announces the availability of NHTSA's first two of four high priority safety reports describing the agency's current and planned activities to address vehicle compatibility and rollover mitigation. The reports are available from the Docket Management System, U.S. Department of Transportation, at *http://dms.dot.gov* or on NHTSA's Web site at *http://www.nhtsa.dot.gov/people/iptreports.html.* While the documents are final, the agency is offering the public the opportunity to comment on the agency's planned activities. The comments will be considered for future agency efforts.

DATES: Comments must be received no later than August 4, 2003.

ADDRESSES: You may submit comments identified by Vehicle Compatibility DOT DMS Docket Number [NHTSA–2003–14623] and/or Rollover Mitigation DOT DMS Docket Number [NHTSA–2003–14622] by any of the following methods:

- *Web Site: http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Instructions: All submissions must include the agency name and docket number. Note that all comments received will be posted without change to *http://dms.dot.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT:

Vehicle Compatibility—Roger A. Saul, National Highway Traffic Safety Administration, Room 5307, 400 Seventh Street, SW., Washington, DC 20590, Telephone: 202–366–1740, or Dee Y. Williams, National Highway Traffic Safety Administration, Room 5208, 400 Seventh Street, SW., Washington, DC 20590. Telephone: 202–366–0498.

Rollover Mitigation—Jim Simons, National Highway Traffic Safety Administration, Room 5208, 400 Seventh Street, SW., Washington, DC 20590, Telephone: 202–366–2555, or Dee Y. Williams, National Highway Traffic Safety Administration, Room 5208, 400 Seventh Street, SW., Washington, DC 20590. Telephone: 202–366–0498.

SUPPLEMENTARY INFORMATION:

Vehicle Compatibility

Since the 1970s, vehicle compatibility has been a concern to NHTSA. Recent sales and registrations of LTVs have steadily increased as a percentage of the passenger vehicle fleet, with LTVs representing 50 percent of new vehicle sales in 2001 and 37 percent of vehicle registrations. Consequently, this has led to an increased number of fatalities to car occupants who are struck by LTVs. This increase in passenger car fatalities has occurred even while the overall fatalities for the U.S. fleet has stabilized or decreased over the past several years. Therefore, NHTSA has made vehicle compatibility one of the agency's highest priorities. Initiatives the agency plans to pursue in improving vehicle compatibility include:

1. Vehicle Strategies
   a. Partner Protection
   b. Self Protection
   c. Lighting/Glare

d. Reform CAFE
2. Roadway Strategies
a. Improve Structural Engagement with Roadside Hardware
b. Increase Awareness
3. Behavioral Strategies
a. Consumer Information Program

Vehicle Rollover

Vehicle rollover is also a great concern to NHTSA. Many factors contribute to the occurrence of rollover crashes. Rollover crashes closely correlate with unsafe and reckless driving behaviors, poor road design and vehicle type. Certain categories of vehicles, such as sport utility vehicles and small pickup trucks, are more prone to rollover than other classes of light motor vehicles. In recognition of the increasing rollover problem, NHTSA has also made finding solutions one of the agency's highest priorities. Initiatives the agency plans to pursue in reducing deaths and injuries attributable to rollover crashes include:

1.Vehicle Strategies
a. Handling and Stability
b. Reform CAFE
c. Ejection Mitigation
d. Roof Crush
2. Roadway and Roadside Improvements
3. Consumer Information Program
4. Rollover Causation Study

NHTSA believes the initiatives described in these two IPT reports will lead to both near-term and longer-term solutions to improve vehicle compatibility in the fleet and reduce crashes attributable to rollover.

NHTSA has also assembled IPTs to address two other highway safety programs of high interest: safety belt use and impaired driving. For each of these programs, the agency will issue final IPT reports and provide the public with the same opportunity to comment on the planned agency activities. Similar to the reports on vehicle compatibility and rollover mitigation, the documents will be final and comments received will be evaluated and incorporated, as appropriate into future agency efforts. Each of these documents can be found at future dates on NHTSA's Web site at *http://www.nhtsa.dot.gov/people/iptreports.html* and also on DOT's docket management system (DMS) at *http://dms.dot.gov/.* The docket numbers for each of the respective reports will be as follows:

❑ Safety Belt Use NHTSA–2003–14620; and

❑ Impaired Driving NHTSA–2003–14621.

Each document will describe the safety problem and provide strategies the agency plans to pursue in increasing safety belt use and reducing impaired driving.

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the Docket number of this document (Vehicle Compatibility, NHTSA–2003–14623; Rollover Mitigation, NHTSA–2003–14622) in your comments.

Please send two paper copies of your comments to Docket Management or submit them electronically. The mailing address is U.S. Department of Transportation Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. If you submit your comments electronically, log onto the Docket Management System Web site at *http://dms.dot.gov* and click on ''Help & Information'' or ''Help/Info'' to obtain instructions.

How Can I Be Sure That My Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How Do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, send three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NCC–01, National Highway Traffic Safety Administration, Room 5219, 400 Seventh Street, SW., Washington, DC 20590. Include a cover letter supplying the information specified in our confidential business information regulation (49 CFR part 512).

In addition, send two copies from which you have deleted the claimed confidential business information to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590.

Will the Agency Consider Late Comments?

In our response, NHTSA will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES.** To the extent possible, we will also consider comments that Docket Management receives after that date.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

How Can I Read the Comments Submitted By Other People?

You may read the comments by visiting Docket Management in person at Room PL–401, 400 Seventh Street, SW., Washington, DC from 10 a.m. to 5 p.m., Monday through Friday.

You may also see the comments on the Internet by taking the following steps:

- Go to the Docket Management System (DMS) Web page of the Department of Transportation (*http://dms.dot.gov*).
- On that page, click on ''search.''
- On the next page ((*http://dms.dot.gov/search/*) type in the five-digit Docket number shown at the beginning of this document (Vehicle Compatibility -14623; Rollover Mitigation—14622). Click on ''search.''
- On the next page, which contains Docket summary information for the Docket you selected, click on the desired comments. You may also download the comments.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Authority: 49 U.S.C. 30111, 30117, 30168; delegation of authority at 49 CFR 1.50 and 501.8.

Issued on: June 12, 2003.

Rose A. McMurray,

Associate Administrator for Planning, Evaluation & Budget.

[FR Doc. 03–15239 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 68, No. 117
Wednesday, June 18, 2003

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

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection, Comment Request—Food Stamp Program: Federal Collection of State Plan of Operations, Operating Guidelines and Forms

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Food and Nutrition Service (FNS) is publishing for public comment, a summary of a proposed information collection. The proposed collection is a revision of a collection currently approved under OMB No. 0584–0083.

DATES: Comments on this notice must be received by August 18, 2003, to be assured of consideration.

ADDRESSES: Send comments and requests for copies of this information collection to Barbara Hallman, Chief, State Administration Branch, Food Stamp Program, Food and Nutrition Service, USDA, 3101 Park Center Drive, Alexandria, VA 22302.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments will be summarized and included in the request for Office of Management and Budget approval of the information collection. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Barbara Hallman, telephone number (703) 305–2383.

SUPPLEMENTARY INFORMATION: *Title:* Operating Guidelines, Forms and Waivers.

OMB Number: 0584–0083.

Expiration Date: December 2005.

Type of Request: Revision of a currently approved collection.

Abstract: In accordance with section 11(e) of the Food Stamp Act of 1977 (the Act), 7 U.S.C. 2020(e), State agencies are required to submit a Plan of Operation specifying the manner in which the Food Stamp Program will be conducted. The State Plan of Operations, in accordance with current rules at 7 CFR 272.2, consists of a Federal/State Agreement, annual budget and activity statements, and specific attachments (such as plans if the State elects to conduct program information activities or provide nutrition educational services). State Plans of Operation are a one-time effort with updates that are provided as necessary.

Under section 16 of the Act, 7 U.S.C. 2025, the Secretary is authorized to pay each State agency an amount equal to 50 percent of all administrative costs involved in each State agency's operation of the FSP. Under corresponding FSP regulations at 7 CFR 272.2, the State agencies must submit annually to FNS for approval, a Budget Projection Statement (Form FNS–366A), which projects the total costs for major areas of FSP operations, and a Program Activity Statement (Form FNS–366B), which provides a summary of FSP operations during the preceding fiscal year. The reports are required to substantiate the costs the State agency expects to incur during the next fiscal year. Form FNS–366A is submitted annually by August 15, for the upcoming fiscal year and Form FNS–366B must be submitted no later than 45 days after the end of each State agency's fiscal year.

FNS is proposing to add a new category of information to the FNS–366A to report data on Employment and Training (E&T) grants for able-bodied adults without dependent children (ABAWDs). Section 4121(b) of the Farm Security and Rural Reinvestment Act of 2002, Public Law 107–171, which was signed into law on May 13, 2002, gave FNS $20 million in new 100% funds (the ABAWD grants). FNS has determined that it needs the new category of information on the FNS–366A to separately track these funds in its budget information system. The funds benefit ABAWD food stamp recipients (who are subject to a 3-month time limit for FSP participation) to help them get jobs. The funding amount is allocated by FNS to the State agency for the ABAWD grant. Because the funding amount figure for this item is provided by FNS, the impact on the burden is negligible, and so there is no additional burden for this as a budget item. The FNS–366A data for this item will allow FNS to compare this budget item against actual expenditures.

Beginning July 1997, State agencies were allowed to submit the FNS–366B data electronically to the national database files stored in FNS' FSP Integrated Information System in lieu of a paper report. The voluntary changeover from paper to electronic reporting of FNS–366B data by States was done as part of FNS' State Cooperative Data Exchange (SCDEX) Project. This project is being expanded over time as more FNS forms are transformed to electronic formats for State data entry. As of February 2003, a total of nine State agencies submitted the FNS–366B data electronically and 44 State agencies submitted paper reports.

Under section 11(o) of the Act, 7 U.S.C. 2020(o), each State agency was required to develop a plan, no later than October 1, 1987, for implementing an automated data processing (ADP) and information retrieval system to administer the FSP. Corresponding FSP regulations at 7 CFR 277.18 require that a written plan of action, called an Advance Planning Document (APD), be prepared to acquire proposed ADP services, systems or equipment. The frequency of the APD submission is at the discretion of the State agency.

Under section 7(i) of the Act, 7 U.S.C. 2016(i), the Secretary is authorized to permit State agencies to implement on-line electronic benefit transfer (EBT) systems. The Secretary is authorized to establish standards for the required

testing prior to implementation of any EBT system and analysis of the results of implementation in a limited pilot project area before expansion of the system. Any State requesting funding for an EBT system must submit an APD.

Respondents: State agencies that administer the FSP.

Number of Respondents: 53.

Estimated Number of Responses per Respondent: Plan of Operation Updates: 53 State agencies once a year.

Form FNS–366A: 53 State agencies once a year.

Form FNS–366B: 53 State agencies once a year.

Advance Planning Documents: 15 State agencies once a year.

Advance Planning Documents for EBT Systems: 10 State agencies once a year.

EBT Reporting: 41 State agencies reporting four times a year.

Estimate of Burden: Plan of Operation Updates: The State agencies submit Plan updates at an estimate of 10 hours per respondent, or 530 total hours.

Form FNS–366A: The State agencies submit Form FNS–366A at an estimate of 13 hours per respondent, or 689 total hours.

Form FNS–366B: The total burden for the collection of information for Form FNS–366B is 18 hours per respondent, or 954 hours.

Outreach Plans: We estimate that up to 25 States may submit an Outreach Plan over the next year at an estimate of 1 hour per respondent or 25 total hours.

PRWORA Plan Updates: We estimate 34 States will choose one or more options, and thus will have to respond, at an average .25 hours per response, or a total burden of 8.5 hours.

Advance Planning Documents: Approximately 15 State agencies submit an APD each year at an estimate of 10 hours per respondent or 150 total hours.

Advance Planning Documents for EBT Systems: Approximately ten State agencies submit an APD each year for an EBT system at an estimate of 35 hours per respondent, or 350 total hours.

EBT Reporting: None.

Estimated Total Annual Burden on Respondents: The total annual reporting and recordkeeping burden for OMB No. 0584–0083 is estimated to be 2,707 hours, a decrease of 225 hours from the previous estimate and currently approved burden of 2,932 hours. The decrease in the burden is due to a decrease in the number of States who submit an APD and the time to complete an APD.

Dated: June 11, 2003.

Roberto Salazar,

Administrator.

[FR Doc. 03–15350 Filed 6–17–03; 8:45 am]

BILLING CODE 3410–30–U

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Youth Conservation Corps

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension of a previously approved information collection for forms FS–1800–18, Youth Conservation Corps Application, and FS–1800–3, Youth Conservation Corps Medical History. The collected information will help the Forest Service evaluate the employment eligibility of youth 15–18 years old through the Youth Conservation Corps Program. Under this Program, the Forest Service cooperates with other Federal agencies to provide seasonal employment for youth.

DATES: Comments must be received in writing on or before August 18, 2003 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: All comments should be addressed to: United States Department of Agriculture, Forest Service, Director, Youth Conservation Corps, Senior, Youth and Volunteer Programs, Mail Stop 1136, PO Box 96090, Washington, DC 20090–1136.

Comments also may be submitted via facsimile to (703) 605–5115 or by e-mail to: *syvp/wo@fs.fed.us.*

The public may inspect comments at the Office of the Director, Senior, Youth and Volunteer Programs, Forest Service, USDA, Room 1010, 1621 North Kent Street, Arlington, VA 22209. Visitors are asked to call (703) 605–4831 in advance to facilitate entrance into the office.

FOR FURTHER INFORMATION CONTACT: Ransom Hughes, Youth Conservation Corps, Senior, Youth and Volunteer Program at (703) 605–4854.

SUPPLEMENTARY INFORMATION:

Background

Under the Youth Conservation Corps Act of August 13, 1970, as amended (16 U.S.C. 1701)—1706), the U.S. Department of Agriculture Forest Service in cooperation with the U.S. Department of the Interior Fish and Wildlife Service, National Park Service and Bureau of Land Management provide seasonal employment for eligible youth 15 to 18 years old.

Youth who seek training and employment with the Forest Service through the Youth Conservation Corps must complete the following forms: (1) FS 1800–18, Youth Conservation Corps Application, and (2) FS–1800–3, Youth Conservation Corps Medical History. Forest Service and Department of the Interior employees use the information to evaluate the eligibility of each applicant.

The Youth Conservation Corps stresses three important objectives:

1. Accomplish needed conservation work on public lands;

2. Provide gainful employment for 15 to 18 year old males and females from all social, economic, ethnic, and racial backgrounds; and

3. Foster, on the part of the 15 to 18 year old youth, an understanding and appreciation of the Nation's natural resources and heritage.

Description of Information Collection

1. *Title:* FS–1800–18, Youth Conservation Corps (YCC) Application.

OMB Number: 0596–0084.

Expiration Date of Approval: September 30, 2003.

Type of Request: Extension of an information collection previously approved by the Office of Management and Budget.

Abstract: Employees of the U.S. Department of Agriculture, Forest Service and the U.S. Department of the Interior, Fish and Wildlife Service, National Park Service and Bureau of Land Management will evaluate the data and determine the eligibility of each youth for employment with the Youth Conservation Corps. To be considered for employment with the Corps, each youth must complete FS–1800–18, Youth Conservation Corps Application Form. Applicants are asked to answer questions that include their name, social security number, date of birth, mailing address, and telephone number. The applicant's parents or guardian must sign the form.

Data gathered in this information collection are not available from other sources.

Estimate of Annual Burden: 6 minutes.

Type of Respondents: Youth 15 to 18 years old.

Estimated Annual Number of Respondents: 18,000.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 1,800 hours.

Description of Information Collection

2. *Title:* FS–1800–3, Youth Conservation Corps Medical History.

OMB Number: 0596–0084.

Expiration Date of Approval: September 30, 2003.

Type of Request: Extension of an information collection previously approved by the Office of Management and Budget.

Abstract: To be considered for employment with the Corps, each youth must complete FS–1800–3, Youth Conservation Corps Medical History Form. Applicants are asked to answer questions regarding their personal health. The purpose of FS–1800–3 is to certify the youth's physical fitness to work in the seasonal employment Program. The applicant's parents or guardian must sign the form.

Data gathered in this information collection are not available from other sources.

Estimate of Annual Burden: 14 minutes.

Type of Respondents: Youth 15 to 18 years old.

Estimated Annual Number of Respondents: 18,000.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 4,200 hours.

Comment Is Invited

The agency invites comments on the following: (a) Whether the proposed collection of information is necessary for the stated purpose and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Use of Comments

All comments received in response to this notice, including names and address when provided, will become a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget.

Dated: June 11, 2003.

Irving W. Thomas,

Acting Deputy Chief Operations.

[FR Doc. 03–15314 Filed 6–17–03; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 061203F]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: National Marine Sanctuaries - Socioeconomic Impacts of Marine Reserves.

Form Number(s): None.

OMB Approval Number: 0648-0408.

Type of Request: Regular submission.

Burden Hours: 1,330.

Number of Respondents: 665.

Average Hours Per Response: 2.

Needs and Uses: NOAA's National Marine Sanctuaries are authorized under the National Marine Sanctuary Act to use zoning to prohibit or restrict uses in certain portions (zones) of sanctuaries. Ecological Reserves, Sanctuary Preservation Areas, or Marine Reserves (no-take zones) are being proposed. There is a need to evaluate the socioeconomic impact that no-take zones might have on different user groups. Those activities that might be displaced from no-take zones include commercial fishing operations, recreational fishing operations, and individuals takes of anything in the area. The surveys will collect socioeconomic data for use by NOAA, sanctuary advisory councils, and similar participants in the planning process.

Affected Public: Business or other for-profit organizations, individuals or households, and not-for-profit institutions.

Frequency: Annually, one-time.

Respondent's Obligation: Voluntary.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: June 11, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–15404 Filed 6–17–03; 8:45 am]

BILLING CODE 3510–NK–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 061203G]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Northeast Region Vessel Monitoring and Communications.

Form Number(s): None.

OMB Approval Number: 0648–0404.

Type of Request: Regular submission.

Burden Hours: 974.

Number of Respondents: 150.

Average Hours Per Response: 1 hour for installation of a vessel monitoring system (VMS); 2 minutes for verification of installation; 5 seconds for an automatic position report; and 2 minutes for a Letter of Authorization Exemption request.

Needs and Uses: Owners or operators of vessels that have caught 500 metric tons of herring in the past year, or intend to catch 500 metric tons in the current year, must equip their vessels with an approved Vessel Monitoring System (VMS). The VMS units automatically report the vessel's position at least once per hour when the vessel is underway. Vessel owners must submit proof that the VMS has been installed. Herring carriers may be exempted from this requirement by obtaining a letter of authorization from NOAA.

Affected Public: Business or other for-profit organizations, individuals or households.

Frequency: On occasion, hourly.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance

Officer, (202) 482-0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: June 11, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–15405 Filed 6–17–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 060603E]

Intent to Analyze the Effects of the Subsistence Taking of Northern Fur Seals on the Pribilof Islands, Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent; scoping meetings; request for comments.

SUMMARY: NMFS intends to prepare an Environmental Impact Statement (EIS) regarding possible changes to the subsistence harvest of the Pribilof Islands stock of northern fur seals. The scope of the EIS will consist of a broad review of the subsistence harvest management on the Pribilof Islands including the manner in which the harvest is conducted. NMFS intends to hold scoping meetings to receive public input on the issues of concern and the appropriate range of management alternatives to be addressed in the EIS. In addition to holding the scoping meetings, NMFS solicits written comments related to the scope of the analysis.

DATES: Written comments will be accepted through September 16, 2003.

ADDRESSES: Written comments should be addressed to the Assistant Regional Administrator, Protected Resources Division, NMFS, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Durall. Requests to be included on a mailing list of persons interested in the EIS should be sent to Mr. David Cormany at 222 West 7th Avenue, Box 43, Anchorage, AK 99513. Comments may also be hand-delivered to NMFS, Federal Building, 709 West 9th Street, Juneau, AK, or NMFS, Federal Building, Room 517, 222 West 7th Avenue, Anchorage, AK. NMFS is not accepting email or internet comments.

FOR FURTHER INFORMATION CONTACT: David Cormany, (907) 271–5006.

SUPPLEMENTARY INFORMATION: On July 9, 1985 (50 FR 27914), NMFS published an emergency interim rule to govern the subsistence taking of fur seals by Alaska Native (Aleut) residents of the Pribilof Islands. A final rule was subsequently published on July 9, 1986 (51 FR 24828). The subsistence harvest of northern fur seals on the Pribilof Islands is governed by regulations at 50 CFR 216 Subpart F—Pribilof Islands, Taking for Subsistence Purposes. These regulations were published under the authority of the Fur Seal Act (FSA), 16 U.S.C. 1151 *et seq.*, and the Marine Mammal Protection Act (MMPA), 16 U.S.C. 1361 *et seq.* The purpose of these regulations was to provide for the subsistence needs of the Pribilof Aleuts using humane harvesting methods and to restrict taking by sex, age, and season for herd management purposes.

The Need for an EIS on this Action

An Environmental Assessment and a Finding of No Significant Impact of the harvest on the fur seal population have been considered adequate to address the Agency's NEPA compliance responsibilities in the past. However, evidence is building that continued management under the harvest regulations in combination with other past, present, and future actions, may be having a significant impact on the human environment. Therefore, preparation of an EIS for the proposed action may be required by NEPA and implementing regulations at 40 CFR 1501.4.

NMFS is required to publish a Notice of Intent (NOI) to, among other things, describe the proposed scoping process, including any scoping meetings to be held. The NOI also serves as the official notice that a Federal agency is commencing preparation of an EIS pursuant.

NMFS will examine all activities addressing the conduct of the subsistence harvest management. The cumulative effects section of the EIS will address the incremental cumulative effects of these management alternatives on northern fur seals when added to the effects of past, other present, or reasonably foreseeable future actions including the significant effects finding of the Steller Sea Lion Protection Measures EIS (NMFS 2001). The EIS for Steller sea lions examined the effects of management measures implemented in the groundfish fisheries in the Bering Sea and Aleutian Islands (BSAI) to protect endangered Steller sea lions in the area. In the analyses of the cumulative effects of the action on the environment, it was determined that commercial fishing and environmental changes (effects of a regime shift) may result in a conditionally significant adverse effect on northern fur seals. Therefore, while the subsistence harvest is not likely to have any direct or indirect effects on the fur seal population that would be considered significant under NEPA, the cumulative effects of the subsistence harvest alternatives when added to the effects of the groundfish fisheries on the harvest alternatives may result in a similar cumulative effects finding as identified in NMFS (2001).

Information and Comments Solicited

NMFS solicits comments and information to identify the complete range of alternatives to be analyzed. Alternatives analyzed in this EIS may include those identified below, plus additional alternatives identified through the public scoping process and through working with the Tribal Governments and other constituent groups. Potential alternatives that have already been identified include the following: (1) status quo alternative- No action will be taken to change existing regulations at 50 CFR 216 subpart F. The conduct and management of the harvest will remain as it has been; (2) an alternative that combines some of the existing regulations with agreed upon stipulations identified in the co-management agreements between NMFS and the Tribal Governments pursuant to section 119 of the MMPA; and (3) a harvest regime that is completely managed through co-management pursuant to section 119 of the MMPA.

NMFS has entered into co-management agreements with the Tribal Governments of St. Paul Island and St. George Island under section 119 of the MMPA in 2000 and 2001, respectively. These agreements are specific to the conservation and management of northern fur seals and Steller sea lions on the Pribilof Islands, with particular attention to the subsistence take and use of these animals. NMFS has worked with both communities to integrate the agreements into one management plan for the purpose of recovering and maintaining the fur seal population. Under this alternative all current regulations would be eliminated.

NMFS is also seeking information on the environmental, social and economic issues to be considered in the analysis.

The direct and indirect effects sections of the EIS will present the impacts of each identified alternative on the human environment. Major issues are likely to include: the impact of subsistence and commercial fisheries removals on this stock, the impacts of regulated harvests on the subsistence needs, traditional and cultural values of Alaskan Natives, and co-management of the subsistence harvest under section 119 of the MMPA.

Public Involvement

Scoping is an open process for determining the scope of issues to be addressed and for identifying the significant issues related to the proposed action. A principle objective of this process is to identify a range of reasonable management alternatives that, with analysis, will provide a clear basis for distinguishing between the alternatives and selecting a preferred alternative.

Scoping meetings will be held on the Pribilof Islands, AK, and in Anchorage, AK. Dates have not been set at this time and will follow the cessation of the 2003 subsistence harvest. Times and locations of the scoping meetings will also be published in a subsequent notice.

Dated: June 11, 2003.

Donna Wieting,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–15407 Filed 6–17–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 031203A]

Small Takes of Marine Mammals Incidental to Specified Activities; Harbor Activities at Vandenberg Air Force Base, CA

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of issuance of incidental harassment authorization.

SUMMARY: In accordance with provisions of the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that an Incidental Harassment Authorization (IHA) to take small numbers of marine mammals by harassment incidental to harbor activities related to the Delta IV/Evolved Expendable Launch Vehicle (EELV) at South Vandenberg Air Force Base, CA (VAFB) has been issued to The Boeing Company (Boeing).

DATES: Effective from May 20, 2003, until May 20, 2004.

ADDRESSES: A copy of the IHA and/or the application is available by writing to Ms. Kaja Brix, Acting Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3225, or by telephoning one of the contacts listed here.

FOR FURTHER INFORMATION CONTACT: Kimberly Skrupky, (301) 713–2322, ext. 163 or Christina Fahy, (562) 980–4023.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, notice of a proposed authorization is provided to the public for review.

Permission for incidental takings may be granted if NMFS finds that the taking will have no more than a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and that the permissible methods of taking and requirements pertaining to the monitoring and reporting of such taking are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as:

> an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Subsection 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. The MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [''Level A harassment'']; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [''Level B harassment''].

Subsection 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On January 28, 2003, NMFS received an application from Boeing requesting an authorization for the harassment of small numbers of Pacific harbor seals (*Phoca vitulina richardsi*) and California sea lions (*Zalophus californianus*) incidental to harbor activities related to the Delta IV/EELV, including: transport vessel operations, cargo movement activities, harbor maintenance dredging, and kelp habitat mitigation operations. In addition, northern elephant seals (*Mirounga angustirostris*) may also be incidentally harassed but in smaller numbers. The harbor where activities will take place is on south VAFB approximately 2.5 mi (4.02 km) south of Point Arguello, CA, and approximately 1 mi (1.61 km) north of the nearest marine mammal pupping site (i.e., Rocky Point). An Incidental Harassment Authorization (IHA) was issued to Boeing on May 20, 2002 and remains in effect for a one-year period (see 67 FR 36151, May 23, 2002).

Specified Activities

Additional information of the work proposed for 2003 is contained in the application, which is available upon request (see **ADDRESSES**) and in the Final US Air Force Environmental Assessment for Harbor Activities Associated with the Delta IV Program at Vandenberg Air Force Base (ENSR International, 2001).

Comments and Responses

On April 9, 2003 (68 FR 17351), NMFS published a notice of receipt and a 30–day public comment period was provided on the application and proposed authorization. That notice described the activity and anticipated effects on marine mammals. Comments were received from Boeing which requested that the mitigation measure be modified to allow for the continuation of activities while seals are present. As the Notice stated, the rocks near the VAFB harbor are not typically used by large numbers of harbor seals nor is there pupping: ''...on average the number of harbor seals hauled out near the site is less than 30 and there is no pupping at nearby sites'' (68 Fed. Reg. 17351 at 17353). The monitoring that was performed for the VAFB harbor dredging during the fall of 2001 and

winter of 2002 established that seals routinely hauled out on the adjacent rocks during ongoing activities within the harbor. On several occasions, these seals flushed, apparently due to activities on the dock or in the harbor. However, when they did leave the rocks during low tide they would quickly return or be replaced by other individuals in the same resting place. This quick return to the original haulout suggests that the response was short term and transient. Boeing's experience last year with the dredging and other harbor activities, however, also demonstrated that stopping work when seals are present on the adjacent rocks can have a considerable impact to schedules and costs. The data collected during last year's harbor activities, which is documented in the application for the IHA, supports the conclusion reached by NMFS in the proposed IHA that the occasional flushing of a limited number of seals from the rocks while harbor activities are underway has minimal impact on the species. Accordingly, Boeing requests that the IHA provide that the continuation of activities at VAFB harbor is authorized while seals are present even in the event of flushing seals.

NMFS concurs that continuation of activities would have a minimal impact on pinnipeds and has thus modified the mitigation measures contained in the authorization to allow for continuation of activities while seals are present. The mitigation measures still require marine mammal monitoring during all Boeing activities in the harbor and reporting of any possible disturbance of the harbor seals associated with those activities.

Mitigation

To reduce the potential for disturbance from visual and acoustic stimuli associated with the activities Boeing will undertake the following marine mammal mitigating measures:

(1) If activities occur during nighttime hours, lighting will be turned on before dusk and left on the entire night to avoid startling harbor seals at night.

(2) Activities will be initiated before dusk.

(3) Construction noises must be kept constant (i.e., not interrupted by periods of quiet in excess of 30 minutes) while harbor seals are present.

(4) If activities cease for longer than 30 minutes and harbor seals are in the area, start-up of activities will include a gradual increase in noise levels.

(5) A NMFS-approved marine mammal observer will visually monitor the harbor seals on the beach adjacent to the harbor and on rocks for any flushing or other behaviors as a result of Boeing's activities.

(6) The Delta Mariner and accompanying vessels will enter the harbor only when the tide is too high for harbor seals to haul-out on the rocks and the vessel will reduce speed 1.5 to 2 knots once the vessel is within 3 mi (4.83 km) of the harbor. The vessel will enter the harbor stern first, approaching the wharf and its mooring dolphins at less than 0.75 knot.

(7) As alternate dredge methods are explored, the dredge contractor may introduce quieter techniques and equipment.

Monitoring

As part of its application, Boeing provided a proposed monitoring plan for assessing impacts to harbor seals from the activities at south VAFB harbor and for determining when mitigation measures should be employed.

A NMFS-approved and VAFB-designated biologically trained observer will monitor the area for pinnipeds during all harbor activities. During nighttime activities, the harbor area will be illuminated, and the monitor will use a night vision scope. Monitoring activities will consist of:

(1) Conducting baseline observation of pinnipeds in the project area prior to initiating project activities.

(2) Conducting and recording observations on pinnipeds in the vicinity of the harbor for the duration of the activity occurring when tides are low enough for pinnipeds to haul out (2 ft, 0.61 m, or less).

(3) Conducting post-construction observations of pinniped haul-outs in the project area to determine whether animals disturbed by the project activities return to the haul-out.

Reporting

Boeing will notify NMFS 2 weeks prior to initiation of each activity. After each activity is completed, Boeing will provide a report to NMFS 120 days prior to the expiration of this Authorization or within 120 days after the expiration of this Authorization if a new Authorization is not being requested. This report will provide dates and locations of specific activities, details of seal behavioral observations, and estimates of the amount and nature of all takes of seals by harassment or in other ways. In addition, the report will include information on the weather, the tidal state, the horizontal visibility, and the composition (species, gender, and age class) and locations of haul-out group(s). In the unanticipated event that any cases of pinniped injury or mortality are judged to result from these activities, this will be reported to NMFS immediately.

Consultation

This action will not affect those marine mammal species listed under the Endangered Species Act (ESA), that are under the jurisdiction of NMFS, as these species are not expected to haulout on VAFB and thereby potentially be affected through harassment and fleeing from the haulout. No other marine species listed under the ESA will be affected by Boeing's harbor activities related to the Delta IV/EELV at VAFB. VAFB formally consulted with U.S. Fish and Wildlife Service (FWS) in 1998 on the possible take of southern sea otters during Boeing's harbor activities at south VAFB. A Biological Opinion was issued in August 2001. Southern sea otters were discussed in these documents and FWS recognized that Boeing will restore sea otter habitat (i.e., kelp beds) in the vicinity of the harbor to replace kelp destroyed during dredging. In addition, the FWS noting that VAFB has committed to a southern sea otter monitoring program designed to detect the presence and possible disturbance at the VAFB harbor area during dredging activities.

NEPA

In accordance with section 6.01 of the NOAA Administrative Order 216–6 (Environmental Review Procedures for Implementing the National Environmental Policy Act, May 20, 1999), NMFS has determined, based on the content and analysis of Boeing's request for an IHA, and the Final EA for Harbor Activities Associated with the Delta IV Program at VAFB (ENSRI, 2001) that the proposed issuance of this IHA to Boeing by NMFS will not individually or cumulatively result in a significant impact on the quality of the human environment as defined in 40 CFR 1508.27. Impacts are not expected to be outside the scope of that EA. Therefore, this action meets the definition of a ''Categorical Exclusion'' and is exempted from further environmental review.

Determinations

NMFS had determined that the impact of harbor activities related to the Delta IV/EELV at VAFB, including: transport vessel operations, cargo movement activities, harbor maintenance dredging, and kelp habitat mitigation will result in the harassment of small numbers of Pacific harbor seals, California sea lions, and northern elephant seals; would have no more negligible impact on these marine mammal stocks; and would not have an

unmitigable adverse impact on the availability of marine mammal stocks for subsistence uses. Northern fur seals, Guadalupe fur seals, and Steller sea lions are unlikely to be found in the area and therefore will not be affected. While behavioral modifications may be made by those pinniped species ashore in order to avoid the resultant acoustic and visual stimuli from the activity, there is no potential for large-scale movements, such as stampedes, since harbor seals, California sea lions, and elephant seals haul out in small numbers near the site (maximum number of harbor seals hauled out in one day estimated at 43 seals, averaging at 21 seals per day, maximum number of California sea lions hauled out in one day is estimated at six). The effects of Boeing's harbor activities are expected to be limited to short-term and localized behavioral changes.

Due to the localized nature of these activities, the number of marine mammals potentially taken by harassment are estimated to be small. In addition, no take by injury and/or death is anticipated, and the potential for temporary or permanent hearing impairment is unlikely given the low noise levels expected at the site. No rookeries, mating grounds, areas of concentrated feeding, or other areas of special significance for marine mammals occur within or near south VAFB harbor.

Authorization

NMFS has issued an IHA to Boeing for harbor activities related to the Detla IV/EELV program at south VAFB for a 1–year period. A copy of this IHA is available upon request (see **ADDRESSES**). The issuance of this IHA is contigent upon adherence to the previously mentioned mitigation, monitoring, and reporting requirements.

Dated: June 10, 2003.

Donna Wieting,

Acting Office Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–15406 Filed 6–17–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 061203I]

Small Takes of Marine Mammals Incidental to Specified Activities; Movement of Steel Drilling Caisson through the Beaufort Sea from Cross Island, McCovey Prospect to Herschel Island, Yukon Territory

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of receipt of application and proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received a request from EnCana Oil and Gas (USA) Inc. (EnCana) for an authorization to take small numbers of marine mammals by harassment incidental to movement of a Steel Drilling Caisson (SDC) from Cross Island, McCovey Prospect, AK through the Beaufort Sea to Herschel Island in the Yukon Territory and for associated activities in the Beaufort Sea. If there is a problem with this location for the SDC, the U.S. Outer Continental Shelf waters north of West Dock has been named as the backup location. Under the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to authorize EnCana to incidentally take, by harassment, small numbers of bowhead whales, beluga whales, ringed seals, bearded seals, and spotted seals in the above mentioned areas during August 2003 through January 2004 for SDC preparation, movement, refueling, and removal of equipment. The incidental take of polar bears and walrus from EnCana's planned activities are not covered by this proposed incidental harassment authorization, as these species are under jurisdiction of the U.S. Fish and Wildlife Service (USFWS). EnCana is applying for a Letter of Authorization from the USFWS for potential takes of polar bear and Pacific walrus.

DATES: Comments and information must be received no later than July 18, 2003.

ADDRESSES: Comments on the application should be addressed to Kaja Brix, Acting Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3225. A copy of the application used in this document may be obtained by writing to this address or by telephoning one of the contacts listed here.

FOR FURTHER INFORMATION CONTACT: Kimberly Skrupky, (301) 713–2322, ext 163 or Brad Smith, (907) 271–3023.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, notice of a proposed authorization is provided to the public for review.

Permission for incidental takings may be granted if NMFS finds that the taking will have no more than a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and that the permissible methods of taking and requirements pertaining to the monitoring and reporting of such taking are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as:

> an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Subsection 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. The MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [''Level A harassment'']; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [''Level B harassment''].

Subsection 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On May 14, 2003, NMFS received an application from EnCana requesting an authorization for the harassment of

small numbers of five species of marine mammals incidental to movement of the SDC from Cross Island, McCovey Prospect, AK through the Beaufort Sea to Herschel Island, Yukon Territory and associated activities beginning on or about August 1, 2003 to ice-up later in the year. The SDC will lift-off from its current location and will be towed to the new set down location. Once the SDC reaches Herschel Island, it will go into cold stack mode. Helicopter supported one-day reconnaissance trips to the SDC may occur to check on winterization conditions on-board the SDC. A detailed description of these activities proposed for 2003–2004 is contained in the application (Lynx Enterprises, Inc., 2003), which is available upon request (see **ADDRESSES**)

Description of Marine Mammals Affected by the Activity

The Beaufort Sea supports many marine mammals under NMFS jurisdiction, including bowhead whales (*Balaena mysticetus*), beluga whales(*Delphinapterus leucas*), ringed seals (*Phoca hispida*), bearded seals (*Erignathus barbatus*) and spotted seals (*Phoca largha*). Descriptions of the biology, distribution, and current status of these species can be found in NMFS Stock Assessment Reports (2000, 1999, and 1997). Please refer to those documents for more information on these species. These documents can be downloaded electronically from: *http://www.nmfs.noaa.gov/pr/PR2/Stock__Assessment__Program/individual__sars.html*

Potential Effects of SDC Mobilization and Associated Activities on Marine Mammals

Potential harassment of marine mammals will result from the noise generated by the operation of towing vessels during SDC mobilization between Cross Island and Herschel Island and the noise generated during equipment removal of the SDC. The physical presence of the SDC tow vessels and helicopter could also lead to disturbance of marine mammals by visual or other cues. The potential for collisions between tug vessels and whales will be reduced by the slow tow speed (2 knots) and visual monitoring by on-board marine mammal observers.

Marine mammal species with the highest likelihood of being harassed during the SDC mobilization phase (August) are: beluga whales, ringed seals, and bearded seals. Spotted seals are less likely to be harassed during the SDC mobilization phase because they reside closer to the shore. Bowhead whales are the only species listed under the ESA that could potentially be affected by these activities. However, they are not expected to be encountered during the mobilization phase because the majority of the whales will be at their summer feeding grounds in Canada. However, a few transitory whales may be encountered along the routes. Beluga whales occur in the Beaufort Sea during the summer, but are expected to be found near the pack ice edge north of the proposed SDC relocation routes. Depending on seasonal ice conditions, it is possible that belugas may be encountered during the transit.

Based on past surveys, ringed seals should represent the vast majority of marine mammals encountered during the transit. Ringed seals are expected to be present all along the SDC mobilization routes. There is the possibility that bearded and spotted seals will also be harassed during transit. Spotted seals may be present in Prudhoe Bay, but it is likely that they may be closer to shore and therefore are not expected to be harassed during transit phase.

It is not likely that bowhead whales will be impacted by transit operations since EnCana plans to finish the relocation operations and shutdown (i.e., cold stack ''quiet'' mode) the SDC by late August, when bowhead whales begin their westward fall migration in the Beaufort Sea. According to 23 years of survey data collected by the Minerals Management Service (MMS), North Slope Borough, the Alaska Eskimo Whaling Commission (AEWC), and many more years of traditional knowledge from Cross Island-based whale hunters, the annual fall migration of the bowhead whales is normally many kilometers north of the McCovey Prospect, where the SDC currently resides. However, because the fall migration path of the bowhead whales is dependent on environmental conditions (i.e., extent of ice coverage) that vary from year-to-year, the extreme southern edge of the fall migration corridor may pass closer to McCovey Prospect, increasing the likelihood that bowhead whales may be harassed by activities. Transitory bowhead whales traveling ahead of the herd may be encountered during relocation. Beluga whales migrate along the pack ice edge north of the proposed relocation routes and are not expected to be seen.

Potential Effects of SDC Mobilization and Associated Activities on Habitat

The activity will not result in the disturbance of any habitat for the affected species.

Numbers of Marine Mammals Expected to Be Taken

The number of marine mammals that may be taken as a result of the SDC mobilization operation is unpredictable. Operations are scheduled to occur prior to the westward migration and associated subsistence bowhead whale hunts to purposely avoid any take of this species. Noise disturbance from vessels and helicopters or from noise generated from SDC might qualify as harassment to seals, but previous surveys have indicated little behavioral reaction from these animals to slow-moving or stationary vessels.

Effects of SDC Mobilization and Associated Activities on Subsistence Needs

No impact is anticipated on the availability of marine mammal species and stocks for subsistence uses since an amendment to the existing Conflict Avoidance Agreement (CAA) and Plan of Cooperation has been negotiated with the Alaska Eskimo Whaling Commission (AEWC) and affected village Whaling Captains Associations. EnCana has taken steps to disclose its project plans in initial consultation with the Executive Director and the president of the AEWC, the Mayor of the North Slope Borough, and village Whaling Captains. EnCana coordinated with the AEWC and amended the existing CAA to include the 2003 SDC relocation. The operation is scheduled to occur prior to the annual fall bowhead whale hunt.

Mitigation

During mobilization of the SDC from Cross Island at the McCovey Prospect through the Beaufort Sea to Herschel Island, EnCana will have on-board marine mammal monitors throughout the transit. The program will commence with the reoccupation of SDC at the current McCovey deployment and will continue on a nearly 24–hour basis until the rig exits U.S. waters and goes into cold stack mode in Canada.

EnCana proposes to mitigate the potential negative impacts from its relocation and supply removal activities by planning the timing of operations in such a way as to reduce the production of noise during the fall bowhead whale migration. This includes putting the SDC into cold stack mode during the entire bowhead migration period (approximately late-August through mid-October). In addition to these mitigation measures, EnCana worked with the AEWC, North Slope Borough, and other whaling communities and amended the existing CAA to include the 2003 relocation to eliminate impacts

to subsistence hunting of bowheads and thereby on bowheads themselves.

Monitoring

As part of its application, EnCana proposed a visual monitoring program for assessing impacts to marine mammals during the SDC's transit from Cross Island, McCovey Prospect to Herschel Island or the backup location in Federal Waters north of West Dock near Prudhoe Bay, Alaska.

EnCana proposes to initiate a comprehensive training program for all potential marine mammal observers that includes learning the identification and behavior of all local species known to use the areas where EnCana will be operating. This training would be conducted by professional marine biologists and experienced Native observers participating in the monitoring program. The observer protocol would be to scan the area around vessels and the SDC with binoculars of sufficient power. Range finding equipment will be supplied to observers in order to better estimate distances. Observers would collect data on the presence, distribution, and behavior of marine mammals relative to EnCana activities as well as climatic conditions at the time of marine mammal sightings. Observations would be made on a nearly 24–hour basis from the time the SDC leaves Cross Island until the SDC crosses the Canadian border or, if the backup deployment in U.S. waters is used, is placed in cold stack mode. If the backup deployment in U.S. waters is used and re-supply efforts are necessary between the end of the fall bowhead whale harvest and ice-over, observers would be re-deployed on the SDC and supply vessels. All personnel stationed aboard the SDC during the open water season of 2003 would also receive training on marine mammal monitoring and utilize marine mammal reporting forms to document any incidental takes of marine mammals.

As required by the MMPA, this proposed monitoring plan will be subject to review and approval by NMFS.

Reporting

All monitoring data collected would be reported to NMFS and the USFWS on a weekly basis. EnCana must provide a final report on 2003–2004 activities to NMFS within 90 days of the completion of the activity. This report will provide dates and locations of the SDC movements and other operational activities, weather conditions, dates and locations of any activities related to monitoring the effects on marine mammals, and the methods, results, and interpretation of all monitoring activities, including estimates of the level and type of take, species name and numbers of each species observed, direction of movement of species, and any observed changes or modifications in behavior.

Endangered Species Act (ESA) Consultation

The effects of oil and gas exploration activities in the U.S. Beaufort Sea, which includes this proposed activity, on listed species were analyzed as part of a consultation on oil and gas leasing and exploration activities in the Beaufort Sea, Alaska, and authorization of small takes under the MMPA. A biological opinion on these activities was issued on May 25, 2001. Pursuant to section 7 of the ESA, NMFS has begun consultation on the proposed issuance of an IHA to EnCana. The only species listed in the ESA that could be taken during these activities are bowhead whales. The effects of the proposed IHA on bowhead whales will be compared with the analysis contained in the 2001 biological opinion. If an authorization to incidentally harass marine mammals listed under the ESA is issued for this activity under the MMPA, NMFS will issue an Incidental Take Statement under section 7 of the ESA.

National Environmental Policy Act

In 1997, NMFS prepared and released an EA that addressed the impacts on the human environment from issuance of an authorization for taking marine mammals incidental to moving an oil drilling structure through the Beaufort Sea during the summer and conducting oil exploration activities in the eastern Beaufort Sea and the alternatives to that proposed action. A Finding of No Significant Impact was signed on September 25, 1997. Because the action discussed in this document is not substantially different from the 1997 action, and because no significant new scientific information or analyses have been developed in the past several years significant enough to warrant new NEPA documentation, this action is categorically excluded from further review under NOAA Administrative Order 216–6. A copy of that EA is available upon request (see **ADDRESSES**).

Preliminary Conclusions

NMFS has preliminarily determined that the short-term impact of SDC mobilization from Cross Island, McCovey Prospect, AK through the Beaufort Sea to Herschel Island, Yukon Territory, or mobilization to the U.S. Outer Continental Shelf waters north of West Dock, and associated activities will result, at worst, in a temporary modification in behavior by certain species of whales and pinnipeds. While behavioral modifications may be made by these species to avoid the resultant noise or visual cues, this behavioral change is expected to have a negligible impact on the survival and recruitment of stocks.

While the number of potential incidental harassment takes will depend on the year-to-year distribution and abundance of marine mammals in the area of operations, due to the distribution and abundance of marine mammals during the projected period of activity and the location of the proposed activity, the number of potential harassment takings is estimated to be small. In addition, no take by injury and/or death is anticipated, and there is no potential for temporary or permanent hearing impairment as a result of the activities. No rookeries, mating grounds, areas of concentrated feeding, or other areas of special significance for marine mammals occur within or near the relocation route.

The principal measures undertaken to ensure that the SDC relocation will not have an adverse impact on subsistence activities is a Conflict Avoidance Agreement (CAA), Plan of Cooperation, and an operation schedule prior to the annual bowhead whale subsistence hunt, as amended on June 3, 2003.

Proposed Authorization

NMFS proposes to issue an IHA for the harassment of marine mammals incidental to movement of a SDC from Cross Island, McCovey Prospect, AK through the Beaufort Sea to Herschel Island, Yukon Territory, or, as a backup, to the U.S. Outer Continental Shelf waters north of West Dock, and associated activities. This IHA proposal is contingent upon incorporation of the previously mentioned mitigation, monitoring, and reporting requirements. NMFS has preliminarily determined that the proposed activity would result in the harassment of small numbers of bowhead whales, beluga whales, ringed seals, bearded seals and spotted seals; would have no more than a negligible impact on these marine mammal stocks; and would not have an unmitigable adverse impact on the availability of marine mammal stocks for subsistence uses once the Plan of Cooperation and CAA is amended.

Information Solicited

NMFS requests interested persons to submit comments, and information, concerning this request to Kaja Brix,

Acting Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3225.

Dated: June 12, 2003.

Stephen L. Leathery,

Acting Office Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–15408 Filed 6–17–03; 8:45 am]

BILLING CODE 3510–22–S

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

AGENCY: Consumer Product Safety Commission, Washington, DC 20207.

TIME AND DATE: Tuesday, June 24, 2003, 2 p.m.

LOCATION: Room 410, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Closed to the Public—Pursuant to 5 U.S.C. 552b(f)(1) and 16 CFR 1013.4(b)(3), (7), (9), and (10) and submitted to the **Federal Register** pursuant to 5 U.S.C. 552b(e)(3).

MATTER TO BE CONSIDERED: The staff will brief the Commission on the status of various compliance matters.

For a recorded message containing the latest agenda information, call (301) 504–7948.

FOR FURTHER INFORMATION CONTACT: Todd A. Stevenson, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20207, (301) 504–7923.

Dated: June 16, 2003.

Todd A. Stevenson,

Secretary.

[FR Doc. 03–15546 Filed 6–16–03; 4:01 p.m.]

BILLING CODE 6335–01–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Invention; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The invention listed below is assigned to the United States Government as represented by the Secretary of the Navy and is available for licensing by the Department of the Navy. Navy Case No. 82,897, entitled ''Anti-Charging Layer for Beam Lithography and Mask Fabrication.''

ADDRESSES: Requests for information about the invention cited should be directed to the Naval Research Laboratory, Code 1004, 4555 Overlook Avenue, SW., Washington, DC 20375–5320, and must include the Navy Case number.

FOR FURTHER INFORMATION CONTACT: Catherine M. Cotell, Ph.D., Head, Technology Transfer Office, NRL Code 1004, 4555 Overlook Avenue, SW., Washington, DC 20375–5320, telephone (202) 767–7230. Due to temporary U.S. Postal Service delays, please fax (202) 404–7920, E-Mail: *cotell@nrl.navy.mil* or use courier delivery to expedite response.

(Authority: 35 U.S.C. 207, 37 CFR Part 404.)

Dated: June 11, 2003.

E.F. McDonnell,

Major, U.S. Marine Corps, Federal Register Liaison Officer.

[FR Doc. 03–15321 Filed 6–17–03; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Invention; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The invention listed below is assigned to the United States Government as represented by the Secretary of the Navy and is available for licensing by the Department of the Navy. U.S. Patent No. 6,459,079 B1 entitled, ''SHIPBOARD CHEMICAL AGENT MONITOR—PORTABLE (SCAMP).''

ADDRESSES: Requests for copies of the patent cited should be directed to the Naval Surface Warfare Center, Dahlgren Div., Code XDC1, 17320 Dahlgren Rd., Dahlgren, VA 22448–5100.

FOR FURTHER INFORMATION CONTACT: Matthew J. Bussan, Patent Counsel, Naval Surface Warfare Center, Dahlgren Div., Code XDC1, 17320 Dahlgren Rd., Building 183, Room 4, Dahlgren, VA 22448–5100, telephone (540) 653–8061.

(Authority: 35 U.S.C. 207, 37 CFR Part 404.)

Dated: June 11, 2003.

E.F. McDonnell,

Major, U.S. Marine Corps, Federal Register Liaison Officer.

[FR Doc. 03–15322 Filed 6–17–03; 8:45 am]

BILLING CODE 3810–FF–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2003–0078, FRL–7514–6]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reporting Under EPA's Landfill Methane Outreach Program

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB): Reporting Under EPA's Landfill Methane Outreach Program, ICR Number 1849.02, OMB Control Number 2060–0446, expiration October 31, 2003. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before August 18, 2003.

ADDRESSES: Follow the detailed instructions in **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Brian Guzzone, Climate Protection Partnerships Division, Office of Atmospheric Programs, 6202J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–2666; fax number: (202) 565–2079; e-mail address: *guzzone.brian@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number OAR–2003–0078, which is available for public viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public

docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice, and according to the following detailed instructions: Submit your comments to EPA online using EDOCKET (our preferred method), by e-mail to *a-and-r-docket@epamail.epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Air and Radiation Docket and Information Center, MC 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, *see* EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *www.epa.gov./edocket.*

Affected Entities: Entities potentially affected by this action are those local agencies and municipalities that own landfills; State agencies; manufacturers and suppliers of equipment/knowledge to capture and utilize landfill gas; utility companies; end users of energy from the landfill.

Title: Reporting Under EPA's Landfill Methane Outreach Program (OMB Control Number 2060–0446; EPA ICR Number 1849.02; expiring October 31, 2003).

Abstract: The Landfill Methane Outreach Program (LMOP) is an EPA-sponsored voluntary program that encourages landfill owners, communities, and project developers to reduce emissions of methane, a potent greenhouse gas, by implementing landfill gas technologies that collect and utilize the methane as a source of energy. The Landfill Methane Outreach Program further encourages utilities and other energy customers to support and promote the use of landfill methane at their facilities. The Landfill Methane Outreach Program signs voluntary Memoranda of Understanding (MOU) with these organizations to enlist their support in promoting cost-effective landfill gas utilization. The information collection includes completion and submission of the MOU, and annual online completion and submission of information forms that include basic information on the organizations that sign the MOU and landfill methane projects in which they are involved. The information collection is to be utilized to maintain up-to-date data and information about Landfill Methane Outreach Program partners and landfill methane projects in which they are involved. In addition, the information collection will assist LMOP to evaluate the reduction of methane emissions from landfills. Responses to the information collection are voluntary.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Burden Statement: The annual public reporting and recordkeeping burden for this (3) three year collection of information is estimated to equal 1,531 hours and to average 3.6 hours per year per respondent. The estimated number of respondents averaged over (3) three years is 422. The average capital, start-up, and operation and maintenance cost resulting from this three year collection of information is $212 per respondent.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: May 29, 2003.

Kathleen Hogan,

Director.

[FR Doc. 03–15362 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7514–8]

Technical Peer Review Meeting on the Draft Document Entitled, Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster

AGENCY: Environmental Protection Agency.

ACTION: Notice of meeting.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a technical peer review meeting, organized and convened by Versar, Inc., a contractor to the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development, for review of the draft document entitled, Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster (EPA/600/P–02/002A). The document was prepared by NCEA. The draft document was already subjected to public review and comment. NCEA will consider those public comments and any additional comments provided by the expert peer-review panel in revising the document.

DATES: The peer review meeting will be held on Monday, July 14 and Tuesday, July 15, 2003, from 9 a.m. to 5 p.m., eastern daylight time (EDT) each day. On December 27, 2002, the draft report was announced in the **Federal Register** (67 FR 79079) and made available for a 60-day public comment period that ended on February 25, 2003. The comment period was subsequently extended (**Federal Register** (68 FR

10723) dated March 6, 2003) until April 7, 2003. Copies of the public comments received by EPA have been provided to the expert peer reviewers.

ADDRESSES: The meeting will be held at the Sofitel New York Hotel, 45 West 44th Street, New York, NY 10036; telephone (212) 354–8844. Versar, Inc., an EPA contractor, will convene and facilitate the meeting. To attend the meeting as an observer, register by July 10, 2003, 5 p.m. EDT by visiting *http://www.versar.com/epa/wtcpeerreview.htm* or contacting Ms. Traci Bludis, Versar, Inc.; telephone: (703) 750–3000, extension 449; facsimile: (703) 642–6954; e-mail: bluditra@versar.com. There will be a limited time for oral comments from the public (registration is required). If you wish to make a statement during the observer comment period of the workshop, please check the appropriate box when you register at the Web site. Space is limited, and registration for attendance and oral comments will be accepted on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: For workshop information and logistics please contact Versar, Inc. The draft document, Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster, is available via the Internet on the NCEA Web site at *http://www.epa.gov/ncea/wtc.htm.* Copies are not available from Versar, Inc. For information regarding the draft document, please contact Linda C. Tuxen, U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment (8601–D), Washington, DC 20460; telephone: (202) 564–3332; fax: (202) 565–0090; e-mail: *tuxen.linda@epa.gov.*

SUPPLEMENTARY INFORMATION: Immediately following the September 11, 2001, terrorist attack on New York City's World Trade Center, many federal agencies, including the EPA, were called upon to focus their technical and scientific expertise on the national emergency issues. EPA, other federal agencies, New York City, and New York State public health and environmental authorities focused on numerous air monitoring activities to better understand the ongoing human health impact of the disaster. Many EPA offices and programs quickly became involved with these activities, providing scientific, engineering, public health, and management expertise to help cope with the aftereffects of the collapse of the World Trade Center.

As part of these activities, a human health evaluation of exposure to air pollutants resulting from the World Trade Center disaster was initiated. This draft evaluation is the subject of the technical peer review meeting announced today. The primary purpose and scope of the draft report were to evaluate the environmental levels of various air pollutants to which the public could potentially be exposed as a result of the collapse of the towers. These data were evaluated in terms of available health benchmark concentrations and typical background concentrations for New York City or other urban areas. The draft evaluation concludes that, with the exception of those exposed immediately following the collapse and perhaps during the next few days, people in the surrounding community are not likely to suffer from serious long- or short-term health effects. While the primary focus of EPA's draft evaluation is on outdoor levels of various air pollutants to which the public could potentially be exposed as a result of the collapse of the towers, some information on indoor and occupational exposures is summarized in EPA's draft report.

Both the processes of public review and comment and expert scientific peer review are the usual steps that EPA takes to ensure full and open participation by interested parties. These steps help EPA identify areas where a draft document could be improved to strengthen both clarity and completeness of the draft. Comments from the public and from the expert peer reviewers during this meeting will be used to improve the draft report before it is finalized.

Dated: June 12, 2003.

George W. Alapas,

Deputy Director, National Center for Environmental Assessment.

[FR Doc. 03–15364 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7514–4]

Clean Water Act Section 303(d): Final Agency Action Adding Waters to the Arkansas 2002 Section 303(d) List

AGENCY: Environmental Protection Agency.

ACTION: Final agency action.

SUMMARY: This notice announces EPA's final agency action on the Arkansas 2002 section 303(d) list pursuant to Clean Water Act section 303(d).

On June 9, 2003, EPA took final action on its March 10, 2003, proposed decision to add 52 water quality limited segments (WQLSs) and associated pollutants to Arkansas' 2002 303(d) list.

ADDRESSES: Copies of the documents which explain the rationale for EPA's final decision, response to public comments, and a list of the 50 WQLSs that EPA added to Arkansas' 2002 section 303(d) list can be obtained from EPA Region 6's Web site at *www.epa.gov/earth1r6/6wq/artmdl.htm,* or by writing or calling Ms. Ellen Caldwell, Environmental Protection Specialist, Water Quality Protection Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, TX 75202–2733, telephone (214) 665–7513, facsimile (214) 665–6490, or e-mail: *caldwell.ellen@epa.gov.* Documents from the administrative record for these decisions also are available for public inspection at the above address. Please contact Ms. Caldwell to schedule an inspection.

FOR FURTHER INFORMATION CONTACT: Ellen Caldwell at (214) 665–7513.

SUPPLEMENTARY INFORMATION: Section 303(d) of the Clean Water Act (CWA) requires that each state identify those waters for which existing technology-based pollution controls are not stringent enough to attain or maintain state water quality standards. For those waters, states are required to establish total maximum daily loads according to a priority ranking.

On March 10, 2003, EPA approved Arkansas' listing of 76 WQLSs and associated priority rankings. EPA disapproved Arkansas' decision not to list 52 WQLSs and associated pollutants. EPA proposed to add 52 of these additional WQLSs and pollutants along with priority rankings for inclusion on the 2002 Section 303(d) list and initiated public notice and comment for these proposed listings.

On June 9, 2003, EPA took final agency action not adding two of the proposed additional WQLSs and associated pollutants to the Arkansas 2002 section 303(d) list and adding 50 WQLSs to the Arkansas 2002 section 303(d) list.

Dated: June 9, 2003.

Miguel I. Flores,

Director, Water Quality Protection Division, Region 6.

[FR Doc. 03–15254 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–60–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7514–3]

Public Water System Supervision Program Revision for the State of Louisiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of tentative approval.

SUMMARY: Notice is hereby given that the State of Louisiana is revising its approved Public Water System Supervision Program. Louisiana has revised its administrative penalty authority, revised its definition for public water system, and adopted a consumer confidence report rule for all community water systems. EPA has determined that these revisions are no less stringent than the corresponding federal regulations. Therefore, EPA intends to approve these program revisions. All interested parties may request a public hearing. A request for a public hearing must be submitted by July 18, 2003, to the Regional Administrator at the EPA Region 6 address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by July 18, 2003, a public hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on July 18, 2003. Any request for a public hearing shall include the following information: The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; a brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; and the signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, at the following offices: Louisiana Department of Health and Hospitals, Engineering Services, Safe Drinking Water Program, 6867 Bluebonnet Drive, Baton Rouge, LA 70810 and the United States Environmental Protection Agency, Region 6, Drinking Water Section (6WQ–SD), 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202.

FOR FURTHER INFORMATION CONTACT: David Reazin, EPA Region 6, Drinking Water Section at the Dallas address given above or at telephone (214) 665–7501, or *reazin.david@epa.gov.*

Authority: (Sec. 1413 of the Safe Drinking Water Act, as amended (1996), and 40 CFR part 142 of the National Primary Drinking Water Regulations).

Dated: June 9, 2003.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. 03–15255 Filed 6–17–03; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank has received an application to guarantee up to $198 million of equipment and other goods and services on the behalf of U.S. exporters to a buyer in Egypt. The U.S. exports will enable the Egyptian company to produce anhydrous ammonia from natural gas. The Egyptian company will have a production capacity of 1,850 metric tons of ammonia per day. It is envisioned this new production will be consumed primarily in Jordan and India. Interested parties may submit comments on this transaction by e-mail to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue, NW., Room 1238, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Helene S. Walsh,

Director, Policy Oversight and Review.

[FR Doc. 03–15345 Filed 6–17–03; 8:45 am]

BILLING CODE 6690–01–M

EXPORT-IMPORT BANK

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank has received an application to guarantee up to $25 million of equipment and other goods and services on the behalf of U.S. exporters to a buyer in Mexico. The U.S. exports will enable the Mexican company to produce non-automotive flat glass. The Mexican company will produce 146,000 metric tons of glass with a thickness between 2.4 and 8.0 mm. It is envisioned this new production will be consumed in Mexico and the United States. Interested parties may submit comments on this transaction by e-mail to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue, NW., Room 1238, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Helene S. Walsh,

Director, Policy Oversight and Review.

[FR Doc. 03–15346 Filed 6–17–03; 8:45 am]

BILLING CODE 6690–01–M

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 96–45; DA 03–1881]

Wireline Competition Bureau Seeks Comment on ALLTEL Communications, Inc. Petition for Designation as an Eligible Telecommunications Carrier in the State of Virginia

AGENCY: Federal Communications Commission.

ACTION: Notice; solicitation of comments.

SUMMARY: In this document, the Wireline Competition Bureau sought comment on the ALLTEL Petition. ALLTEL Communications, Inc. (ALLTEL) is seeking designation as an eligible telecommunications carrier (ETC) to receive federal universal service support for service offered throughout its licensed service area in the state of Virginia, including rural and non-rural areas.

DATES: Comments are due on or before June 30, 2003. Reply comments are due on or before July 7, 2003.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. *See* **SUPPLEMENTARY INFORMATION** for further filing instructions.

FOR FURTHER INFORMATION CONTACT: Shannon Lipp, Attorney, Wireline Competition Bureau, Telecommunications Access Policy Division, (202) 418–7400, TTY (202) 418–0494.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Public Notice, CC Docket No. 96–45, released June 3, 2003. On April 14, 2003, ALLTEL Communications, Inc. (ALLTEL), a commercial mobile radio service (CMRS) carrier, filed with the Commission a petition under section 214(e)(6) seeking designation as an eligible telecommunications carrier (ETC) to receive federal universal service support for service offered throughout its licensed service area in the state of Virginia, including rural and

non-rural areas. On May 21, 2003, ALLTEL filed an amendment to its petition with regard to its proposed service areas. Specifically, ALLTEL contends that: the Virginia State Corporation Commission (Virginia Commission) has provided an affirmative statement that it does not regulate CMRS carriers; ALLTEL satisfies all the statutory and regulatory prerequisites for ETC designation; and designating ALLTEL as an ETC will serve the public interest.

Pursuant to § 54.207(c) of the Commission's rules, ALLTEL also requests that the Commission designate ALLTEL as an ETC in service areas defined along boundaries that differ from incumbent rural local exchange company (LEC) study area boundaries. ALLTEL requests that these service areas be redefined on a wire center by wire center basis such that each wire center is a separate service area. ALLTEL intends to serve each proposed wire center in its entirety. The service area requested by ALLTEL for ETC designation partially covers the study areas of Central Telephone Company—Virginia and United Inter-Mountain Telephone. ALLTEL maintains that the proposed redefinition of service areas for ETC purposes is consistent with the factors to be considered when redefining a rural telephone company service area, as enumerated by the Federal-State Joint Board on Universal Service (Joint Board).

The petitioner must provide copies of its petition to the Virginia Commission. The Commission will also send a copy of this Public Notice to the Virginia Commission by overnight express mail to ensure that the Virginia Commission is notified of the notice and comment period.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, interested parties may file comments as follows: comments are due on or before June 30, 2003, and reply comments are due on or before July 7, 2003. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121, May 1, 1998.

Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov*, and should include the following words in the body of the message, ''get form <your e-mail address>.'' A sample form and directions will be sent in reply.

Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Vistronix, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission.

Parties also must send three paper copies of their filing to Sheryl Todd, Telecommunications Access Policy Division, Wireline Competition Bureau, Federal Communications Commission, 445 12th Street SW., Room 5–B540, Washington, DC 20554. In addition, commenters must send diskette copies to the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20054.

Pursuant to § 1.1206 of the Commission's rules, 47 CFR 1.1206, this proceeding will be conducted as a permit-but-disclose proceeding in which ex parte communications are permitted subject to disclosure.

Federal Communications Commission.

Paul Garnett,

Acting Assistant Division Chief, Wireline Competition Bureau, Telecommunications Access Policy Division.

[FR Doc. 03–15303 Filed 6–17–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 96–45; DA 03–1882]

Wireline Competition Bureau Seeks Comment on ALLTEL Communications, Inc. Petition for Designation as an Eligible Telecommunications Carrier in the State of Alabama

AGENCY: Federal Communications Commission.

ACTION: Notice; solicitation of comments.

SUMMARY: In this document, the Wireline Competition Bureau sought comment on the ALLTEL Petition. ALLTEL Communications, Inc. (ALLTEL) is seeking designation as an eligible telecommunications carrier (ETC) to receive federal universal service support for service offered throughout its licensed service area in the state of Alabama, including rural and non-rural areas.

DATES: Comments are due on or before June 30, 2003. Reply comments are due on or before July 7, 2003.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. *See* **SUPPLEMENTARY INFORMATION** for further filing instructions.

FOR FURTHER INFORMATION CONTACT: Shannon Lipp, Attorney, Wireline Competition Bureau, Telecommunications Access Policy Division, (202) 418–7400, TTY (202) 418–0494.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Public Notice, CC Docket No. 96–45, released June 3, 2003. On April 14, 2003, ALLTEL Communications, Inc. (ALLTEL), a commercial mobile radio service (CMRS) carrier, filed with the Commission a petition under section 214(e)(6) seeking designation as an eligible telecommunications carrier (ETC) to receive federal universal service support for service offered throughout its licensed service area in the state of Alabama, including rural and non-rural areas. On May 21, 2003, ALLTEL filed an amendment to its petition with regard to its proposed service areas. Specifically, ALLTEL

contends that: the Alabama Public Service Commission (Alabama Commission) has provided an affirmative statement that it does not regulate CMRS carriers; ALLTEL satisfies all the statutory and regulatory prerequisites for ETC designation; and designating ALLTEL as an ETC will serve the public interest.

Pursuant to § 54.207(c) of the Commission's rules, ALLTEL also requests that the Commission designate ALLTEL as an ETC in service areas defined along boundaries that differ from incumbent rural local exchange company (LEC) study area boundaries. ALLTEL requests that these service areas be redefined on a wire center by wire center basis such that each wire center is a separate service area. ALLTEL intends to serve each proposed wire center in its entirety. The service areas requested by ALLTEL for ETC designation partially cover the study areas of ALLTEL Alabama, Inc. (a wireline affiliate of ALLTEL by virtue of common ownership by ALLTEL Corporation), Butler Telephone Co. Inc., Castleberry Telephone Co. Inc., Frontier Communications of Alabama, Frontier Communications of The South, Graceba Total Communications, GTC Inc.—AL, Gulf Telephone Co., Hayneville Telephone Co. Inc., Millry Telephone Company, Mon-Cre Telephone Cooperative, Pine Belt Telephone Company, Union Springs Telephone Co. Inc. ALLTEL maintains that the proposed redefinition of service areas for ETC purposes is consistent with the factors to be considered when redefining a rural telephone company service area, as enumerated by the Federal-State Joint Board on Universal Service (Joint Board).

The petitioner must provide copies of its petition to the Alabama Commission. The Commission will also send a copy of this Public Notice to the Alabama Commission by overnight express mail to ensure that the Alabama Commission is notified of the notice and comment period.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments as follows: comments are due on or before June 30, 2003, and reply comments are due on or before July 7, 2003. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. See *Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1, 1998.

Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message, ''get form <your e-mail address>.'' A sample form and directions will be sent in reply.

Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Vistronix, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission.

Parties also must send three paper copies of their filing to Sheryl Todd, Telecommunications Access Policy Division, Wireline Competition Bureau, Federal Communications Commission, 445 12th Street SW., Room 5–B540, Washington, DC 20554. In addition, commenters must send diskette copies to the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20054.

Pursuant to § 1.1206 of the Commission's rules, 47 CFR 1.1206, this proceeding will be conducted as a permit-but-disclose proceeding in which ex parte communications are permitted subject to disclosure.

Federal Communications Commission.

Paul Garnett,

Acting Assistant Division Chief, Wireline Competition Bureau, Telecommunications Access Policy Division.

[FR Doc. 03–15304 Filed 6–17–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Monday, June 23, 2003 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, June 26, 2003 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Draft Advisory Opinion 2003–05—National Association of Homebuilders of the United States by counsel, Mark Braden.

Routine Administrative Matters.

FOR FURTHER INFORMATION CONTACT: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 03–15544 Filed 6–16–03; 2:16 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of

1984. Interested parties can review or obtain copies of agreements at the Washington, DC, offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011284–052.

Title: Ocean Carrier Equipment Management Association.

Parties: APL Co. PTE Ltd; American President Lines Ltd; A.P. Moller-Maersk Sealand; CMA CGM, S.A.; Compania Sud Americana de Vapores, S.A.; Evergreen Marine Corp. (Taiwan) Ltd.; Hanjin Shipping Co., Ltd.; Hamburg-Südamerikanische Dampfschifffahrtgesellschaft KG; Hapag-Lloyd Container Linie GmbH; Hyundai Merchant Marine Co., Ltd.; Mitsui O.S.K. Lines, Ltd.; Lykes Lines Limited, LLC; TMM Lines Limited, LLC; Contship Container Lines, a division of CP Ships (UK) Limited; Australia-New Zealand Direct Line, a division of CP Ships (UK) Limited; Orient Overseas Container Line Limited; P&O Nedlloyd B.V.; P&O Nedlloyd Limited; Nippon Yusen Kaisha Line; Yangming Marine Transport Corp.; COSCO Container Lines Company Limited; and Kawasaki Kisen Kaisha, Ltd.

Synopsis: The amendment adds Crowley Maritime Corporation to the membership of the agreement.

Agreement No.: 011510–018.

Title: West African Discussion Agreement.

Parties: A.P. Moller-Maersk Sealand, Atlantic Bulk Carriers, HUAL AS, Mediterranean Shipping Company, P&O Nedlloyd Limited, Safmarine Container Lines, and Zim Israel Navigation Company.

Synopsis: The modification removes Mediterranean Shipping Company as a party to the agreement.

Agreement No.: 011733–008.

Title: Common Ocean Carrier Platform Agreement (INTTRA).

Parties: A.P. Moller-Maersk Sealand, P&O Nedlloyd Limited, Hamburg-Südamerikanische Dampfschifffahrtgesellschaft KG, Mediterranean Shipping Company, CMA CGM, Hapag-Lloyd Container Linie, United Arab Shipping Company, Alianca Navegaçao e Logistica Ltda., Safmarine Container Lines, Nippon Yusen Kaisha, and CP Ships Limited for its ocean common carrier subsidiaries.

Synopsis: The modification adds Tasman Orient Line C.V. as a non-shareholder party to the agreement.

Agreement No.: 011770–002.

Title: NSCSA/Oldendorff Slot Exchange Agreement.

Parties: National Shipping Company of Saudi Arabia, Oldendorff Carriers (Indotrans) Ltd.

Synopsis: The proposed modification reduces the scope of the agreement to the westbound trade from ports in India to U.S. East and Gulf Coast ports; revises the amount of space to be chartered; and revises agreement provisions on termination, notices, and force majeure.

Agreement No.: 011799–002.

Title: Evergreen/Lloyd Triestino/ Hatsu Marine Alliance—TSA Bridging Agreement.

Parties: Evergreen Marine Corp. (Taiwan) Ltd.; Lloyd Triestino di Navegazione S.p.A.; Hatsu Marine Limited; AmericanPresident Lines, Ltd. and APL Co. Pte Ltd. (operating as one carrier); A.P. Moller-Maersk Sealand; CMA CGM S.A.; COSCO Container Lines Ltd.; Hanjin Shipping Co., Ltd.; Hapag-Lloyd Container Linie GmbH; HyundaiMerchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; P&O Nedlloyd B.V.; P&O Nedlloyd Limited; Yangming Marine Transport Corp.

Synopsis: The proposed amendment would extend the duration of the agreement through August 15, 2004.

Agreement No.: 011802–003.

Title: Evergreen/Lloyd Triestino/ Hatsu Marine Alliance—WTSA Bridging Agreement.

Parties: Evergreen Marine Corp. (Taiwan) Ltd.; Lloyd Triestino di Navegazione S.p.A.; Hatsu Marine Limited; AmericanPresident Lines, Ltd. and APL Co. Pte Ltd. (operating as one carrier); China Shipping Container Lines Co., Ltd.; COSCO Container Lines Ltd.; Hanjin Shipping Co., Ltd.; Hapag-Lloyd Container Linie GmbH; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; P&O Nedlloyd B.V.; P&O Nedlloyd Limited; Yangming Marine Transport Corp.

Synopsis: The proposed amendment would extend the duration of agreement through August 15, 2004.

Dated: June 13, 2003.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–15390 Filed 6–17–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuances

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/address	Date reissued
4085F	American Logistics & Purchasing Services, Ltd., 1610 Parkview Avenue, Seaford, NY 11783	April 20, 2003.
1803NF	Blue Sky Blue Sea, Inc. dba America Export Lines, dba International Shipping Company 12919 S. Figueroa Street, Los Angeles, CA 90061.	March 29, 2003.
13754N	L.A.S. Incorporated, 8 Hook Road, Bayonne, NJ 07002	May 11, 2003.
4273NF	Primar International, Inc., 15402 Vantage Parkway East, Suite 314, Houston, TX 77032	May 7, 2003.
6098N	Sunshine Express Line, Inc., 3250 N.W. North River Drive, Miami, FL 33142	May 11, 2003.
3443F	Tradewinds Shipping Corp., 420 Sackett Point Road, Unit 4–B, New Haven, CT 06473–3171	April 20, 2003.
16228N	Air & Sea Pak Co. dba Corrigan Air & Sea Cargo Systems, 6170 Middlebelt Road, Romulus, MI 48174.	April 28, 2003.
18051N	Dominicana Air & Ocean Freight Corp., 1332 NW 36th Street, Jamaica, NJ 33142	May 22, 2003.
3307F	American Freight International, Inc., 8169 NW 7th Street, Miami, FL 33166	May 16, 2003.

Sandra L. Kusumoto,

Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 03–15388 Filed 6–17–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number: 3683F.
Name: Martin Strauss Air Freight Corp.
Address: P.O. Box 300666, JFK International Airport, Jamaica, NY 11434.
Date Revoked: May 27, 2003.
Reason: Surrendered license voluntarily.

License Number: 13475N.
Name: Triple Alliance Company, Inc.
Address: 177–25 Rockaway Blvd., Suite 204, Jamaica, NY 11434.
Date Revoked: May 29, 2003.
Reason: Surrendered license voluntarily.

License Number: 16483N.
Name: UniGlobal Logistics, Inc.
Address: 39 Old Ridgebury Road, Danbury, CT 07817.
Date Revoked: June 9, 2003.
Reason: Surrendered license voluntarily.

License Number: 4378NF.
Name: World 2000 Services, Inc.
Address: 8233 NW., 66th Street, Miami, FL 33166.
Date Revoked: May 21, 2003.
Reason: Surrendered license voluntarily.

Sandra L. Kusumoto,

Director, Bureau of Consumer Complaints, and Licensing.

[FR Doc. 03–15389 Filed 6–17–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR part 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicants

Speedtrans International, Inc., Suite 1001 Federal Tower Condominium, Dasmarinas Street, Binondo, Manila, Officers: Edith P. Vaporoso, Exec. Vice President (Qualifying Individual), Susano D. Gemora, Jr., President.

Pacific-Net Logistics ATL, Inc., 6020 Dawson Blvd., #F, Norcross, GA 30093, Officers: David Hume Shafer, CEO (Qualifying Individual), Michael Tsang, CFO.

Marenas Shipping, L.L.C., 8074 NW., 66 Street, Miami, FL 33166, Officers: Freddy J. Zelaya, Exec. Manager (Qualifying Individual), Jorge Arenas, President.

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants

CAF Worldwide Inc., 154–09 146th Avenue, Jamaica, NY 11434, Officers: Joseph F. Barry, Vice President (Qualifying Individual), Joseph F. Barry, III, President.

M/S Galaxy Multimodal Systems Pvt. Ltd., 7, Kumtha Street, Ballard Estate, Mumbai-400 038, India, Officer: Capt. P. P. Singh, Managing Director (Qualifying Individual).

Dated: June 13, 2003.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–15387 Filed 6–17–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank 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. The notices also will be available for inspection at the office 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 July 2, 2003.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. James Fowler Justiss, III, Jena, Louisiana; to acquire voting shares of JBI Financial Corporation, Jena, Louisiana, and thereby indirectly acquire voting shares of Bank of Jena, Jena, Louisiana.

Board of Governors of the Federal Reserve System, June 12, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–15316 Filed 6–17–03; 8:45 am]

BILLING CODE 6210–01–S

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. The application also will 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 (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank

holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

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 July 12, 2003.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Kankakee Bancorp, Inc., Kankakee, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of State Bank of Aviston, Aviston, Illinois.

In connection with this application, Applicant also has applied to retain control of KFS Bank, F.S.B., Kankakee, Illinois, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4) of Regulation Y.

B. Federal Reserve Bank of Kansas City (James Hunter, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Platte County Bancshares, Inc., Platte City, Missouri; to acquire an additional 6.2 percent, for a total of 18.7 percent, of the voting shares of MidAmerican Bancshares, Inc., Harrisonville, Missouri, and thereby indirectly acquire voting shares of Allen Bank and Trust Company, Harrisonville, Missouri.

2. Peoples Bancshares, Inc., Kansas City, Missouri; to acquire an additional 22.87 percent, for a total of 68.7 percent, of the voting shares of MidAmerican Bancshares, Inc., Harrisonville, Missouri, and thereby indirectly acquire voting shares of Allen Bank and Trust Company, Harrisonville, Missouri.

Board of Governors of the Federal Reserve System, June 12, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–15317 Filed 6–17–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 2, 2003.

A. Federal Reserve Bank of Minneapolis (Richard M. Todd, Vice President and Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. Franklin Bancorp, Inc., DBA Sunrise Community Banks, St. Paul, Minnesota; to engage *de novo* in purchasing participations in loans originated by its subsidiary banks, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, June 12, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–15315 Filed 6–17–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Government in the Sunshine Meeting Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 12 p.m., Monday, June 23, 2003.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED: 1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Assistant to the Board; 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: June 13, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–15420 Filed 6–13–03; 4:17 pm]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Meeting

TIME AND DATE: 9 a.m. (EDT), June 20, 2003.

PLACE: 4th Floor, Conference Room, 1250 H Street, NW., Washington, DC.

STATUS: The meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Discussion of litigation matters.

FOR FURTHER INFORMATION CONTACT: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: June 16, 2003.

Elizabeth S. Woodruff,

Secretary to the Board, Federal Retirement Thrift Investment Board.

[FR Doc. 03–15584 Filed 6–16–03; 4:00 pm]

BILLING CODE 6760–01–M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration

and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTION GRANTED EARLY TERMINATION

ET Date	Trans No.	ET Req Status	Party Name
12–May–03	20030530	G	Networks Associates, Inc.
	.....	G	IntruVert Networks Inc.
	.....	G	IntruVert Networks Inc.
	20030589	G	PRIMEDIA Inc.
	.....	G	PRIMEDIANet Inc.
	.....	G	Cover Concepts Marketing Services, LLC
	.....	G	PRIMEDIA California Digital Inc.
	.....	G	PRIMEDIA Magazine Finance, Inc.
	.....	G	PRIMEDIA Magazines Inc.
	.....	G	PRIMEDIA Speciality Group Inc.
	20030591	G	CVC European Equity Partners III L.P.
	.....	G	E.ON AG.
	.....	G	Viterra Energy Services AG.
	20030592	G	A. Jerrold Perenchio.
	.....	G	Family Stations, Inc.
	.....	G	Family Stations, Inc.
	20030600	G	Laird Norton Company LLC.
	.....	G	DLC Holdings, Inc.
	.....	G	Dixieline Lumber Company.
	.....	G	Dixieline Builders Fund Control, Inc.
	20030603	G	Oxford Industries, Inc.
	.....	G	Viewpoint International, Inc.
	.....	G	Viewpoint International, Inc.
14–May–03	20030483	G	CRH plc.
	.....	G	S.E. Johnson Companies Inc.
	.....	G	S.E. Johnson Companies Inc.
	20030485	G	Carlyle Partners III, L.P.
	.....	G	TA Acquisition Holdings, Inc.
	.....	G	The Aerostructures Corporation.
19–May–03	20030588	G	Sumner M. Redstone.
	.....	G	AOL Time Warner Inc.
	.....	G	Comedy Partners.
	20030596	G	Automatic Data Processing, Inc.
	.....	G	Deutsche Bank AG.
	.....	G	Deutsche Investment Management Americas Inc.
	.....	G	Scudder Trust Company.
	.....	G	Scudder Investments Service Company.
	.....	G	Scudder Distributors, Inc.
	.....	G	Deutsche Realty Holdings (II), LLC.
	20030604	G	Teva Pharmaceutical Industries Limited.
	.....	G	GlaxoSmithKline plc.
	.....	G	Glaxo Group Limited.
	20030607	G	David W. and Freda Barrick.
	.....	G	John D. Gaughan.
	.....	G	Exber, Inc.
	.....	G	Union Plaza Hotel and Casino, Inc.
	.....	G	Union Plaza Operating Company, Inc.
	.....	G	Gaughan South Corp.
	20030609	G	SmartMail, LLC.
	.....	G	Roy R. Ferber.
	.....	G	Drop Ship Express, Inc.
	20030610	G	General Motors Corporation.
	.....	G	Lend Lease Corporation Limited.
	.....	G	CapMark Services, L.P.
	.....	G	Lend Lease Asset Management, L.P.
	.....	G	Lend Lease Equities S.A. de C.V.
	.....	G	Lend Lease Japan Inc.
	.....	G	Lend Lease Real Estate Investments, Inc.
	.....	G	Lend Lease (US) Inc.
	.....	G	Pearl Mortgage, Inc.
	20030611	G	Churchill Equity and ESOP Capital Partners II, L.P.
	.....	G	Code, Hennessy & Simmons III, L.P.
	.....	G	CBSA Holdings, L.L.C.
	20030617	G	Berkshire Hathaway Inc.

TRANSACTION GRANTED EARLY TERMINATION—Continued

ET Date	Trans No.	ET Req Status	Party Name
	.....	G	Wal-Mart Stores, Inc.
	.....	G	McLane Company Inc.
21–May–03	20030621	G	Jupiter Partners II L.P.
	.....	G	Gary Damkoehler.
	.....	G	JSA Healthcare Corporation.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, or Renee Hallman, Legal Technician, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–15365 Filed 6–17–03; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires person contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTION GRANTED EARLY TERMINATION

ET Date	Trans No.	ET Req Status	Party Name
27–MAY–03	20030602	G	Biovail Corporation
	.....	G	Wyeth
	.....	G	American Cyanamid Company
	.....	G	Wyeth Pharmaceuticals Inc.
	20030613	G	Tekelec
	.....	G	Santera Systems Inc.
	.....	G	Santera Systems Inc.
	20030615	G	Delta Electronics (Thailand) Public Company Limited
	.....	G	Ascom Holding AG
	.....	G	Ascom India Prive Ltd.
	.....	G	Ascom Rompower, Inc.
	.....	G	Ascom Energy Systems GmbH
	.....	G	Ascom Energy Systems (Guangzhou) Ltd.
	.....	G	Ascom UK Limited
	.....	G	Ascom Energy Systems AG
	.....	G	Ascom Spain SA
	.....	G	scom Praha spol. s.r.o.
	20030622	G	Johnson & Johnson
	.....	G	Helmut D. Link
	.....	G	Link Spine Group, Inc.
	.....	G	Link Holding Company, Inc.
	20030632	G	Swift Transportation Co., Inc.
	.....	G	Wal-Mart Stores, Inc.
	.....	G	Merit Distribution Services, Inc.
	20030639	G	Bank One Corporation
	.....	G	Quintiles Transnational Corp.
	.....	G	Quintiles Transnational Corp.
	20030640	G	Barry Diller
	.....	G	LendingTree, Inc.
	.....	G	LendingTree, Inc.
28–MAY–03	20030627	G	Fenway Partners Capital Fund II, L.P.
	.....	G	Lincolnshire Equity Fund II, L.P.
	.....	G	Riddell Sports Group, Inc.
	20030628	G	Carlyle Partners III, L.P.
	.....	G	The UIS Industries, Inc. Voting Trust.
	.....	G	Pioneer, Inc.
	.....	G	Neapco Inc.
	.....	G	Wells Manufacturing Corporation.

TRANSACTION GRANTED EARLY TERMINATION—Continued

ET Date	Trans No.	ET Req Status	Party Name
	.....	G	Champion Laboratories, Inc.
	.....	G	Mid-South Mfg., Inc.
	.....	G	Airtex Products, LLC.
	.....	G	Automotive Accessory Co. Ltd.
	.....	G	Talleres Mecanicos Montserrat, S.A. de C.V.
	.....	G	Brummer Mexicana en Puebla, S.A. de C.V.
	.....	G	Brummer Seal de Mexico, S.A. de C.V.
	.....	G	Wells Manufacturing Canada Limited.
	.....	G	Airtex Products S.A.
	.....	G	UIS Industries, Ltd.
	20030631	G	Petroliam Nasional Berhad.
	.....	G	Neptune Orient Lines Limited.
	.....	G	American Eagle Tankers Inc. Limited.
	20030634	G	Hewitt Holdings LLC.
	.....	G	Michael D. Blair.
	.....	G	Cybord Worldwide, Inc.
	20030637	G	SKM Equity Fund III, L.P.
	.....	G	Murray's Inc.
	.....	G	Murray's Inc.
	20030638	G	Green Equity Investors III, L.P.
	.....	G	Werner Holding Co. (PA), Inc.
	.....	G	Werner Holding Co. (PA), Inc.
	20030643	G	Odyssey Investment Partners Fund., L.P.
	.....	G	Scott K. Lemay.
	.....	G	United Site Services, Inc.
29–MAY–03	20030295	G	Southern Union Company.
	.....	G	CMS Energy Corporation.
	.....	G	Panhandle Eastern Pipeline Company.
	20030626	G	McCormick & Company, Inc.
	.....	G	Zatarain's Brands, Inc.
	.....	G	Zatarain's Brands, Inc.
	20030641	G	Olympus Growth Fund III, L.P.
	.....	G	Mettis Group Limited.
	.....	G	Mettis (UK) Limited.
	20030642	G	Brockway Moran & Partners Fund II, L.P.
	.....	G	KKR–FS Associates II LLC.
	.....	G	WS Acquisition Corp.
	20030645	G	Health Management Associates, Inc.
	.....	G	Sisters of Providence, Mother Joseph Providence.
	.....	G	Providence Health System—Washington.
	.....	G	Providence Home Care and Hospice.
	.....	G	Providence Toppenish Hospital.
	.....	G	John Gabriel Ryan Association.
	.....	G	Providence Yakima Medical Center.
02–JUN–03	20030612	G	Probitas Pharma, S.A.
	.....	G	Mitsubishi Chemical Corporation.
	.....	G	Alpha Therapeutic Corporation.
	20030649	G	Palomino Fund Ltd.
	.....	G	Conseco, Inc.
	.....	G	Conseco, Inc.
	20030655	G	Comcast Corporation.
	.....	G	George Lane.
	.....	G	Advanced TeleMedia, LLC
	20030657	G	Ripplewood Partners II, L.P.
	.....	G	Lillian Vernon Corporation.
	.....	G	Lillian Vernon Corporation.
	20030658	G	Citadel Broadcasting Corporation.
	.....	G	Wicks Communications & Media Partners, L.P.
	.....	G	Wilks Broadcasting LLC.
	20030659	G	Tellabs, Inc.
	.....	G	Vivace Networks, Inc.
	.....	G	Vivace Networks, Inc.
04–JUN–03	20030644	G	Yorktown Energy Partners, IV, L.P.
	.....	G	Duke Energy Corporation.
	.....	G	Duke Energy Field Services, L.P.
	.....	G	AIM Pipeline, LLC.
	.....	G	Duke Energy Intrastate Pipeline, LLC.
	.....	G	Duke Energy Field Services Marketing, LLC.
	20030654	G	Career Education Corporation.
	.....	G	Whitman Education Group, Inc.

TRANSACTION GRANTED EARLY TERMINATION—Continued

ET Date	Trans No.	ET Req Status	Party Name
	.....	G	Whitman Education Group, Inc.
	20030656	G	Nautic Partners V, L.P.
	.....	G	Barry L. Downing.
	.....	G	Corporate Lodging Consultants, Inc.
	.....	G	Crew Transport Services, Inc.
	.....	G	Crew Transport Specialists, Inc.
05–JUN–03	20030614	G	ScanSoft, Inc.
	.....	G	SpeechWorks International, Inc.
	.....	G	SpeechWorks International, Inc.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, or Renee Hallman, Legal Technician, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–15368 Filed 6–17–03; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[File No. 021 0006]

Anesthesia Service Medical Group, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before June 30, 2003.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov,* as prescribed in the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: John Wiegand or Kerry O'Brien, FTC Western Regional Office, 901 Market St., Suite 570, San Francisco, CA 94103, (415) 848–5100.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and Section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for May 30, 2003), on the World Wide Web, at ''*http://www.ftc.gov/os/2003/05/index.htm.*'' A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: *consentagreement@ftc.gov.* Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii)).

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an agreement containing a proposed consent order with Anesthesia Service Medical Group, Inc. (''ASMG'' or ''Respondent''). The agreement settles charges that Respondent violated section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, by facilitating and implementing agreements with Grossmont Anesthesia Services Medical Group, Inc. (''GAS'') on fees, quantity of anesthesia services provided, and other competitively significant terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint Allegations

ASMG and GAS are competing anesthesiology groups that provide anesthesia services for a fee to patients in San Diego County, California. ASMG employs approximately 180 anesthesiologists. GAS is composed of approximately 10 anesthesiologists. ASMG and GAS anesthesiologists are

members of the medical staff of Grossmont Hospital in La Mesa, a municipality in central San Diego County, California. ASMG and GAS anesthesiologists make up approximately 75 percent of the anesthesiologists with active medical staff privileges at Grossmont Hospital and work on approximately 70 percent of the cases that require anesthesia services at the hospital.

Anesthesiologists provide anesthesia services to patients primarily at general acute care hospitals and outpatient surgery centers. Those services include evaluating a patient before surgery, consulting with the surgical team, providing pain control and support-of-life functions during surgery, supervising care after surgery in the recovery unit, and medically discharging the patient from the recovery unit. In addition to working on scheduled surgical procedures, anesthesiologists work on unscheduled obstetric and emergency cases at general acute care hospitals. An anesthesiologist who remains available to work on unscheduled cases is said to be ''taking call.''

Anesthesiologists in San Diego County are reimbursed for their services from several sources. Health insurance companies and other third-party payors typically reimburse anesthesiologists for services rendered to their subscribers during scheduled and unscheduled medical procedures and obstetrical cases through contracts that establish fees and other competitively significant terms. In addition, some hospitals pay anesthesiologists ''stipends'' for taking call and/or for rendering services to uninsured patients. Some hospitals pay anesthesiologists stipends through contracts that establish a stipend amount and other competitively significant terms.

Absent agreements among competing anesthesiologists, competing anesthesiologists or anesthesiology groups decide independently whether to seek a stipend from a hospital and the amount of the stipend. They also decide independently whether they will terminate or restrict the services they provide to unscheduled or uninsured patients if the hospital refuses to pay them a stipend or if they are dissatisfied with the stipend.

From as early as February 2001 through March 2002, ASMG and GAS discussed between themselves a joint strategy to secure stipends from Grossmont Hospital for taking obstetric call and for rendering services to uninsured emergency room patients. Eventually, ASMG and GAS agreed on the stipend amount both groups would demand from the hospital for taking obstetric call. ASMG and GAS also discussed reducing their hours of availability for taking call to increase their negotiating power with the hospital. Furthermore, they agreed to maintain a solid front against the hospital to prevent the hospital from (1) negotiating separately with each group to reduce the amount of the stipend or (2) seeking services solely from one group to the exclusion of the other. ASMG and GAS ceased this collusive activity only after the Commission contacted them about this conduct. While the Commission's investigation prevented any anticompetitive effects from occurring, this conduct is a naked restraint, which constitutes an unfair method of competition in violation of section 5 of the FTC Act.

The Proposed Consent Order

The proposed consent order is designed to prevent recurrence of the illegal concerted actions alleged in the complaint while allowing Respondent to engage in legitimate joint conduct.

Paragraph II.A prohibits Respondent from entering into or facilitating agreements between or among medical practices: (1) To negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services; (2) to deal, to refuse to deal, or to threaten to refuse to deal with any payor of anesthesia services; or (3) to reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services. A ''medical practice'' is defined as a bona fide, integrated business entity in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.

Paragraph II.B prohibits Respondent from attempting to engage in any action prohibited by Paragraph II.A. Paragraph II.C prohibits Respondent from encouraging, pressuring, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A and II.B.

Paragraph II contains a proviso that allows Respondent to engage in conduct that is reasonably necessary to the formation or operation of a ''qualified risk-sharing joint arrangement'' or a ''qualified clinically-integrated joint arrangement.'' To be a ''qualified risk-sharing joint arrangement,'' an arrangement must satisfy two conditions. First, all participating providers must share substantial financial risk through the arrangement and thereby create incentives for the participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. To be a ''qualified clinically-integrated joint arrangement,'' an arrangement must satisfy two conditions. First, all participants must join in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among providers to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Both definitions reflect the analyses contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

Paragraphs III through V of the proposed order are reporting and compliance provisions. Paragraph VI is a provision ''sunsetting'' the order after 20 years.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–15366 Filed 6–17–03; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 021 0006]

Grossmont Anesthesia Services Medical Group, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before June 30, 2003.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to:

consentagreement@ftc.gov, as prescribed in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: John Wiegand or Kerry O'Brien, FTC Western Regional Office, 901 Market St., Suite 570, San Francisco, CA 94103, (415) 848–5100.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and Section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for May 30, 2003), on the World Wide Web, at ''*http://www.ftc.gov/os/2003/05/index.htm.*'' A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, D.C. 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: *consentagreement@ftc.gov.* Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with section 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii)).

Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an agreement containing a proposed consent order with Grossmont Anesthesia Services Medical Group, Inc. (''GAS'' or ''Respondent''). The agreement settles charges that Respondent violated section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, by facilitating and implementing agreements with Anesthesia Service Medical Group, Inc. (''ASMG'') on fees, quantity of anesthesia services provided, and other competitively significant terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint Allegations

GAS and ASMG are competing anesthesiology groups that provide anesthesia services for a fee to patients in San Diego County, California. ASMG employs approximately 180 anesthesiologists. GAS is composed of approximately 10 anesthesiologists. GAS and ASMG anesthesiologists are members of the medical staff of Grossmont Hospital in La Mesa, a municipality in central San Diego County, California. GAS and ASMG anesthesiologists make up approximately 75 percent of the anesthesiologists with active medical staff privileges at Grossmont Hospital and work on approximately 70 percent of the cases that require anesthesia services at the hospital.

Anesthesiologists provide anesthesia services to patients primarily at general acute care hospitals and outpatient surgery centers. Those services include evaluating a patient before surgery, consulting with the surgical team, providing pain control and support-of-life functions during surgery, supervising care after surgery in the recovery unit, and medically discharging the patient from the recovery unit. In addition to working on scheduled surgical procedures, anesthesiologists work on unscheduled obstetric and emergency cases at general acute care hospitals. An anesthesiologist who remains available to work on unscheduled cases is said to be ''taking call.''

Anesthesiologists in San Diego County are reimbursed for their services from several sources. Health insurance companies and other third-party payors typically reimburse anesthesiologists for services rendered to their subscribers during scheduled and unscheduled medical procedures and obstetrical cases through contracts that establish fees and other competitively significant terms. In addition, some hospitals pay anesthesiologists ''stipends'' for taking call and/or for rendering services to uninsured patients. Some hospitals pay anesthesiologists stipends through contracts that establish a stipend amount and other competitively significant terms.

Absent agreements among competing anesthesiologists, competing anesthesiologists or anesthesiology groups decide independently whether to seek a stipend from a hospital and the amount of the stipend. They also decide independently whether they will terminate or restrict the services they provide to unscheduled or uninsured patients if the hospital refuses to pay them a stipend or if they are dissatisfied with the stipend.

From as early as February 2001 through March 2002, GAS and ASMG discussed between themselves a joint strategy to secure stipends from Grossmont Hospital for taking obstetric call and for rendering services to uninsured emergency room patients. Eventually, GAS and ASMG agreed on the stipend amount both groups would demand from the hospital for taking obstetric call. GAS and ASMG also discussed reducing their hours of availability for taking call to increase their negotiating power with the hospital. Furthermore, they agreed to maintain a solid front against the hospital to prevent the hospital from (1) negotiating separately with each group to reduce the amount of the stipend or (2) seeking services solely from one group to the exclusion of the other. ASMG and GAS ceased this collusive activity only after the Commission contacted them about this conduct. While the Commission's investigation prevented any anticompetitive effects from occurring, this conduct is a naked restraint, which constitutes an unfair method of competition in violation of section 5 of the FTC Act.

The Proposed Consent Order

The proposed consent order is designed to prevent recurrence of the illegal concerted actions alleged in the

complaint while allowing Respondent to engage in legitimate joint conduct.

Paragraph II.A prohibits Respondent from entering into or facilitating agreements between or among medical practices: (1) To negotiate, to fix, or to establish any fee, stipend, or any other term of reimbursement for the provision of anesthesia services; (2) to deal, to refuse to deal, or to threaten to refuse to deal with any payor of anesthesia services; or (3) to reduce, or to threaten to reduce, the quantity of anesthesia services provided to any purchaser of anesthesia services. A ''medical practice'' is defined as a bona fide, integrated business entity in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.

Paragraph II.B prohibits Respondent from attempting to engage in any action prohibited by Paragraph II.A. Paragraph II.C prohibits Respondent from encouraging, pressuring, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A and II.B.

Paragraph II contains a proviso that allows Respondent to engage in conduct that is reasonably necessary to the formation or operation of a ''qualified risk-sharing joint arrangement'' or a ''qualified clinically-integrated joint arrangement.'' To be a ''qualified risk-sharing joint arrangement,'' an arrangement must satisfy two conditions. First, all participating providers must share substantial financial risk through the arrangement and thereby create incentives for the participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. To be a ''qualified clinically-integrated joint arrangement,'' an arrangement must satisfy two conditions. First, all participants must join in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among providers to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Both definitions reflect the analyses contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

Paragraphs III through V of the proposed order are reporting and compliance provisions. Paragraph VI is a provision ''sunsetting'' the order after 20 years.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–15367 Filed 6–17–03; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary, Assistant Secretary for Planning and Evaluation; Notice of Funding Availability for Policy and Research Grants (State Innovation Grants)

AGENCY: The Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS.

ACTION: Notice of grant competition.

SUMMARY: The Office of the Assistant Secretary for Planning and Evaluation announces its intention to conduct a grant competition for ASPE State Innovation Demonstration Grants. This competition is limited to current recipients of FY 2002 ASPE State Innovation Planning Grants.

The Catalog of Federal Domestic Assistance Number: The CFDA number is 93.239.

Closing Date: The closing date for submitting applications under this announcement is August 18, 2003. Please email Brenda Benesch at *Brenda.Benesch@hhs.gov* by July 8, 2003 to inform the government of your intent to submit an application. Please include the proposed title of the project and the name of the agency submitting the application. Providing notice of intent to submit is not a requirement for submitting an application. However, a notice of intent to submit will help the federal government in planning for the review process.

Mailing Address: Applications should be submitted *to be determined.*

You will receive email confirmation to notify you that your application was received within 14 days of the closing date. If you do not receive confirmation within 14 days of the closing date, please contact *to be determined* at the address above.

The printed **Federal Register** notice is the only official program announcement.

FOR FURTHER INFORMATION CONTACT: Administrative questions should be directed *to be determined* at the address or phone number listed above. Administrative questions will be accepted and responded to up to ten working days prior to closing date of receipt of applications. Technical questions should be directed to Brenda Benesch, either by telephone (202–260–0382), fax (202–690–6562), e-mail (*Brenda.Benesch@hhs.gov*) or in writing at the following address, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 200 Independence Avenue, SW., Room 450G, Hubert H. Humphrey Building, Washington, DC 20201. If you send your question(s) in writing, please call to confirm receipt. Technical questions will be accepted and responded to up to ten working days prior to the closing date of receipt of applications.

Application Materials: Application materials are included in this package and are also available from the ASPE World Wide Web site: *http://aspe.hhs.gov/funding.htm* or by calling *to be determined.*

SUPPLEMENTARY INFORMATION: This program announcement consists of five parts: Part I: Background—Legislative authority, Background information, Purpose, Technical assistance and process evaluation; Part II: Project and Applicant Eligibility—Eligible applicants, Available funds, Budget and project period, and Matching requirements; Part III: The Review Process—Intergovernmental review, Initial screening, and Competitive review and evaluation criteria; Part IV: The Application—Application development, Application submission, Disposition of applications, and Components of a complete application; Part V: Questions and Answers.

Part I. Background

A. Legislative Authority

This announcement is authorized by section 1110 of the Social Security Act (42 U.S.C. 1310) and section 310 of the Public Health Service Act and awards will be made from funds appropriated under the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7).

B. Background Information

In FY 2002 ASPE awarded state innovation demonstration grants to five states and planning grants to ten states to help them implement or develop innovative approaches for providing health and human services more efficiently. Planning grants were awarded for up to a 17-month project period. The following planning grants were awarded:

- Alaska Department of Health and Social Sciences— ''Planning for

Comprehensive Early Childhood Mental Health in Alaska'';

• Arizona Department of Health Services— ''Arizona Diabetic Patient Self-Management Project'';

• Arkansas Department of Human Services— ''Improving Transitions from the Institutions into the Community'';

• Delaware Health and Social Services— ''Self-Directed Supports for Community Living'';

• District of Columbia Department of Health— ''DC Youth Violence Prevention Initiative-'';

• Iowa Department of Human Services— ''Healthy Marriage/ Responsible Fatherhood'';

• Kansas Department of Social and Rehabilitation Services— ''Child Welfare Wrap Around Service Delivery'';

• Maryland Department of Aging— ''Changing Interagency Service Delivery Systems to Help Older Public Housing Residents'';

• New Hampshire State Department of Health and Human Services— ''Granite State Data Archive''; and

• South Carolina Department of Social Services— ''Keep Them Home: An Adult Protective Service Program.''

C. Purpose

ASPE has determined that building on the efforts already underway is the most efficient use of the Fiscal Year 2003 state innovative grant funds. Since fiscal limitations prevent use from funding all ten planning grantees to move into a second-year, transitional planning/ demonstration phase, we plan to conduct a limited competition among the planning grantees in order to select 2–3 that will receive second-year resources. ASPE's goal in supporting this phase is to enable some states to implement their innovative ideas, as well as to improve our understanding of the process of successful innovation. Planning grantees that receive additional funding will be expected to strengthen their activities and begin implementation. We anticipate that lessons learned from the planning and implementation process will assist program directors and state officials across the country in planning and implementing innovative projects. We plan to provide additional funding to 2–3 grantees. Each applicant may request funds in the range of $300,000–$500,000 per year for a maximum of three years. Decision on subsequent funding will be made on a noncompetitive basis based on the availability of funds, the adequate progress of the grantee, and such other similar criteria as the Department determines. Any requested additional funding will be reviewed to determine that the continuation of the project is consistent with the purposes of the announcement.

D. Technical Assistance and Process Evaluation

The Lewin Group will provide a limited amount of tailored technical assistance to the states. The independent process evaluation begun in the FY2002 phase of the State Innovation Grants initiative will be expanded to document the progress of the FY2003 grantees. The process evaluation will, at a minimum, address key research questions:

1. What are the issues and challenges associated with implementing and operating the funded projects?

2. What are the expected short and long-term implications of this intervention for clients, as well as for agencies involved?

3. What other innovative ideas/ projects may grow out of each funded project and the program as a whole?

We expect that the work undertake through this evaluation will result in important operational lessons and sound information about implementing innovative approaches. ASPE expects that this investment will benefit low-income clients and families, state and local health and human service administrators, others who work with low-income people, and the general public.

Part II. Project and Applicant Eligibility

A. Eligible Applicants

This grant competition is limited to the FY2002 State Innovation Grant recipients (see Part I B).

B. Available Funds

Approximately $1 million is expected to be available from ASPE funds appropriated for fiscal year 2003. We estimate that this level of funding will support between 2–3 grants.

C. Budget and Project Period

Awards under this announcement will be made for 12-month budget periods. States may propose projects up to 36 months in duration. Subject to the availability of funds, grantees with projects which last longer then 12 months may be allowed to submit subsequent applications for additional funding, at a lower funding level, for additional budget period(s). Decisions on subsequent funding will be made on a noncompetitive basis based on the availability of funds, the adequacy of grantee progress, and such other similar criteria as the Department may determine. Any requests for additional funding also will be reviewed to ensure that the continuation of the project is consistent with the purpose of the announcement.

After a grant award is made, any purchase of computer hardware or software needs to be requested in writing by the grantee and approved in writing by the ASPE project officer and the grants officer. Purchases of computer hardware or software for routine uses will not be considered. See Part IV, Section II for more information on review criteria for MIS/Data System proposals.

No funds may be paid as profit to grantees or subgrantees, *i.e.,* any amount is excess of allowable direct and indirect costs of the recipient (45 CFR 74.81). Grant monies can be used for client services to the extent that the cost of the services cannot be covered under existing programs.

D. Matching Requirements

Grantees must provide at least 10 percent of the total approved cost of the project. The total approved cost of the project is the sum of the Federal share and the non-Federal share. The non-Federal share may be met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. For example, a state with a project with a total budget (both direct and indirect costs) of $500,000 may request up to $450,000 in federal funds. Matching requirements cannot be met with funds from other federally-funded programs.

If a proposed project activity has approved funding support from other funding sources, the amount, duration, purpose, and source of the funds should be indicated in materials submitted under this announcement. If completion of the proposed project activity is contingent upon approval of funding from other sources, the relationship between the funds being sought elsewhere and from ASPE should be discussed in the budget information submitted as a part of the abstract. In both cases, the contribution that ASPE funds will make to the project should be clearly presented.

Part III. The Review Process

A. Intergovernmental Review

State Single Point of Contact (E.O. No. 12372)—DHHS has determined that this program is not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' Applicants are not required to seek intergovernmental review of their applications within the constraints of E.O. 12372.

B. Initial Screening

Each application submitted under this program announcement will undergo a pre-review to determine that (1) the application was received by the closing date and submitted in accordance with the instructions in this announcement; (2) the applicant is eligible for funding; (3) the applicant has included assurances that they and other relevant participating organizations will be willing to field test strategies, based on their initial planning phase, and will participate in a process evaluation to document the steps taken from planning to implementation [this must be indicated on the page with the project abstract—see part IV, section E, 8(a)]; and (4) is within the page limit (see part IV, section A). Note that applications exceeding the page limit will not be reviewed further and will be ineligible for funding.

C. Competitive Review and Evaluation Criteria

Applications that pass the initial ASPE pre-review screening will be evaluated and rated by an independent review panel on the basis of specific evaluation criteria. The evaluation criteria are designed to assess the quality of the proposed project and to determine the likelihood of its success. The evaluation criteria are closely related and are considered as a whole in judging the overall quality of an application. Points are awarded only to applications that are responsive to the evaluation criteria as provided in this program announcement.

In order to ensure that the interests of the Federal Government are met, in making the final selections, ASPE may consider additional factors, in addition to the review criteria identified below. These additional factors may include such things as the applicants' readiness to transition from a planning to an implementation phase; capacity for continued and sustainable innovation; the potential impact of the innovation on the target population; the potential for building upon funding activities; the extent of partnerships with local entities; and the overall diversity of program activities within the applicant pool.

Proposed projects will be reviewed using the following evaluation criteria:

(1) Approach: (40 points)

The application will be judged on the extent to which the proposed approaches to project activities are adequate and appropriate to meet the objectives for projects in this program as set out in this announcement. As a part of the proposed approach, the application should identify the key, relevant organizations that will be involved in project activity and describe operational relationships that exist or will be put into place among the state, local public, private and non-profit agencies, and any other entities. Plans for cross-agency collaboration should be clearly explained.

Applicants should include a discussion of the proposed approach for implementing and operating the innovative strategies identifying specific steps to be undertaken. The approach should include a discussion of the time frame and action steps necessary before the implementation/demonstration phase of the project becomes operational (*e.g.,* staff must be trained over the next six months; partnerships with local agencies, non-profits, employers, etc. must be established, etc.). Applicants should provide a detailed description of the steps necessary to transition from a planning grant to a larger demonstration grant. Applicants should also describe how the transition to a demonstration grant will affect goals and objectives. In particular, applicants should address whether or not goals and objectives identified for the planning phase will need to be modified for the transition to a demonstration phase. The application will be judged based on the extent to which the proposed project demonstrates a firm commitment of State, and/or local, and/or private funding and/or in-kind contributions dedicated to sustainability of the project, on the extent to which it is innovative, and on its potential for improving outcomes either in target populations or management of state programs.

The application should include a brief discussion of the location of the proposed project to be implemented. Maps or other graphic aids may be attached. Applications should include appropriate information about the size of the target population in the proposed site/area and other data or information available that relate to the project activity.

It may be necessary for agencies to provide data to Lewin or to HHS. The types of data possibly requested under this project may include administrative data, including data on program attendance, or other participation data. Data may also be collected from program managers and staff and from individuals participating in the demonstration program to be implemented. The proposed approach should indicate the availabilty of such data, the source of the data, the extent to which it can be obtained or accessed by the applicant organization, the existence of data exchange agreements with other agencies that are the source of needed data, and the willingness of the applicant agency to obtain data needed for the evaluation. Any limitations regarding data availability or access should be discussed, including any fees for data.

Any application for a project involving the use of personally-identifiable information about patients or clients that grantees collect should describe how the project intends to address the privacy and confidentiality issues presented by the data collection. The description should not include details of collection, consent, security and the like. It should describe the organizational and planning approaches that will ensure that the project addresses these issues in a thoughtful way, respectful of the patients' and clients' privacy and dignity, in accord with all applicable law, and, if appropriate, taking particular account of the special privacy issues created by systems that integrate or link administrative data across several programs that serve the same population.

(2) Objectives and Need for Assistance: (15 points)

The applications should describe (1) issues and challenges which the applicant has considered and dealt with to date in designing and/or implementing strategies for system improvements, including an assessment of the current delivery system and the most urgent needs of the project's target population or system, and (2) the proposed strategy for the transition from a planning to a demonstration phase and ways in which it will significantly enhance innovative services for the target population. (3) A description of existing resources and programs for the target population, barriers in the current delivery system, and gaps in service delivery should also be included. The applicant should include any supporting data or available information gained during the planning phase that further demonstrates why the innovation is needed, and how the planning phase contributed to the development of innovative ways to serve the target populations. Applications will be judged on the relevance of the discussion to the program objectives set out within this announcement. The application will also be judged on the extent to which the innovation proposed will help to address the target population's needs, build the knowledge base, and have

applicability to a range of states and localities.

(3) Results or Benefits Expected: (15 points)

The application should describe how the proposed implementation phase will address the identified needs and improve the delivery of services or activities. The application should identify specific outcome measures (goals) to be achieved through implementation of the innovation.

Goals should be tied to discrete, measurable objectives. Examples include: increase in the proportion of participants entering jobs at higher wage levels; increased partnerships between agencies and employers to support working families; increased access to health and human services benefits; increased integration of programs or services targeting clients with multiple barriers; increased innovation related to ''consumer-directed'' approaches to home and community-based long-term care services; more rapid access to program and client date; etc. The application will be judged on the extent to which the proposed program design or policies can be expected to achieve the stated project goals.

In committing to participate in a process evaluation, applicants should be able to report baseline information, including the size of the target population and the expected number of individuals or families to be served by the project, as appropriate. Interim and final program reports will be required.

(4) Staff and Position Data (10 Points)

The application should include a listing of key individuals who will oversee and work on the project, specifically identifying the key individuals from the applicant agency who will serve as the primary contacts for ASPE and contractor staff, indicating their positions, areas of responsibility and authority, and the proportion of time that will be available for project activity.

Applications will be judged on the extent to which individuals with appropriate authority, positions, and experience will work on the project and the adequacy of time allocated for key staff to the project. In addition, the application will be judged on the extent to which there is a commitment to the project evidenced by the participation of senior state and local officials and managers and on the adequacy of the proposed plans for obtaining advice and direction regarding project work and involvement and assistance to resolve issues or problems, as appropriate.

(5) Adequacy of Workplan (10 points)

Applicants should provide details about how planning projects will be implemented. Applications should delineate tasks for completing the work, indicate staff assignments for each task, and provide a schedule for completing each task. Applicants should also describe mechanisms that will be put in place to maintain quality control over the project. The application will be judged on the appropriateness and timeliness of the work schedule and tasks, staff assignments, and quality assurance plan.

(6) Budget Appropriateness (10 points)

The application must include a narrative description and justification for proposed budget line items and demonstrate that the project's costs are adequate, reasonable and necessary for the activities or personnel to be supported. The budget and narrative should have a clear relationship to the approach. The application will be judged on the extent to which adequate staffing and other resources will be provided as required to successfully carry out the tasks and activities proposed. (Applicants should refer to the budget information presented in the Standard Forms 424 and 424A, which can be found at *http://aspe.hhs.gov/funding.htm*).

Part IV. The Application

A. Application Development

In order to be considered for an award under this program announcement, an application must be submitted on the forms supplied and in the manner prescribed by ASPE. Application materials including forms and instructions are attached to this announcement. Additional copies are available from *to be determined.*

Applicants should refer to the attached application kit for instructions regarding which forms, certifications and assurances are required and for instructions on completing the forms and preparing and submitting the application. Each application package must include an *original and two copies* of the complete application. All pages of the narrative must be sequentially numbered and unbound.

Applications must be received in the following format:

- 12 point font size
- Single line spacing
- 1 inch top, bottom, left, and right margins
- Applications should not exceed 20 pages. Page limits apply to items Section IV, D, 8(b–e) only; page limits do not include standard forms, certificates, and the like. Forms are available from GRANTS OFFICER TO BE DETERMINED or may be obtained electronically from the ASPE World Wide Web site: *http://aspe.hhs.gov/funding.htm.* Applications that are not received in the format described above and/or exceed the page limit, will not be reviewed. Applicants are requested to be concise. Applicants are encouraged *not* to attach or include bound reports or other documents.

B. Application Submission

1. Mailed applications must be postmarked by midnight three days prior to the closing date. Otherwise, they will be classified as late.

2. *Deadline.* The closing date (deadline) for submission of applications is August 18, 2003. Please email Brenda Benesch at *Brenda.Benesch@hhs.gov* by July 8, 2003 to inform the government of your intent to submit an application. Providing notice of intent to submit is not a requirement for submitting an application. However, a notice of intent to submit will help the Federal government in the planning for the review process. USPS mailed applications shall be considered as meeting the announced deadline if they are either received on or before the deadline date or postmarked by midnight three days prior to the closing date and received by ASPE in time for the independent review (within 2 weeks of the deadline): *to be determined.*

If applicants use a commercial mail service, they must ensure that a legibly dated, machine produced postmark of a commercial mail service is affixed to the envelope/package containing the application. To be acceptable as proof of timely mailing, a postmark from a commercial mail service must include the logo/emblem of the commercial mail service company and must reflect the date the package was received by the commercial mail service company from the applicant. Private metered postmarks shall not be acceptable as proof of timely mailing. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

Applications hand-carried by applicants, applicant couriers, or by other representatives of the applicant shall be considered as meeting the announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m. EST, at: *to be determined.* The address must appear on the envelope/package containing the application with the note ''Attention: *to be determined*'' (Applicants are cautioned that express/

overnight mail services do not always deliver as agreed).

Applications transmitted by fax or through other electronic means will not be accepted regardless of date or time of submission or receipt.

3. Late applications. Applications that do not meet the criteria above are considered late applications. *To be determined* shall notify each late applicant that its application will not be considered in the current competition.

4. Extension of deadlines. NICHD may extend an application deadline when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of the mail service, or in other rare cases. Determinations to extend or waive deadline requirements rest with *grants officer to be determined,* the ASPE Grants Management Officer.

C. Disposition of Applications

1. *Approval, disapproval, or deferral.* On the basis of the review of the application, the Assistant Secretary will either (a) approve the application as a whole or in part; (b) disapprove the application; or (c) defer action on the application for such reasons as lack of funds or a need for further review.

2. *Notification of disposition.* The Assistant Secretary for Planning and Evaluation will notify the applicants of the disposition of their applications. If approved, a signed notification of the award will be sent to the business office named in the ASPE checklist.

3. *The Assistant Secretary's Discretion.* Nothing in this announcement should be construed as to obligate the Assistant Secretary for Planning and Evaluation to make any awards whatsoever. Awards and the distribution of awards among the priority areas are contingent on the needs of the Department at any point in time and the quality of the applications that are received.

D. Components of a Complete Application

A complete application consists of the following items in this order:

1. Application for Federal Assistance (Standard Form 424);

2. Budget Information—Non-construction Programs (Standard Form 424A);

3. Assurances—Non-construction Programs (Standard Form 424B);

4. Table of Contents;

5. Budget Justification for Section B Budget Categories;

6. Proof of Non-profit Status, if appropriate;

7. Copy of the applicant's Approved Indirect Cost Rate Agreement, if necessary;

8. Project Narrative Statement, organized in six sections, addressing the following topics (b) through (e) are limited to twenty (20) single-spaced pages:

(a) Abstract (must include assurance of willingness to participate in a process evaluation),

(b) Goals, Objectives and Usefulness of the Project,

(c) Methodology and Design,

(d) Background of the Personnel and Organizational Capabilities,

(e) Work plan (timetable), and

(f) Budget narrative.

9. Certification Regarding Drug-Free Workplace;

10. Certification Regarding Debarment, Suspension, or other Responsibility Matters;

11. Certification and, if necessary, Disclosure Regarding Lobbying;

12. Supplement to Section II—Key Personnel;

13. Application for Federal Assistance Checklist.

Standard forms are available from GRANTS OFFICER TO BE DETERMINED or may be obtained electronically from the ASPE world wide web site: *http://aspe.hhs.gov/funding.htm*

Part V. Questions and Answers

1. Who May Submit an Application Under This Announcement?

State agencies that received ASPE State Innovation Planning grants in FY 2002 are eligible to apply.

The following planning grantees are eligible to apply for an FY 2003 ASPE State Innovation Demonstration grant: (1) Alaska Department of Health and Social Services—''Planning for Comprehensive Early Childhood Mental Health in Alaska''; (2) Arizona Department of Health Services—''Arizona Diabetic Patient Self-Management Project''; (3) Arkansas Department of Human Services—''Improving Transitions from the Institutions into the Community''; (4) Delaware Health and Social Services—''Self-Directed Supports for Community Living''; (5) District of Columbia Department of Health—''DC Youth Violence Prevention Initiative—''; (6) Iowa Department of Human Services—''Healthy Marriage/Responsible Fatherhood''; (7) Kansas Department of Social and Rehabilitation Services—''Child Welfare Wrap Around Service Delivery''; (8) Maryland Department of Aging—''Changing Interagency Service Delivery Systems to Help Older Public Housing Residents''; (9) New Hampshire State Department of Health and Human Services—''Granite State Data Archive''; and (10) South Carolina Department of Social Services—''Keep Them Home: An Adult Protective Service Program''.

2. How Much Money Is Available for Grants Under This Announcement?

The total that is available under this announcement is approximately $1 million. ASPE anticipates that individual awards will be between $300,000–$500,000 per year.

3. How Many Awards Will Be Made or How Many Applications Will Be Approved?

ASPE anticipates awarding 2–3 grants.

4. Are There Page Limits or Other Page Guidelines for the Narrative Section of the Application

Yes, there are page limits for the applications. Applicants are requested to be concise. The announcement indicates that applications are not expected to be lengthy (see Part III, Section C). Applications must be no longer than 20 pages. Applications must be typed in 12 point font size, with single line spacing, and 1 inch top, bottom, right, and left margins. Applications that exceed the page limits and other guidelines will not be considered.

5. Where Should Applications To Be Sent?

An original and two copies of the complete application should be sent to: *To be determined.*

6. What Is the Application Submission Deadline?

Applications must be received or postmarked by August 18, 2003.

7. What Is the Deadline for Applications Sent via Overnight Courier Services?

Applications that are hand-carried will be considered as meeting the deadline if they are *received on or before the deadline date between the hours of 8 a.m. and 4:30 p.m. EST* at NICHD, Grants Management Branch, U.S. Department of Health and Human Services, 6100 Executive Boulevard, Room 8A01 Bethesda, Maryland 20892–7510 (Regular Mail) or Rockville, Maryland 20852 (Express Mail), Phone: (301) 435–6997, Fax: (301) 402–0915. The address must include the designation: ''Attention: *Grants Officer To Be Determined.''* (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

8. May Applications Be Faxed or Sent Electronically?

No. Applications transmitted by fax or through other electronic means will not be accepted regardless of date or time of submission or receipt.

9. Where Can Additional Copies of the Announcement and/or Forms Be Obtained?

The complete package, announcement and standard forms, may be obtained by calling *to be determined.*

Dated: June 9, 2003.

William F. Raub,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 03–15385 Filed 6–17–03; 8:45 am]

BILLING CODE 4154–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–79]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: National Healthcare Safety Network (NHSN)—New—National Center for Infectious Disease (NCID), Centers for Disease Control and Prevention (CDC). OMB first approved the information collection now known as the ''National Nosocomial Infections Surveillance (NNIS) System'' (OMB No.0920–0012) in 1970; it approved the ''National Surveillance System for Healthcare Workers(NaSH)'' (OMB 0920–0417) in 1997, and the ''Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers'' (OMB No. 0920–0442) in 1999. These three data collections have been modified and are being merged to create the NHSN. The NHSN will evolve with the addition of modules and participating healthcare institutions from a wide spectrum of settings.

The NHSN is a knowledge system for accumulating, exchanging, and integrating relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and to promote healthcare safety. Specifically, the data will be used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. They will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks.

Healthcare institutions that participate in NHSN voluntarily report their data to the Division of Healthcare Quality Promotion in the National Center for Infectious Diseases at the Centers for Disease Control and Prevention through the National Electronic Disease Surveillance System that uses a web browser-based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. The cost to participating institutions is a computer capable of supporting an internet service provider (ISP) and access to an ISP. The table below shows the estimated annual burden in hours to collect and report data.

Title	Number of respondents	Number of responses/ respondent	Burden per response (in hrs.)	Total burden (hrs.)
NHSN Application/Annual Survey	350	1	1	350
Dialysis Application/Annual Survey	80	1	1	80
Patient Safety Monthly Reporting Plan	350	9	25/60	1,313
Patient Data	350	111	5/60	3,238
Surgical Site Infection (SSI)	200	27	25/60	2,250
Pneumonia (PNEU)	200	54	25/60	4,500
Primary Bloodstream Infection (BSI)	230	54	25/60	5,175
Urinary Tract Infection (UTI)	150	45	25/60	2,813
Dialysis Incident (DI)	80	90	12/60	1,440
Denominator for Procedure	200	540	5/60	9,000
Denominator for Specialty Care Area (SCA)	75	9	5	3,375
Denominator for Neonatal Intensive Care Unit (NICU)	100	9	4	3,600
Denominator for Intensive Care Unit (ICU)/Other locations (Not NICU or SCA)	245	18	5	22,050
Denominator for Outpatient	80	9	5/60	60
Antimicrobia 1 Use and Resistance (AUR)—Pharmacy	20	36	2	1,440
Healthcare Personnel Safety Reporting Plan	90	2	10/60	30
Healthcare Personnel Exposures to Blood/Body Fluids	90	42	1	3,780
Healthcare Personnel Post-exposure Prophylaxis	90	6	15/60	135
Healthcare Personnel Demographic Data	90	42	10/60	630
Healthcare Personnel Vaccination History	90	42	15/60	945
Healthcare Personnel Facility Survey	90	1	6	540
Healthcare Personnel Implementation of Engineering Controls	90	1	6	540
Healthcare Personnel Survey	30	1	10/60	5

Title	Number of respondents	Number of responses/ respondent	Burden per response (in hrs.)	Total burden (hrs.)
Total				67,289

Dated: June 12, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–15330 Filed 6–17–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

RIN 0920–AA03

Control of Communicable Diseases

AGENCIES: Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice of embargo and prohibition on transportation or offering for transportation in interstate commerce, or sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of certain rodents and Prairie dogs.

SUMMARY: Shipments of rodents (order *Rodentia*) from Africa capable of transmitting monkeypox virus in humans are being imported into the United States and further distributed. In the United States, Prairie dogs (*Cynomys sp.*) and certain rodents from Africa may further transmit the monkeypox virus in humans.

Because of the public health threat posed by the importation of rodents from Africa, CDC is implementing an immediate embargo on the importation of all rodents (order *Rodentia*) from Africa until further notice. In addition, as a public health measure, CDC and FDA are prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale or offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of Prairie dogs and the following rodents from Africa: Tree squirrels (*Heliosciurus sp.*); Rope squirrels (*Funisciurus sp.*); Dormices (*Graphiurus sp.*); Gambian Giant Pouched Rats (*Cricetomys sp.*); Brush-tailed porcupines (*Atherurus sp.*), Striped mice (*Hybomys sp.*).

This prohibition does not apply to individuals who transport listed animals to veterinarians or animal control officials or other entities pursuant to guidance or instructions issued by Federal, State, or local government authorities.

This action is being taken because at least six different species of potentially infected rodents have been implicated in the current outbreak of monkeypox virus in humans. Monkeypox virus was also subsequently transmitted from infected rodents to native Prairie dogs. Based on epidemiologic and scientific knowledge gathered to date, specific interstate restrictions on the species within these genera are required to contain further movement of implicated animals. A ban on the intrastate sale or offering for sale or offering for any other type of commercial or public distribution of the species within these genera is also necessary because of the potential impact on interstate disease spread. Furthermore, a ban on the importation of shipments of all rodents from Africa is necessary to mitigate the harm of further introductions of monkeypox virus into the United States.

DATES: This embargo and prohibition is effective on June 11, 2003, and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT: Thomas A. Demarcus, National Center for Infectious Diseases (E03), Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, 770–488–7100, or Gloria Dunnavan, Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place (HFV–230), Rockville, MD 20855, 301–827–1168.

SUPPLEMENTARY INFORMATION:

I. Background

As of June 10, a total of 50 persons with suspected monkeypox had been reported from Wisconsin, Illinois, Indiana, and New Jersey. Monkeypox had been confirmed by laboratory tests in four persons. Seven of the people with suspected monkeypox had been hospitalized for their illness; there have been no deaths related to the outbreak. The number of cases and States involved in the outbreak will likely change as the investigation continues.

Onset of illness among patients began in early May. All patients reported direct or close contact with Prairie dogs, most of which were sick. In May, the Prairie dogs were sold by a Milwaukee animal distributor to two pet shops in the Milwaukee area and during a pet ''swap meet'' (pets for sale or exchange) in northern Wisconsin. The Milwaukee animal distributor had obtained Prairie dogs and a Gambian giant rat that was ill at the time from a northern Illinois animal distributor. On the basis of preliminary findings from the trace-back investigation of the Prairie dogs and the Gambian giant rat, it appears that the source of the infection was a shipment of rodents from Africa, which included six distinct species of rodents. It appears that the primary route of transmission may be from infected rodents from Africa to native Prairie dogs and then to humans as a result of close contact.

II. Public Health Risks

Monkeypox is a rare zoonotic viral disease that occurs primarily in the rain forest countries of central and west Africa. Studies have shown that rodents from Africa are capable of transmitting monkeypox virus in humans. In humans, the illness produces a vesicular and pustular rash similar to that of smallpox. Limited person-to-person spread of infection has been reported in disease-endemic areas in Africa; the incubation period is about 12 days. Case-fatality ratios in Africa have ranged from 1 percent to 10 percent. It is likely the virus entered the United States via imported rodent species from Africa. Further transmission of the virus likely occurred in the storage and handling of these imported rodents during sale and distribution within the United States. This resulted in secondary transmission to domestic Prairie dogs housed in the same animal-holding facility or pet shop.

III. Immediate Action

Introduction of exotic species, such as rodents from Africa, poses a serious public health threat because of the potential of human monkeypox virus infection. Transportation in interstate commerce or sale or any other type of commercial or public distribution, including release into the environment, of species of rodents linked to the initial

infected shipment and Prairie dogs poses a serious public health threat because of the potential for further spread of the monkeypox virus to other species and humans.

The scope of this communicable disease problem is inherently and necessarily an interstate problem that cannot be controlled by individual state health authorities. Thus, the appropriate measures taken by the health authorities of any state or possession are insufficient to prevent the interstate spread of human monkeypox virus infection. Accordingly, CDC and FDA, pursuant to 42 CFR 70.2 and 21 CFR 1240.30, are prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of Prairie dogs and the following rodents from Africa: Tree squirrels (*Heliosciurus sp.*); Rope squirrels (*Funisciurus sp.*); Dormices (*Graphiurus sp.*); Gambian Giant Pouched Rats (*Cricetomys sp.*); Brush-tailed porcupines (*Atherurus sp.*), Striped mice (*Hybomys sp.*).

This prohibition does not apply to individuals who transport listed animals to veterinarians or animal control officials or other entities pursuant to guidance or instructions issued by Federal, State, or local government authorities. In addition, pursuant to 42 CFR 71.32(b), CDC is implementing an immediate embargo on the importation of all rodents from Africa (order *Rodentia*).

Dated: June 12, 2003.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention.

Dated: June 12, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

[FR Doc. 03–15423 Filed 6–13–03; 5:07 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0234]

Canned Asparagus Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Chiquita Processed Foods, LLC, and Crown Cork & Seal Co., to market test a product designated as ''VERI-GREEN Cut Asparagus Spears'' that deviates from the U.S. standard of identity for canned asparagus. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the food.

DATES: This permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but no later than September 16, 2003.

FOR FURTHER INFORMATION CONTACT: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Chiquita Processed Foods, LLC, P.O. Box 458, Walla Walla, WA 99362, and to Crown Cork & Seal Co., 11535 South Central Ave., Alsip, IL 60803.

The permit covers limited interstate marketing tests of a product designated as ''VERI-GREEN Cut Asparagus Spears'' that deviates from the U.S. standard of identity for canned asparagus (21 CFR 155.200) in that the test product will contain added zinc chloride and stannous chloride at a maximum level of 75 parts per million (ppm) of zinc and 35 ppm of stannous chloride in the finished food. The test product meets all requirements of the standard with the exception of the variation. The purpose of the variance is to test the use of added zinc chloride and stannous chloride to retain the green color of the food and fresh taste.

The permit provides for the temporary marketing of 387,192 pounds (lb) of the test product (175,200 kilograms (kg)) (10,000 cases, each containing 6 lb, 7 ounce (2.92 kg) cans). The product will be manufactured at Chiquita Processed Foods, LLC, 516 West Rose, Walla Walla, WA 99362. The product will be distributed in the United States.

For the purpose of the permit, the name of the product is ''VERI-GREEN Cut Asparagus Spears.'' Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR parts 101 and 130. The permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but not later than September 16, 2003.

Dated: June 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15403 Filed 6–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Physicians' Experience of Ethical Dilemmas and Resource Allocation

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National institute of Dental and Craniofacial Research (NIDCR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Physicians' Experience of Ethical Dilemmas and Resource Allocation. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* Health care costs are rising ceaselessly and there are currently no generally accepted way of controlling them. This study will access the experience of physicians regarding resource allocation in clinical practice, and how allocation decisions made at other levels shapes this experience. The primary objectives of the study are to determine if physicians make decisions to withhold interventions on the basis of cost, how often they report doing so, what types of care are withheld, and what criteria are used in making such decisions. The findings will provide valuable information concerning: (1) The practice if resource allocation in clinical practice, (2) the possible effects of perceived constraints on this practice, and (3) international comparisons on these two aspects. *Frequency of Response:* Once. *Affected Public:* Individuals or households; businesses or other for-profit; not-for-profit institutions. *Type of Respondents:* Physicians. The annual reporting burden is as follows: *Estimated number of Respondents:* 250; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:*

.0.3674; and *Estimated Total Annual Burden Hours Requested:* 91.85. The annualized cost to respondents is estimated at: $5,218. There are no capital costs, operating costs and/or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Samia Hurst, Department of Clinical Bioethics, Building 10, room 1C118, National Institutes of Health, Bethesda, MD 20892, or call non-toll-free number (301) 435–8713 or E-mail your request, including your address to: *shurst@cc.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: May 29, 2003.

David K. Henderson,

Deputy Director, Warren G. Magnuson Clinical Center, National Institutes of Health.

Ezekiel J. Emanuel,

Director, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health.

[FR Doc. 03–15372 Filed 6–17–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel, ENCODE Determination and Technology.

Date: July 14–15, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rudy O. Pozzatti, PhD, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301–402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: June 10, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15374 Filed 6–17–03; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, National Research Service Award.

Date: July 15, 2003.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Brian R. Pike, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–18K, Bethesda, MD 20892, 301–594–3907, *pikbr@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.86, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 10, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15373 Filed 6–17–03; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(a)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, RFP–NICHD–2003–12 ''Determinants of Male and Female Fecundity and Fertility''.

Date: July 14, 2003.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: Ramada Inn Rockville, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Hameed Khan, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 435–6902, *khanh2mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 10, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15375 Filed 6–17–03; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, RFP–NICHD–2003–02—BPCA Coordinating Center Review.

Date: July 16, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20552, (Telephone Conference Call).

Contact Person: Hameed Khan, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 435–6902, *khanh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 10, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15376 Filed 6–17–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, ITV Conflicts Cooperative Agreements.

Date: June 19, 2003.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Martha Ann Carey, PhD, RN, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9608, Bethesda, MD 20892–9608, 301–443–1606, *mcarey@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: June 10, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15377 Filed 6–17–03; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, Initiative for Minority Student Development.

Date: July 14–15, 2003.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: N. Kent Peters, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 18ANK, Bethesda, MD 20892, (301) 594—2408, *petersn@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance, Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 11, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15378 Filed 6–17–03; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Minority Programs Review Committee, MBRS Review Subcommittee B.

Date: July 10–11, 2003.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Shiva P. Singh, PhD, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS–13J, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 11, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15379 Filed 6–17–03; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Bariatric Surgery Clinical Research Consortium.

Date: July 24–25, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 2899 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Paul A. Rushing, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 747, 6706 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892. (301) 594–8895. *rushingp@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS.)

Dated: June 11, 2003.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15380 Filed 6–17–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Training and Career Development Subcommittee.

Date: July 16, 2003.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Elaine Lazar-Wesley, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, 301–451–4530.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Transdisciplinary Prevention Research Centers.

Date: July 17–18, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Mark R. Green, PhD, Chief, CEASRB, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, Room 3158, MSC 9547, 6001 Executive Boulevard, Bethesda, MD 20892–9547, (301) 435–1431.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Translating Tobacco Addiction Research to Treatment.

Date: July 21, 2003.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Park Hyatt, 1201 24th Street, Washington, DC 20037.

Contact Person: Khursheed Asghar, PhD, Chief, Basic Sciences Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, (301) 443–2620.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: June 10, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–15381 Filed 6–17–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Center for Mental Health Services (CMHS) National Advisory Council in June 2003.

A portion of the meeting will be open and will include a roll call, general announcements, a budget update, and discussions about the President's New Freedom Commission on Mental Health, the Substance Abuse and Mental Health Services Administration's (SAMHSA) activities in translating science to services, SAMHSA/CMHS' Report to Congress on Co-occurring Disorder, and consumer/survivor issues. In addition, the meeting will include an orientation session for new council members.

Public comments are welcome. Please communicate with the individual listed as contact below for guidance. If anyone needs special accommodations for persons with disabilities please notify the contact listed below.

The meeting will also include the review, discussion, and evaluation of grant applications. Therefore, a portion of the meeting will be closed to the public as determined by the SAMHSA Administrator, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2. & 10(d).

A summary of the meeting and a roster of Council members may be obtained from Ms. Tracey Cooper, Committee Management Coordinator, CMHS, Room 17–99, Parklawn Building, Rockville, Maryland 20857, telephone (301) 443–1158.

Substantive program information may be obtained from the contact person listed below.

Committee Name: CMHS National Advisory Council.

Meeting Date: June 25–26, 2003.

Place: The Melrose Hotel, 2430 Pennsylvania Ave., NW, Washington, DC 20037. 202–955–6400.

Type:

Closed: June 25, 2003–8:30 a.m.–10:30 a.m.

Open: June 25, 2003–11 a.m.–5 p.m.

Open: June 26, 2003–8:30 a.m.–11:30 a.m.

FOR FURTHER INFORMATION CONTACT: Dale Kaufman, MPH, MA, Executive Secretary, 5600 Fishers Lane, Parklawn Building, Room 17–99, Rockville, Maryland 20857, Telephone: (301) 443–2660 and FAX (301) 443–1563.

Dated: June 11, 2003.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–15340 Filed 6–17–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG 2003–14779]

Information Collection Under Review by the Office of Management and Budget (OMB): OMB Control Numbers 1625–0070, 1625–0047, and 1625–0084

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the Coast Guard has forwarded the three Information Collection Requests (ICRs) abstracted below to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) for review and comment. (The Coast Guard has withdrawn a fourth ICR (1625–0077) under this docket number and will revise it and resubmit it to OMB for approval separately.) Our ICRs describe the information we seek to collect from the public. Review and comment by OIRA ensures that we impose only paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before July 18, 2003.

ADDRESSES: To make sure that your comments and related material do not enter the docket (USCG 2003–14779) more than once, please submit them by only one of the following means:

(1)(a) By mail to the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. (b) By mail to OIRA, 725 17th Street, NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard. Caution: Because of recent delays in the delivery of mail, your comments may reach the Facility more quickly if you choose one of the other means described below.

(2)(a) By delivery to room PL–401 at the address given in paragraph (1)(a) above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329. (b) By delivery to OIRA, at the address given in paragraph (1)(b) above, to the attention of the Desk Officer for the Coast Guard.

(3) By fax to (a) the Facility at 202–493–2251 and (b) OIRA at 202–395–5806, or e-mail to OIRA at *oira_docket@omb.eop.gov* attention: Desk Officer for the Coast Guard.

(4)(a) Electronically through the Web site for the Docket Management System at *http://dms.dot.gov.* (b) OIRA does not have a Web site on which you can post your comments.

The Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 (Plaza level), 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

Copies of the complete ICRs are available for inspection and copying in public dockets. They are available in docket USCG 2003–14779 of the Docket Management Facility between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays; for inspection and printing on the internet at *http://dms.dot.gov;* and for inspection from the Commandant (G–CIM–2), U.S. Coast Guard, room 6106, 2100 Second Street, SW., Washington, DC, between 10 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Barbara Davis, Office of Information Management, 202–267–2326, for questions on this document; Dorothy Beard, Chief, Documentary Services Division, U.S. Department of Transportation, 202–366–5149, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Regulatory History

This request constitutes the 30-day notice required by OIRA. The Coast Guard has already published (68 FR 16065 (April 2, 2003)) the 60-day notice required by OIRA. That notice elicited no comments.

Request for Comments

The Coast Guard invites comments on the proposed collections of information to determine whether the collections are necessary for the proper performance of the functions of the Department. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collections; (2) the accuracy of the Department's estimated burden of the collections; (3)

ways to enhance the quality, utility, and clarity of the information that is the subject of the collections; and (4) ways to minimize the burden of collection on respondents, including the use of automated collection techniques or other forms of information technology.

Comments, to DMS or OIRA, must contain the OMB Control Number of the ICR addressed. Comments to DMS must contain the docket number of this request, USCG 2003–14779. Comments to OIRA are best assured of having their full effect if OIRA receives them 30 or fewer days after the publication of this request.

Information Collection Request

1. *Title:* Vessel Identification System.
OMB Control Number: 1625–0070.
Type of Request: Extension of a currently approved collection.
Affected Public: Governments of States and territories.
Form: This collection of information does not require the public to fill out forms, but does require the information to be collected electronically.
Abstract: The Coast Guard must establish a nationwide vessel-identification system (VIS) and centralize certain vessel-documentation functions. VIS provides participating States and territories with access to data on vessels numbered by States and territories. Participation in it is voluntary.
Annual Estimated Burden Hours: The estimated burden is 6,045 hours a year.

2. *Title:* Vital System Automation.
OMB Control Number: 1625–0047.
Type of Request: Extension of a currently approved collection.
Affected Public: Designers, manufacturers, and owners of vessels and shipyards.
Form: This collection of information does not require the public to fill out forms, but does require the information to be in written format to the Coast Guard.
Abstract: This collection pertains to the vital-system automation on commercial vessels that is necessary to protect personnel and property on board U.S.-flag vessels.
Annual Estimated Burden Hours: The estimated burden is 57,375 hours a year.

3. *Title:* Audit Reports under the International Safety Management Code.
OMB Control Number: 1625–0084.
Type of Request: Extension of a currently approved collection.
Affected Public: Owners and operators of vessels, and organizations authorized to issue certificates of compliance with the ISM Code for the United States.
Form: This collection of information does not require the public to fill out forms, but does require the information to be in written format to the Coast Guard.
Abstract: This information helps to determine whether U.S. vessels, subject to SOLAS 74, engaged in international trade, are in compliance with that treaty. Organizations recognized by the Coast Guard conduct ongoing audits of vessels' and companies' safety-management-systems
Annual Estimated Burden Hours: The estimated burden is 8,440 hours a year.

Dated: June 11, 2003.

Clifford I. Pearson,

Director of Information and Technology.

[FR Doc. 03–15301 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4815–N–33]

Notice of Submission of Proposed Information Collection to OMB: Previous Participation Certification

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: July 18, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0118) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–6974; e-mail: *Lauren_Wittenberg@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Previous Participation Certification.

OMB Approval Number: 2502–0118.

Form Numbers: HUD–2530.

Description of the Need for the Information and its Proposed Use: The collection of this information aids in protecting HUD's Multifamily Housing Programs by ensuring participation by responsible individuals and organizations. HUD evaluates the feasibility of applicants with respect to their previous track records. Respondents such as owners, managers, consultants, general contractors, and nursing home operators and administrators will be subject to review.

Respondents: Individuals or households, Business or other for-profit, Not-for-profit institutions.

Frequency of Submission: On occasion.

	Number of respondents	×	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden:	4,300		1		0.5		2,150

Total Estimated Burden Hours: 2,150.

Status: Revision of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 11, 2003.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 03–15298 Filed 6–17–03; 8:45 am]

BILLING CODE 4210–72–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4817–N–08]

Notice of Proposed Information Collection for Public Comment for the Section Eight Management Assessment Program (SEMAP)

AGENCY: Office of the Assistant Secretary for Public and Indian Housing.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* August 18, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing & Urban Development, 451—7th Street, SW., Room 4249, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708–0614, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number). For hearing- and speech-impaired persons, this telephone number may be accessed via TTY (Text telephone) by calling the Federal Information Relay Services at 1–800–877–8339 (toll-free).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

This notice also lists the following information:

Title of Proposal: Section Eight Management Assessment Program (SEMAP).

OMB Control Number: 2577–0215.

Description of the Need for the Information and Proposed Use: Public Housing Agencies (PHAs) prepare and submit an electronic submission to HUD that certifies the PHA's SEMAP performance in 14 key program areas involving the administration and operation of the Housing Choice Voucher Program. The certification profile is reviewed by HUD. Following review, HUD assigns each PHA an annual SEMAP score and performance designation denoting whether the PHA is a High, Standard or Troubled PHA. PHAs that are designated High or Standard must correct all cited deficiencies within a stand timeframe and may be required to develop a corrective action plan to resolve the areas of program non-compliance. PHAs designated Troubled must submit a corrective action plan to HUD for review and approval that outlines the areas of program non-compliance and details the corrective strategies the PHA will implement to resolve the cited deficiencies. During the recovery process, HUD will monitor the success of the recovery progress and provide technical assistance to the PHA. Following completion of the corrective action plan, HUD will confirm the success of the recovery effort and remove the PHA from HUD's listing of troubled PHAs.

Agency form number: HUD–52648.

Members of the Affected Public: PHAs, State and Local Governments, businesses or other for-profits.

Estimation Including the Total Number of Hours Needed to Prepare the Information Collection for the Number of Respondents, Frequency of Response, and Hours of Response: The number of respondents (2500 PHAs) are required to submit an electronic SEMAP certification to HUD each year within 60 calendar days following the end of the PHA's fiscal year end date. The number of hours that are anticipated regarding the certification process should not exceed two hours per PHA per year, therefore, 5,000 hours. In addition, the number of hours that are anticipated regarding the requirement for the PHAs to examine samples of tenant file data, for quality control purposes, should not exceed 80 hours per PHA per year, therefore, 200,000 hours.

Of that number, it is anticipated that approximately 10 percent or 250 PHAs will be troubled and required to develop and implement a corrective active plan. The number of hours that are anticipated regarding the development and implementation of a corrective action plan for those PHAs that are designated troubled, varies based on the number and extent of program violations at each troubled PHA as well as the extent of correction that will be required to remedy the actual violation. The number of hours that will be required for this process are too difficult to estimate.

Status of the Proposed Information Collection: Extension is not anticipated to result in any substantive changes concerning the foregoing requirements.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: June 11, 2003.

Michael Liu,

Assistant Secretary for Public and Indian Housing.

BILLING CODE 4210–33–P

Section 8 Management Assessment Program (SEMAP) Certification

U.S. Department of Housing and Urban Development
Office of Public and Indian Housing

OMB Approval No. 2577-0215 (exp. 8/31/2003)

Public reporting burden for this collection of information is estimated to average 12 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. This agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This collection of information is required by 24 CFR sec 985.101 which requires a Public Housing Agency (PHA) administering a Section 8 tenant-based assistance program to submit an annual SEMAP Certification within 60 days after the end of its fiscal year. The information from the PHA concerns the performance of the PHA and provides assurance that there is no evidence of seriously deficient performance. HUD uses the information and other data to assess PHA management capabilities and deficiencies, and to assign an overall performance rating to the PHA. Responses are mandatory and the information collected does not lend itself to confidentiality.

Instructions Respond to this certification form using the PHA's actual data for the fiscal year just ended.

PHA Name	For PHA FY Ending (mm/dd/yyyy)	Submission Date (mm/dd/yyyy)

Check here if the PHA expends less than $300,000 a year in Federal awards ☐
Indicators 1 - 7 will not be rated if the PHA expends less than $300,000 a year in Federal awards and its Section 8 programs are not audited for compliance with regulations by an independent auditor. A PHA that expends less than $300,000 in Federal awards in a year must still complete the certification for these indicators.

Performance Indicators

1. Selection from the Waiting List. (24 CFR 982.54(d)(1) and 982.204(a))
(a) The PHA has written policies in its administrative plan for selecting applicants from the waiting list.

PHA Response **Yes** ☐ **No** ☐

(b) The PHA's quality control samples of applicants reaching the top of the waiting list and of admissions show that at least 98% of the families in the samples were selected from the waiting list for admission in accordance with the PHA's policies and met the selection criteria that determined their places on the waiting list and their order of selection.

PHA Response **Yes** ☐ **No** ☐

2. Reasonable Rent. (24 CFR 982.4, 982.54(d)(15), 982.158(f)(7) and 982.507)
(a) The PHA has and implements a reasonable written method to determine and document for each unit leased that the rent to owner is reasonable based on current rents for comparable unassisted units (i) at the time of initial leasing, (ii) before any increase in the rent to owner, and (iii) at the HAP contract anniversary if there is a 5 percent decrease in the published FMR in effect 60 days before the HAP contract anniversary. The PHA's method takes into consideration the location, size, type, quality, and age of the program unit and of similar unassisted units, and any amenities, housing services, maintenance or utilities provided by the owners.

PHA Response **Yes** ☐ **No** ☐

(b) The PHA's quality control sample of tenant files for which a determination of reasonable rent was required shows that the PHA followed its written method to determine reasonable rent and documented its determination that the rent to owner is reasonable as required for (check one):

PHA Response ☐ **At least 98% of units sampled** ☐ **80 to 97% of units sampled** ☐ **Less than 80% of units sampled**

3. Determination of Adjusted Income. (24 CFR part 5, subpart F and 24 CFR 982.516)
The PHA's quality control sample of tenant files shows that at the time of admission and reexamination, the PHA properly obtained third party verification of adjusted income or documented why third party verification was not available; used the verified information in determining adjusted income; properly attributed allowances for expenses; and, where the family is responsible for utilities under the lease, the PHA used the appropriate utility allowances for the unit leased in determining the gross rent for (check one):

PHA Response ☐ **At least 90% of files sampled** ☐ **80 to 89% of files sampled** ☐ **Less than 80% of files sampled**

4. Utility Allowance Schedule. (24 CFR 982.517)
The PHA maintains an up-to-date utility allowance schedule. The PHA reviewed utility rate data that it obtained within the last 12 months, and adjusted its utility allowance schedule if there has been a change of 10% or more in a utility rate since the last time the utility allowance schedule was revised.

PHA Response **Yes** ☐ **No** ☐

5. HQS Quality Control Inspections. (24 CFR 982.405(b))
A PHA supervisor (or other qualified person) reinspected a sample of units during the PHA fiscal year, which met the minimum sample size required by HUD (see 24 CFR 985.2), for quality control of HQS inspections. The PHA supervisor's reinspected sample was drawn from recently completed HQS inspections and represents a cross section of neighborhoods and the work of a cross section of inspectors.

PHA Response **Yes** ☐ **No** ☐

6. HQS Enforcement. (24 CFR 982.404)
The PHA's quality control sample of case files with failed HQS inspections shows that, for all cases sampled, any cited life-threatening HQS deficiencies were corrected within 24 hours from the inspection and, all other cited HQS deficiencies were corrected within no more than 30 calendar days from the inspection or any PHA-approved extension, or, if HQS deficiencies were not corrected within the required time frame, the PHA stopped housing assistance payments beginning no later than the first of the month following the correction period, or took prompt and vigorous action to enforce the family obligations for (check one):

PHA Response ☐ **At least 98% of cases sampled** ☐ **Less than 98% of cases sampled**

7. Expanding Housing Opportunities. (24 CFR 982.54(d)(5), 982.153(b)(3) and (b)(4), 982.301(a) and 983.301(b)(4) and (b)(12)).
Applies only to PHAs with jurisdiction in metropolitan FMR areas.
Check here if not applicable ☐

(a) The PHA has a written policy to encourage participation by owners of units outside areas of poverty or minority concentration which clearly delineates areas in its jurisdiction that the PHA considers areas of poverty or minority concentration, and which includes actions the PHA will take to encourage owner participation.
PHA Response **Yes** ☐ **No** ☐

(b) The PHA has documentation that shows that it took actions indicated in its written policy to encourage participation by owners outside areas of poverty and minority concentration.
PHA Response **Yes** ☐ **No** ☐

(c) The PHA has prepared maps that show various areas, both within and neighboring its jurisdiction, with housing opportunities outside areas of poverty and minority concentration; the PHA has assembled information about job opportunities, schools and services in these areas; and the PHA uses the maps and related information when briefing voucher holders.
PHA Response **Yes** ☐ **No** ☐

(d) The PHA's information packet for voucher holders contains either a list of owners who are willing to lease, or properties available for lease, under the voucher program, or a list of other organizations that will help families find units and the list includes properties or organizations that operate outside areas of poverty or minority concentration.
PHA Response **Yes** ☐ **No** ☐

(e) The PHA's information packet includes an explanation of how portability works and includes a list of neighboring PHAs with the name, address and telephone number of a portability contact person at each.
PHA Response **Yes** ☐ **No** ☐

(f) The PHA has analyzed whether voucher holders have experienced difficulties in finding housing outside areas of poverty or minority concentration and, where such difficulties were found, the PHA has considered whether it is appropriate to seek approval of exception payment standard amounts in any part of its jurisdiction and has sought HUD approval when necessary.
PHA Response **Yes** ☐ **No** ☐

8. Payment Standards. The PHA has adopted current payment standards for the voucher program by unit size for each FMR area in the PHA jurisdiction and, if applicable, for each PHA-designated part of an FMR area, which do not exceed 110 percent of the current applicable FMR and which are not less than 90 percent of the current FMR (unless a lower percent is approved by HUD). (24 CFR 982.503)

PHA Response **Yes** ☐ **No** ☐

Enter current FMRs and payment standards (PS)

0-BR FMR _____	1-BR FMR _____	2-BR FMR _____	3-BR FMR _____	4-BR FMR _____
PS _____	PS _____	PS _____	PS _____	PS _____

If the PHA has jurisdiction in more than one FMR area, and/or if the PHA has established separate payment standards for a PHA-designated part of an FMR area, attach similar FMR and payment standard comparisons for each FMR area and designated area.

9. Annual Reexaminations. The PHA completes a reexamination for each participating family at least every 12 months. (24 CFR 982.516)

PHA Response **Yes** ☐ **No** ☐

10. Correct Tenant Rent Calculations. The PHA correctly calculates tenant rent in the rental certificate program and the family rent to owner in the rental voucher program. (24 CFR 982, Subpart K)

PHA Response **Yes** ☐ **No** ☐

11. Precontract HQS Inspections. Each newly leased unit passed HQS inspection before the beginning date of the assisted lease and HAP contract. (24 CFR 982.305)

PHA Response **Yes** ☐ **No** ☐

12. Annual HQS Inspections. The PHA inspects each unit under contract at least annually. (24 CFR 982.405(a))

PHA Response **Yes** ☐ **No** ☐

13. Lease-Up. The PHA executes assistance contracts on behalf of eligible families for the number of units that has been under budget for at least one year.

PHA Response **Yes** ☐ **No** ☐

14a. Family Self-Sufficiency Enrollment. The PHA has enrolled families in FSS as required. (24 CFR 984.105)
Applies only to PHAs required to administer an FSS program.
Check here if not applicable ☐

PHA Response

a. Number of mandatory FSS slots (Count units funded under the FY 1992 FSS incentive awards and in FY 1993 and later through 10/20/1998. Exclude units funded in connection with Section 8 and Section 23 project-based contract terminations; public housing demolition, disposition and replacement; HUD multifamily property sales; prepaid or terminated mortgages under section 236 or section 221(d)(3); and Section 8 renewal funding. Subtract the number of families that successfully completed their contracts on or after 10/21/1998.)

or, Number of mandatory FSS slots under HUD-approved exception

b. Number of FSS families currently enrolled

c. Portability: If you are the **initial** PHA, enter the number of families currently enrolled in your FSS program, but who have moved under portability and whose Section 8 assistance is administered by another PHA

Percent of FSS slots filled (b + c divided by a)

14b. Percent of FSS Participants with Escrow Account Balances. The PHA has made progress in supporting family self-sufficiency as measured by the percent of currently enrolled FSS families with escrow account balances. (24 CFR 984.305)
Applies only to PHAs required to administer an FSS program.
Check here if not applicable ☐

PHA Response **Yes** ☐ **No** ☐

Portability: If you are the **initial** PHA, enter the number of families with FSS escrow accounts currently enrolled in your FSS program, but who have moved under portability and whose Section 8 assistance is administered by another PHA

Deconcentration Bonus Indicator (Optional and only for PHAs with jurisdiction in metropolitan FMR areas).

The PHA is submitting with this certification data which show that:

(1) Half or more of all Section 8 families with children assisted by the PHA in its principal operating area resided in low poverty census tracts at the end of the last PHA FY;

(2) The percent of Section 8 mover families with children who moved to low poverty census tracts in the PHA's principal operating area during the last PHA FY is at least two percentage points higher than the percent of all Section 8 families with children who resided in low poverty census tracts at the end of the last PHA FY;

or

(3) The percent of Section 8 mover families with children who moved to low poverty census tracts in the PHA's principal operating area over the last two PHA FYs is at least two percentage points higher than the percent of all Section 8 families with children who resided in low poverty census tracts at the end of the second to last PHA FY.

PHA Response **Yes** ☐ **No** ☐ **If yes, attach completed deconcentration bonus indicator addendum.**

I hereby certify that, to the best of my knowledge, the above responses under the Section 8 Management Assessment Program (SEMAP) are true and accurate for the PHA fiscal year indicated above. I also certify that, to my present knowledge, there is not evidence to indicate seriously deficient performance that casts doubt on the PHA's capacity to administer Section 8 rental assistance in accordance with Federal law and regulations.

Warning: HUD will prosecute false claims and statements. Conviction may result in criminal and/or civil penalties. (18 U.S.C. 1001, 1010, 1012; 31 U.S.C. 3729, 3802)

Executive Director, signature

Date (mm/dd/yyyy) _____

Chairperson, Board of Commissioners, signature

Date (mm/dd/yyyy) _____

The PHA may include with its SEMAP certification any information bearing on the accuracy or completeness of the information used by the PHA in providing its certification.

SEMAP Certification - Addendum for Reporting Data for Deconcentration Bonus Indicator

Date (mm/dd/yyyy) _____

PHA Name _____

Principal Operating Area of PHA _____
(The geographic entity for which the Census tabulates data)

Special Instructions for State or regional PHAs. Complete a copy of this addendum for each metropolitan area or portion of a metropolitan area (i.e., principal operating areas) where the PHA has assisted 20 or more Section 8 families with children in the last completed PHA FY. HUD will rate the areas separately and the separate ratings will then be weighted by the number of assisted families with children in each area and averaged to determine bonus points.

1990 Census Poverty Rate of Principal Operating Area _____

Criteria to Obtain Deconcentration Indicator Bonus Points

To qualify for bonus points, a PHA must complete the requested information and answer yes for only one of the 3 criteria below. However, State and regional PHAs must always complete line 1) b for each metropolitan principal operating area.

1) _____ a. Number of Section 8 families with children assisted by the PHA in its principal operating area at the end of the last PHA FY who live in low poverty census tracts. A low poverty census tract is a tract with a poverty rate at or below the overall poverty rate for the principal operating area of the PHA, or at or below 10% whichever is greater.

_____ b. Total Section 8 families with children assisted by the PHA in its principal operating area at the end of the last PHA FY.

_____ c. Percent of all Section 8 families with children residing in low poverty census tracts in the PHA's principal operating area at the end of the last PHA FY (line a divided by line b).

Is line c 50% or more? **Yes** ☐ **No** ☐

2) _____ a. Percent of all Section 8 families with children residing in low poverty census tracts in the PHA's principal operating area at the end of the last completed PHA FY.

_____ b. Number of Section 8 families with children who moved to low poverty census tracts during the last completed PHA FY.

_____ c. Number of Section 8 families with children who moved during the last completed PHA FY.

_____ d. Percent of all Section 8 mover families with children who moved to low poverty census tracts during the last PHA fiscal year (line b divided by line c).

Is line d at least two percentage points higher than line a? **Yes** ☐ **No** ☐

3) _____ a. Percent of all Section 8 families with children residing in low poverty census tracts in the PHA's principal operating area at the end of the second to last completed PHA FY.

_____ b. Number of Section 8 families with children who moved to low poverty census tracts during the last two completed PHA FYs.

_____ c. Number of Section 8 families with children who moved during the last two completed PHA FYs.

_____ d. Percent of all Section 8 mover families with children who moved to low poverty census tracts over the last two completed PHA FYs (line b divided by line c).

Is line d at least two percentage points higher than line a? **Yes** ☐ **No** ☐

If one of the 3 criteria above is met, the PHA may be eligible for 5 bonus points.

See instructions above concerning bonus points for State and regional PHAs.

[FR Doc. 03–15299 Filed 6–17–03; 8:45 am]
BILLING CODE 4210–33–C

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Central Arizona Project, Arizona; Water Allocations

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of final decision to modify the Secretary of the Interior's record of decision.

SUMMARY: The Department hereby issues notice of its final decision to modify the 1983 Central Arizona Project (CAP) Water Allocation Decision to delete the mandatory effluent pooling provision. As supported by public comment, we now view that provision as an impediment to effluent exchanges and effective water management in central Arizona. The decision that we are publishing in this notice eliminates the requirement for a mandatory effluent pooling provision in CAP water service subcontracts. We will grant the requests by the cities of Chandler and Mesa to amend their water service subcontracts to remove the mandatory effluent pooling provision and we will delete the mandatory effluent pooling provision in other CAP municipal and industrial water service subcontracts upon request.

DATES: This final decision is effective June 18, 2003 and amends the previous allocation decision published by Secretary Watt on March 24, 1983 (48 FR 12446).

ADDRESSES: To receive a copy of the Final Environmental Assessment and responses thereto, contact John McGlothen, NEPA Specialist, Phoenix Area Office, Bureau of Reclamation, P.O. Box 81169, Phoenix, Arizona 85069, telephone: 602–216–3866.

FOR FURTHER INFORMATION CONTACT: Paul Nelson, Contracts and Repayment Specialist, Phoenix Area Office, Bureau of Reclamation, telephone: (602) 216–3878.

SUPPLEMENTARY INFORMATION:

I. Previous Notices Related to CAP Water

Previous notices related to CAP water were published in the **Federal Register** as 37 FR 28082, Dec. 20, 1972; 40 FR 17297, Apr. 18, 1975; 41 FR 45883, Oct. 18, 1976; 45 FR 52938, Aug. 8, 1980; 45 FR 81265, Dec. 10, 1980; 48 FR 12446, Mar. 24, 1983; 56 FR 29704, Jun. 28, 1991; 57 FR 4470, Feb. 5, 1992; and 57 FR 48388, Oct. 23, 1992. The above listed notices and decisions were made pursuant to the authority vested in the Secretary by the Reclamation Act of 1902 as amended and supplemented (32 Stat. 388, 43 U.S.C. 391), the Boulder Canyon Project Act of December 21, 1928 (45 Stat. 1057), the Colorado River Basin Project Act of September 30, 1968 (82 Stat. 885, 43 U.S.C. 1501) and in recognition of the Secretary's trust responsibility to Indian tribes.

II. Background

Following the 1983 CAP Water Allocation Decision, the Bureau of Reclamation, the Central Arizona Water Conservation District (CAWCD), and each of the non-Indian CAP water allottees desiring CAP water entered into three-party water service subcontracts providing for the delivery of CAP water. In order to ensure implementation of the mandatory effluent pooling provision, municipal and industrial (M&I) water service subcontractors who choose to circumvent the effluent pooling provision and directly exchange their effluent with Indian tribes are subject to a reduction in their entitlement to CAP water under their subcontracts by the amount of CAP water received from the effluent exchange.

The Department indicated in the 1983 CAP Water Allocation Decision that CAP M&I water allocations could be made more firm by execution of feasible non-potable effluent exchanges with Indian tribes. The 1983 CAP Water Allocation Decision also implemented a pooling provision whereby all M&I water service subcontractors share in the benefits of effluent exchanges. In a time of shortage of CAP water under the effluent pooling provision, the additional CAP water made available as a result of any effluent exchanges with Indian tribes would be shared by all M&I subcontractors, thereby reducing the amount of shortage for each subcontractor. The pooling provision was included in the CAP M&I water service subcontracts.

The 1983 CAP Water Allocation Decision also provided that the Department could require Indian tribes located in close proximity to metropolitan areas to take delivery of effluent in lieu of CAP water. This requirement was eliminated by a Secretarial decision published in the **Federal Register** on October 23, 1992, so that any effluent exchanges involving Indian tribes would occur on a voluntary basis.

The major cities in Maricopa County, which are the sources of most of the exchangeable effluent, prefer to exchange effluent on their own, incur all related treatment and transportation expenses, and receive any benefits from the exchange.

The notice of proposed modification of the Secretary of the Interior's Record of Decision to remove the mandatory effluent pooling provision and request for comments was published in the **Federal Register** (67 FR 38514, June 4, 2002). Implementation of the proposed modification was the only option presented.

III. Rationale for Final Decision

The Department favors elimination of the mandatory effluent pooling provision from the 1983 CAP Water Allocation Decision for the following reasons:

(1) In response to public comments submitted by the City of Phoenix in 1992 concerning the mandatory effluent pooling provision, the Department committed to re-evaluate this provision at a later date after consultation with the Arizona Department of Water Resources (ADWR) (*see* 57 FR 48389, Oct. 23, 1992). In part, the City of Phoenix stated ''* * * The City of Phoenix agrees with the reasons for deleting the mandatory substitute water provision from the Indian CAP Contracts and believes that it is equally important to remove the provision from CAP M&I subcontracts that would penalize a subcontractor for entering into a direct effluent exchange with an Indian Community for CAP water.'' The Department acknowledged the City of Phoenix's concerns that the provisions of the effluent exchange article in the CAP M&I water service subcontracts may no longer be critical to the management of water supplies in central Arizona.

(2) The mandatory effluent pooling provision removes any incentive for a municipality to exchange effluent with an Indian tribe. The Department believes that effluent producing entities, Indian tribes, the State of Arizona, and other local organizations should be free to pursue local water management decisions that are in the best interest of the local economies, and that they should not be constrained in such water management decisions by the mandatory effluent pooling provision.

(3) ADWR now supports removing the mandatory effluent pooling provision from the 1983 CAP Water Allocation Decision and the CAP M&I water service subcontracts.

(4) CAWCD, as a party to the CAP M&I water service subcontracts, does not object to deletion of the mandatory

effluent pooling provision from the subcontracts.

(5) The Department is aware of two pending effluent exchange agreements that require Departmental approval. The cities of Chandler and Mesa each have a proposed effluent exchange agreement with the Gila River Indian Community (GRIC). The benefits resulting from the proposed exchanges to the cities and GRIC will not occur unless and until the mandatory effluent provision is removed from the cities' CAP water service subcontracts.

(6) The Department received four responses to the proposed action during the **Federal Register** notice public comment period. Each respondent provided rationale and recommendations that support the option of modifying the Secretary's Record of Decision to remove the mandatory effluent pooling provision. The Department received no objections to this proposed action.

IV. Comments on the Proposed Modification and Responses

(1) Salt River Project, July 5, 2002

Comment 1–1: ''SRP agrees with the Department's determination that the mandatory effluent pooling provision is an impediment to effluent exchanges and effective water management in central Arizona. For example, without the modification the cities of Chandler and Mesa will not be able to undertake effluent-CAP water exchanges pursuant to the Reclaimed Water Exchange Agreement portion of the Gila River Indian Community Settlement.''

Response 1–1: SRP's expression of support for the Department's proposal is noted.

(2) City of Phoenix, July 5, 2002

Comment 1–2: ''The City of Phoenix has long supported the removal of that sentence. In 1982 the City sent two letters to then Secretary of the Interior James Watt asking that the mandatory effluent exchange pooling concept be eliminated from the Secretary's proposed allocation decision. We maintained then that the inclusion of such a provision would serve to inhibit future exchanges which would otherwise be mutually beneficial to the exchanging parties * * *. We are pleased that you are now proposing to eliminate the mandatory effluent exchange pooling requirement from both the Secretary's record of decision and also from the CAP M&I subcontracts.''

Response 1–2: The City of Phoenix position has remained consistent throughout the period following the Secretary's decision. It has been instrumental in spurring the Department's investigation of the issues arising from the mandatory effluent exchange provision.

(3) City of Chandler, July 3, 2002

Comment 1–3: ''The City of Chandler, Arizona submits this letter in support of the proposed modification of the Secretary of Interior's March, 1983 Record of Decision, which deletes the mandatory effluent pooling provision from Central Arizona Project (''CAP'') water service contracts. This provision, and the related M&I subcontracts' effluent exchanges restriction, prevent municipalities from exchanging effluent for CAP water held by Indian communities. The proposed modification encourages better water management, and will allow for a necessary effluent exchange as part of the Gila River Indian Community water rights settlement.''

Response 1–3: The Department acknowledges the City of Chandler's statements of support for the Secretary's proposed modification of the 1983 Record of Decision. It also notes that Chandler's position supports and is consistent with its formal request for an amendment of its CAP water service contract to remove the mandatory effluent pooling provision, which is pending.

(4) City of Mesa, June 17, 2002

Comment 1–4: ''The City of Mesa fully supports the Department's proposal to modify the 1983 Central Arizona Project (CAP) Water Allocation Decision to delete the mandatory effluent pooling provision. We agree with Department's determination that the mandatory effluent pooling provision is an impediment to effluent exchanges and effective water management in central Arizona. * * * The City of Mesa intends to enter into an effluent exchange agreement with the Gila River Indian Community (GRIC) through the proposed GRIC water rights settlement. The benefits resulting from the proposed exchanges to Mesa and GRIC will not occur unless and until the mandatory effluent provision is removed from Mesa's CAP water service subcontracts * * * We urge the Secretary to amend Mesa's CAP water service subcontracts to delete the mandatory effluent pooling provision.''

Response 1–4: The Department acknowledges and accepts the City of Mesa's statements of support for the Secretary's proposed modification of the 1983 Record of Decision. Its comments are consistent with its formal request for an amendment of its CAP water service contract to remove the mandatory effluent pooling provision, which is pending.

V. Compliance With NEPA

The Department has completed a Final Environmental Assessment (EA) on the impact of modifying the 1983 CAP Water Allocation Decision to delete the mandatory effluent pooling provision. The Final EA resulted in a ''Finding of No Significant Impact'' (FONSI) to the human environment and was signed August 5, 2002 by Reclamation's Phoenix Area Office Manager, Phoenix, Arizona.

Final Decision

The following sentence is hereby deleted from the 1983 CAP Water Allocation Decision (March 24, 1983, 48 FR 12447): ''This allocation is subject to adoption of a pooling concept whereby all M&I allottees share in the benefits of effluent exchanges.''

Dated: May 14, 2003.

Gale A. Norton,

Secretary of the Interior.

[FR Doc. 03–15280 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–020–1010–AC]

Notice of Public Meeting, Eastern Montana Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior, Montana, Billings and Miles City field offices.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Eastern Montana Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting will be held August 14, 2003, in Billings, MT beginning at 8 a.m. When determined, the meeting place will be announced in a News Release. The public comment period will begin at approximately 11 a.m. and the meeting will adjourn at approximately 3:30 p.m.

FOR FURTHER INFORMATION CONTACT: Mark Jacobsen, Public Affairs Specialist, Miles City Field Office, 111 Garryowen Road, Miles City, Montana, 59301, telephone (406) 233–2831.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in Montana. At this meeting, topics we plan to discuss include: Sustaining Working Landscapes Initiative, OHV Update, National RAC meeting report, Weatherman Draw Subcommittee update, Oil and Gas EIS Update and other topics the council may raise.

All meetings are open to the public. The public may present written comments to the Council. Each formal Council meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided above.

Dated: June 6, 2003.

David McIlnay,

Field Manager.

[FR Doc. 03–15331 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR113–5882–PF, HAG03–0197]

Notice of Resource Advisory Committee Field Trips and Meetings

AGENCY: Medford District, Bureau of Land Management, Interior.

ACTION: Notice of Resource Advisory Committee field trips and meetings.

SUMMARY: The Medford District BLM will be hosting a series of field trips and meetings for the Medford Resource Advisory Committee. The purpose of the field trips and meetings will be to discuss and make recommendations for projects submitted for funding under the Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 106–393). The committee will also be reviewing the progress of projects funded in previous years.

The field trips will leave from the BLM office at 3040 Biddle Road, Medford, Oregon at 8:30 a.m. and will return to the BLM office at approximately 4 p.m. on July 14, 2003 and July 28, 2003. The itinerary of the field trips will vary depending on the types of projects to be visited, but all locations will be within the Medford BLM District.

The primary office meeting of the Resource Advisory Committee will be held on August 11, 2003 at the BLM office at 3040 Biddle Road, Medford, Oregon beginning at 10 a.m. The objective of this meeting is to review proposals for projects to be funded in Fiscal Year 2004. If there is not enough time to adequately consider all the proposed projects, a follow-up meeting will be held at the BLM office on August 14, 2003, also beginning at 10 a.m.

DATES: The field trips will take place on July 14 and July 28. They will leave the BLM office at 8:30 and return at approximately 4 p.m. The meeting will take place at the BLM building on August 11, 2003 beginning at 10 a.m.; a follow-up meeting will take place at the BLM office on August 14, 2003, if necessary to review all the proposals and make recommendations. These times and dates will be published on the Medford District Web site *http://www.or.blm.gov/Medford* and in the ''Medford Mail Tribune'' and ''Grant's Pass Courier'' newspapers.

FOR FURTHER INFORMATION AND ADDRESSES: Comments and questions should be sent to Roger Schnoes, Bureau of Land Management, 3040 Biddle Road, Medford, Oregon, 97504, (541) 618–2417, or fax to (541) 618–2400, or e-mail to *110mb@or.blm.gov*.

SUPPLEMENTARY INFORMATION: The Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 106–393) established the Resource Advisory Committees associated with the BLM Districts and National Forests in western Oregon to assist the BLM and Forest Service fund projects to restore stability and predictability to the annual payments to the States and counties and to benefit public schools, roads and other purposes. The Medford BLM Resource Advisory Committee has met in 2001 and 2002 and made recommendations for funding projects. Projects for Fiscal Year 2004 have been submitted by BLM staff and by the public and these have been made available to the Resource Advisory Committee. They will also be published on the BLM Web site at *http://www.or.blm.gov/Medford.* The Resource Advisory Committee will have two opportunities to visit project sites during the field trips in July which are the subject of this notice. The field trips will include some of the projects being proposed for Fiscal Year 2004 as well as some of the projects already approved and funded in Fiscal Years 2002 and 2003.

At the formal meeting, the Resource Advisory Committee will discuss the projects which were submitted for funding in Fiscal Year 2004. The public will be able to comment on those projects at that time. The Resource Advisory Committee will make recommendations on project funding to the Designated Federal Official, who is the Medford BLM District Manager. The Designated Federal Official will then make a final determination on which projects will be funded in Fiscal Year 2004.

The purposes of the field trips and the meetings are to allow the Resource Advisory Committee to discuss and fully understand the projects. They will have the opportunity to ask questions of BLM managers and staff as well as the public parties who made the submissions. Considering the proposals in a meeting format will allow the Committee to exchange information and alternatives and reach a set of recommendations for funding.

Authority: Federal Land Policy and Management Act (FLPMA) and Secure Rural Schools and Community Self-Determination Act of 2000.

Dated: June 10, 2003.

Mary L. Smelcer,

Acting District Manager, Medford District, Bureau of Land Management.

[FR Doc. 03–15332 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–957–02–1420–BJ]

Plats of Survey Filing; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey, Wyoming.

SUMMARY: The Bureau of Land Management (BLM) has filed the plats of survey of the lands described below in the BLM Wyoming State Office, Cheyenne, Wyoming, on June 9, 2003.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 5353 Yellowstone Road, PO Box 1828, Cheyenne, Wyoming 82003.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Land Management, and are necessary for the management of resources. The lands surveyed are:

The plat representing the dependent resurvey of a portion of the subdivisional lines, and the subdivision of section 28, and the metes and bounds

survey of Parcel A, section 28 Township 26 north, Range 105 west, Sixth Principal Meridian, Wyoming, was accepted June 9, 2003.

The plat representing the dependent resurvey of a portion of the subdivisional lines and the subdivision of section lines and the subdivision of section 27, Township 34 north, Range 109 west, Sixth Principal Meridian, Wyoming, was accepted June 9, 2003.

Copies of the preceding described plats are available to the public.

Dated: June 12, 2003.

John P. Lee,

Chief Cadastral Surveyor, Division of Support Services.

[FR Doc. 03–15328 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–957–02–1910–BJ]

Plats of Survey; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey, Wyoming.

SUMMARY: The Bureau of Land Management (BLM) is scheduled to file the plat of survey of the lands described below, thirty (30) calender days from the date of this publication in the BLM Wyoming State Office, Cheyenne, Wyoming.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 5353 Yellowstone Road, PO Box 1828, Cheyenne, Wyoming 82003.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Indian Affairs and are necessary for the managements of resources. The lands surveyed are:

The plat representing the dependent resurvey of portion of the First Guide Merdian west, through Township 5 N, between Ranges 4 and 5 west, and a portion of the subdivisional lines, and the subdivision of section 24, Township 5 North, Range 5 west, Wind River Meridian, Wyoming, was accepted June 9, 2003.

Copies of the preceding described plat is available to the public.

Dated: June 12, 2003.

John P. Lee,

Chief Cadastral Surveyor, Division of Support Services.

[FR Doc. 03–15329 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

Jamestown Project Development Concept Plan, Final Environmental Impact Statement, Colonial National Historical Park, Jamestown Unit, Jamestown, Virginia, and Jamestown National Historic Site, Jamestown, Virginia

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of availability of a record of decision on the final environmental impact statement for the Jamestown Project Development Concept Plan, Colonial National Historical Park, Jamestown Unit, and Jamestown National Historic Site.

SUMMARY: Pursuant to § 102(2)(C) of the National Environmental Policy Act of 1969 Pub. L. 91–190, 83 Stat. 852, 853, codified as amended at 42 U.S.C. 4332(2)(C), the National Park Service announces the availability of the Record of Decision for the Jamestown Project Development Concept Plan, Environmental Impact Statement, Colonial National Historical Park, Jamestown Unit, Jamestown, Virginia, and Jamestown National Historic Site, Jamestown, Virginia. ON May 13, 2003, the Director, Northeast Region, approved the Record of Decision for the project. As soon as practicable, the National Park Service will begin to implement the Preferred Alternative contained in the Final Environmental Impact Statement issued on April 2, 2003. The Preferred Alternative includes strategies for an updated interpretive experience; the improvement or repalcement of facilities (including the current Visitor Center, collections storage, and parking); the addition of comfort/ hospitality services and new interpretive venues; and enhanced and multimodal transportation options (including water taxis/tours/ hike/bike trails, and shuttle services). This course of action and 4 alternatives were analyzed in the Draft and Final Environmental Impact Statements. The full range of foreseeable environmental consequences was assessed, and appropriate mitigating measures were identified.

The Record of Decision includes a statement of the decision made, a description of the project background, a detailed description of the alternative to be implemented, the basis for the decision, synopses of other alternatives considered, an overview of public and agency involvement in the decision-making process, findings on impairment of park resources and values, a description of the environmentally preferred alternative, and a listing of measures to minimize and/or mitigate environmental harm. It also includes the Programmatic Agreement between and the NPS, the Advisory Council on Historic Preservation, and the Virginia State Historic Preservation Office for Implementation of the Jamestown Project Development Concept Plan; the Statement of Findings on Floodplains and Wetlands; and the U.S. Fish and Wildlife Service Biological Opinion.

FOR FURTHER INFORMATION CONTACT: Mike Litterst, Information Officer, Colonial National Historical Park, (757) 898–2409, *Mike_Litterst@nps.gov*.

SUPPLEMENTARY INFORMATION: Copies of the Record of Decision may be obtained from the contact listed above or online at *http://www.nps.gov/colo.*

Dated: May 13, 2003.

Marie Rust,

Regional Director, Northeast Region, National Park Service.

[FR Doc. 03–15306 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–78–M

DEPARTMENT OF THE INTERIOR

National Park Service

Chesapeake and Ohio Canal National Historic Park Advisory Commission; Notice of Public Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Chesapeake and Ohio Canal National Historic Park Advisory Commission will be held at 10 a.m. on Friday, June 20, 2003, at park headquarters, 1850 Dual Highway, Suite 100, Hagerstown, Maryland.

The Commission was established by Public Law 91–664 to meet and consult with the Secretary of the Interior on general policies and specific matters related to the administration and development of the Chesapeake and Ohio Canal National Historical Park.

The members of the Commission are as follows: Mrs. Sheila Rabb Weidenfeld, Chairman, Mr. Charles J. Weir, Mr. Barry A. Passett, Mr. Terry W. Hepburn, Ms. Elise B. Heinz, Ms. JoAnn M. Spevacek, Mrs. Mary E. Woodward, Mrs. Donna Printz, Mrs. Ferial S. Bishop, Ms. Nancy C. Long, Mrs. Jo Reynolds, Dr. James H. Gilford, Mrs. Sue Ann Sullivan, Brother James Kirkpatrick.

Topics that will be presented during the meeting include:

1. Status of the draft Lands Protection Plan.

2. Major construction/development projects.
3. Historic Leasing program.
4. Mecklenburg warehouse planning project.
5. Western Maryland Railroad right-of-way planning study.
6. Business Plan.

The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning the matters to be discussed. Persons wishing further information concerning this meeting, or who wish to submit written statements, may contact Douglas D. Faris, Superintendent, C&O Canal National Historic Park, 1850 Dual Highway, Suite 100, Hagerstown, Maryland, 21740.

Minutes of the meeting will be available for public inspection six (6) weeks after the meeting at park headquarters, Hagerstown, Maryland.

Dated: May 5, 2003.

Douglas Faris,

Superintendent, C&O Canal National Historical Park.

[FR Doc. 03–15307 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–6V–M

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before May 31, 2003. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by July 3, 2003.

Carol D. Shull,

Keeper of the National Register of Historic Places.

California

Sacramento County

Ehrhardt, William, House, Dartmoor Way and Percheron Dr., Elk Grove, 03000614

Yolo County

Union Church of Dunnigan, 3615 Cty Rd. 89A, Dunnigan, 03000613

Colorado

Boulder County

Jamestown Town Hall, 118 Main St., Jamestown, 03000615

Louisiana

East Baton Rouge Parish

Broussard House, 4512 Highland Rd., Baton Rouge, 03000616

Maine

Cumberland County

Freeman Farm Historic District, 342 W. Gray Rd., Gray, 03000621

Knox County

Beechnut Hut Historic District, 316 Beech Hill Rd., Rockport, 03000617

Lincoln County

Arch Bridge, Over the Pemaquid R on Benner Rd., Bristol, 03000618

Oxford County

Bell Hill Meetinghouse, 191 Bell Hill Rd., Otisfield, 03000620
Bell Hill School, 185 Bell Hill Rd., Otisfield, 03000619

Michigan

Alpena County

Fishing Tug Katherine V, 491 Johnson St., Alpena, 03000622

Benzie County

Watervaile Historic District, 975–1422 Watervale Rd., Blaine Township, 03000624

Houghton County

Vivian, Jr., J., and Company Building, 342 Hecla St., Laurium, 03000625

Leelanau County

Fountain Point, 990 South Lake Leelanau Dr., Suttoms Bay Township, 03000623

Texas

Bexar County

Bungalow Colony Historic District, Roughly bounded by Duncan Dr., Crockett Dr., Walker Rd. and Robins Dr., San Antonio, 03000627
Kelly Field Historic District, Roughly encompassing the 1600 abd 1700 Areas of Kelly AFB, San Antonio, 03000626

Utah

Salt Lake County

Crown Cleaning and Dyeing Company Building, (Sugar House Business District MPS), 1989 South 1100 East, Salt Lake City, 03000633
Granite LDS Stake Tabernacle, (Sugar House Business District MPS), 2005 South 900 East, Salt Lake City, 03000630
Granite Lumber Company Building, (Sugar House Business District MPS), 1090 East 2100 South, Salt Lake City, 03000629
Petty Motor Company Annex, (Sugar House Business District MPS), 2030 South 900 East, Salt Lake City, 03000634
Redman Van and Storage Company Building, (Sugar House Business District MPS), 1240 East 2100 South, Salt Lake City, 03000635
Richardson—Bower Building, (Sugar House Business District MPS), 1019 East 2100 South, Salt Lake City, 03000636
Sprague Branch of the Salt Lake City Public Library, (Sugar House Business District MPS), 2131 S. Highland Dr., Salt Lake City, 03000637
Sugar House LDS Ward Building, (Sugar House Business District MPS), 1950 South 1200 East, Salt Lake City, 03000631
Sugar House Monument, (Sugar House Business District MPS), 1100 East and 2100 South, Salt Lake City, 03000638
Utah State Liquor Agency #22, (Sugar House Business District MPS), 1938 South 1100 East, Salt Lake City, 03000639

Sanpete County

Mortensen—Nelson House, 291 East 100 South, Moroni, 03000632

Virginia

Arlington County

Al's Motors, 3910 Wilson Blvd., Arlington, 03000628

[FR Doc. 03–15309 Filed 6–17–03; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before May 24, 2003. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, (202) 371–6447. Written or faxed comments should be submitted by July 3, 2003.

Carol D. Shull,

Keeper of the National Register of Historic Places.

AMERICAN SAMOA

Eastern District

Thompson, Sadie, Building, along main road, Malaloa, 03000582.

CALIFORNIA

Madera County

Gerry Building, 910 S. Los Angeles St., Los Angeles, 03000583.

DISTRICT OF COLUMBIA

District of Columbia

Capitol Hill Historic District (Boundary Increase), Roughly bounded by 7th St. NE, I–295, M St. SE and 11th St. SE, Washington, 03000585.
Connecticut Avenue Bridge, Connecticut Ave., NW., of Rock Creek, Washington, 03000584.

GEORGIA

Jeff Davis County

Pace House, 61 E. Coffee St., Hazlehurst, 03000591.

IDAHO

Lincoln County

Wood River Center Grange No. 87, 375 W 4 Mile Rd., Shoshone, 03000586.

MISSISSIPPI

Bolivar County

Downtown Cleveland Historic District (Boundary Increase), 201 S. Court St. and 200–215 N. Pearman Ave., Cleveland, 03000588.

Coahoma County

Clark, John, House, 211 Clark St., Clarksdale, 03000589.

Lauderdale County

Terminal Building, Old, Hangar and Powerhouse at Key Field, 2525 U.S. 11 S, Meridian, 03000587.

NEW YORK

Allegany County

Belmont Literary and Historical Society Free Library, 2 Willets Ave., Belmont, 03000599.
Bolivar Free Library, 390 Main St., Bolivar, 03000606.

Cattaraugus County

Bedford Corners Historic District, NY 305 at Deer Creek and Dodge Creek Rds., Portville, 03000590.
Bryant Hill Cemetery, Bryant Hill Rd. near Crane Rd., Ellicottville, 03000605.

Columbia County

Clermont Civic Historic District, (Clermont MRA) 1795 US 9, Clermont, 03000604.

Erie County

Reformed Mennonite Church, Former, 5178 Main St., Williamsville, 03000596.

Nassau County

Underhill, George, House, 28 Factory Pond Rd., Locust Valley, 03000592.

Onondaga County

Fuller, James and Lydia Canning, House, (Freedom Trail, Abolitionism, and African American Life in Central New York MPS) W. Genesee St., Skaneateles, 03000595.

Rensselaer County

Sherman Farm, 35 Sherman Rd., Pittstown, 03000597.

Rockland County

Perry, Jacob P., House, 15 Sickeletown Rd., Pearl River, 03000594.

Saratoga County

First United Methodist Church, 36 Second St., Lion, 03000601.

Steuben County

Wombough, William, House, 145 E. Front St., Addison, 03000593.

Tioga County

Waverly Village Hall, 358–360 Broad St., Waverly, 03000600.

Ulster County

Childs, Walstein, House, Sand Hill Rd., Wallkill Correctional Facility, Wallkill, 03000602.
Forsyth, James and Mary, House, 31 Albany Ave., Kingston, 03000603.

Westchester County

St. Peter's Episcopal Church, 137 N. Division St., Peekskill, 03000598.

NORTH CAROLINA

Dare County

Bodie Island Light Station, Off NC 12, Nags Head, 03000607.

OHIO

Summit County

Lutz—Martin Farm, 2470 Martin Rd., Bath, 03000608.

SOUTH DAKOTA

Lake County

Lake Badus Rural Agricultural Historic District, Roughly bounded by US 81, Cty Rte. 16, Cty Rte. 37, and Cty Rte 20, Nunda, 03000609.

TEXAS

Gonzales County

Spooner, Thomas Harrison and Mollie, House, 207 St. Francis St., Gonzales, 03000610.

The following resource is being REMOVED for procedural error:

NORTH CAROLINA

Pitt County

Greenville Commercial Historic District, Roughly bounded by West Third, South Evans and East and West Fifth St.s, Greenville 03000419.

A request for a MOVE has been made for the following resource:

LOUISIANA

St. John the Baptist Parish

Graugnard House, 2294 LA 44, Reserve vicinity, 94001249.

[FR Doc. 03–15310 Filed 6–17–03; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Realty Action Proposed Exchange of Interests in Federally-Owned Land for Privately-Owned Lands Located in Montgomery County, State of Maryland

AGENCY: National Park Service, Interior.

ACTION: Notice of realty action for proposed land exchange.

SUMMARY: The following described interests in federally-owned land which was acquired by the National Park Service has been determined to be suitable for disposal by exchange. The authority for this exchange is section 3 of Public Law 91–664 (84 Stat. 1978), which authorized the donation, purchase with donated or appropriated funds, or exchange of land and interests therein on the Chesapeake and Ohio Canal National Historical Park, and section 5 of Public Law 90–401 (82 Stat. 356), which also authorizes land exchanges.

DATES: Comments on this proposed land exchange will be accepted through August 4, 2003.

ADDRESSES: Detailed information concerning this exchange including precise legal descriptions, Land Protection Plan, environmental and cultural analysis and reports are available at the National Trails Land Resources Program Center, 1314 Edwin Miller Boulevard, PO Box 908, Martinsburg, West Virginia 25402. Comments may also be mailed to this address.

FOR FURTHER INFORMATION CONTACT: Judy L. Brumback, Chief, Acquisition Division, National Park Service, National Trails Resources Program Center, PO Box 908, Martinsburg, WV 25402–0908. Phone (304) 263–4943.

SUPPLEMENTARY INFORMATION: The selected interest in federal land is located within the boundaries of the Chesapeake and Ohio Canal National Historical Park and is not required for inclusion into the park unit area. The land has been surveyed for cultural resources and endangered and threatened species. These reports are available upon request.

The United States of America will acquire a 16.10-acre parcel of land currently owned by Jacob R. Ramsburg, Jr., *et al.,* lying within the boundaries of the Chesapeake and Ohio Canal National Historical Park. Three cabins are located on the tract. Acquisition of this land will allow the Park to consolidate its inholdings and provide

for visitor access by foot to the Potomac River and Canal. The land is being acquired in fee simple subject to a reservation of a 17-year term estate for use and occupancy of structures located on the land.

In exchange for the land described in the previous paragraph, the United States will convey a term estate, for seventeen years, for use and occupancy of structures located on the following federally-owned property: Tract 17–116 is an interest in a 21.38-acre tract acquired in fee (formerly Tract 17–101) by the United States of America by deed recorded in Book 4598, Page 621, in the Land Records of Montgomery County, State of Maryland. Twenty-two cabins are located on the tract. Conveyance of the interests in land by the United States of America will be done by Quitclaim Deed.

The land to be acquired by the United States of America is described as follows: Tract 17–100 is a 16.10-acre tract acquired by Jacob R. Ramsburg, Jr., *et al.,* and recorded in Book 5322, Page 501, in Land Records of Montgomery County, State of Maryland. Conveyance of the fee simple title will be done by a Special Warranty Deed as approved by the Solicitor's Office.

The value of the interests and land to be exchanged has been determined by a current fair market value appraisal and the value of land and/or interests to be conveyed is equal.

Interested parties may submit written comments to the address listed in the **ADDRESSES** paragraph. Adverse comments will be evaluated and this action may be modified or vacated accordingly. In the absence of any action to modify or vacate, this realty action will become the final determination of the Department of the Interior.

Dated: February 25, 2003.

Kevin Brandt,

Acting Superintendent, Chesapeake and Ohio Canal National Historical Park.

[FR Doc. 03–15308 Filed 6–17–03; 8:45 am]

BILLING CODE 4310–6V–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

June 5, 2003.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation, contact Darrin King on 202–693–4129 (this is not a toll-free number) or E-Mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment Standards Administration, Office of Management and Budget, Room 10235, Washington, DC 20503 (202–395–7316 / this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Employment Standards Administration (ESA).

Type of Review: Extension of a currently approved collection.

Title: 29 CFR Part 825, The Family and Medical Leave Act of 1993.

OMB Number: 1215–0181.

Frequency: On occasion.

Type of Response: Recordkeeping and third party disclosure.

Affected Public: Individuals or households; business or other for-profit; Not-for-profit institutions; farms; Federal Government; and State, Local, or Tribal Government.

Number of Respondents: 6,655,000.

Information collection requirement	Annual responses	Average response time	Annual burden hours
Employee Notice of Need for FMLA Leave	4,150,000	0.02	69,167
Notice to Employees of FMLA Rights— WH–381: Providing Guidance	388,000	0.17	64,667
Providing Written Notice to Employees	4,150,000	0.08	345,833
Medical Certifications and Recertifications (Serious Health Condition)—WH–380:			
Medical Certifications—Initial	1,660,000	0.33	553,333
Medical Certifications—Additional	166,000	0.33	55,333
Medical Recertifications	83,000	0.33	27,667
Fitness-for-Duty Medical Certifications	207,500	0.17	34,583
Notice to Employees of Change 12-Month Period for Determining FMLA Entitlement	38,800	0.17	6,467
Key Employee Notification:			
First Notice	41,500	0.08	3,458
Second Notice	20,750	0.08	1,729
Recordkeeping	4,150,000	0.05	207,500
Total	15,055,550	.....	1,369,737

Total Annualized capital/startup costs: $0.

Total annual costs (operating/maintaining systems or purchasing services): $0.

Description: The Family and Medical Leave Act of 1993 (FMLA), Public Law 103–3, 107 Stat. 6, 29 U.S.C. 2601, which became effective on August 5, 1993, requires private sector employers of 50 or more employees, and public agencies to provide up to 13 weeks of unpaid, job-protected leave during any 12-month period to eligible employees for certain family and medical reasons.

This ICR contains recordkeeping and notification requirements associated with the Act and implementing regulations found at 29 CFR Part 825. Two optional forms are included in this information collection request. The WH–380, Certification of Health Care Provider, may be used to certify a serious health condition under FMLA. The WH–381, Employer Response to Employee Request for Family or Medical Leave may be used by an employer to respond to a leave request under FMLA. Both forms are third-party notifications and are sent to the employee; they are not submitted to the Department of Labor. This information collection is currently approved for use through July 31, 2003.

The Department of Labor seeks OMB approval for the extension of this information collection in order to ensure that both employers and employees are aware of and can exercise their rights and meet their respective obligations under FMLA, and in order for the Department of Labor to carry out its statutory obligation under FMLA to investigate and ensure employer compliance have been met.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 03–15342 Filed 6–17–03; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

June 11, 2003.

The Department of Labor (DOL) has submitted the following public information collection requests (ICR's) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of the ICR's, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation, contact Vanessa Reeves on 202–693–4121 (this is not a toll-free number) or E-Mail: *reeves.vanessa2@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employee Benefits Security Agency, Office of Management and Budget, Room 10235, Washington, DC 20503 (202–395–7316/this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: Employee Benefits Security Administration (EBSA).

Type of Review: Extension of a currently approved collection.

Title: Prohibited Transaction Class Exemptions for Multiple Employer & Multiple Employer Apprenticeship Plans, PTCE 76–1, PTCE 77–10, PTCE 78–6.

OMB Number: 1210–0058.

Affected Public: Business or other for-profit and individuals or households.

Frequency: On occasion.

Type of Response: Recordkeeping.

Number of Respondents: 4,810.

Information collection requirements	Annual responses	Average response time (hours)	Annual burden hours
PTCE 76–1, Part A	0	0.00	0
PTCE 76–1, Part B	58	0.25	15
PTCE 76–1, Part C	4,623	0.25	1,156
PTCE 77–10	0	0.00	0
PTCE 78–6	645	0.08	54
Total	5,326		1,225

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: Prohibited Transaction Class Exemption 76–1, approved under OMB No. 1210–0058, provides an exemption, under specified conditions, from certain of ERISA's prohibited transaction provisions at section 406(a) for various transactions involving multi-employer or multi employer plans (together, multiple employer plans). Part A of PTCE 76–1 provides that an agreement between a plan and an employer for extending the time for a contribution must be in writing. Part B provides that permanent financing for construction loans involving plans and participating employers must be in writing, and records must be maintained for six years. Part C permits plans to lease office space and provide administrative services or sell goods to a participating employer, employee organization, participating employer association or to another multiple employer plan that is a party in interest. A related exemption, PTCE 77–10, also approved under OMB No. 1210–0058, complements Part C of PTCE 76–1 by providing an exemption from sections 406(a) and 407(a) of ERISA.

The Department proposes to combine the information collection under PTCE 76–1 with the information collection in PTCE 78–6, currently approved under OMB No. 1210–0080, by incorporating the information collection provisions of PTCE 78–6 into the revision ICR number OMB No. 1210–0058 and allowing the control number for PTCE 78–6 to expire. PTCE 78–6 provides an exemption to multiple employer apprenticeship plans for the purchase of personal property or the lease of real property by a plan to a contributing employer. The Department believes that the public will benefit by having the opportunity to comment on the three information collection provisions at the same time because the three exemptions are closely related in that they provide relief from prohibited transactions for multiple employer plans or multiple employer apprenticeship plans and they

have the same recordkeeping provisions.

Agency: Employee Benefits Security Administration (EBSA).

Type of Review: Extension of a currently approved collection.

Title: Bank Collective Investment Funds; Prohibited Transaction Class Exemption 91–38.

OMB Number: 1210–0082.

Affected Public: Business or other for-profit; individuals or households; and not-for-profit institutions.

Frequency: On occasion.

Type of Response: Recordkeeping.

Number of Respondents: 1,036.

Number of Annual Responses: 1,036.

Estimated Time Per Responses: 5 minutes.

Total Burden Hours: 86.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: Prohibited Transaction Class Exemption 91–38 provides an exemption from the prohibited transaction provisions of ERISA for certain transactions between a bank collective investment fund and persons who are parties in interest with respect to a plan provided that the plan's participation in the collective investment fund does not exceed a specific percentage of the total assets in the collective investment fund. To insure that the exemption is not abused, that the rights of the participants and beneficiaries are protected, and that a bank is complying with the conditions of the exemption, the Department requires records pertaining to the exempted transaction to be maintained by the bank for six years. The recordkeeping requirement is the subject of this proposed extension of an ICR.

Agency: Employee Benefits Security Administration (EBSA).

Type of Review: Extension of a currently approved collection.

Title: Prohibited Transaction Class Exemptions 90–1; Pooled Separate Accounts.

OMB Number: 1210–0083.

Affected Public: Business or other-for profit; individuals or households; and not-for-profit institutions.

Frequency: On occasion.

Type of Response: Recordkeeping.

Number of Respondents: 128.

Number of Annual Responses: 128.

Estimated Time Per Responses: 5 minutes.

Total Burden Hours: 11.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: Prohibited Transaction Class Exemption 90–1 provides an exemption from certain provisions of the Employee Retirement Income Security Act of 1974 (ERISA) for certain transactions involving insurance company pooled separate accounts in which employee benefit plans participate and which are otherwise prohibited by ERISA. Specifically, the exemption allows persons who are parties in interest to a plan that invests in a pooled separate account, such as a service provider, to engage in transactions with the separate account if the plan's participation in the separate account does not exceed specified limits. This ICR covers the recordkeeping requirements for insurance companies.

Agency: Employee Benefits Security Administration (EBSA).

Type of Review: Extension of a currently approved collection.

Title: Foreign Exchange Transactions; Prohibited Transaction Class Exemption 94–20.

OMB Number: 1210–0085.

Affected Public: Business or other-for profit; individuals or households; and not-for-profit institutions.

Frequency: On occasion.

Type of Response: Recordkeeping.

Number of Respondents: 130.

Number of Annual Responses: 650.

Estimated Time Per Responses: 5 minutes.

Total Burden Hours: 54.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: Prohibited Transaction Class Exemption 94–20 permits the purchase and sale of foreign currencies between an employee benefit plan and a bank or a broker-dealer or an affiliate thereof that is a party in interest with respect to such plan. In the absence of this exemption, certain aspects of these transactions could be prohibited by section 406(a) and 406(b) of the Employee Retirement Income Security Act of 1974. This ICR covers the disclosure and recordkeeping requirements for a bank, broker-dealer, or affiliate thereof.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 03–15343 Filed 6–17–03; 8:45 am]

BILLING CODE 4510–29–M

DEPARTMENT OF LABOR

Office of the Secretary

Women's Bureau; Women in Apprenticeship and Nontraditional Occupations (WANTO) Act of 1992 FY–2003 Budget, Training and Employment Services (TES) 1630174

AGENCY: Women's Bureau, Department of Labor.

ACTION: Notice of Availability of Funds and Solicitation For Grant Applications (SGA 03–12).

This notice contains all of the information needed to apply for grant funding. Grant proposals that are not completed as directed will be judged non-responsive and will not be evaluated.

SUMMARY: The Women's Bureau, U.S. Department of Labor (DOL), announces the 2003 Solicitation for Grant Applications (SGA) authorized under the *Women in Apprenticeship and Nontraditional Occupations (WANTO) Act of 1992.* The purpose of this program is to assist employers and labor unions in the placement and retention of women in apprenticeship and nontraditional occupations. To that end, WANTO grant funds are disbursed to eligible community-based organizations, which may be faith-based, which, in turn, provide employers and labor unions with technical assistance geared towards the successful placement and retention of women in apprenticeship and nontraditional occupations.

DATES: One signed original, complete grant application plus two copies of the Technical Proposal and two copies of the Cost Proposal must be submitted. The original and copies must be submitted by 4:45 p.m. e.s.t., August 11, 2003. Hand-delivered applications must be received by that time. An application received after August 11, 2003, will not be considered unless it is received before awards are made and:

1. It was sent by registered or certified mail not later than August 6, 2003.

2. It is determined by the government that the late receipt was due solely to mishandling by the government after receipt at the U.S. Department of Labor at the address listed under **ADDRESSES**; or

3. It was sent by U.S. Postal Service Express Mail Next Day Service—Post Office to Addressee, not later than 4:45 p.m. e.s.t. on August 9, 2003.

The only acceptable evidence to establish the date of mailing of a late application sent by registered or certified mail is the U.S. Postal Service postmark on the envelope or wrapper

and on the original receipt from the U.S. Postal Service. If the postmark is not legible, an application received after the specified time and date will be processed as if mailed late. ''Postmark'' means a printed, stamped, or otherwise placed impression (not a postage meter machine impression) that is readily identifiable without further action as having been applied and affixed by an employee of the U.S. Postal Service on the date of mailing. Therefore, applicants shall request that the postal clerk place a legible hand cancellation bull's-eye postmark on both the receipt and the wrapper or envelope.

The only acceptable evidence to establish the date of mailing of a late application sent by U.S. Postal Service Mail Next Day Service—Post Office to Addressee is the date entered by the post office receiving clerk on the ''Express Mail Next Day Service-Post Office to Addressee'' label and the postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. ''Postmark'' has the same meaning as defined in the preceding paragraph. Therefore, applicants shall request that the postal clerk place a legible hand cancellation bull's-eye postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the time of receipt at the U.S. Department of Labor is the date/time stamp of the Office of Procurement Services on the application wrapper or other documentary evidence of receipt maintained by that office. Applications sent by other delivery services, such as Federal Express, UPS, etc., will also be accepted; however, the applicant bears the responsibility of timely submission.

ADDRESSES: Applications must be directed to the U.S. Department of Labor, Procurement Services Center, Attention: Cassandra Willis, Reference SGA 03–12, Room N–5416, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: *All applicants are advised that U.S. mail delivery in the Washington, DC area has been erratic due to concerns involving anthrax contamination. All applicants must take this into consideration when preparing to meet the application deadline.* You assume the risk for ensuring a timely submission; that is, if, because of these mail problems, the Department does not receive an application or receives it too late to give it proper consideration, even if it was timely mailed, the Department is not required to consider the application. Therefore, it is recommended that you confirm receipt of your application by contacting Cassandra Willis, U.S. Department of Labor, Procurement Services Center; (202) 693–4570 (this is not a toll-free number), prior to the closing deadline.

Application announcements or forms will not be mailed. The **Federal Register** may be obtained from your nearest government office or library. In addition, a copy of this notice and the application requirements may be downloaded from the Women's Bureau's Web site at *http://www.dol.gov/wb/nontra.htm.*

All questions about this SGA should be directed to Cassandra Willis, U.S. Department of Labor, Procurement Services Center, Room N–5416, 200 Constitution Avenue, NW., Washington, DC 20210; 202–693–4570.

SUPPLEMENTARY INFORMATION:

Part I. Background

A. *Authority and Funding.* The Women in Apprenticeship and Nontraditional Occupations (WANTO) Act of 1992 (29 U.S.C. 2501 *et seq.*) authorizes the Department of Labor (DOL) to disburse technical assistance grants. The WANTO grants for Fiscal Year (FY) 2003 are funded by DOL FY 2003 Budget: Training and Employment Services (TES) 1630174. The Women's Bureau (WB) co-administers the WANTO program with the DOL Office of Apprenticeship Training, Employer and Labor Services (ATELS). WB has responsibility for implementing the grant process.

B. *Purpose.* The WANTO Act's purpose is to provide technical assistance to employers and labor unions (E/LU) to encourage employment of women in apprenticeships and nontraditional occupations (A/NTO). WANTO grants are awarded to community-based organizations (CBOs), which may be faith-based, to deliver technical assistance to E/LU to prepare them to successfully recruit, train, employ and retain women in A/NTO. DOL has found that placement and retention of women in A/NTO pose significant challenges.

C. *Grant Awards.* The WB is soliciting proposals on a competitive basis for the WANTO program. The WB anticipates awarding grants of $50,000 to $100,000 to approximately 10 grantees to conduct innovative projects that comply with the goals set forth in the WANTO Act and this SGA. The period of performance begins September 30, 2003, and ends on September 29, 2004. The initial performance period may be extended once, for up to three months, at no additional cost to DOL, so that a grantee can finish its final report. Each application shall clearly state the applicant's intention to begin performance no later than October 1, 2003.

D. *Acronyms and Definitions.* The following terms are defined for the convenience of prospective applicants:

WANTO refers to Women in Apprenticeship and Nontraditional Occupations.

A/NTO refers to apprenticeship and nontraditional occupations.

E/LU refers to employers and labor unions.

ATELS refers to the Apprenticeship Training, Employer and Labor Services office of the Employment and Training Administration, U.S. Department of Labor.

WB refers to the Women's Bureau, U.S. Department of Labor.

TA refers to technical assistance.

NTO (Nontraditional Occupations) are those where women account for less than 25 percent of all persons employed in a single occupational group. For the most recent listing of nontraditional jobs, *see* the WB Web site at *www.dol.gov/wb/stats/main.htm.*

Pre-Apprenticeship Programs are those programs that prepare individuals for apprenticeship or entry-level employment in NTO. Depending on the apprenticeable or other nontraditional occupation for which the program is preparing students, the curriculum would vary. For example, a curriculum for the construction trades may include pre-vocational identification and use of tools, blueprint reading, basic shop skills, safety procedures, math skills, and physical conditioning. English as a Second Language and team-building skills such as effective listening and feedback might be included in curricula preparing students for some entry-level nontraditional jobs.

Apprenticeship is a formal employment relationship designed to promote skill training and learning on the job. ''Hands on'' learning takes place in conjunction with related theoretical instruction (often in a classroom setting). An apprentice who successfully completes an ATELS registered program, which usually requires 3 to 5 years, is awarded a certificate of completion. An ATELS-registered program is one in which employers, or groups of employers, and unions design, organize, manage, and finance apprenticeship programs under the standards developed and registered with ATELS or ATELS-recognized State Apprenticeship Agencies. Employers, or groups of employers, and unions also select apprentices who are trained to meet certain predetermined occupational standards. For more

information, *see* the ATELS Web site at *http://www.doleta.gov/atels_bat/.*

High-technology occupations are those in which cutting-edge, state-of-the-art technologies are used. The technologies shape the design, development, and introduction of new products and innovative production processes. These scientific, technical and engineering occupations require in-depth knowledge of the theories and principles of science, engineering, and mathematics, acquired through post-secondary specialized education. For the purposes of this solicitation, this definition also includes other occupations which have many high-tech aspects, for example, repairing the products used in high-tech industries.

CBO (Community-Based Organization) is a private nonprofit organization, which may be faith-based, that is representative of a community or a significant segment of a community, and that has demonstrated experience administering programs that train women for A/NTO.

Part II. Eligible Applicants

An applicant must be a community-based organization. That is, it must:

- Be a private, nonprofit organization. *A public body such as a governmental body, public school, college, or hospital is not a CBO.*
- Represent a community or a significant segment of a community.
- Have demonstrated experience administering programs that train women for A/NTO.

In addition, a CBO must not be classified under the IRS Tax Code as a 501(c)(4) entity.

All proposals must document that these eligibility requirements have been, and will continue to be, satisfied.

A faith-based organization is an eligible applicant provided it meets the eligibility requirements stated above.

A consortium of CBOs may apply for a grant provided they include a copy of the consortium agreement and identify the entity/entities that will administer the grant.

Applications that fail to establish eligibility according to these criteria will not be evaluated.

Part III. Application Contents

A. Technical Proposal

The technical proposal text is limited to twenty (20) 8½ by 11 inch pages (not including the Table of Contents and any attachments), numbered, double-spaced, single-sided, in 8 to 12 pitch (font size).

The following information is required:

1. A Table of Contents, listing the application sections.

2. Documentation of applicant eligibility, as described in part II of this notice.

3. A 2-page abstract, summarizing the proposed project.

4. Documentation of its experience, capability, and qualifications for providing TA to E/LU for the purpose of recruiting, training, hiring and retaining women in A/NTO, as described in part IV, section A1 ''Organizational Overview'' of this notice.

5. Documentation of commitments from a minimum of six (6) up to a maximum of eight (8) E/LU to receive TA, and a description of the E/LU's previous experience in recruiting, training, placing and retaining women in A/NTO, as described in part iv, section A2 ''Established Employer and Labor Union Linkages'' of this notice.

6. A Statement of Work as described in part IV section A3 ''Scope of WANTO Project and Projected Outcomes'' of this notice.

7. A list of all items for which grant funds will be expended. Do not include any cost information, only expenditure items.

8. The CBO's budget and major funding sources for the past three (3) years, including foundation and government funds, as well as other types of funding.

B. Cost Proposal

The Cost Proposal is a physically separate document and must not be included within the twenty-page limit of the technical proposal. The Cost Proposal must include the following:

1. A Standard Form (SF) 424, ''Application for Federal Assistance.'' All copies of the SF 424 must have original signatures of the legal entity applying for grant funding. Applicants must indicate on the SF 424 the organizations IRS status. The Catalogue of Federal Domestic Assistance (CFDA) number for this program is 17.700, which should be entered on the SF 424, block 10.

2. A certification prepared within the last six (6) months, attesting to the adequacy of the entity's fiscal management and accounting systems to account for and safeguard Federal funds properly. The certification should be obtained as follows:

a. For incorporated organizations, a certification from a Certified Public Accountant or

b. For other applicants, their employers' identification number (EIN) issued by the IRS;

3. Budget Information Form 424A, with a narrative of description of each line item.

4. A copy of the most current Indirect Cost Rate Agreement issued by the cognizant federal agency, if applicable.

5. Applications from a consortium of organizations also must include a copy of the consortium agreement and must identify the consortium that will act as the administrative entity for the project. No member of a consortium shall make a separate application under his grant program. In addition, the agreement must specify the consortium's arrangements for handling the administrative and financial responsibilities for the program.

6. The applicants must include the Assurances and Certifications Signature Page.

Potential applicants who do not have the current version of the standard grant forms 424 and 424A listed above can download them from the following OMB Web site address: *http://www.whitehouse.gov/omb/grants/grants_forms.html.* The Assurances and Certifications Signature Page will be available on the WB WANTO Web site at *http://www.dol.gov/wb/nontra.htm.*

Part IV. Evaluation Criteria and Selection Process

Technical proposals will be carefully reviewed by an evaluation panel using the following criteria under section A of this part. Up to 115 points may be awarded to an application. This total is based on up to 100 points for the required information described in A. 1, 2, and 3 below, and up to 15 bonus points for special program emphasis described in A. 4 below. The ranked scores of the proposals will serve as the primary basis for selection of applicants for a potential award in accordance with the process in section B of this part.

A. Technical Evaluation Criteria/Points

1. Organizational Overview (Up to 20 Points Awarded)

The applicant must demonstrate its experience, capability and qualifications for administering a grant project to provide technical assistance to E/LU. The applicant must:

(a) Describe the organization's experience and leadership in providing *technical assistance to E/LU* for the purpose of recruiting, training, placing and retaining women in A/NTO.

(b) Highlight the qualifications of the key staff and the organizational structure that would ensure the success of the project. Include the CBO's organizational chart and the names and full resumes of all primary staff managing the grant project.

(c) Include job descriptions which identify all key tasks, the hours required

for the completion of such tasks, and the persons responsible for completing each task.

(d) Indicate if tradeswomen or women in nontraditional occupations serve as active members of the organization, as either employed staff or as board members.

(e) Where applicable, differentiate between the CBO and any proposed consultants or subcontractors, providing information on each of the above.

2. Established Employer and Labor Union Linkages (Up to 20 Points Awarded)

The applicant must demonstrate commitments from a minimum of six (6) E/LU up to a maximum of eight (8) E/LU to receive technical assistance during the grant award period. The applicant must also demonstrate a level of understanding of the E/LU's previous experiences with recruitment, training, placement, and retention of women in A/NTO sufficient to enable the applicant to provide targeted technical assistance. The applicant must:

(a) Document commitments (in the form of written agreements or letters) from a minimum of six (6) E/LU up to a maximum of eight (8) E/LU to receive technical assistance for the purpose of training or employing women in A/NTO. As stated in the WANTO Act, at a minimum such agreements or letters should include: (1) A description of the need for technical assistance; (2) a description of the types of apprenticeable occupations or nontraditional occupations in which the employer or labor union would like to train or employ women; (3) assurances that there are or will be suitable and appropriate positions available in the apprenticeable occupations program or in the nontraditional occupations being targeted; and (4) commitments that reasonable efforts shall be made to place qualified women in apprenticeable occupations or nontraditional occupations.

(b) Document the previous programs and experiences, and success or lack thereof, of the E/LU in recruiting, training, placing, and retaining women in A/NTO. Such documentation may include descriptions of previous outreach and orientation provided to women, mentoring programs, support groups, networks, workplace consultations, employee and supervisory workshops, and other workplace-specific strategic planning to increase the participation of women in apprenticeship and nontraditional occupations.

3. Scope of WANTO Project and Projected Outcomes (Up to 60 Points Awarded)

The applicant must demonstrate comprehensive, targeted, and effective technical assistance to be provided to E/LU with WANTO funding. The applicant must also project the types and amounts of successful outcomes that can reasonably be expected as a result of the TA provided with WANTO funding. The WB considers the successful placement of women in *apprenticeships* and *nontraditional occupations* the primary successful outcome a grantee can achieve with WANTO funding.

The applicant must include a Statement of Work which:

(a) Details all forms of technical assistance to be provided to the E/LU identified in the previous section, ''Established Employer and Labor Union Linkages.'' (According to the WANTO Act, technical assistance provided with WANTO grant funds may include: (1) Developing outreach and orientation sessions to recruit women into the employers' apprenticeable occupations and nontraditional occupations; (2) developing preapprenticeable occupations or nontraditional skills training to prepare women for A/NTO; (3) providing ongoing orientations for E/LU and workers on creating a successful environment for women in A/NTO; (4) setting up support groups and facilitating networks for women in A/NTO on or off the job site to improve their retention; (5) setting up a local computerized data base referral system to maintain a current list of tradeswomen who are available for work; (6) serving as a liaison between tradeswomen and E/LU to address workplace issues related to gender; and (7) conducting exit interviews with tradeswomen to evaluate their on-the-job experience and to assess the effectiveness of the program.)

(b) Documents any leveraging or co-funding anticipated for the accomplishment of the proposed project. This must include a description of the value-added of the WANTO grant, *i.e.,* what technical assistance will be provided to E/LU *as a result of WANTO grant funding*?

(c) Describes the outcomes the applicant projects *as a result of WANTO funding.* This must include the number of women to be placed in (1) pre-apprenticeships; (2) apprenticeships; and (3) nontraditional occupations.

4. Bonus Points (Up to 15 Points Awarded)

Bonus points will be awarded for projects that demonstrate their experience or indicate their plans to provide one or more of the following:

a. Opportunities for women to be placed and retained in A/NTO in high technology occupations. (Up to 5 points awarded.)

b. Services for disabled women to be placed in A/NTO. (Up to 5 points awarded.)

c. Mentoring services to at least one other CBO that is providing technical assistance to E/LU. (Up to 5 points awarded.)

B. Total Score

The review panel's recommendations are advisory in nature and not binding on the Grant Officer. Final awards will be made based on the best interest of the government, including, but not limited to, such factors as technical quality, geographic balance, occupational and/or industrial impact, and past grant performance. The submission of a successful previous application for a WANTO grant from any prior year does not guarantee an award under this solicitation. A previous grantee's failure to complete a WANTO grant project within the grant award period, or failure to provide required reports in a timely manner are aspects of past grant performance that may result in denial of a 2003 grant.

Although the government reserves the right to award on the basis of the applicant's initial submissions, the government may establish a competitive range or technically acceptable range based upon proposal evaluation for the purpose of selecting qualified applicants. The government reserves the right to ask for clarification or hold discussion, but may elect to award a grant without such discussion. The Grant Officer's determination of award under this SGA is the final agency action.

Part V. Deliverables

This section is provided so that applicants may more accurately estimate the staffing budgetary requirements when preparing their proposal. Applicants are to exclude from their cost proposal the cost of any requested travel to Washington, DC.

A. Post Grant Award Conference.

No later than *eight (8)* weeks after an award, the grantees shall meet with the WB and ATELS at the Post-Award Conference to discuss the project, related components and TA; timelines; technical assistance outcomes; assessment for comment; and final approval. The grantees and the WB will discuss and make decisions on the following program activities:

1. The proposed TA commitments for employment, registered apprenticeship, and related skilled nontraditional occupation activities and responsibilities; the number of targeted partnerships with E/LU; and the number of women who will be served.

2. The methodology the proposed partnership will use to support/change management and employee attitudes to promote female workers in A/NTO.

3. The types of systemic change anticipated by the TA strategies that will be incorporated into ongoing employer recruitment, hiring, training, and promotion of women in A/NTO.

4. The occupational, industrial, and geographical impact anticipated.

5. The supportive services to be provided to employers and women after successful placement into A/NTO.

The WB and ATELS will provide further input orally or in writing, if necessary, within *ten (10)* working days after the Post-Award Conference.

B. Grant Plan of Action.

If revisions have been necessary, no later than *ten (10)* weeks after an award, the grantees and the WB will confirm the ''plan of action'' and detailed time-line for program implementation.

C. Grant Implementation.

No later than *twelve (12)* weeks after an award, the grantee(s) shall have begun providing E/LU with TA to recruit, select, train, place, retain, and otherwise prepare women for A/NTO, with progress to be measured in terms of employment growth and rising earnings.

D. Quarterly Reports

1. No more than *thirty (30)* calendar days after the end of each quarter, the grantee shall submit a progress report of work done under this grant.

2. Quarterly reports shall generally contain brief information on each of the following:

(a) A comparison of actual accomplishments with the goals and objectives established for the period. This must include discussion of placements in pre-apprenticeship programs, apprenticeships and nontraditional jobs, giving the name and address of each workplace/company involved; and TA provided to E/LU, giving the E/LU name and address as well as the nature of the TA provided.

(b) Reasons why established goals were not met, if appropriate.

(c) Any problems that may impede the performance of the grant and the proposed corrective action.

(d) Any changes in the proposed work to be performed during the next reporting period.

3. In addition, between scheduled reporting dates, the grantee(s) shall immediately inform the Women's Bureau National Office Grant Officer's Technical Representative of significant developments affecting the ability to accomplish the work.

E. Final Report

1. The Final Report shall cover findings, final performance data, outcome results, an assessment of the grant project, and any employer or labor organization plans for follow-up of participants. It shall include an Executive Summary of no more than three (3) pages.

2. No later than *ninety (90)* days after the expiration of the grant award, the grantee(s) shall submit two (2) copies of the camera-ready final report, each bound in a professional manner in a loose-leaf notebook. These materials must be paid for with grant funds.

3. Upon request of either the Women's Bureau or the grantee, the grantee shall submit a draft final report no more than *sixty (60)* days after the expiration of the grant award. The Women's Bureau will then review the draft report, consult with ATELS as necessary, and provide written comments to the grantee within *fifteen (15)* days of receipt.

Part VII. Grant Requirements

A. Administrative Standards and Provisions

Except as specifically provided, DOL acceptance of a proposal and an award of Federal funds to sponsor any program(s) does not provide a waiver of any grant requirements and/or procedures. For example, the OMB Grants Management circulars (available on the OMB Web site at *http://www.whitehouse.gov/omb/grants/grants_circulars.html*) require, and an entity's procurement procedures must require, that all procurement transactions will be conducted, as practical, to provide open and free competition. If a proposal identifies a specific entity to provide the services, the DOL award does not provide the justification or basis to sole-source the procurement, *i.e.,* avoid competition.

The grants awarded under this SGA shall be subject to the following administrative standards and provisions as applicable:

29 CFR part 97—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

29 CFR part 96—Federal Standards for Audit of Federally Funded Grants, Contracts, and Agreements.

29 CFR part 95—Uniform Administrative Requirements for Grants and Cooperative Agreements with Institutions of Higher Education, etc.

B. Allowable Costs

The WB shall determine what constitutes allowable costs in accordance with the following applicable Federal cost principles: (1) State and Local Government—OMB Circular A–87; (2) Educational Institutions—OMB Circular A–21; (3) Nonprofit Organizations—OMB Circular A–122; and (4) Profit-making Commercial Firms—48 CFR Part 31.

C. Grant Nondiscrimination Assurances

As a condition of the awards, applicants must certify that they will comply fully with the nondiscrimination and equal opportunity provisions of the following laws:

29 CFR part 31—Nondiscrimination in Federally-assisted programs of the Department of Labor, effectuation of title VI of the Civil Rights Act of 1964.

29 CFR part 32—Nondiscrimination on the Basis of Disability in Programs and Activities Receiving or Benefiting from Federal Assistance. (Implementing section 504 of the Rehabilitation Act, 29 U.S.C. 794)

29 CFR part 36—Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance. (Implementing title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.*)

The applicant must include assurances and certifications that it will comply with these laws in its grant application. The assurances and certifications are attached as Appendix C.

In addition, this program is subject to the provisions of the ''Jobs for Veterans Act,'' Public Law 107–288, which provides priority of service to veterans and spouses of certain veterans for the receipt of employment, training, and placement services in any job training program directly funded, in whole or in part, by the Department of Labor. Please note that, to obtain priority of service, a veteran must meet those programs' eligibility requirements. Comprehensive policy guidance is being developed and will be issued in the near future.

Part VIII. Paperwork Reduction Act Notice (Public Law 104–13)

This collection of information is approved under the Office of Management and Budget (OMB) control number 1225–0080, which expires 12/

31/05. Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number. The public reporting burden for this collection of information is estimated to average six (6) to twelve (12) hours to complete the grant application; two (2) to five (5) hours for quarterly reports; and four (4) to ten (10) hours for the final report. These estimates include the time for reviewing instructions, researching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Women's Bureau, U.S. Department of Labor, Room S3311, 200 Constitution Ave., NW., Washington, DC 20210, to the attention of Diane Faulkner. Please reference OMB control number 1225–0080.

Signed in Washington, DC, this 12th day of June, 2003.

Lawrence J. Kuss,

Grant Officer.

Appendix

A. Standard Form 424: Application for Federal Assistance
B. Standard Form 424A: Budget Information—Non-Construction Programs
C. Assurances and Certifications Signature Page
D. Survey on Ensuring Equal Opportunity for Applicants, OMB No. 1225–0083

BILLING CODE 4510–23–P

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED	Applicant Identifier
June 5, 2003	

1. TYPE OF SUBMISSION:		3. DATE RECEIVED BY STATE	State Application Identifier
Application ☐ Construction ☐ Non-Construction	Preapplication ☐ Construction ☐ Non-Construction	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, State, and zip code):*	Name and telephone number of person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER *(EIN):*

☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es) ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other*(specify):*

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

☐☐ — ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(Cities, Counties, States, etc.):*

13. PROPOSED PROJECT		14. CONGRESSIONAL DISTRICTS OF:	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ 0.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. No. ☐ PROGRAM IS NOT COVERED BY E. O. 12372
☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

a. Type Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

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Standard Form 424 (Rev. 7-97)
Prescribed by OMB Circular A-102

INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:
1.	Self-explanatory.
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).
3.	State use only (if applicable).
4.	If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5.	Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7.	Enter the appropriate letter in the space provided.
8.	Check appropriate box and enter appropriate letter(s) in the space(s) provided: -- "New" means a new assistance award. -- "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. -- "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9.	Name of Federal agency from which assistance is being requested with this application.
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12.	List only the largest political entities affected (e.g., State, counties, cities).
13.	Self-explanatory.
14.	List the applicant's Congressional District and any District(s) affected by the program or project.
15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BUDGET INFORMATION - Non-Construction Programs

OMB Approval No. 0348-0044

SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$ 0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY (1)	(2)	(3)	(4)	Total (5)
a. Personnel	$	$	$	$	$ 0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges *(sum of 6a-6h)*	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS *(sum of 6i and 6j)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
7. Program Income	$	$	$	$	$ 0.00

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Standard Form 424A (Rev. 7-97)
Prescribed by OMB Circular A-102

Previous Edition Usable

SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$ 0.00
9.				0.00
10.				0.00
11.				0.00
12. TOTAL *(sum of lines 8-11)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$ 0.00	$	$	$	$
14. Non-Federal	0.00				
15. TOTAL *(sum of lines 13 and 14)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTAL *(sum of lines 16-19)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges:	22. Indirect Charges:
23. Remarks:	

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INSTRUCTIONS FOR THE SF-424A

Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0044), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary Lines 1-4 Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in *Column* (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g)

For new applications, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-i - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount, Show under the program

INSTRUCTIONS FOR THE SF-424A (continued)

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8-11 Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) - Enter the contribution to be made by the applicant.

Column (c) - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) - Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) - Enter totals of Columns (b), (c), and (d).

Line 12 - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 - Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 - Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 - Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16-19 - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 - Provide any other explanations or comments deemed necessary.

ASSURANCES AND CERTIFICATIONS - SIGNATURE PAGE

The Department of Labor will not award a grant or agreement where the grantee/recipient has failed to accept the ASSURANCES AND CERTIFICATIONS contained in this section. By signing and returning this signature page, the grantee/recipient is providing the certifications set forth below:

1. Assurances - Non-Construction Programs

2. Certifications Regarding Lobbying, Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions and Certifications Regarding Drug-Free/Tobacco-Free Workplace Requirements.

3. Certification of Release of Information

4. Applicant is not a 501 (c) (4) organization

APPLICANT NAME and LEGAL ADDRESS:

If there is any reason why one of the assurances or certifications listed cannot be signed, please explain. Applicant need only submit and return this signature page with the grant application. All other instructions shall be kept on file by the applicant.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL TITLE

APPLICANT ORGANIZATION DATE SUBMITTED

Please Note: **This signature page and any pertinent attachments which may be required by these assurances and certifications shall be attached to the applicant's Cost Proposal.**

SURVEY ON ENSURING EQUAL OPPORTUNITY FOR APPLICANTS

Federal Agency Use Only

OMB No. 1225-0083 Exp. 02/28/2006

NOTE: Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

Purpose: This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?

☐ Yes ☐ No

2. How many full-time equivalent employees does the applicant have? *(Check only one box).*

☐ 3 or Fewer ☐ 15-50
☐ 4-5 ☐ 51-100
☐ 6-14 ☐ over 100

3. What is the size of the applicant's annual budget? *(Check only one box.)*

☐ Less Than $150,000
☐ $150,000 - $299,999
☐ $300,000 - $499,999
☐ $500,000 - $999,999
☐ $1,000,000 - $4,999,999
☐ $5,000,000 or more

4. Is the applicant a faith-based/religious organization?

☐ Yes ☐ No

5. Is the applicant a non-religious community-based organization?

☐ Yes ☐ No

6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?

☐ Yes ☐ No

7. Has the applicant ever received a government grant or contract (Federal, State, or local)?

☐ Yes ☐ No

8. Is the applicant a local affiliate of a national organization?

☐ Yes ☐ No

Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c)(3) status is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.

2. For example, two part-time employees who each work half-time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.

3. Annual budget means the amount of money your organization spends each year on all of its activities.

4. Self-identify.

5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.

6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.

7. Self-explanatory.

8. Self-explanatory

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **1225-0083**. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to:** Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. **If you have comments or concerns regarding the status of your individual submission of this form, write directly to:** Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

[FR Doc. 03–15344 Filed 6–17–03; 8:45 am]
BILLING CODE 4510–23–C

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. *Type of submission, new, revision, or extension:* Revision.

2. *The title of the information collection:* 10 CFR part 150, ''Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274''.

3. *The form number if applicable:* Not applicable.

4. *How often the collection is required:* 10 CFR 150.16(b), 150.17(c), and 150.19(c) require the submission of reports following specified events, such as the theft or unlawful diversion of licensed radioactive material. The source material inventory reports required under 10 CFR 150.17(b) must be submitted annually by certain licensees.

5. *Who will be required or asked to report:* Agreement State licensees authorized to possess source or special nuclear material at certain types of facilities, or at any one time and location in greater than specified amounts.

6. *An estimate of the number of annual responses:* 12.

7. *The estimated number of annual respondents:* 9 Agreement State licensees.

8. *An estimate of the total number of hours needed annually to complete the requirement or request:* 35 hours.

9. *An indication of whether Section 3507(d), Pub. L. 104–13 applies:* Not applicable.

10. *Abstract:* 10 CFR part 150 provides certain exemptions from NRC regulations for persons in Agreement States. Part 150 also defines activities in Agreement States and in offshore waters over which NRC regulatory authority continues, including certain information collection requirements. The information is needed to permit NRC to make reports to other governments and the International Atomic Energy Agency in accordance with international agreements. The information is also used to carry out NRC's safeguards and inspection programs.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by July 18, 2003. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. Bryon Allen, Office of Information and Regulatory Affairs (3150–0032), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3087.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

Dated at Rockville, Maryland, this 11th day of June, 2003.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 03–15349 Filed 6–17–03; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–08963]

Notice of Finding of No Significant Impact and Availability of Environmental Assessment for License Amendment of Materials License No. 29–15354–01, Aventis Pharmaceuticals, Inc, East Millstone, NJ

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Aventis Pharmaceuticals, Inc. for Materials License No. 29–15354–01, to authorize release of its facility in East Millstone, New Jersey for unrestricted use and has prepared an Environmental Assessment (EA) in support of this action in accordance with the requirements of 10 CFR Part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate.

II. EA Summary

The purpose of the proposed action is to allow for the release of the licensee's East Millstone, New Jersey facility for unrestricted use. Aventis Pharmaceuticals, Inc. has been authorized by NRC since August 10, 2000, to use radioactive materials for research and development including animal studies at the site. On January 20, 2003, Aventis Pharmaceuticals, Inc. requested that NRC release the facility for unrestricted use. Aventis Pharmaceuticals, Inc. has conducted surveys of the facility and determined that the facility meets the license termination criteria in Subpart E of 10 CFR Part 20.

III. Finding of No Significant Impact

The NRC staff has evaluated Aventis Pharmaceuticals, Inc.'s request and the results of the surveys and has concluded that the completed action complies with the criteria in Subpart E of 10 CFR part 20. The staff has prepared the EA (summarized above) in support of the proposed license amendment to terminate the license and release the facility for unrestricted use. On the basis of the EA, NRC has concluded that the environmental impacts from the proposed action are expected to be insignificant and has determined not to prepare an environmental impact statement for the proposed action.

IV. Further Information

The EA and the documents related to this proposed action, including the application for the license amendment and supporting documentation, are available for inspection at NRC's Public Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html* (ADAMS Accession Nos. ML031620018, ML030280251, ML030870319, and ML031611141. These documents are also available for inspection and copying for a fee at the Region I Office, 475 Allendale Road, King of Prussia, PA 19406. Any questions with respect to this action should be referred to Judy Joustra, Nuclear Materials Safety Branch 2, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, telephone (610) 337–5355, fax (610) 337–5269.

Dated at King of Prussia, Pennsylvania this 11th day of June, 2003.

For the Nuclear Regulatory Commission.

John D. Kinneman,

Chief, Nuclear Materials Safety Branch 2, Division of Nuclear Materials Safety, Region I.

[FR Doc. 03–15348 Filed 6–17–03; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Form S–11, OMB Control No. 3235–0067, SEC File No. 270–064

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget request for extension of the previously approved collection of information discussed below.

Form S–11 is the registration statement form used to register securities issued in real estate investment trusts by issuers whose business is primarily that of acquiring and holding investment interest in real estate under the Securities Act of 1933. The information filed with the Commission permits verifications of compliance with securities law requirements and assures public availability and dissemination of such information. Information provided is mandatory. Approximately 150 issuers file Form S–11 annually and it takes approximately 1,892 hours per response for a total burden of 283,800 hours. It is estimated that 25% of the total burden hours (70,950 reporting burden) is prepared by the company. Finally, persons who respond to the collection of information contained in Form S–11 are not required to respond unless the form displays a currently valid control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503; and (ii) Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: June 10, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15311 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–26073; 812–12859]

Dresdner Bank AG, *et al.*; Notice of Application

June 11, 2003.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under section 12(d)(1)(J) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 12(d)(1) of the Act, under sections 6(c) and 17(b) of the Act for an exemption from section 17(a) of the Act, under section 6(c) of the Act for an exemption from section 17(e) of the Act, and under section 17(d) of the Act and rule 17d–1 under the Act to permit certain joint transactions.

Summary of Application: Applicants request an order to permit: (a) Certain registered investment companies and certain private investment companies to use cash collateral from securities lending transactions (''Cash Collateral'') to purchase shares (''Shares'') of certain registered open-end management investment companies (''Registered Investment Funds'') and private investment companies (''Private Investment Funds'', together with the Registered Investment Funds, the ''Investment Funds''); (b) certain registered investment companies to pay an affiliated lending agent a fee based on a share of the revenue derived from securities lending activities; (c) Dresdner Bank AG (''Bank''), Dresdner Kleinwort Wassertein Securities LLC (''DKWS'') and any other Dresdner Entity (as defined below) (each, an ''Affiliated Borrower'') to engage in principal transactions with, and receive brokerage commissions from, certain registered investment companies that are affiliated persons because they hold 5% or more of the outstanding voting securities of an Investment Fund; and (d) certain registered investment companies to lend portfolio securities to Affiliated Borrowers.

Applicants: Bank, DKWS and PIMCO Funds: Multi-Manager Series (the ''Trust'').

Filing Dates: The application was filed on July 19, 2002 and amended on June 2, 2003.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on July 7, 2003, and should be accompanied by proof of service on applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Applicants, c/o Robert Boyd, Dresdner Bank AG, New York Branch, 75 Wall Street, 31st Floor, New York, NY 10005.

FOR FURTHER INFORMATION CONTACT: Emerson S. Davis, Sr., Senior Counsel, at (202) 942–0714, or Nadya B. Roytblat, Assistant Director, 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 from the Commission's Public Reference Branch, 450 5th Street, NW., Washington DC 20549–0102 (telephone (202) 942–8090).

Applicants' Representations

1. The Bank, a German public limited company, is wholly-owned by Allianz AG (''Allianz''), a German international financial services company. DKWS, registered as a broker-dealer under the Securities Exchange Act of 1934, is a wholly-owned subsidiary of Allianz. The Trust, a Massachusetts business trust, is an open-end management investment company registered under the Act and advised by PIMCO Advisors Fund Management LLC, an investment adviser under the Investment Advisers Act of 1940 that is an indirect subsidiary of Allianz. Series of the Trust and any other registered management investment companies or series thereof currently or in the future advised by the Bank or any entity controlling, controlled by, or under common control with the Bank (the Bank and each

entity, a ''Dresdner Entity'') are referred to as ''Affiliated Lending Funds.'' [1]

2. The New York branch of the Bank operates a securities lending program (''Program''). Lenders in the Program include, among others: (a) Affiliated Lending Funds, (b) other registered management investment companies or series thereof (''Other Lending Funds,'' together with the Affiliated Lending Funds, the ''Registered Lending Funds'') and (c) investment entities excluded from the definition of investment company under section 3(c)(1) or 3(c)(7) of the Act (''Private Lending Funds,'' together with the Registered Lending Funds, the ''Lending Funds'').

3. The Registered Investment Funds will be open-end management investment companies registered under the Act and advised by a Dresdner Entity. The Private Investment Funds will rely on section 3(c)(1) or 3(c)(7) of the Act and will be advised by a Dresdner Entity. Shares of the Investment Funds will not be subject to any sales load, redemption fee, asset-based sales charge or service fee, as defined in rule 2830(b)(9) of the Conduct Rules of the National Association of Securities Dealers, Inc. (''NASD Conduct Rules''). Certain Investment Funds will hold themselves out as money market funds and will comply with rule 2a–7 under the Act. Other Investment Funds will seek to achieve a high level of current income consistent with the preservation of capital and the maintenance of liquidity and will invest in high quality securities with relatively short maturities.

4. Under the Program, the Bank will enter into an agreement (''Lending Agreement'') with each Lending Fund that appoints the Bank to serve as its lending agent and authorizes the Bank to enter into a master borrowing agreement (''Borrowing Agreement'') with persons designated by the Lending Fund as eligible to borrow its portfolio securities (each a ''Borrower''). Under the Lending Agreement, the Bank will invest any Cash Collateral received in the Program on behalf of a Lending Fund directly in various types of instruments, accounts and investment vehicles, including Shares of one or more Investment Funds. The Lending Agreement and the Borrowing Agreement will also establish for each transaction the initial and on-going collaterization requirements and the types of collateral that may be accepted. Personnel providing day-to-day lending agency services to the Affiliated Lending Funds will not provide investment advisory services to the Affiliated Lending Funds or participate in any way in the selection of portfolio securities for, or other aspects of the management of, the Affiliated Lending Funds. The duties to be performed by the Bank as lending agent with respect to any Registered Lending Fund will not exceed the parameters described in Norwest Minnesota, N.A., SEC No-Action Letter (pub. avail. May 25, 1995). The Bank will not purchase Shares of an Investment Fund with Cash Collateral unless participation in the Program has been approved by a majority of the directors or trustees of the Registered Lending Fund that are not ''interested persons'' within the meaning of section 2(a)(19) of the Act.

5. When a securities loan is collateralized by Cash Collateral, the Borrower is entitled to receive a fixed return on the collateral for the term of the loan (''Borrower's Rebate''). The difference between the Borrower's Rebate and the actual return on the investment of the collateral will be divided between the Lending Fund and the Bank in accordance with the terms of the Lending Agreement. When the collateral is not Cash Collateral, the Lending Agreement will set a loan fee to be paid by the Borrower, which likely will approximate the return the Lending Fund would receive had the Borrower delivered Cash Collateral. The amount of the fee will be divided between the Lending Fund and the Bank in accordance with the terms of the Lending Agreement.

6. The applicants request relief to permit: (a) The Lending Funds to invest Cash Collateral in the Investment Funds, (b) the Registered Lending Funds to pay the Bank a fee based on a share of the revenue derived from securities lending activities, (c) Affiliated Lending Funds to lend portfolio securities to the Affiliated Borrowers, and (d) a Dresdner Entity to engage in principal transactions with, and receive brokerage commissions from, the Other Lending Funds.

Applicants' Legal Analysis

A. Investment of Cash Collateral by the Lending Funds in the Investment Funds

1. Section 12(d)(1)(A) of the Act provides that no registered investment company may acquire securities of another investment company representing more than 3% of the acquired company's outstanding voting stock, more than 5% of the acquiring company's total assets, or, together with the securities of other investment companies, more than 10% of the acquiring company's total assets. Section 12(d)(1)(B) of the Act provides that no registered open-end investment company may sell its securities to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person or transaction from any provision of section 12(d)(1) if and to the extent that the exemption is consistent with the public interest and the protection of investors.

2. Applicants request an exemption under section 12(d)(1)(J) to permit the Lending Funds to invest Cash Collateral in Shares of the Registered Investment Funds in excess of the limits imposed by section 12(d)(1)(A), and each Registered Investment Fund to sell its Shares to the Lending Funds in excess of the limits in section 12(d)(1)(B).

3. Applicants state that none of the abuses meant to be addressed by section 12(d)(1) of the Act will be created by the proposed investment of Cash Collateral in the Registered Investment Funds. Applicants represent that the proposed arrangement will not result in an inappropriate layering of fees because Shares of the Investment Funds will be sold without a sales load, redemption fee, asset-based sales charge or service fee as defined in the NASD Conduct Rules. Applicants also represent that no Investment Fund will acquire shares of any other investment company in excess of the limits contained in section 12(d)(1)(A) of the Act.

4. Sections 17(a)(1) and 17(a)(2) of the Act prohibit an affiliated person of a registered investment company, or any affiliated person of the affiliated person (''second-tier affiliate'') from selling any security to, or purchasing any security from, the registered investment company. Section 2(a)(3) of the Act defines an ''affiliated person'' of another person to include: any person directly or indirectly owning, controlling, or holding with power to vote 5% or more of the outstanding voting securities of the other person; any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person; any person directly or indirectly controlling, controlled by, or under common control with, the other person; and, in the case of an investment company, its investment adviser. Control is defined

[1] All existing Affiliated Lending Funds that currently intend to rely on the requested relief have been named as applicants. Any other existing or future entity may rely on the requested relief only in accordance with the terms and conditions of the application.

in section 2(a)(9) of the Act to mean ''the power to exercise a controlling influence over the management or policies of a company, unless such power is solely the result of an official position with such company.''

5. Applicants state that because Dresdner Entities will serve as investment advisers to Affiliated Lending Funds and the Investment Funds, the Dresdner Entities could be deemed to control the Affiliated Lending Funds and the Investment Funds, and the Dresdner Entities are under common control. Accordingly, the Affiliated Lending Funds and the Investment Funds may be deemed to be under common control and affiliated persons of each other. Further, applicants state that if any Other Lending Fund acquires 5% or more of an Investment Fund's Shares, the Investment Fund may be deemed an affiliated person of the Other Lending Fund. As a result, applicants state that the sale of Shares of the Investment Funds to the Registered Lending Funds, and the redemption of such Shares in connection with the investment of Cash Collateral may be prohibited under Section 17(a).

6. Section 17(b) of the Act authorizes the Commission to exempt a transaction from section 17(a) if the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policy of each registered investment company concerned and with the general purposes of the Act. Section 6(c) of the Act authorizes the Commission to exempt any person or transaction from any provision of the Act if the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

7. Applicants request an order under sections 6(c) and 17(b) of the Act to permit the Registered Lending Funds to invest Cash Collateral in Shares of the Investment Funds. Applicants submit that the terms of the proposed transactions, including the consideration to be paid or received, are reasonable and fair, do not involve overreaching and are consistent with the general purposes of the Act as well as the policies of the respective Registered Lending Funds. The Registered Lending Funds will purchase and redeem Shares on the same terms and the same basis as the Shares are purchased and redeemed by all other shareholders of the Investment Funds. Applicants state that the Registered Lending Funds will only be permitted to invest in an Investment Fund if that Investment Fund invests in instruments that the Registered Lending Fund has previously determined are acceptable medium for the investment for Cash Collateral. Applicants state that Cash Collateral of a Registered Lending Fund that is a money market fund will not be used to acquire Shares of any Investment Fund that does not comply with rule 2a–7 under the Act. Applicants further state that the investment of Cash Collateral will comply with all present and future Commission and staff positions concerning securities lending arrangements. Applicants also state that the Private Investment Funds will comply with the provisions of the Act dealing with affiliated transactions, leveraging and issuing senior securities, and rights of redemption.

8. Section 17(d) of the Act and rule 17d–1 under the Act prohibit any affiliated person or principal underwriter for a registered investment company, or any second tier affiliate, acting as principal, from effecting any transaction in connection with any joint enterprise or other joint arrangement or profit sharing plan in which the investment company participates, without an order of the Commission. Under rule 17d–1, in passing on applications for orders under section 17(d), the Commission considers whether the participation of the registered investment company is consistent with the provisions, policies, and purposes of the Act and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

9. Applicants state that the Lending Funds (by purchasing and redeeming Shares of the Investment Funds), the Dresdner Entities (by managing the portfolio securities of the Affiliated Lending Funds and Investment Funds at the same time that the Affiliated Lending Funds' Cash Collateral is invested in Shares), the Bank (by acting as lending agent, investing Cash Collateral in Shares, and receiving a portion of the revenue generated by securities lending transactions), and the Investment Funds (by selling Shares to and redeeming Shares from the Lending Funds) could be deemed to be participants in a joint enterprise or other joint arrangement within the meaning of section 17(d) of the Act and rule 17d–1 under the Act. Applicants request an order in accordance with section 17(d) and rule 17d–1 to permit the transactions incident to the investment of Cash Collateral of the Lending Funds in the Investment Funds.

10. Applicants state that the investment by the Lending Funds in Shares will be on the same basis and will be indistinguishable from any other shareholder account maintained by the Investment Funds. In addition, applicants state that all investors in Shares will be subject to the same eligibility requirements imposed by the Investment Funds and all Shares will be priced in the same manner and will be redeemable under the same terms.

B. Payment of Lending Agent Fees to the Bank

1. Applicants also believe that a lending agent agreement between the Registered Lending Funds and the Bank, under which compensation is based on a share of the revenue generated by the Program, may be a joint enterprise or other joint arrangement within the meaning of section 17(d) of the Act and rule 17d–1 under the Act. Consequently, applicants request an order permitting the Registered Lending Funds to pay, and the Bank, as lending agent, to accept fees based on a share of the revenue generated by securities lending transactions under the Program.

2. Applicants propose that each Affiliated Lending Fund adopt the following procedures to ensure that the proposed fee arrangement and the other terms governing the relationship with the Bank, as lending agent, will meet the standards of rule 17d–1:

(a) In connection with the approval of the Bank as lending agent for an Affiliated Lending Fund and implementation of the proposed fee arrangement, a majority of the board of directors or trustees of the Affiliated Lending Fund (the ''Board''), including a majority of the directors or trustees that are not ''interested persons'' as defined in section 2(a)(19) of the Act (''Independent Directors''), will determine that (i) the Lending Agreement with the Bank is in the best interests of the Affiliated Lending Fund and its shareholders, (ii) the services to be performed by the Bank are appropriate for the Affiliated Lending Fund, (iii) the nature and quality of the services provided by the Bank are at least equal to those services offered and provided by others, and (iv) the fees for the Bank's services are within the range of, but in any event no higher than, the fees charged by the Bank to comparable unaffiliated securities lending clients for services of the same nature and quality.

(b) Each Affiliated Lending Fund's Lending Agreement with the Bank for lending agent services will be reviewed annually by the Board and will be approved for continuation only if a majority of the Board, including a

majority of Independent Directors, makes the findings referred to in paragraph (a) above.

(c) In connection with the initial implementation of an arrangement whereby the Bank will be compensated as lending agent based on a percentage of the revenue generated by an Affiliated Lending Fund's participation in the Program, the Affiliated Lending Fund's Board shall secure a certificate from the Bank attesting to the factual accuracy of clause (iv) in paragraph (a) above. In addition, the Board will request and evaluate, and the Bank shall furnish, such information and materials as the Board, with and upon the advice of agents, consultants or counsel, determines to be appropriate in making the findings referred to in paragraph (a) above. Such information shall include, in any event, information concerning the fees charged by the Bank to other institutional investors for providing similar services.

(d) The Board of each Affiliated Lending Fund, including a majority of the Independent Directors, will (i) determine at each regular quarterly meeting that the loan transactions during the prior quarter were effected in compliance with the conditions and procedures set forth in the application and (ii) review no less frequently than annually the conditions and procedures set forth in the application for continuing appropriateness.

(e) Each Affiliated Lending Fund will (i) maintain and preserve permanently in an easily accessible place a written copy of the procedures and conditions described in the application and (ii) maintain and preserve for a period of not less than six (6) years from the end of the fiscal year in which any loan transaction pursuant to the Program occurred, the first two (2) years in an easily accessible place, a written record of each such loan transaction setting forth a description of the security loaned, the identity of the person on the other side of the loan transaction, the terms of the loan transaction, and the information or materials upon which the determination was made that each loan was made in accordance with the procedures set forth above and the conditions to the application.

3. With respect to Other Lending Funds, applicants state that the affiliations with the Bank arise solely as result of the investment of Cash Collateral in the Investment Funds. Applicants state that a Dresdner Entity would not have any influence over the decisions made by any Other Lending Fund, and that any fee arrangement between the Other Lending Funds and the Bank will be the product of arm's-length bargaining.

C. Lending to Affiliated Borrowers

1. Section 17(a)(3) of the Act makes it unlawful for any affiliated person of a registered investment company or second-tier affiliate, acting as principal, to borrow money or other property from the registered investment company. Under section 2(a)(3)(C) of the Act, an Affiliated Borrower would be deemed a second-tier affiliate of Affiliated Lending Funds for which Dresdner Entities serve as investment advisers. In addition, applicants state that to the extent that an Affiliated Lending Fund or Other Lending Fund acquires Shares of an Investment Fund, an Affiliated Borrower also could be deemed a second-tier affiliate of the Affiliated Lending Fund or Other Lending Fund. Accordingly, section 17(a)(3) would prohibit the Affiliated Borrowers from borrowing securities from the Registered Lending Funds.

2. As noted above, section 17(d) and rule 17d–1 generally prohibit joint transactions involving registered investment companies and their affiliates unless the Commission has approved the transaction. Applicants request relief under sections 6(c) and 17(b) of the Act exempting the Registered Lending Funds from section 17(a)(3), and under section 17(d) and rule 17d–1 to permit the Registered Lending Funds to lend portfolio securities to Affiliated Borrowers.

3. Applicants state that each loan to an Affiliated Borrower by an Affiliated Lending Fund will be made with a spread that is no lower than that applied to comparable loans to unaffiliated Borrowers.[2] Applicants further state that at least 50% of the loans made by the Affiliated Lending Funds, on an aggregate basis, will be made to unaffiliated Borrowers. Moreover, all loans will be made with spreads that are no lower than those set forth in a schedule of spreads which will be established by each Affiliated Lending Fund's Board and a majority of the Independent Directors and monitored by an officer of the Affiliated Lending Fund. The Board, including a majority of the Independent Directors, also will review quarterly reports on all lending activity.

[2] A ''spread'' is the compensation earned by a Lending Fund from a securities loan, which compensation is in the form either of a lending fee payable by the Borrower to the Lending Fund (when non-cash collateral is posted) or of the excess retained by the Lending Fund over a rebate rate payable by the Lending Fund to the Borrower (when Cash Collateral is posted and then invested by the Lending Fund).

D. Transactions by Other Lending Funds with Dresdner Entities

1. As noted above, sections 17(a)(1), (2) and (3) prohibit certain principal transactions between a registered investment company and its affiliates. To the extent that a Dresdner Entity and the Investment Funds are deemed to be under common control, they could be affiliated persons of one another. Applicant also asserts that each Dresdner Entity that serves as investment adviser to an Investment Fund could be deemed an affiliated person of the Investment Fund and a second-tier affiliate of an Other Lending Fund that owns 5% or more of an Investment Fund.

2. Applicants request relief under sections 6(c) and 17(b) from section 17(a) to permit principal transactions between Other Lending Funds and Dresdner Entities where the affiliation between the parties arises solely as a result of an investment by an Other Lending Fund in Shares of the Investment Funds. Applicants state that there will be no element of self-dealing because the Dresdner Entities will have no influence over the decisions made by any Other Lending Fund. Applicants assert that each transaction will be the product of arm's length bargaining. Because the interests of the Other Lending Funds' investment advisers are solely and directly aligned with those of the Other Lending Funds, applicants believe it is reasonable to conclude that the consideration paid to or received by the Other Lending Funds in connection with a principal transaction with a Dresdner Entity will be reasonable and fair.

3. Section 17(e) of the Act makes it unlawful for any affiliated person of a registered investment company, or any second-tier affiliate, acting as a broker in connection with the sale of securities to or by that registered investment company, to receive from any source a commission for effecting the transaction that exceeds specified limits. Rule 17e–1 provides that a commission shall be deemed an usual and customary broker's commission if certain procedures are followed by the registered investment company.

4. Applicants request relief under section 6(c) from section 17(e) to the extent necessary to permit Dresdner Entities to receive fees or commissions for acting as broker or agent in connection with the purchase or sale of securities for any Other Lending Fund for which a Dresdner Entity becomes a second-tier affiliate solely because of the investment by the Other Lending Fund in Shares of Investment Funds.

5. Applicants submit that brokerage or similar transactions by Dresdner Entities for the Other Lending Funds raise no possibility of self-dealing or any concern that the Other Lending Funds would be managed in the interest of the Dresdner Entities. Applicants believe that each transaction between an Other Lending Fund and a Dresdner Entity would be the product of arm's length bargaining because each investment adviser to an Other Lending Fund would have no interest in benefiting a Dresdner Entity at the expense of an Other Lending Fund.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

General

1. The securities lending program of each Registered Lending Fund will comply with all present and future applicable guidelines of the Commission and its staff regarding securities lending arrangements.

2. The approval of an Affiliated Lending Fund's Board, including a majority of the Independent Directors, shall be required for the initial and subsequent approvals of the Bank's service as lending agent for the Affiliated Lending Fund pursuant to the Program, for the institution of all procedures relating to the Program as it relates to the Affiliated Lending Fund, and for any periodic review of loan transactions for which the Bank acted as lending agent pursuant to the Program.

3. No Registered Lending Fund will purchase Shares of any Investment Fund unless participation in the Program has been approved by a majority of the Independent Directors of the Registered Lending Fund. The Independent Directors will evaluate the Program no less frequently than annually and determine that investing Cash Collateral in the Investment Funds is in the best interests of the shareholders of the Registered Lending Fund.

Investment of Cash Collateral

4. Investment in Shares of an Investment Fund by a particular Registered Lending Fund will be consistent with the Registered Lending Fund's investment objectives and policies. A Registered Lending Fund that complies with rule 2a-7 under the Act will not invest its Cash Collateral in an Investment Fund that does not comply with the requirements of rule 2a–7 under the Act.

5. Investment in Shares of an Investment Fund by a particular Registered Lending Fund will be in accordance with the guidelines regarding the investment of Cash Collateral specified by the Registered Lending Fund in the Lending Agreement. A Registered Lending Fund's Cash Collateral will be invested in a particular Investment Fund only if that Investment Fund has been approved for investment by the Registered Lending Fund and if that Investment Fund invests in the types of instruments that the Registered Lending Fund has authorized for the investment of its Cash Collateral.

6. An Investment Fund will not acquire securities of any investment company in excess of the limits in Section 12(d)(1)(A).

7. Shares will not be subject to a sales load, redemption fee, asset-based sales charge or service fee (as defined in rule 2830(b)(9) of the NASD Conduct Rules).

Private Investment Funds

8. Each Registered Lending Fund will purchase and redeem Shares of a Private Investment Fund as of the same time and at the same price, and will receive dividends and bear its proportionate share of expenses on the same basis as other shareholders of the Private Investment Fund. A separate account will be established in the shareholder records of the Private Investment Fund for the account of each Registered Lending Fund.

9. Each Private Investment Fund in which a Registered Lending Fund invests will comply with the requirements of sections 17(a), (d), and (e), and 18 of the Act as if the Private Investment Fund were a registered open-end investment company. With respect to all redemption requests made by a Registered Lending Fund, the Private Investment Fund will comply with section 22(e) of the Act. The Dresdner Entity serving as investment adviser, trustee, general partner or managing member of a Private Investment Fund will adopt procedures designed to ensure that the Private Investment Fund will comply with the requirements of sections 17(a), (d), and (e), 18, and 22(e) of the Act, will periodically review and periodically update as appropriate such procedures, will maintain books and records describing such procedures, and will maintain the records required by rules 31a–1(b)(1), 31a–1(b)(2)(ii), and 31a–1(b)(9) under the Act. All books and records required to be maintained pursuant to this condition will be maintained and preserved for a period of not less than six years from the end of the fiscal year in which any transaction occurred, the first two years in an easily accessible place, and will be subject to examination by the Commission and its staff.

10. The net asset value per Share with respect to Shares of the Private Investment Funds will be determined separately for each Private Investment Fund by dividing the value of the assets belonging to that Private Investment Fund, less the liabilities of that Private Investment Fund, by the number of Shares outstanding with respect to that Private Investment Fund.

11. Any Private Investment Fund that operates as a money market fund and uses the amortized cost method of valuation, as defined in rule 2a-7 under the Act, will comply with rule 2a-7. With respect to each such Private Investment Fund, the Dresdner Entity serving as investment adviser, trustee, general partner or managing member shall adopt and monitor the procedures described in rule 2a-7(c)(7) under the Act and will take such other actions as are required to be taken pursuant to these procedures. The Registered Lending Funds may only purchase Shares of such Private Investment Fund if the Dresdner Entity serving as investment adviser, trustee, general partner or managing member determines on an ongoing basis that the Private Investment Fund is in compliance with rule 2a-7. Such investment adviser, trustee, general partner or managing member shall preserve for a period not less than six years from the date of determination, the first two years in an easily accessible place, a record of such determination and the basis upon which the determination was made. This record will be subject to examination by the Commission and its staff.

Loans to Affiliated Borrowers

12. The Affiliated Lending Funds, on an aggregate basis, will make at least 50% of their portfolio securities loans to unaffiliated Borrowers.

13. An Affiliated Lending Fund will not make any loan to an Affiliated Borrower unless the income attributable to such loan fully covers the transaction costs incurred in making the loan.

14. a. All loans will be made with spreads no lower than those set forth in a schedule of spreads which will be established and may be modified from time to time by each Affiliated Lending Fund's Board and by a majority of the Independent Directors (the ''Schedule of Spreads'').

b. The Schedule of Spreads will set forth rates of compensation to the Affiliated Lending Funds that are reasonable and fair and that are

determined in light of those considerations set forth in the application.

c. The Schedule of Spreads will be uniformly applied to all Borrowers of the Affiliated Lending Fund's portfolio securities, and will specify the lowest allowable spread with respect to a loan of securities to any Borrower.

d. If a security is lent to an unaffiliated Borrower with a spread higher than the minimum set forth in the Schedule of Spreads, all comparable loans to Affiliated Borrowers will be made at no less than the higher spread.

e. The securities lending program for each Affiliated Lending Fund will be monitored on a daily basis by an officer of each Affiliated Lending Fund who is subject to section 36(a) of the Act. This officer will review the terms of each loan to Affiliated Borrowers for comparability with loans to unaffiliated Borrowers and conformity with the Schedule of Spreads, and will periodically, and at least quarterly, report his or her findings to the Affiliated Lending Fund's Board, including a majority of the Independent Directors.

15. The total value of securities loaned to any one Borrower on the approved list of Borrowers of securities from an Affiliated Lending Fund will be in accordance with a schedule to be approved by the Board of each Affiliated Lending Fund, but in no event will the total value of securities loaned to any one Affiliated Borrower exceed 10% of the net assets of the Affiliated Lending Fund, computed at market.

16. The Boards of the Affiliated Lending Funds, including a majority of the Independent Directors, (a) will determine no less frequently than quarterly that all transactions with the Affiliated Borrowers effected during the preceding quarter were effected in compliance with the requirements of the procedures adopted by the Boards and the conditions of this order if granted and that such transactions were conducted on terms that were reasonable and fair; and (b) will review no less frequently than annually such requirements and conditions for their continuing appropriateness.

17. The Affiliated Lending Funds will maintain and preserve permanently in an easily accessible place a written copy of the procedures (and any modifications thereto) which are followed in lending securities, and shall maintain and preserve for a period of not less than six years from the end of the fiscal year in which any loan occurs, the first two years in an easily accessible place, a written record of each loan setting forth the number of shares loaned, the face amount of the securities loaned, the fee received (or the rebate rate remitted), the identity of the Borrower, the terms of the loan, and any other information or materials upon which the finding was made that each loan made to an Affiliated Borrower was fair and reasonable, and that the procedures followed in making such loan were in accordance with the procedures and other undertakings set forth in the application.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15312 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 26076; 812–12674]

Franklin Gold and Precious Metals Fund, et al.; Notice of Application

June 12, 2003.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under section 12(d)(1)(J) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 12(d)(1)(A) and (B) of the Act, under sections 6(c) and 17(b) of the Act for an exemption from section 17(a) of the Act, and under section 17(d) of the Act and rule 17d–1 under the Act to permit certain joint transactions.

APPLICANTS: Franklin Gold and Precious Metal Fund, Franklin Capital Growth Fund, Franklin High Income Trust, Franklin Custodian Funds, Inc., Franklin California Tax-Free Income Fund, Inc., Franklin New York Tax-Free Income Fund, Franklin Federal Tax-Free Income Fund, Franklin Tax-Free Trust, Franklin California Tax-Free Trust, Franklin New York Tax-Free Trust, Franklin Investors Securities Trust, Institutional Fiduciary Trust, Franklin Value Investors Trust, Franklin Managed Trust, Franklin Municipal Securities Trust, Franklin Floating Rate Master Trust, Franklin Strategic Mortgage Portfolio, Franklin Strategic Series, Adjustable Rate Securities Portfolios, Franklin Templeton International Trust, Franklin Global Trust, Franklin Real Estate Securities Trust, Franklin Templeton Global Trust, Franklin Templeton Variable Insurance Products Trust, Franklin Universal Trust, Franklin Multi-Income Trust, Franklin Templeton Fund Allocator Series, Franklin Money Fund, Franklin Templeton Money Fund Trust, Franklin Federal Money Fund, Franklin Tax-Exempt Money Fund, Franklin Mutual Series Fund Inc., Franklin Floating Rate Trust, The Money Market Portfolios (collectively, the ''Franklin Funds''); Templeton Growth Fund, Inc., Templeton Funds, Inc., Templeton Global Smaller Companies Fund, Inc., Templeton Income Trust, Templeton Capital Accumulator Fund (formerly, Templeton Capital Accumulator Fund Inc.), Templeton Global Opportunities Trust, Templeton Institutional Funds, Inc., Templeton Developing Markets Trust, Templeton Global Investment Trust, Templeton Emerging Markets Fund (formerly Templeton Emerging Markets Fund, Inc.), Templeton Global Income Fund, Inc., Templeton Emerging Markets Income Fund, Templeton China World Fund, Inc., Templeton Dragon Fund, Inc., Templeton Russia and East European Fund, Inc. (formerly, Templeton Russia Fund, Inc.) (collectively, the ''Templeton Funds'') FTI Funds; (the Franklin Funds, the Templeton Funds and the FTI Funds are collectively, together with any other registered management investment company or series thereof advised by an Adviser, as defined below, the ''Franklin Templeton Funds''); Franklin Advisers, Inc., Franklin Advisory Services, LLC, Franklin Investment Advisory Services Inc., Franklin Mutual Advisers, LLC, Franklin Private Client Group, Inc., Templeton/Franklin Investment Services Inc., Templeton Investment Counsel, LLC, Franklin Templeton Asset Strategies, LLC, Fiduciary International, Inc., Franklin Templeton Investment Management Limited, Franklin Templeton Investments (Asia) Limited, Franklin Templeton Investments Corp., Templeton Asset Management LTD., Templeton Global Advisors Limited, Fiduciary Investment Management International, Inc., Fiduciary Trust International Limited, FTI Institutional, LLC (''Advisers''), together with any entity controlling, controlled by, or under common control with Advisers that acts in the future as investment adviser for the Franklin Templeton Funds, the Unregistered Funds (as defined below), or a Managed Account (as defined below) (included in the term ''Advisers''); the Advisers on behalf of certain private investment companies or series thereof that are excluded from the definition of ''investment company'' pursuant to section 3(c)(1), section 3(c)(7) or section 3(c)(11) of the 1940 Act for which one of the Advisers

currently or in the future serves as investment adviser or trustee (the ''Unregistered Funds''); and the Advisers on behalf of institutional and individual accounts that are not pooled investment vehicles for which one of the Advisers currently or in the future serves as investment adviser (the ''Managed Accounts'').

SUMMARY OF APPLICATION: The applicants request an order that would permit (a) certain registered management investment companies, Unregistered Funds and Managed Accounts to invest uninvested cash and cash collateral in affiliated registered and unregistered money market funds, and (b) the registered investment companies and certain affiliated entities to continue to engage in purchase and sale transactions involving portfolio securities in reliance on rule 17a–7 under the Act. The order would supersede a prior order.[1] The order also would amend a prior order.[2]

FILING DATES: The application was filed on October 26, 2001 and amended on October 18, 2002, and June 10, 2003.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on July 7, 2003, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, NW., Washington, DC 20549–0609; Applicants, c/o David P. Goss, Esq., Franklin Templeton Investments, One Franklin Parkway, San Mateo, CA 94403–1906.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 942–0574 or Todd Kuehl, Branch Chief, 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 Commission's Public Reference Branch, 450 Fifth Street, NW, Washington, DC 20549–0102 (telephone (202) 942–8090).

Applicants' Representations

1. The Franklin Templeton Funds are organized as Maryland Corporations, California Corporations, Massachusetts business trusts, or Delaware statutory trusts. The Franklin Templeton Funds are registered under the Act as open-end or closed-end management investment companies. The Advisers are each registered under the Investment Advisers Act of 1940 (''Advisers Act'') together with any entity controlling, controlled by and under common control with Advisers that acts in the future as investment adviser for the Franklin Templeton Funds, an Unregistered Fund, as defined below, Managed Account, as defined below, included in the term Advisers.[3]

2. Certain of the Franklin Templeton Funds or series thereof are money market funds subject to the requirements of rule 2a–7 under the Act (''Registered Money Market Funds''). The Franklin Templeton Funds or series thereof that are not money market funds are the ''Registered Funds.'' Certain of the Unregistered Funds that rely on section 3(c)(1) or 3(c)(7) of the Act also operate as cash management vehicles (''Unregistered Money Market Funds,''[4] together with the Registered Money Market Funds, the ''Money Market Funds''). The Unregistered Money Market Funds will comply with rule 2a–7 under the Act.

3. The Registered Funds, Unregistered Funds and Managed Accounts (''Participating Funds'') have, or may be expected to have, cash that has not been invested in portfolio securities (''Uninvested Cash'').[5] Uninvested Cash may result from a variety of sources, including dividends or interest received on portfolio securities, unsettled securities transactions, reserves held for strategic purposes, scheduled maturity of investments, liquidation of investment securities to meet anticipated redemptions and dividend payments, and new monies received from investors. Certain of the Registered Participating Funds have the ability to increase their income by participating in a securities lending program (''Securities Lending Program'') under which they may lend portfolio securities to registered broker-dealers or other institutional investors deemed by the respective Adviser to be of good standing. The loans are continuously secured by collateral which may include cash (''Cash Collateral,'' together with Uninvested Cash, ''Cash Balances'') equal at all times in value to at least the market value of the securities loaned.

4. Applicants request an order of the Commission to permit: (i) The Participating Funds to use their Cash Balances to purchase shares of one or more of the Money Market Funds; (ii) the Money Market Funds to sell their shares to, and purchase (redeem) such shares from, the Participating Funds; and (iii) the Advisers to effect the above transactions (the ''Proposed Transactions''). The requested order also would permit the Participating Funds and the Money Market Funds to continue to engage in interfund purchase and sale transactions (''Interfund Transactions'').

Applicants' Legal Analysis

I. Investment of Cash Balances by the Participating Funds in the Money Market Funds

A. Section 12(d)(1)

1. Section 12(d)(1)(A) of the Act provides that no registered investment company may acquire securities of another investment company, and no investment company may inquire securities of a registered investment company, if such securities represent more than 3% of the acquired company's outstanding voting stock, more than 5% of the acquiring company's total assets, or if such securities, together with the securities of other acquired investment companies, represent more than 10% of the acquiring company's assets. Section 12(d)(1)(B) of the Act provides that no registered open-end investment company may sell its securities to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be

[1] *Franklin Gold Fund, et. al,* Investment Company Act Release Nos. 23633 (Jan. 5, 1999)(Notice) and 23675 (Feb. 2, 1999)(Order).

[2] *Franklin Templeton Fund Manager, et. al,* Investment Company Act Release Nos. 21964 (May 20, 1996)(Notice) and 22022(June 17, 1996)(Order) (the ''Fund of Funds Order'').

[3] All existing Advisers and Franklin Templeton Funds that currently intend to rely on the requested order are named as applicants. Any other entity will not rely on the relief requested except in accordance with the terms and conditions in the application.

[4] In addition to cash management vehicles that are excluded from the definition of an investment company pursuant to section 3(c)(1) or section 3(c)(7) of the 1940 Act, Unregistered Money Market Funds may include one or more entities that are organized offshore and offer their shares privately to U.S. investors (''Offshore Money Market Funds,'' included in the term ''Unregistered Money Market Funds''). Any Offshore Money Market Fund will have as its investment adviser or trustee one of the Advisers.

[5] The Participating Funds that are Registered Funds are the ''Registered Participating Funds.'' The Participating Funds that are Unregistered Funds and Management Accounts are the ''Unregistered Participating Funds.''

owned by investment companies. Any entity that is excluded from the definition of investment company under section 3(c)(1) or 3(c)(7) of the Act is deemed to be an investment company for the purposes of the 3% limitation specified in sections 12(d)(1)(A) and (B) with respect to purchases by and sales to such entity of securities of a registered investment company.

2. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction from any provision of section 12(d)(1) if and to the extent that such exemption is consistent with the public interest and the protection of investors. Applicants request relief under section 12(d)(1)(J) to permit the Participating Funds to use their Cash Balances to acquire shares of the Registered Money Market Funds in excess of the percentage limitations in section 12(d)(1)(A), provided however, that in all cases a Registered Participating Fund's aggregate investment of Uninvested Cash in shares of the Money Market Funds will not exceed 25% of the Registered Participating Fund's total assets at any time. Applicants also request relief to permit the Registered Money Market Funds to sell their securities to the Participating Funds in excess of the percentage limitations in section 12(d)(1)(B).[6]

3. Applicants state that the proposed arrangement will not result in the abuses that sections 12(d)(1)(A) and (B) were intended to prevent. Applicants state that because each Registered Money Market Fund maintains a highly liquid portfolio and the Advisers will serve as investment advisers to both the Participating Funds and the Money Market Funds, the Advisers will not be susceptible to undue influence regarding their management of the Registered Money Market Funds due to threatened redemptions or loss of fees. Applicants state that the proposed arrangement will not result in inappropriate layering of fees. Shares of the Money Market Funds sold to the Participating Funds will not be subject to a sales load, redemption fee, distribution fee under a plan adopted in accordance with rule 12b–1 under the Act or service fee (as defined in rule 2830(b)(9) of the Conduct Rules of the National Association of Securities Dealers Inc., (a ''Service Fee''). If a Money Market Fund offers more than one class of shares, a Registered Participating Fund will invest in the class with the lowest expense ratio at the time of investment. Before the next meeting of the board of directors or trustees (''Board'') of the Registered Participating Fund that invests in the Money Market Fund is held for the purpose of voting on an advisory contract under section 15 of the Act, the Adviser will provide the Board with specific information regarding the approximate cost to the Adviser for, or portion of the advisory fee under the existing advisory contract attributable to, managing the Uninvested Cash of the Registered Participating Fund that can be expected to be invested in the Money Market Fund. Before approving any advisory contract under section 15, the Board of the Registered Participating Fund, including a majority who are not ''interested persons,'' as that term is defined in section 2(a)(19) of the Act (''Disinterested Directors''), shall consider to what extent, if any, the advisory fees charged to the Registered Participating Fund by the Adviser should be reduced to account for reduced services provided to the Registered Participating Fund by the Adviser as a result of Uninvested Cash being invested in the Money Market Funds. Applicants represent that no Money Market Fund will acquire securities of any other investment company in excess of the limitations contained in section 12(d)(1)(A) of the Act.

B. Section 17(a) of the Act

1. Section 17(a) of the Act makes it unlawful for any affiliated person of a registered investment company, acting as principal, to sell or purchase any security to or from the investment company. Section 2(a)(3) of the Act defines an affiliated person of an investment company to include any person directly or indirectly owning, controlling, or holding with power to vote 5% or more of the outstanding voting securities of the other person or, any person 5% or more of whose outstanding securities are directly or indirectly owned, controlled, or held with power to vote by such other person, any person directly or indirectly controlling, controlled by, or under common control with the other person, and any investment adviser to the investment company. Because the Advisers serve, or will serve, as investment adviser or trustee exercising investment discretion for the Participating Funds and Money Market Funds, they may be deemed to be under common control and therefore, affiliated persons of each other. In addition, if a Participating Fund purchases more than 5% of the voting securities of a Money Market Fund, the Money Market Fund and the Participating Fund may be affiliated persons of each other. As a result, section 17(a) would prohibit the sale of the shares of Money Market Funds to the Participating Funds, and the redemption of the shares by the Participating Funds.

2. Section 17(b) of the Act authorizes the Commission to exempt a transaction from section 17(a) of the Act if the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policy of each registered investment company concerned and with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any person or transactions from any provision of the Act, if the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

3. Applicants submit that their request for relief to permit the purchase and redemption of shares of the Money Market Funds by the Participating Funds satisfies the standards in sections 6(c) and 17(b) of the Act. Applicants note that the consideration paid and received on the sale and redemption of shares of the Money Market Funds will be based on the net asset value per share of the Money Market Funds. Applicants state that the Registered Participating Funds will retain their ability to invest Cash Balances directly in money market instruments and other short-term obligations as authorized by their respective investment objectives and policies. Applicants represent that a Money Market Fund reserves the right to discontinue selling shares to any of the Participating Funds if the Money Market Fund's Board determines that such sale would adversely affect the Money Market Fund's portfolio management and operations.

C. Section 17(d) of the Act and Rule 17d–1 Under the Act

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates, unless the Commission has approved the joint arrangement. Applicants state that the Participating Funds and the Money

[6] Applicants also seek relief to allow the Registered Participating Funds to acquire shares of an offshore Money Market Fund in excess of the limits in section 12(d)(1)(A) of the Act.

Market Funds, by participating in the proposed transactions, and the Advisers by managing the proposed transactions, could be deemed to be participating in a joint arrangement within the meaning of section 17(d) and rule 17d–1.

2. In considering whether to approve a joint transaction under rule 17d–1, the Commission considers whether the investment company's participation in the joint transaction is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants. Applicants submit that the Proposed Transactions meet the standards for an order under rule 17d–1.

II. Interfund Transactions

1. Applicants state that they currently rely on rule 17a–7 under the Act to conduct Interfund Transactions. Rule 17a–7 under the Act provides an exemption from section 17(a) for a purchase or sale of certain securities between registered investment companies that are affiliated persons (or an affiliated person of an affiliated person), or between a registered investment company, and a person that is an affiliated person of such company (or an affiliated person of such person) solely by reason of having a common investment adviser, common officers and/or common directors or trustees. Applicants state that the Participating Funds and Money Market Funds may not be able to rely on rule 17a–7 when purchasing or selling portfolio securities to each other, because some of the Participating Funds may own 5% or more of the outstanding voting securities of a Money Market Fund and, therefore, an affiliation would not exist solely by reason of having a common investment adviser, common officers and/or common directors or trustees.

2. Applicants request relief under sections 6(c) and 17(b) of the Act to permit the Interfund Transactions. Applicants submit that the requested relief satisfies the standards for relief in sections 6(c) and 17(b). Applicants state that the Funds will comply with rule 17a–7 under the Act in all respects, other than the requirement that the participants be affiliated solely by reason of having a common investment adviser, common directors and/or common officers. Applicants state that by complying with the conditions of Rule 17a–7, the interests of the shareholders of the Registered Participating Funds and the Registered Money Market Funds are protected. Thus, the Applicants submit that the Interfund Transactions are reasonable and fair, do not involve overreaching, and will be consistent with the purposes of the Act.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. The shares of the Money Market Funds sold to and redeemed from the Participating Funds will not be subject to a sales load, redemption fee, asset-based distribution fee under a plan adopted in accordance with Rule 12b–1, or Service Fee.

2. Before the next meeting of the Board of the Registered Participating Fund that invests in the Money Market Fund is held for the purpose of voting on an advisory contract pursuant to section 15 of the Act, the Adviser will provide the Board with specific information regarding the approximate cost to the Adviser for, or portion of the advisory fee under the existing advisory contract attributable to, managing the Uninvested Cash of the Registered Participating Fund that can be expected to be invested in the Money Market Funds. Before approving any advisory contract pursuant to section 15 of the Act, the Board of the Registered Participating Fund, including a majority of the Disinterested Directors, shall consider to what extent, if any, the advisory fees charged to the Registered Participating Fund by the Adviser should be reduced to account for reduced services provided to the Registered Participating Fund by the Adviser as a result of Uninvested Cash being invested in the Money Market Funds. The minute books of Registered Participating Fund will record fully the Board's consideration in approving the advisory contract, including the considerations relating to fees referred to above.

3. Each Registered Participating Fund's aggregate investment of Uninvested Cash in the Money Market Funds will not exceed 25% of the Registered Participating Fund's total assets. For purposes of this limitation, each Registered Participating Fund or series thereof will be treated as a separate investment company.

4. Investment in shares of the Money Market Funds will be in accordance with the investment policies and restrictions of each Registered Participating Fund as set forth in its registration statement.

5. Each Registered Fund and Managed Account that may rely on the order shall be advised by an Adviser. Each Unregistered Fund shall be advised by, or have as its trustee, an Adviser.

6. No Money Market Fund shall acquire securities of any investment company in excess of the limits contained in section 12(d)(1)(A) of the Act.

7. The Unregistered Money Market Funds will comply with the requirements of sections 17(a), (d), and (e), and 18 of the 1940 Act. With respect to all redemption requests made by a Participating Fund, the Unregistered Money Market Funds will comply with section 22(e) of the Act. The Advisers will adopt procedures designed to ensure that each Unregistered Money Market Fund complies with sections 17(a), (d), (e), 18 and 22(e) of the Act. The Advisers also will periodically review and update as appropriate the procedures, and will maintain books and records describing such procedures, and will maintain books and records describing such procedures, and will maintain the records required by rules 31a–1(b)(1), 31a–1(b)(2)(ii), and 31a–1(b)(9) under the Act. All books and records required to be made pursuant to this condition will be maintained and preserved for a period of not less than six years from the end of the fiscal year in which any transaction occurred, the first two years in an easily accessible place, and will be subject to examination by the Commission and its staff.

8. Each Unregistered Money Market Fund will comply with rule 2a–7. With respect to each Unregistered Money Market Fund, the Advisers will adopt and monitor the procedures described in rule 2a–7(c)(7) under the Act and will take such other actions as are required to be taken under those procedures. A Participating Fund may only purchase shares of an Unregistered Money Market Fund if the Adviser determines on an ongoing basis that the Unregistered Money Market Fund is in compliance with rule 2a–7. The Advisers will preserve for a period of not less than six years from the date of determination, the first two years in an easily accessible place, a record of such determination and the basis upon which the determination was made. This record will be subject to examination by the Commission and its staff.

9. Each Participating Fund will purchase and redeem shares of any Unregistered Money Market Fund as of the same time and at the same price, and will receive dividends and bear its proportionate share of expenses on the same basis, as other shareholders of the Unregistered Money Market Fund. A separate account will be established in the shareholder records of each Unregistered Money Market Fund for the account of each Participating Fund

that invests in such Unregistered Money Market Fund.

10. To engage in Interfund Transactions, the Registered Funds, Unregistered Funds, Managed Accounts and Money Market Funds will comply with rule 17a–7 under the Act in all respects other than the requirement that the parties to the transaction be affiliated persons (or affiliated persons of affiliated persons) of each other solely by reason of having a common investment adviser, or investment advisers which are affiliated persons of each other, common officers, and/or common directors or trustees, solely because a Participating Fund and a Money Market Fund might become affiliated persons within the meaning of section 2(a)(3)(A) and (B) of the Act.

11. The net asset value per share with respect to shares of an Unregistered Money Market Fund will be determined separately for each Unregistered Money Market Fund by dividing the value of the assets belonging to that Unregistered Money Market Fund, less the liabilities of that Unregistered Money Market Fund, by the number of shares outstanding with respect to that Unregistered Money Market Fund.

12. Before a Registered Participating Fund may participate in the Securities Lending Program, a majority of the Board (including a majority of the Disinterested Directors) will approve the Registered Participating Fund's participation in the Securities Lending Program. No less frequently than annually, the Board also will evaluate, with respect to each Registered Participating Fund, any securities lending arrangement and its results and determine that any investment in Cash Collateral in the Money Market Funds is in the best interest of the Registered Participating Fund.

Condition 2 to the Fund-of-Funds Order is amended to read as follows: ''No Underlying Portfolio will acquire securities of any other investment company in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent that the Underlying Portfolio other than a money market fund acquires securities of another registered or unregistered investment company pursuant to exemptive relief from the Commission permitting the Underlying Portfolio to purchase securities of an affiliated registered or unregistered money market fund for short-term cash management purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15354 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 26075; 812–12779]

American Performance Funds, et al.; Notice of Application

June 12, 2003.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 12(d)(1)(J) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 12(d)(1)(A) and (B) of the Act, under sections 6(c) and 17(b) of the Act for an exemption from section 17(a) of the Act, and under section 17(d) of the Act and rule 17d–1 under the Act to permit certain joint transactions.

SUMMARY OF APPLICATION: Applicants request an order that would permit certain registered management investment companies to invest uninvested cash and cash collateral in one or more affiliated money market funds in excess of the limits in sections 12(d)(1)(A) and (B) of the Act. Prior to relying on the requested order, Applicants would cease relying on a prior order.[1]

APPLICANTS: American Performance Funds, AmSouth Funds, BNY Hamilton Funds, Inc. (''BNY Hamilton Funds''), Citizens Funds, Fifth Third Funds, HSBC Advisor Funds Trust, HSBC Investor Funds and HSBC Investor Portfolios (collectively, the ''HSBC Funds''), Legacy Funds Group (''Legacy Funds''), Mercantile Funds, Inc. (''Mercantile Funds''), Old Westbury Funds, Inc. (''Old Westbury Funds''), Performance Funds Trust (''Performance Funds''), The Victory Portfolios, Vintage Mutual Funds, BOk Investment Advisers, Inc. (''BOk'') (formerly, Investment Concepts, Inc.), AmSouth Investment Management Company, LLC (''AmSouth''), The Bank of New York (''BNY''), Citizens Advisers, Inc. (''Citizens Advisers''), Fifth Third Asset Management, Inc. (''Fifth Third''), HSBC Asset Management (Americas) Inc. (''HSBC''), First Financial Capital Advisors LLC (''First Financial''), Bessemer Investment Management LLC (''Bessemer''), Mercantile Capital Advisors, Inc. (''Mercantile''), Trustmark Investment Advisors, Inc. (formerly, Trustmark Financial Services, Inc.) (''Trustmark''), Victory Capital Management, Inc. (''Victory'') and Investors Management Group, Ltd. (''Investors Management Group'').

Filing Dates: The application was filed on February 1, 2002 and was amended on June 9, 2003. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on July 7, 2003, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, NW., Washington, DC 20549–0609; Applicants, c/o Ryan M. Louvar, Esq., BISYS, 60 State Street, Suite 1300, Boston, MA 02109.

FOR FURTHER INFORMATION CONTACT: Jean E. Minarick, Senior Counsel, at (202) 942–0527 or Annette M. Capretta, Branch Chief, 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 Commission's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (telephone (202) 942–8090).

[1] On February 19, 2000, the Commission issued an order amending prior orders under Sections 6(c) and 17(b) of the Act that exempted certain Applicants and certain other entities who are not parties to the application from the provisions of Section 12(d)(1)(A) and Section 17(a) of the Act and that permitted pursuant to rule 17d–1, certain joint transactions in accordance with Section 17(d) and rule 17d–1. *See* Investment Company Act Rel. Nos. 24274 (Feb. 1, 2000) (notice) and 24325 (Feb. 19, 2000) (order); Investment Company Act Rel. Nos. 23962 (Aug. 23, 1999) (notice) and 24021 (Sept. 21, 1999) (order); Investment Company Act Rel. Nos. 23393 (Aug. 18, 1998) (notice) and 23436 (Sept. 15, 1998); Investment Company Act Rel. Nos. 22636 (April 24, 1997) (notice) and 22677 (May 20, 1997) (order); Investment Company Act Rel. Nos. 19695 (Sept. 9, 1993) and 19759 (Oct. 5, 1993) (order).

Applicants' Representations

1. American Performance Funds, AmSouth Funds, Citizens Funds, Fifth Third Funds, HSBC Advisor Funds Trust, HSBC Investor Funds, Legacy Funds and Old Westbury Funds are Massachusetts business trusts that are registered under the Act as open-end management investment companies. BNY Hamilton Funds, Mercantile Funds and Vintage Mutual Funds are Maryland corporations that are registered under the Act as open-end management investment companies. HSBC Investor Portfolios is a New York trust that is registered under the Act as an open-end investment management company. The Performance Funds and The Victory Portfolios are Delaware statutory trusts that are registered under the Act as open-end management investment companies.

2. BOk is the investment adviser to each of the twelve series of the American Performance Funds. AmSouth is the investment adviser to the twenty-four series of the AmSouth Funds. Citizens Advisers is the investment adviser to the twelve series of the Citizens Funds. BNY is the investment adviser to the twenty series of BNY Hamilton Funds. Fifth Third serves as the investment adviser to thirty-five of the thirty-six series of the Fifth Third Funds. HSBC serves as investment adviser to the twenty-one series of the HSBC Funds. First Financial serves as the investment adviser to the three series of the Legacy Funds. Mercantile serves as the investment adviser to the fourteen series of the Mercantile Funds. Bessemer serves as the investment adviser to the five series of the Old Westbury Funds. Trustmark is the investment adviser to the seven series of the Performance Funds. Victory is the investment adviser to the twenty-six series of The Victory Portfolios. Investors Management Group is the investment adviser to the nine series of the Vintage Mutual Funds.

3. The American Performance Funds, AmSouth Funds, BNY Hamilton Funds, Citizens Funds, Fifth Third Funds, the HSBC Funds, Legacy Funds, Mercantile Funds, Old Westbury Funds, Performance Funds, The Victory Portfolios and the Vintage Mutual Funds and their respective series (each series, a ''Fund,'' and collectively, the ''Funds'') each is in the American Performance, AmSouth, BNY Hamilton, Citizens, Fifth Third, HSBC, Legacy, Mercantile, Old Westbury, Performance, Victory and Vintage group of investment companies, respectively, within the meaning of section 12(d)(1)(G)(ii) of the Act (each a ''Fund Group'').

4. Applicants request that relief be extended to any registered open-end management investment company or series thereof for which BOk, AmSouth, BNY, Citizen Advisers, Fifth Third, HSBC, First Financial, Bessemer, Mercantile, Trustmark, Victory or Investors Management Group (each an ''Adviser,'' and any entity controlled by, controlling or under common control with each Adviser, an ''Adviser'')[2] now or in the future serves as investment adviser (collectively with the Funds, the ''Funds'').[3]

5. Each Fund Group has one or more money market Funds (''Money Market Funds''). The Money Market Funds comply with rule 2a–7 under the Act. The Funds that are not Money Market Funds invest in a variety of debt and/or equity securities or other investments in accordance with their respective investment objectives and policies.

6. Applicants state that certain Funds (''Investing Funds'') have, or may be expected to have, cash that has not been invested in portfolio securities (''Uninvested Cash''). Uninvested Cash may result from a variety of sources, including dividends or interest received on portfolio securities, unsettled securities transactions, strategic reserves, matured investments, proceeds from liquidation of investment securities, dividend payments, or money received from investors. The Investing Funds may participate in a securities lending program under which a Fund may lend its portfolio securities to registered broker-dealers or other institutional investors. The loans are continuously secured by collateral equal at all times to at least the market value of the securities loaned. Collateral for these loans may include cash (''Cash Collateral,'' and together with Uninvested Cash, ''Cash Balances'').

7. Applicants request an order to permit each of the Investing Funds to invest its Cash Balances in one or more of the Money Market Funds within the same Fund Group, and to permit each of the Money Market Funds to sell its shares to, and redeem its shares from, the Investing Funds within the same Fund Group. Investment of Cash Balances in shares of the Money Market Funds will be made only to the extent that such investments are consistent with each Investing Fund's investment objectives, restrictions, and policies as set forth in its prospectus and statement of additional information. Applicants believe that the proposed transactions may reduce transaction costs, create more liquidity, increase returns, and diversify holdings.

Applicants' Legal Analysis

1. Section 12(d)(1)(A) of the Act provides, in pertinent part, that no registered investment company may acquire securities of another investment company if the securities represent more than 3% of the acquired company's outstanding voting stock, more than 5% of the acquiring company's total assets, or if such securities, together with the securities of other acquired investment companies, represent more than 10% of the acquired company's total assets. Section 12(d)(1)(B) of the Act provides, in pertinent part, that no registered open-end investment company may sell its securities to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies.

2. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction from any provision of section 12(d)(1) if, and to the extent that, the exemption is consistent with the public interest and the protection of investors. Applicants request relief under section 12(d)(1)(J) of the Act from the limitations of sections 12(d)(1)(A) and (B) to permit the Investing Funds to invest Cash Balances in the Money Market Funds.

3. Applicants state that the proposed arrangement will not result in the abuses that sections 12(d)(1)(A) and (B) were intended to prevent. Applicants state that because each Money Market Fund will maintain a highly liquid portfolio, an Investing Fund would not be in a position to gain undue influence over a Money Market Fund. Applicants represent that the proposed arrangement will not result in an inappropriate layering of fees because shares of the Money Market Funds sold to the Investing Funds will not be subject to a sales load, redemption fee, distribution fee under a plan adopted in accordance with rule 12b–1 under the Act or service fee (as defined in rule 2830(b)(9) of the National Association of Securities Dealers, Inc. (''NASD'') Conduct Rules) or if such shares are subject to any such sales load, redemption fees, distribution fees or service fees, the Adviser will waive its advisory fee for each Investing

[2] Each Adviser is registered under the Investment Advisers Act of 1940 or will be exempt from registration.

[3] Each Fund that currently intends to rely on the order has been named as an applicant. Any other Fund that may rely on the order in the future will do so only in accordance with the terms and conditions of the application.

Fund in an amount that offsets the amount of such fees incurred by the Investing Fund. Applicants state that if a Money Market Fund offers more than one class of shares, each Investing Fund will invest only in the class with the lowest expense ratio (taking into account the expected impact of the Investing Fund's investment) at the time of the investment. In connection with approving any advisory contract for an Investing Fund, the Investing Fund's board of directors/trustees (the ''Board''), including a majority of the directors/trustees who are not ''interested persons,'' as defined in section 2(a)(19) of the Act (''Disinterested Directors''), will consider to what extent, if any, the advisory fees charged to the Investing Fund by the Adviser should be reduced to account for the reduced services provided to the Investing Fund by the Adviser as a result of the investment of Uninvested Cash in a Money Market Fund. Applicants represent that no Money Market Fund will acquire securities of any other investment company in excess of the limitations contained in section 12(d)(1)(A) of the Act.

4. Section 17(a) of the Act generally prohibits sales or purchases of securities between a registered investment company and an affiliated person of a registered investment company or an affiliated person of such person acting as principal. Section 2(a)(3) of the Act defines an ''affiliated person'' of another person to include: (a) Any person directly or indirectly controlling, controlled by, or under common control with the other person; (b) any officer or director of such other person; and (c) if such other person is an investment company, any investment adviser thereof. Applicants state that each Fund within the same Fund Group may be deemed to be affiliated persons of one another by virtue of having a common board of directors or common investment advisers. In light of these possible affiliations, section 17(a) could prevent a Money Market Fund from selling shares to and redeeming shares from an Investing Fund.

5. Section 17(b) of the Act authorizes the Commission to grant an order exempting a transaction otherwise prohibited by section 17(a) if (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of the registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any person or transaction from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

6. Applicants submit that their request for relief to permit the purchase and redemption of shares of the Money Market Funds by the Investing Funds satisfies the standards for relief under sections 6(c) and 17(b) of the Act. Applicants note that the shares of the Money Market Funds will be purchased and redeemed by the Investing Funds at their net asset value, the same consideration paid and received for these shares by any other shareholder. Applicants state that the Investing Funds will retain their ability to invest Cash Balances directly in money market instruments as authorized by their respective investment objectives and policies if they believe they can obtain a higher rate of return, or for any other reason. Applicants also state that a Money Market Fund has the right to discontinue selling shares to any of the Investing Funds if the Money Market Fund's Board determines that such sale would adversely affect its portfolio management and operations.

7. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates. Applicants state that each Investing Fund (by purchasing shares of Money Market Funds), the Adviser for each Investing Fund (by managing the assets of the Investing Funds invested in Money Market Funds), and each Money Market Fund (by selling shares to Investing Funds) could be deemed to be participants in a joint enterprise or arrangement within the meaning of section 17(d) of the Act and rule 17d–1 under the Act.

8. Rule 17d–1 permits the Commission to approve a proposed joint transaction covered by the terms of section 17(d) of the Act. In determining whether to approve a transaction, the Commission is to consider whether the proposed transaction is consistent with the provisions, policies, and purposes of the Act, and the extent to which participation by the registered investment company is on a basis different from, or less advantageous than, that of other participants. Applicants submit that the investment by the Investing Funds in shares of the Money Market Funds would be indistinguishable from any other shareholder account maintained by the Money Market Fund and that the transactions will be consistent with the Act.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

1. Shares of the Money Market Funds sold to and redeemed by the Investing Funds will not be subject to a sales load, redemption fee, distribution fee under a plan adopted in accordance with rule 12b–1 under the Act, or service fee (as defined in rule 2830(b)(9) of the NASD Conduct Rules), or if such shares are subject to any such fee, the Adviser for the Investing Fund will waive its advisory fee for each Investing Fund in an amount that offsets the amount of such fees that are incurred by the Investing Fund.

2. Prior to reliance on the order, an Investing Fund will hold a meeting of the Board for the purpose of voting on the advisory contract under section 15 of the Act. The Adviser to the Investing Fund will provide the Board with specific information regarding the approximate cost to the Adviser of, or portion of the advisory fee under the existing advisory contract attributable to, managing the Uninvested Cash of the Investing Fund that can be expected to be invested in the Money Market Funds. Before approving any advisory contract for an Investing Fund, the Board, including a majority of the Disinterested Directors, taking into account all relevant factors, shall consider to what extent, if any, the advisory fees charged to the Investing Fund by such Fund's Adviser should be reduced to account for reduced services provided to the Investing Fund by the Adviser as a result of Uninvested Cash being invested in one or more of the Money Market Funds. The minute books of the Investing Fund will record fully the Board's consideration in approving the advisory contract, including the considerations relating to fees referred to above.

3. Each Investing Fund will invest Uninvested Cash in, and hold shares of, Money Market Funds only to the extent that the Investing Fund's aggregate investment in such Money Market Funds does not exceed 25 percent of the Investing Fund's total assets. For purposes of this limitation, each Investing Fund will be treated as a separate investment company.

4. Investment of Cash Balances in shares of the Money Market Funds will

be in accordance with each Investing Fund's respective investment restrictions and will be consistent with each Investing Fund's policies as set forth in its prospectus and statement of additional information.

5. Each Investing Fund that may rely on the order may invest only in Money Market Funds within the same Fund Group as the Investing Fund.

6. So long as its shares are held by an Investing Fund no Money Market Fund shall acquire securities of any other investment company in excess of the limits contained in section 12(d)(1)(A) of the Act.

7. Before a Fund may participate in the Securities Lending Arrangements, a majority of the Board, including a majority of the Disinterested Directors, will approve the Fund's participation in the Securities Lending Arrangements. Such Disinterested Directors also will evaluate the Securities Lending Arrangements and their results no less frequently than annually and determine that any investment of Cash Collateral in the Money Market Funds is in the best interest of the shareholders of the Fund.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15356 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–48027; File No. PCAOB–2003–01]

Public Company Accounting Oversight Board; Notice of Filing of Proposed Bylaws and Amendment No. 1 Thereto

June 13, 2003.

Pursuant to section 107(b) of the Sarbanes-Oxley Act of 2002 (the ''Sarbanes-Oxley Act'' or ''Act''),[1] notice is hereby given that on March 3, 2003, the Public Company Accounting Oversight Board (the ''Board'' or the ''PCAOB'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule as described in Items I, II, and III below, which items have been prepared by the Board. On April 30, 2003, the PCAOB filed Amendment No. 1 to the proposed rule. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

[1] 15 U.S.C. 7217(b).

I. Board's Statement of the Terms of Substance of the Proposed Rule

On January 9, 2003, the Board adopted its bylaws. On April 25, 2003, the Board adopted an amendment to Article VI of the bylaws to specify the powers of the Chair. In general, the bylaws implement Title I of the Sarbanes-Oxley Act by establishing a principal office in Washington, DC, and by establishing the composition of a Governing Board, and the powers and duties of the Governing Board and officers. The bylaws are intended by the Board to be effective as of their initial adoption by a unanimous vote of the Board members. The Board is therefore proposing that the Commission approve the bylaws effective as of January 9, 2003.

II. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule

In its filing with the Commission, the Board included statements concerning the purpose of, and basis for, the proposed rule and discussed any comments it received on the proposed rule. The text of these statements may be examined at the places specified in Item IV below. The Board has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule

The Sarbanes-Oxley Act established the Board as a nonprofit corporation, subject to and with all the powers conferred upon a nonprofit corporation by the District of Columbia Nonprofit Corporation Act, to oversee the audits of public companies that are subject to the securities laws, and related matters, in order to protect the interests of investors and further the public interest in the preparation of informative, accurate, and independent audit reports for companies the securities of which are sold to, and held by and for, public investors.

The Board's bylaws implement Title I of the Sarbanes-Oxley Act by establishing a principal office in Washington, DC, and by establishing the composition of a Governing Board, and the powers and duties of the Governing Board and officers. Among the provisions of the bylaws are rules for establishing a quorum and providing that an act approved by majority vote of the members of the Governing Board present at a meeting of the Board at which a quorum is present shall be an act of the Board. The bylaws also provide for including a recused Board member in the count for quorum purposes only in exigent circumstances, in which the Board is required to act within a limited period of time or in which the public interest or the protection of investors otherwise prevents the deferral of action until a quorum of non-recused members is available.

The Board's bylaws also provide that the Governing Board shall hold at least one public meeting each month, on the first Tuesday of the month (the ''Regular Public Meeting'') or at such other time as the Chair shall determine. The bylaws require the Board to adopt a written Open Meeting Policy defining the circumstances under which meetings of the Board will be open to the public and to include in that Open Meeting Policy procedures to ensure that the public is informed, at least five calendar days in advance, of the time, location, and general topics scheduled for discussion at each Regular Public Meeting. The bylaws also permit the Governing Board to hold additional meetings (''Special Meetings''), which may be public or non-public (in accordance with the Open Meeting Policy), as it deems necessary or appropriate to further the purposes of the Sarbanes-Oxley Act. The bylaws require that the Open Meeting Policy set forth procedures for providing the public with reasonable notice of public Special Meetings, and they permit the Governing Board to meet by telephone, provided that, in the case of a public meeting, at least one Board member is present at the location specified in the meeting notice.

The bylaws provide that the Chair shall also be the President and Chief Executive Officer of the Corporation and that the other Governing Board members shall also be Vice Presidents of the Corporation. Section 6.2 of the bylaws provides that the other officers of the Corporation shall include a Secretary, Treasurer, General Counsel, Chief Auditor, Chief Administrative Officer, Director of Inspections and Registration, Director of Investigations and Enforcement, and such other officers as the Governing Board may establish in accordance with such rules of the Board as may be adopted for establishing officers.

Section 6.3 of the bylaws provides that the Chief Executive Officer is responsible for, and has authority over, the management and administration of the Corporation, including: (i) Responsibility and authority for the appointment, dismissal, and supervision of personnel (other than Board members and personnel

employed regularly and full-time within the immediate offices of the Board members); (ii) the distribution of business among such personnel and among organizational units of the Corporation; (iii) the use and expenditure of funds (including the procurement of goods and services); and (iv) the development (for Board review) of strategic policy initiatives.

The bylaws also provide that in carrying out any of the responsibilities under the provisions of section 6.3 of the bylaws, the Chief Executive Officer shall be governed by the general policies of the Governing Board and by such rules and decisions as the Governing Board may lawfully make. The bylaws also provide that the appointment by the Chief Executive Officer of the officers of the Corporation designated in and established under section 6.2 shall be subject to the approval of, and made in consultation with, the Governing Board. The bylaws also provide that the dismissal of the officers of the Corporation designated in and established under section 6.2 shall be made in consultation with the Governing Board, except that when the Board determines that the dismissal arises out of a conflict regarding the general policies of the Governing Board, it is also subject to the approval of the Governing Board.

The bylaws also provide that each Board member has the responsibility and authority for the appointment, dismissal, and supervision of personnel employed regularly and full-time within the immediate office of the Board member. The Board member's responsibility and authority for these persons would be subject to the Governing Board's overall personnel policies.

The bylaws also provide that the Chief Executive Officer has the responsibility and authority to develop, and present to the Board for approval, an annual budget as well as mid-year adjustments, if any. The bylaws further provide that there is reserved to the Governing Board its responsibility and authority with respect to determining the distribution of funds according to major programs and purposes, including those related to salary schedules and other conditions of employment.

The bylaws also provide that no contract entered into by or on behalf of the Corporation shall personally obligate any employee, officer, or Governing Board member, including the employee, officer or Governing Board member authorizing or executing such a contract. Further, unless otherwise prohibited by law, the bylaws provide for the Corporation to indemnify employees, officers, and Governing Board members, and any former employees, officers, or Governing Board members, against any and all expenses and liabilities actually and necessarily incurred by him or her, or imposed on him or her, in connection with any claim, action, suit, or proceeding (whether actual or threatened, civil, criminal, administrative, or investigative, including appeals), to which he or she may be or is made a party by reason of being or having been an employee, officer, or Board member, except that there shall be no indemnification in relation to matters as to which the Board finds that the employee, officer, or Board member acted in bad faith or engaged in willful misconduct in the performance of a duty to the Corporation. Amounts paid in indemnification of expenses and liabilities may include, but shall not be limited to, counsel and other related fees, costs and disbursements, and judgments, fines and penalties against, and amounts paid in settlement by, such employee, officer, or Board member. The bylaws further permit the Corporation to advance expenses to, or where appropriate to itself, at its expense, undertake the defense of any employee, officer, or Board member, so long as the employee, officer, or Board member undertakes to repay or reimburse such expense if it should be ultimately determined that he or she is not entitled to indemnification under the bylaws.

The bylaws also permit the Governing Board to purchase insurance on behalf of any employee, officer, or Governing Board member against any liability which may be asserted against or incurred by him or her which arises out of such person's status as an employee, officer, or Board member, whether or not the Corporation would have the power to indemnify such person against that liability under law.

The bylaws permit the Governing Board to adopt such rules of the Corporation as it deems necessary or appropriate to discharge its responsibilities under the Sarbanes-Oxley Act. The bylaws also prohibit any capital expenditure or investment without the approval of the Board, except as expressly delegated by the Governing Board. Finally, the bylaws require the Governing Board to retain an accounting firm to annually audit the Corporation's financial records, which firm shall not perform any other services, except tax services, for the Corporation.

In the event that the Commission approves the Board's bylaws, the Board seeks that they be approved so as to be retroactively effective as of January 9, 2003.

B. Board's Statement on Burden on Competition

The proposed rule does not impose any burden on competition.

C. Board's Statement on Comments on the Proposed Rule Received From Members, Participants or Others

The Board has not solicited, and does not intend to solicit, comments on this proposed rule. The Board has not received any unsolicited written comments.

III. Date of Effectiveness of the Proposed Rule and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Board consents the Commission will:

(a) by order approve such proposed rule; or

(b) institute proceedings to determine whether the proposed rule should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule is consistent with the requirements of Title I of the Sarbanes-Oxley Act and the Exchange Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room in Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the PCAOB. All submissions should refer to File No. SR–PCAOB–2003–01 and should be submitted by July 9, 2003.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15355 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–48023; File No. SR–Amex–2003–53]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange LLC Relating to Maximum Bid/Offer Differentials for Option Contracts

June 12, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 2, 2003, the American Stock Exchange LLC (the ''Amex'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to amend Exchange Rule 958 to set the maximum bid/offer differential for option contracts at $0.40 where the prevailing bid is at or above $2 but does not exceed $5, and $0.80 where the prevailing bid is more than $10 but does not exceed $20. The text of the proposed rule change is set forth below. [Bracketing] indicates text to be deleted, and *italics* indicates text to be added.

* * * * *

Options Transactions of Registered Traders

Rule 958

(a)–(b) No change

(c) With respect to each class of options as to which he is assigned by the Exchange, a Registered Trader, whenever he enters the trading crowd in other than a floor brokerage capacity, or is called upon by a Floor Official or a Floor Broker acting in an agency capacity, is required to make competitive bids and offers as reasonably necessary to contribute to the maintenance of a fair and orderly market and shall engage, to a reasonable degree under the existing circumstances, in dealings for his own account when there exists a lack of price continuity, a temporary disparity between the supply of and demand for option contracts of a particular series, or a temporary distortion of the price relationships between option contracts of the same class. Without limiting the foregoing, a Registered Trader is expected to perform the following activities in the course of maintaining a fair and orderly market:

(i) If the underlying security is a stock or Exchange-Traded Fund Share, bidding and offering so as to create differences of no more than $0.25 between the bid and the offer for each option contract for which the prevailing bid is less than $2, no more than [$0.37] *$0.40* where the prevailing bid is $2 but does not exceed $5, no more than $0.50 where the prevailing bid is more than $5 but does not exceed $10, no more than [$0.75] *$0.80* where the prevailing bid is more than $10 but does not exceed $20, and no more than $1 where the last prevailing bid is more than $20. In the event the bid/ask differential in the underlying security is greater than the bid/ask differential set forth herein, the permissible price differential for any in-the-money option series may be identical to those in the underlying security market.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Amex has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

(1) Purpose

Pursuant to the industry-wide conversion of the pricing of securities from fractions to decimals, the Exchange converted all stocks and options pricing in its rules to decimals. Among the rules affected was Exchange Rule 958, which sets forth the obligations of registered options traders and options specialists.[3] Subparagraph (c)(i) of Rule 958 requires registered options traders and options specialists, in the course of maintaining a fair and orderly market, to adhere to maximum bid/offer differentials specified in the rule.[4] In connection with this conversion from fractions to decimals, the Exchange converted (i) the maximum bid/offer differential of 3/8 of $1 to $0.37 where the prevailing bid is at or above $2 but does not exceed $5; and (ii) the maximum bid/offer differential of 3/4 of $1 to $0.75 where the prevailing bid is more than $10 but does not exceed $20.

The requirements of related Exchange Rule 952, however, created anomalies in the maximum bid/offer differentials as stated in Rule 958. Amex Rule 952, which sets forth the minimum price variation (''MPV'') for option contracts, requires a MPV of $0.05 where an option contract trades less than $3.00 and a MPV of $0.10 where an option contract trades at or above $3. Consequently, option contracts trading at or above $2 but less than $3 are restricted to a maximum bid/offer differential of $0.35, not $0.37, because the MPV at those prices is $0.05, and option contracts trading at or above $3 but not exceeding $5 are restricted to a maximum bid/offer differential of $0.30, not $0.37, because the MPV at those prices is $0.10. Similarly, option contracts where the prevailing bid is more than $10 but does not exceed $20 are allowed a maximum bid/offer differential of $0.75 under Amex Rule 958, but since the MPV is $0.10 at those prices, registered options traders and options specialists are required to quote with a maximum differential of $0.70.

Because maximum bid/offer differentials were reduced from levels permitted before the conversion from fractions to decimals, the Exchange now proposes to amend Amex Rule 958 to increase the maximum bid/offer differential (i) from $0.37 to $0.40 where the prevailing bid is at or above $2 but does not exceed $5; and (ii) from $.075 to $0.80 where the prevailing bid is more than $10 but does not exceed $20. These changes will conform Amex Rule 958 to the Exchange's current practice of allowing registered options traders and options specialists to quote bids and offers with maximum bid/offer

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240 19b–4.

[3] Exchange Rule 950(n) requires options specialists to adhere to the maximum bid/offer differentials set forth in Amex Rule 958(c).

[4] The maximum bid/offer differential varies depending upon the prevailing bid for the option contract.

differentials of $0.40 and $0.80 under the abovementioned conditions.[5]

(2) Basis

The proposed rule change is consistent with section 6(b) of the Act[6] in general and furthers the objectives of section 6(b)(5) of the Act[7] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become immediately effective pursuant to section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6)[9] thereunder because (i) it does not significantly affect the protection of investors or the public interest; (ii) it does not impose any significant burden on competition; and (iii) by its terms, it does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Acceleration of the operative delay will permit the Amex to amend Rule 958 without undue delay. For this reason, the Commission designates the proposal to be effective upon filing with the Commission.[10] At any time within sixty (60) days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–2003–53 and should be submitted by July 9, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15352 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

[5] Under Amex Rule 958(c)(i), the Exchange may establish, where appropriate, maximum bid/offer differentials other than those set forth in the rule.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–48024; File No. SR–Amex–2003–36]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change and Amendments No. 1 and 2 by the American Stock Exchange LLC To Initiate a Pilot Program That Allows the Listing of Strike Prices at One-Point Intervals for Certain Stocks Trading Under $20

June 12, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2003, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed Amendments No. 1 and 2 to the proposal on June 3, 2003,[3] and June 11, 2003,[4] respectively. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons and to grant accelerated approval to the proposed rule change, as amended, through June 5, 2004.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to initiate a pilot program (''Pilot Program'') that will allow the Exchange to list options on selected stocks trading below $20 at one-point intervals. The text of the proposed rule change appears below. Additions are in *italics.*

Rule 903. Series of Options Open for Trading

(a)–(d) No Change.

Commentary

.01–.03 No Change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 replaces and supersedes the original filing in its entirety.

[4] *See* letter from Jeffrey P. Burns, Associate General Counsel, Amex, to Nancy Sanow, Division of Market Regulation, Commission, dated June 10, 2003 (''Amendment No. 2''). Amendment No. 2 revises the proposal to indicate that: (1) The pilot program will expire on June 5, 2004; (2) the strike price interval for options on individual stocks will be $5 or greater where the strike price is greater than $25 but less than $200 and $10 or greater where the strike price is greater than or equal to $200; and (3) the strike price interval for options on Exchange-Traded Fund Shares (''ETFs'') will be $5 or greater where the strike price is over $200.

.04 The interval between strike prices of series of options on individual stocks may be (a) $2.50 or greater where the strike price is $25 or less, provided however, that the Exchange may not list $2.50 intervals below $20 (e.g. $12.50, $17.50) for any class included within the $1 Strike Price Pilot Program, as detailed below in Commentary .05, if the addition of $2.50 intervals would cause the class to have strike price intervals that are $0.50 apart; (b) $5 or greater where the strike price is greater than $25 but less than $200; or (c) $10 or greater where the strike price is greater than or equal to $200. For series of options on Exchange-Traded Fund Shares that satisfy the criteria set forth in Commentary .06 to Rule 915, the interval of strike prices may be $1 or greater where the strike price is $200 or less or $5 or greater where the strike price is over $200. Exceptions to the strike price intervals above are set forth in Commentaries .05 and .06 below.

.05 The interval between strike prices of series of options on individual stocks may be:

a. $1.00 or greater (''$1 Strike Prices'') provided the strike price is $20 or less, but not less than $3. The listing of $1 strike prices shall be limited to option classes overlying no more than five (5) individual stocks (the ''$1 Strike Price Pilot Program'') as specifically designated by the Exchange. The Exchange may list $1 Strike Prices on any other option classes if those classes are specifically designated by other national securities exchanges that employ a similar $1 Strike Price Pilot Program under their respective rules.

b. To be eligible for inclusion into the $1 Strike Price Pilot Program, an underlying security must close below $20 in the primary market on the previous trading day. After a security is added to the $1 Strike Price Pilot Program, the Exchange may list $1 Strike Prices from $3 to $20 that are no more than $5 from the closing price of the underlying on the preceding day. For example, if the underlying security closes at $13, the Exchange may list strike prices from $8 to $18. The Exchange may not list series with $1 intervals within $0.50 of an existing $2.50 strike price (e.g. $12.50, $17.50) in the same series. Additionally, for an option class selected for the $1 Strike Price Pilot Program, the Exchange may not list $1 Strike Prices on any series having greater than nine (9) months until expiration.

c. A security shall remain in the $1 Strike Price Pilot Program until otherwise designated by the Exchange. The $1 Strike Price Pilot Program shall expire on June 5, 2004.

.06 The options exchanges may select up to 200 options classes on individual stocks for which the interval of strike prices will be $2.50 where the strike price is greater than $25 but less than $50. The 200 options classes are selected by the various options exchanges pursuant to any agreement mutually agreed to by the individual exchanges and approved by the Commission. In addition to those options selected by the Exchange, the strike price interval may be $2.50 in any multiply-traded option once another exchange trading that option selects such option, as part of this program. The Exchange and any of the other options exchanges may also list strike prices of $2.50 on any option class that was selected by the NYSE pursuant to this program.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Amex proposes to amend Amex Rule 903, ''Series of Options Open for Trading,'' to implement the Pilot Program, which will operate until June 5, 2004. The Pilot Program will allow the Amex to list options on up to five underlying equities trading below $20 at one-point intervals and to list $1 strike prices on any equity option included in the $1 strike price pilot program of any other options exchange.

In addition to implementing the Pilot Program, the Amex proposes to amend Amex Rule 903 to codify certain existing strike price interval guidelines that the Commission approved but that have not been codified in Amex Rule 903.[5] In this regard, the Amex proposes to amend Amex Rule 903 to indicate that: (1) the strike price interval for series of options on individual stocks may be $2.50 or greater where the strike price is $25 or less,[6] $5 or greater where the strike price is greater than $25 but less than $200 (except for options included in the options exchanges' $2 ½-point strike price program, as described below), or $10 or greater where the strike price is greater than or equal to $200; and (2) the strike price interval for series of options on ETFs may be $1 or greater where the strike price is $200 or less or $5 or greater where the strike price is over $200. In addition, the Amex proposes to revise Amex Rule 903 to describe more specifically the options exchanges' 2½-point strike price program.[7]

Pilot Program

The Amex notes that stock prices in general have dropped over the past few years, with many listings suffering severe declines. As a result, there has been a proliferation of stocks trading below $20. The Amex lists options on more than 900 of these stocks. Some of these stocks are among the most widely held and actively traded equity securities listed on the New York Stock Exchange, Inc., the Amex, and Nasdaq, including, for example, Cisco, Oracle, Lucent, JDS Uniphase, AT&T, and Motorola. Accordingly, the options overlying these stocks are among the most actively traded options.

When a stock underlying an option trades at a lower price, it requires a larger percentage gain in the price of the stock for an option to become in-the-money. For example, when a stock trades at $10 an investor that wants to purchase a slightly out-of-the-money call option would have to buy the $12.50 call. At these levels, the stock

[5] *See* Securities Exchange Act Release Nos. 21929 (April 10, 1985), 50 FR 15258 (April 17, 1985) (File No. SR–Amex–85–6) (order approving $2.50 strike price intervals for options on individual stocks where the strike price is $25 or less) (''April 1985 Order''); 21644 (January 9, 1985), 50 FR 2360 (January 16, 1985) (File No. SR–Amex–84–31) (order approving $5 strike price intervals for options on stocks trading below $200); and 40157 (July 1, 1998), 63 FR 37426 ((July 10, 1998) (File No. SR–Amex–96–44) (order approving strike price intervals of $1 or greater for options on ETFs up to a strike price of $200 and strike price intervals of $5 or greater for ETF options where the strike price is over $200).

[6] As discussed more fully below, the Pilot Program will impose certain limitations on the Amex's ability to list $2½-point strike prices on options included in the Pilot Program.

[7] *See* Securities Exchange Act Release No. 40662 (November 12, 1998), 63 FR 64297 (November 19, 1998) (File Nos. SR–Amex–98–21; SR–CBOE–98–29; SR–PCX–98–31; and SR–PHLX–98–26) (order permanently approving the 2½-point strike price pilot program). The 2½-point strike price program allows the Amex, the Chicago Board Options Exchange, Inc. (''CBOE''), the Pacific Exchange, Inc., and the Philadelphia Stock Exchange, Inc. to list up to 200 equity options trading at a strike price greater than $25 but less than $50 at 2½-point intervals.

price would need to increase by 25% to reach in-the-money status. According to the Amex, a 25% or higher gain in the price of the underlying stock is especially large given the lessened degree of volatility that has accompanied many stocks and options over the past several months. Accordingly, Amex member firms have expressed an interest in listing additional strike prices on these classes so that they can provide their customers with greater flexibility in achieving their investment strategies. For this reason, the Exchange proposes to implement the proposed Pilot Program.

1. *Pilot Program Eligibility:* The Exchange proposes to amend Amex Rule 903 to allow the Exchange to list options on selected stocks trading below $20 at one-point intervals, provided that the strike prices are $20 or less, but not less than $3. An option would become eligible for inclusion in the Pilot Program provided that the underlying stock closed below $20 in its primary market on the preceding trading day. Once the underlying stock is part of the Pilot Program, the Exchange may continue to list $1 strike prices provided the underlying stock remains below $20. As described more fully below, although an option class will not be removed automatically from the Pilot Program if the underlying stock trades at or above $20, the Amex will not add $1 strike prices when the underlying stock closes above $20. Once the stock closes below $20, it will again be eligible for the addition of $1 strike prices. An underlying stock will remain in the Pilot Program until the Amex removes it from the Pilot Program. Options on stocks trading under $20 that are not included in the Pilot Program may continue to trade in $2.50 and $5.00 strike price intervals. Although the Amex may only select up to five individual stock options for its Pilot Program, the Exchange will not be precluded from also listing at $1 strike price intervals equity options included in the $1 strike price programs of other option exchanges.

2. *Procedure for Adding $1 Strike Price Intervals:* The Exchange proposes to amend Amex Rule 903 to set forth the standards regarding the addition of $1 strike price intervals. Under the Pilot Program, the closing price of the underlying stock serves as the reference point for determining which $1 strike prices the Exchange may open for trading. To minimize the proliferation of options series, the Exchange intends to restrict the number of $1 strike prices that may be added to those strikes that fall within a $5 range of the price of the underlying stock. The Amex will not add strike prices outside of the $5 range. For example, if the underlying stock trades at $6, the Exchange could list $1 strike prices from $3 to $11, while if the underlying stock trades at $10, the Exchange could list $1 strikes from $5 to $15. By restricting the number of strike prices that may be listed to a predetermined $5 range, the Exchange believes it will be able to provide investors with more flexibility without burdening The Options Price Reporting Authority (''OPRA'') capacity by bringing up strike prices that are not reasonably related to the price of the underlying stock.

Currently, when an underlying stock trades below $25, the Exchange may list strike prices with $2.50 intervals.[8] For this reason, several classes have $7.50, $12.50, and $17.50 strike prices. To further avoid the proliferation of series, the Exchange does not intend to list $1 strike prices at levels that ''bracket'' existing $2.50 intervals (*e.g.*, $7 and $8 strikes around a $7.50 strike). Accordingly, the Exchange does not intend to list $7, $8, $12, $13, $17, and $18 levels in an expiration month where there is a corresponding $2.50 level. As the $2.50 intervals are ''phased-out,'' as described below, the Exchange will introduce the $1 levels that bracket the phased-out price. For example, when a $7.50 series expires, the Exchange will replace it by issuing a new expiration month with $7 and $8 strike price intervals.

3. *Procedures for Phasing-Out $2.50 Strike Price Intervals:* When an individual stock becomes a part of the Pilot Program, the Exchange will begin to phase-out the existing $2.50 strike price intervals for options on that stock in favor of the $1 strike price intervals. To phase-out the $2.50 strike price intervals, the Exchange first will delist any $2.50 series for which there is no open interest. Second, the Exchange will no longer add new expiration months at $2.50 strike price intervals below $20 when existing months expire. This will cause the $2.50 strike price intervals below $20 to be phased-out when the farthest-out month with a $2.50 interval expires.

4. *$1 Strikes for Longer Dated Options:* The Exchange will not list $1 strikes on any series of individual equity option classes that have greater than nine months until expiration.

5. *Procedures for Adding Expiration Months:* Amex Rule 903(a)(i) will govern the addition of expiration months for $1 strikes series. Pursuant to this rule, the Exchange generally opens up to four expiration months for each class upon the initial listing of an options class for trading. Thus, for options included in the Pilot Program, the Amex will list an additional expiration month upon expiration of the near-term month, provided that the underlying stock prices closes below $20 on Expiration Friday. If the underlying closes at or above $20 on its primary market on Expiration Friday, the Exchange will not list an additional month of $1 strike price series until the stock again closes below $20.

6. *Procedures for Delisting $1 Strike Price Intervals:* At any time, the Exchange may cease listing $1 strike prices on existing series by submitting a cessation notice to The Options Clearing Corporation (''OCC'').[9] As discussed above, if the underlying closes at or above $20 on its primary market on Expiration Friday, the Amex will not list any additional months with $1 strike prices until the stock subsequently closes below $20. If the underlying stock does not subsequently close below $20, thereby precluding the listing of additional strike prices and months, the existing $1 series eventually will expire. When the near-term month is the only series available for trading, the Exchange may submit a cessation notice to OCC. Upon submission of that notice, the underlying stock would no longer count towards the five option classes available on the Exchange pursuant to the Pilot Program, thereby allowing the Exchange to list options on an additional stock at $1 strike price intervals. Once the Exchange submits the cessation notice it will not list any additional months pursuant to the Pilot Program for trading with strikes below $20, unless the underlying stock again closes below $20.[10]

7. *OPRA Capacity:* The Exchange believes that OPRA has the capacity to accommodate the increase in the number of series that could be added pursuant to the Pilot Program. In this regard, the Amex notes that, on a daily basis, the options exchanges use an average of less than 7,000 messages per second (''mps'') during peak periods,

[8] *See* April 1985 Order, *supra* note 5.

[9] The reasons for submitting a cessation notice are as follows: (1) Expiration of available $1 strikes (*i.e.* the underlying stock price remains at or above $20); (2) series proliferation concerns; and (3) delisting because of, among other things, low price, merger, or takeover. In any event, with prior notice to the membership and customers, the Amex will continue to have the ability to cease trading any series that has became inactive and has no open interest.

[10] If the underlying stock trades below $20 after the Amex submits a cessation notice, the Amex could again list options on that stock at $1 strike prices provided the Amex included the class as one of its five allowable classes.

which is less than 25% of the total system capacity of 32,000 mps. According to the Amex, the Amex listed approximately 108,094 series in December 2000, approximately 100,632 series in September 2001, and approximately 88,494 series in April 2003. The Amex believes that the increase in the number of series resulting from the Pilot Program should be substantially less than the decreases in listed series experienced by the Exchange.

Furthermore, the Amex states that, to date, the options exchanges have not exceeded 11,000 mps for any extended period of time.[11] Therefore, the Amex believes that implementing the Pilot Program would not have a negative impact on OPRA system capacity.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with section 6(b) of the Act [12] in general and furthers the objectives of section 6(b)(5),[13] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of change, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will impose no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filings will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Amex–2003–36 and should be submitted by July 9, 2003.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[14] In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act,[15] which requires, among other things, that the rules of a national securities exchange be designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Commission believes that the proposed listing of one point strike price intervals in selected equity options on a pilot basis should provide investors with more flexibility in the trading of equity options overlying stocks trading at more than $3 but less than $20, thereby furthering the public interest by allowing investors to establish equity options positions that are better tailored to meet their investment objectives. The Commission also believes that the Exchange's limited Pilot Program strikes a reasonable balance between the Exchange's desire to accommodate market participants by offering a wide array of investment opportunities and the need to avoid unnecessary proliferation of options series. The Commission expects the Exchange to monitor the applicable equity options activity closely to detect any proliferation of illiquid options series resulting from the narrower strike price intervals and to act promptly to remedy this situation should it occur. In addition, the Commission requests that the Amex monitor the trading volume associated with the additional options series listed as a result of the Pilot Program and the effect of these additional series on market fragmentation and on the capacity of the Exchange's, OPRA's, and vendors' automated systems.

As noted above, the Commission is approving the Amex's proposal on a pilot basis. In the event that Amex proposes to extend the Pilot Program beyond June 5, 2004, expand the number of options eligible for inclusion in the Pilot Program, or seek permanent approval of the Pilot Program, it should submit a Pilot Program report to the Commission along with the filing of such proposal.[16] The report must cover the entire time the Pilot Program was in effect, and must include: (1) Data and written analysis on the open interest and trading volume for options (at all strike price intervals) selected for the Pilot Program; (2) delisted options series (for all strike price intervals) for all options selected for the Pilot Program; (3) an assessment of the appropriateness of $1 strike price intervals for the options the Amex selected for the Pilot Program; (4) an assessment of the impact of the Pilot Program on the capacity of the Amex's, OPRA's, and vendors' automated systems; (5) any capacity problems or other problems that arose during the operation of the Pilot Program and how the Amex addressed them; (6) any complaints that the Amex received during the operation of the Pilot Program and how the Amex addressed them; and (7) any additional information that would help to assess the operation of the Pilot Program.

The Commission believes that the proposal to codify previously approved options strike price interval guidelines in Amex Rule 903 and to revise Amex Rule 903 to describe the options' exchanges existing 2½-point strike price program with greater specificity should help to clarify the Amex's rules and facilitate compliance with them, thereby protecting investors and the public interest.

The Commission finds good cause for approving the proposal, as amended, prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Amex's Pilot Program is identical to a CBOE pilot program (''CBOE Pilot'') that the

[11] According to the Amex, on November 6, 2002, the OPRA five-minute message peak was 8,203 mps and on November 13, 2002, the one-minute peak was 10,091 mps.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78f(b)(5).

[16] The Commission expects the Amex to submit a proposed rule change at least 60 days before the expiration of the Pilot Program in the event the Amex wishes to extend, expand, or seek permanent approval of the Pilot Program.

Commission approved.[17] Notice of the CBOE Pilot was published for comment [18] and the Commission received one comment letter, which supported the CBOE's proposal. Accordingly, the Commission believes that the Amex's Pilot Program raises no issues of regulatory concern. Amendment No. 2 clarifies the proposal by specifying the expiration date for the Pilot Program and the strike price intervals for options on individual stocks and ETFs. For these reasons, the Commission believes that there is good cause, consistent with sections 6(b)(5) and 19(b) of the Act,[19] to approve the Amex's proposal, as amended, on an accelerated basis, through June 5, 2004.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[20] that the proposed rule change (SR–Amex–2003–36) and Amendments No. 1 and 2 thereto are hereby approved, on an accelerated basis and as a pilot program, through June 5, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[21]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15353 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–48019; File No. SR–PCX–2003–16]

Self-Regulatory Organizations; Notice of Filing and Order Accelerating Approval of Proposed Rule Change and Amendment No. 1 Thereto by the Pacific Exchange, Inc. Relating to an Amendment to the Auto-Ex Incentive Program

June 11, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on May 21, 2003, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. On June 6, 2003, the Exchange filed Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and is approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

PCX proposes to amend its rules to extend the Automatic Execution System (''Auto-Ex'') Incentive Pilot Program until June 30, 2004. The text of the proposed rule change is available at the Office of the Secretary, PCX and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. PCX has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On September 25, 2001, the Commission approved, as a nine-month pilot program, the Exchange's proposal to amend Rule 6.87, which governs the operation of Auto-Ex,[4] to provide an Auto-Ex Incentive Program for apportioning Auto-Ex trades among Market Makers.[5] On June 7, 2002, the Commission extended the Auto-Ex Incentive Program pilot for six months [6] and on December 24, 2002, the Commission extended the pilot for an additional six months.[7] The pilot program is currently set to expire on June 24, 2003.

The Auto-Ex Incentive Program allows the Exchange to assign Auto-Ex orders to logged-on Market Makers according to the percentage of their in-person agency [8] contracts traded in an issue (excluding Auto-Ex contracts) compared to all of the Market Maker in-person agency contracts traded (excluding Auto-Ex contracts) during the review period. The review period is determined by the Options Floor Trading Committee (''OFTC'') and may be for any period of time not in excess of two weeks.[9] The percentage distribution determined for a review period will be effective for the succeeding review period.

The Exchange is requesting an additional extension of the pilot program from June 24, 2003 through June 30, 2004. The added time permits the Exchange to phase-in the Exchange's new trading platform for options, ''PCX Plus'', on an issue-by-issue basis.[10] As each issue is phased into PCX Plus, the Exchange will simultaneously phase-out such issue from the Auto-Ex Incentive Program. PCX Plus will eventually replace the Auto-Ex Incentive Program in its entirety. Therefore, the Exchange believes that an extension of the program is warranted until June 30, 2004, the date on which PCX Plus will be completely operative.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, is consistent with section 6(b)[11] of the Act, in general, and furthers the objectives of

[17] *See* Securities Exchange Act Release No. 47991 (June 5, 2003) (order approving File No. SR–CBOE–2001–60).

[18] *See* Securities Exchange Act Release No. 47753 (April 29, 2003), 68 FR 23784 (May 5, 2003).

[19] 15 U.S.C. 78f(b)(5) and 78s(b).

[20] 15 U.S.C. 78s(b)(2).

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Letter from Tania J. Cho, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, dated June 5, 2003 (''Amendment No. 1''). In Amendment No. 1, PCX amended its proposal to request an extension of its Auto-Ex Incentive Program pilot until June 30, 2004, rather than June 24, 2004, as stated in the original proposal, so that the pilot's expiration coincides with the date on which the Exchange's ''PCX Plus'' system will be completely operative. *See supra* n. 10 and accompanying text.

[4] Auto-Ex is the Exchange's Automated Execution system feature of POETS for market or marketable limit orders. The Pacific Options Exchange Trading System (''POETS'') is the Exchange's automated trading system comprised of an options order routing system, an automatic execution system (''Auto-Ex''), an on-line limit order book system and an automatic market quote update system. Option orders can be sent to POETS via the Exchange's Member Firm Interface (''MFI''). Market and marketable limit orders sent through the MFI will be executed by Auto-Ex if they meet the order type and size requirements of the Exchange.

[5] *See* Exchange Act Release No. 44847 (September 25, 2001), 66 FR 50237 (October 2, 2001) (SR–PCX–01–05).

[6] *See* Exchange Act Release No. 46115 (June 25, 2002), 67 FR 44494 (July 2, 2002) (SR–PCX–2002–34).

[7] *See* Exchange Act Release No. 47088 (December 24, 2002), 68 FR 140 (January 2, 2003) (SR–PCX–2002–78).

[8] Agency contracts are those contracts that are represented by an agent and do not include contracts traded between Markets Makers in person in the trading crowd.

[9] The OFTC has set a two-week review period for all options classes and the OFTC will not vary the term of the review period except for exigent circumstances.

[10] *See* Exchange Act Release No. 47838 (May 13, 2003), 68 FR 27129 (May 19, 2003) (''PCX Plus Order'').

[11] 15 U.S.C. 78f(b).

section 6(b)(5),[12] in particular, in that it is designed to facilitate transactions in securities, to promote just and equitable principles of trade, to enhance competition and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change, as amended, will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of PCX. All submissions should refer to the File No. SR–PCX–2003–16 and should be submitted by July 9, 2003.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Exchange has requested that the Commission approve this proposed rule change on an accelerated basis. After careful consideration, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of section 6(b)(5) of the Act.[13] The Commission notes that this proposal is the latest in a series of Auto-Ex Incentive Pilot Program extensions previously approved by the Commission.[14] Further, the Commission notes that the Auto-Ex Incentive Pilot Program itself has remained substantively unchanged since it was originally approved by the Commission as a nine-month pilot.[15] The Commission believes that an extension until June 30, 2004 provides an appropriate period of time for the Exchange to continue its Auto-Ex Incentive Program while it phases-in its new trading platform for options, ''PCX Plus,'' on an issue-by-issue basis. Once ''PCX Plus'' is fully implemented, the Exchange no longer will need to operate its Auto-Ex system.[16] Accordingly, the Commission finds good cause for approving the proposed rule change, as amended, prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**.

V. Conclusion

Is it therefore ordered, pursuant to section 19(b)(2) of the Act,[17] that the proposed rule change (SR–PCX–2003–16), as amended, is hereby approved on an accelerated basis, as a pilot program scheduled to expire on June 30, 2004.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[18]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–15313 Filed 6–17–03; 8:45 am]

BILLING CODE 8010–01–P

[12] 15 U.S.C. 78f(b)(5).

[13] Id. In approving this rule, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[14] *See* Exchange Act Release No. 47088 (December 24, 2002), 68 FR 140 (January 2, 2003) (SR–PCX–2002–78) (six-month extension); Securities Exchange Act Release No. 46115 (June 25, 2002); 67 FR 44494 (July 2, 2002) (SR–PCX–2002–34) (six-month extension).

[15] *See* Exchange Act Release No. 44847 (September 25, 2001), 66 FR 50237 (October 2, 2001) (SR–PCX–01–05).

[16] *See* PCX Plus Order, supra n. 10.

[17] 15 U.S.C. 78s(b)(2).

[18] 17 CFR200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3498]

State of Tennessee; (Amendment #5)

In accordance with a notice received from the Department of Homeland Security—Federal Emergency Management Agency, effective June 10, 2003, the above numbered declaration is hereby amended to include Blount, Cocke, Jefferson and Sevier Counties in the State of Tennessee as disaster areas due to damages caused by severe storms, tornadoes and flooding occurring on May 4, 2003 and continuing through May 30, 2003.

In addition, applications for economic injury loans from small businesses located in the contiguous counties of Greene and Hamblen in the State of Tennessee; and Haywood and Madison counties in the State of North Carolina may be filed until the specified date at the previously designated location. All other counties contiguous to the above named primary counties have been previously declared.

All other information remains the same, *i.e.*, the deadline for filing applications for physical damage is July 7, 2003, and for economic injury the deadline is February 6, 2004.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: June 12, 2003.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 03–15357 Filed 6–17–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3510]

Commonwealth of Virginia

Southampton County and the contiguous counties of Greensville, Isle of Wight, Surry, Sussex, and the Independent Cities of Franklin and Suffolk in the Commonwealth of Virginia; and Gates, Hertford, and Northampton Counties in the State of North Carolina constitute a disaster area due to damages caused by severe storms, hail, and tornadoes that occurred on May 9, 2003. Applications for loans for physical damage may be filed until the close of business on August 11, 2003 and for economic injury until the close of business on March 11, 2004 at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd., South 3rd Floor, Niagara Falls, NY 14303.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	5.625
Homeowners without credit available elsewhere	2.812
Businesses with credit available elsewhere	5.906

	Percent
Businesses and non-profit organizations without credit available elsewhere	2.953
Others (including non-profit organizations) with credit available elsewhere	5.500
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	2.953

The numbers assigned to this disaster for physical damage are 351012 for Virginia and 351112 for North Carolina. The numbers assigned to this disaster for economic damage are 9V8100 for Virginia and 9V8200 for North Carolina.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: June 11, 2003.

Hector V. Barreto,

Administrator.

[FR Doc. 03–15358 Filed 6–17–03; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 4351]

United States International Telecommunication Advisory Committee Information Meeting on the World Summit on the Information Society and the U.S. Preparatory Process

The Department of State announces meetings of the U.S. International Telecommunication Advisory Committee (ITAC). The purpose of the Committee is to advise the Department on matters related to telecommunication and information policy matters in preparation for international meetings pertaining to telecommunication and information issues.

The ITAC will meet to discuss the matters related to the World Summit on the Information Society (WSIS), which will take place in December 2003, including U.S. preparations for the WSIS. The meeting will take place on Wednesday, July 9, 2003 from 10:30 a.m. to 12 p.m. at the Historic National Academy of Science Building. The National Academy of Sciences is located at 2100 C St. NW., Washington, DC.

This meeting announcement does not meet the official deadline due to constraints imposed by the travel of senior officials who will brief on WSIS. Members of the public are welcome to participate and may join in the discussions, subject to the discretion of the Chair. People intending to attend a meeting at the Department of State should send the following data by fax to (202) 647–7407 or e-mail to *worsleydm@state.gov* not later than 24 hours before the meeting: (1) Name of the meeting, (2) your name, and (3) organizational affiliation. A valid photo ID must be presented to gain entrance to the National Academy of Sciences Building. Directions to the meeting location may be obtained by calling the ITAC Secretariat at 202 647–2592 or e-mail to *worsleydm@state.gov.*

Dated: June 5, 2003.

Joseph P. Richardson,

Office of Multilateral Affairs, International Communications and Information Policy, Department of State.

[FR Doc. 03–15386 Filed 6–17–03; 8:45 am]

BILLING CODE 4710–45–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Proposed Advisory Circular; Turbine Rotor Strength Requirements

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of availability of proposed advisory circular and request for comments.

SUMMARY: The Federal Aviation Administration (FAA) announces the availability of proposed advisory circular (AC) Number 33.27–1, Turbine Rotor Strength Requirements of 14 CFR 33.27.

DATES: Comments must be received on or before August 1, 2003.

ADDRESSES: Send all comments on the proposed AC to the Federal Aviation Administration, Attn: Tim Mouzakis, Engine and Propeller Standards Staff, ANE–110, 12 New England Executive Park, Burlington, MA 01803–5299.

FOR FURTHER INFORMATION CONTACT: Tim Mouzakis, Engine and Propeller Standards Staff, ANE–110, at the above address; telephone: (781) 238–7114; fax: (781) 238–7199; e-mail: *timoleon.mouzakis@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

A copy of the subject AC may be obtained by contacting the person named under **FOR FURTHER INFORMATION CONTACT** or by donwloading the proposed AC from the following Internet Web site: *http://www.airweb.faa.gov/rgl.* The FAA invites interested parties to comment on the proposed AC. Comments should identify the subject of the AC and be submitted to the individual identified under **FOR FURTHER INFORMATION CONTACT**. The FAA will consider all communications received by the closing date before issuing the final AC.

Background

This AC provides guidance and acceptable methods, but not the only methods, for demonstrating compliance with the rotor strength (overspeed) requirements of § 33.27 of title 14 of the Code of Federal Regulations (14 CFR 33.27).

(Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.)

Issued in Burlington, Massachusetts, on June 11, 2003.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03–15402 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petitions for Waivers of Compliance

In accordance with title 49 Code of Federal Regulations (CFR) section 211.41, and 49 U.S.C. 20103, this notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety regulations. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being sought, and the petitioner's argument in favor of relief.

Canadian National Railway; FRA Waiver Petition No. FRA–2003–15012

Canadian National Railway (CN) located in Montreal, Canada, seeks a permanent waiver of compliance from 49 CFR 241.7(c), *United States Locational Requirements for Dispatching of United States Rail Operations,* to allow the continuation of Canadian dispatching of that part of the Sprague Subdivision located in the United States, extending between Baudette, Minnesota, and International Boundary, Minnesota, approximately 43.8 miles and on those parts of the Strathroy and Flint Subdivisions located in the United States, forming a continuous line between Sarnia, Ontario, Canada, through the St. Clair River Tunnel, and Port Huron, Michigan, approximately 3.1 miles, as defined in appendix A to part 241. This request formalizes the request for waiver requirement contained in part 241, specifically § 241.7(c)(3), which refers to territory that was previously

grandfathered in the exceptions to extraterritorial dispatching contained in FRA's Interim Final Rule (*see* 66 FR 63942, December 11, 2001).

In this regard, the track segments identified in the Interim Final Rule remains the same as identified above. With respect to the Sprague Subdivision, this is part of a continuous line extending between Rainy River, Ontario, and Navin, Manitoba, Canada, a distance of 145.2 miles, a portion of which cuts across a corner of the State of Minnesota, from the U.S./Canadian border near Baudette, Minnesota (milepost 1.1), and the U.S./Canadian border at a point identified as International Boundary, Minnesota, milepost 44.9, a distance of approximately 43.8 miles. Approximately 15 trains per day are operated over this segment. Each train that traverses this territory is operated by the same crew. The entire Sprague Subdivision is single track and is operated under a Centralized Traffic Control system, controlled from a single dispatching desk at CN's Rail Traffic Control Center in Edmonton, Alberta, Canada. With respect to the Strathroy and Flint Subdivisions, this is part of a continuous line extending between London, Ontario, Canada, and Port Huron, Michigan, a distance of 61.7 miles, a 3.1 mile portion of which is located in the United States. Approximately 26 trains per day are operated over this segment. Each train that traverses this territory is operated by the same crew. This segment consists of a single track for approximately 1.1 miles, and two main tracks for the remaining 2.0 miles, and is operated under a Centralized Traffic Control system, controlled from a single dispatching desk at CN's Rail Traffic Control Center in Toronto, Ontario, Canada. Dispatching of all trackage of the Sprague Subdivision and the Strathroy and Flint Subdivisions is an entirely English operation and fully dispatched in English. Canadian Rail Operating Rules (CROR) and CN's Timetable and Special Instructions govern train operations on this trackage. CN uses English (or Imperial) units for all aspects of railroad operations, including distance, speed, and location. The CN dispatchers are covered under their company drug and alcohol policies and their dispatching office is under 24-hour security. Transport Canada Rail Safety Directorate has the legislative safety jurisdiction over CN in accordance with the provisions contained in the Railway Safety Act over all federally regulated railways operating in Canada.

Based on the foregoing, CN seeks a permanent waiver of compliance from 49 CFR 241.7(c), *United States Locational Requirements for Dispatching of United States Rail Operations,* to allow the continuation of Canadian dispatching on that part of the Sprague Subdivision located in the United States and on those parts of the Strathroy and Flint Subdivisions located in the United States, as described above.

Interested parties are invited to participate in this proceeding by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with the request for a waiver of certain regulatory provisions. If any interested party desires an opportunity for oral comment, he or she should notify FRA, in writing, before the end of the comment period and specify the basis for his or her request. All communications concerning these proceedings should identify the appropriate docket number (Docket Number FRA 2003–15012) and must be submitted to the DOT Docket Management Facility, Room PL–401 (Plaza level) 400 Seventh Street, SW., Washington, DC 20590. All documents in the public docket, including CN's detailed waiver request, are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.* Communications received within 30 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning this proceeding are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility.

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Issued in Washington, DC on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15394 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petitions for Waivers of Compliance

In accordance with Title 49 Code of Federal Regulations (CFR) section 211.41, and 49 U.S.C. 20103, this notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety regulations. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being sought, and the petitioner's argument in favor of relief.

Canadian Pacific Railway; FRA Waiver Petition No. FRA–2003–15010

Canadian Pacific Railway (CP) located in Montreal, Canada, seeks a permanent waiver of compliance from 49 CFR 241.7(c), *United States Locational Requirements for Dispatching of United States Rail Operations* to allow the continuation of Canadian dispatching of that part of the Windsor Subdivision located in the United States, extending between Windsor, Ontario, Canada, and Detroit, Michigan, approximately 1.8 miles, as defined in appendix A to part 241. This request formalizes the request for waiver requirement contained in part 241, specifically § 241.7(c)(3), which refers to territory that was previously grandfathered in the exceptions to extraterritorial dispatching contained in FRA's Interim Final Rule (*see* 66 FR 63942, December 11, 2001).

In this regard, the track segment identified in the Interim Final Rule remains the same as identified above. All trains operated into the United States are of very short distances to an interchange point with a U.S. railroad and are always under the control of a single crew. All dispatching is conducted in English. All units of measure are the same as those used in the U.S. Because of the very short distances, all train operations in the U.S. are under the control of a single dispatching desk, located in CP's Network Management Center in Montreal, Quebec, Canada. CP operates approximately 6 to 8 trains a day over this segment. The trackage is operated under a Centralized Traffic Control system and consists of two main tracks for the entire 1.8 mile distance. Movements are governed by the Canadian Rail Operating Rules (CROR) and CP's Timetable and Special Instructions. CP's train dispatchers are covered under their company drug and

alcohol policies and their dispatching office is under 24-hour security. Transport Canada Rail Safety Directorate has the legislative safety jurisdiction over CP in accordance with the provisions contained in the Railway Safety Act over all federally regulated railways operating in Canada.

Based on the foregoing, CP seeks a permanent waiver of compliance from 49 CFR 241.7(c), *United States Locational Requirements for Dispatching of United States Rail Operations,* to allow the continuation of Canadian dispatching on that part of the Windsor Subdivision located in the United States, between Windsor, Ontario, Canada, and Detroit, Michigan, approximately 1.8 miles.

Interested parties are invited to participate in this proceeding by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with the request for a waiver of certain regulatory provisions. If any interested party desires an opportunity for oral comment, he or she should notify FRA, in writing, before the end of the comment period and specify the basis for his or her request. All communications concerning these proceedings should identify the appropriate docket number (Docket Number FRA 2003–15010) and must be submitted to the DOT Docket Management Facility, Room PL–401 (Plaza level) 400 Seventh Street, SW., Washington, DC 20590. All documents in the public docket, including CP's detailed waiver request, are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.* Communications received within 30 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning this proceeding are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility.

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Issued in Washington, DC, on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15391 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Dakota, Minnesota & Eastern Railroad

[Docket Number FRA–2003–14986]

Dakota, Minnesota & Eastern Railroad (DM&E) seeks a waiver of compliance from the provisions of the *Track Safety Standards,* 49 CFR 213.113(a), regarding defective rails.

The DM&E is petitioning for a waiver which would provide relief from replacing rails that contain bolt hole/rail crack-outs that emanate from the edge of the rail to the bolt hole 'one' location of various rail joint locations.

The petitioner states that rails with bolt-hole/rail crack-outs up to 6″ maximum from the end of the rail to the bolt hole 'one' location can be allowed to remain in service as the broken-out piece of rail remains tightly held by the joint bars and thus poses less danger of breaking loose. The petitioner proposes to institute a 10 MPH slow order at these locations as well as schedule daily visual inspections in lieu of constant visual inspection of each operation over that defect (for up to no more than 30 days for any instance) by qualified personnel as per 49 CFR 213.7. If the cracks grow greater than 6″ from the edge of rail or the rail section becomes loose, priority will be given to that location for an immediate rail replacement. The petitioner feels that this will enable the DM&E to more efficiently utilize its limited resources.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA in writing before the end of the comment period and specify the basis for their request.

All communication concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver Petition Docket Number 2003–14986) and must be submitted to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (volume 65, number 70; pages 19477–78), or you may visit *http://dms.dot.gov.*

Issued in Washington, DC on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15399 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petitions for Waivers of Compliance

In accordance with title 49 Code of Federal Regulations (CFR) section 211.41 and 49 U.S.C. 20103, this notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety regulations. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being

sought, and the petitioner's argument in favor of relief.

Eastern Maine Railway; FRA Waiver Petition No. FRA–2003–15011

Eastern Maine Railway (EMRY), located in St. John, New Brunswick, Canada, seeks a permanent waiver of compliance from 49 CFR 241.7(c), *United States Locational Requirements for Dispatching of United States Rail Operations,* to allow the continuation of Canadian dispatching of that part of Mattawamkeag Subdivision located in the United States extending between Vanceboro, Maine, and Brownville Junction, Maine, approximately 99 miles, as defined in Appendix A to Part 241. This request was submitted in accordance with § 241.7(c)(3), which permits waiver of the requirements found in Part 241 that all dispatching of U.S. rail operations be conducted in the U.S. This territory was previously grandfathered in the exceptions to extraterritorial dispatching contained in FRA's Interim Final Rule (*see* 66 FR 63942, December 11, 2001).

In this regard, the track segment identified in the Interim Final Rule remains the same as identified above. This segment consists of a single main track dispatched from a single desk at the EMRY's Rail Traffic Control office in St. John, New Brunswick, Canada, under Canadian Rail Operating Rules (CROR), and the EMRY's Timetable and Special Instructions. The trackage is non-signaled and operated under Occupancy Control System rules. All dispatching is conducted in English. All units of measure are the same as those used in the U.S. EMRY operates approximately 2 trains a day over this segment. The train dispatchers who perform the dispatching function for the EMRY are employed by the New Brunswick Southern Railway (NBSR) and are therefore covered under the NBSR's company drug and alcohol policies and their dispatching office is under 24-hour security. The Department of Transportation of the Province of New Brunswick, Canada, is the regulatory authority which exercises safety jurisdiction over the New Brunswick Southern Railway, which provides dispatching services for the EMRY.

Based on the foregoing, EMRY seeks a permanent waiver of compliance from 49 CFR 241.7(c), *United States Locational Requirements for Dispatching of United States Rail Operations,* to allow the continuation of Canadian dispatching on that part of the Mattawamkeag Subdivision located in the United States, as described above.

Interested parties are invited to participate in this proceeding by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with the request for a waiver of certain regulatory provisions. If any interested party desires an opportunity for oral comment, he or she should notify FRA, in writing, before the end of the comment period and specify the basis for his or her request. All communications concerning these proceedings should identify the appropriate docket number (Docket Number FRA 2003–15011) and must be submitted to the DOT Docket Management Facility, Room PL–401 (Plaza level) 400 Seventh Street, SW., Washington, DC 20590. All documents in the public docket, including EMRY's detailed waiver request, are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.* Communications received within 30 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning this proceeding are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility.

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the Federal Register published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Issued in Washington, DC on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15395 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with part 211 of title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favour of relief.

National Railroad Passenger Corporation

[Docket Number FRA–2003–14444]

The National Railroad Passenger Corporation (Amtrak) has petitioned for a permanent waiver of compliance for the Acela trainsets and HHP–8 Electric locomotives from certain dimensional requirements of the Railroad *Passenger Equipment Safety Standards,* 49 CFR 238.429 and Safety Appliance Standards, 49 CFR 231.14. Amtrak requests this relief due to the unique carbody design of this new equipment and its structural frame that precludes installation of safety appliances compliant with the safety standards. Amtrak and the equipment's manufacturer have made every effort to bring the safety appliance arrangement into compliance, but find it not possible for the following items:

• Requirements of § 238.429(d)(4) & § 231.14(c)(3)(ii)—''The maximum and minimum distances from the top of the rail for vertical handrails and handholds shall be 51 inches * * *''.

Proposed alternate compliance—The current handholds are approximately 68 inches from the top of the rail. The structural integrity of the carbody side sill would be compromised by strict adherence to this dimensional requirement. Amtrak proposes an alternate solution with the installation of additional horizontal handholds on either side of the cab door, approximately 53 to 54 inches from the top of the rail. These additional handholds will provide personnel the support necessary for a safe ingress to the powercar or locomotive cab area while eliminating the danger of weakening the side sill structure. Additionally, carbody clearance constraints and strict infrastructure clearance limits dictate that the horizontal handholds have a maximum clearance of 2.0 inches.

• Requirements of § 238.429(d)(5)—''Vertical handrails and handholds shall continue to a point equal to the top edge of the control cab door.''

Relief Requested—The powercar's structural members are arranged such that they extend to a point several inches below the top of the control cab door to maximize the integrity of the upper framework. The vertical handholds are arranged to avoid interference with these structural members. Serious consideration was

given toward applying a horizontal handhold on the uppermost portion of the doorframe interior as an alternate compliance, but after further analysis Amtrak determined that this would pose a greater safety risk during the ingress and egress of personnel at this location. Therefore, permanent relief from the requirement that the vertical handhold continue to a point equal to the top edge of the control cab door is requested.

• Requirements of § 238.429(e)(4) & 231.14(b)(2)—''The minimum clear depth of the sill step shall be 8 inches''.

Regarding the sill steps, to decrease the distance in the vertical rise measurement from the original 21 inches it was necessary to raise the upper step. This revised design maintains the clear depth measurement at 7.5 inches. Amtrak believes that decreasing the vertical rise while maintaining the depth between the step and the carbody ensures a safer sill step area.

• Requirements of § 238.429(e)(6) & § 231.14(b)(4)—''Sill steps shall not have a vertical rise between treads exceeding 18 inches''.

Proposed alternate compliance—The original sill step configuration had a vertical rise of 21 inches due to constraints with the design of the carbody's side sill. This alternate design lowers this distance to approximately 20 inches. However, further decrease of this dimension would result in a corresponding decrease of the 7.5-inch clear depth of the sill step.

• Requirements of § 238.429(e)(10)—''50% of the tread surface area of each sill step shall be open space''.

Proposed alternate compliance—Amtrak believes that the current serrated design for the lower step, with 2.25-inch high foot guards on each side, combined with a non-skid surface material would provide a safer tread surface than a more traditional open space design.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (Waiver Petition Docket Number FRA–2003–14444) and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401, Washington, DC, 20590–0001. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.—5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the Federal Register published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Issued in Washington, DC on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15392 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR part 236 as detailed below.

Docket No. FRA–2003–15301

Applicant: Burlington Northern and Santa Fe Railway, Mr. William G. Peterson, Director Signal Engineering, 4515 Kansas Avenue, Kansas City, Kansas 66106.

Burlington Northern and Santa Fe Railway (BNSF) seeks approval of the proposed modification of the traffic control system, on the two main tracks at Burlington, Iowa, milepost 205.48, on the Nebraska Division, Ottumwa Subdivision. The proposed changes consist of the conversion of the power-operated switch to hand operation, equipped with an electric lock, and removal of the three associated absolute controlled signals on Main Track No. 2, and the discontinuance and removal of the back to back intermediate signals on Main Track No. 1.

The reasons given for the proposed changes are that the switch at one time was used for passenger service to the depot, but now the track is used to tie up a switch engine once or twice a week, and due to the short blocks on Main Track No. 1.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

All communications concerning this proceeding should be identified by the docket number and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by the FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the internet at the docket facility's Web site at *http://dms.dot.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15393 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to title 49 Code of Federal Regulations (CFR) part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR part 236 as detailed below.

Docket No. FRA–2003–15145

Applicant: Burlington Northern and Santa Fe Railway, Mr. William G. Peterson, Director Signal Engineering, 4515 Kansas Avenue, Kansas City, Kansas 66106.

Burlington Northern and Santa Fe Railway (BNSF) seeks approval of the proposed discontinuance and removal of the automatic block signal system, between Hettinger, North Dakota, milepost 926.0 and Terry, Montana, milepost 1078.9, on the Montana Division, Hettinger Subdivision, a distance of approximately 153 miles, with governance of train movements by Track Warrant Control.

The reason given for the proposed changes is that due to an ice storm which disabled about 35 percent of the pole line on the Subdivision, the signal pole line is in need of large amounts of replacement capital to restore and rehabilitate this line. BNSF believes that this scarce capital would be much better spent on other lines with greater track density, because this line averages only four trains per day.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

All communications concerning this proceeding should be identified by the docket number and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by the FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the internet at the docket facility's Web site at *http://dms.dot.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC, on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15397 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) Part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR part 236 as detailed below.

Docket No. FRA–2003–15194

Applicant: CSX Transportation, Incorporated, Mr. Eric G. Peterson, Assistant Chief Engineer, Signal Design and Construction, 4901 Belfort Road, Suite 130 (S/C J–370), Jacksonville, Florida 32256.

CSX Transportation, Incorporated seeks approval of the proposed modification of the traffic control system at South Wye, milepost ANA 587.80, near Waycross, Georgia, on the Jesup Subdivision, Jacksonville Service Lane. The proposed change consists of the discontinuance and removal of controlled absolute signal 220RD, associated with the addition of aspects to controlled absolute signal 222RA to govern southward diverging routes from Rice Yard to the Main Track.

The reason given for the proposed changes is to eliminate facilities no longer needed in present day operation.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

All communications concerning this proceeding should be identified by the docket number and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by the FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the internet at the docket facility's Web site at *http://dms.dot.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

FRA expects to be able to determine these matters without an oral hearing.

However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC, on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15398 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR part 236 as detailed below.

Docket No. FRA–2003–15102

Applicant: Norfolk Southern Corporation, Mr. Brian L. Sykes, Chief Engineer C&S Engineering, 99 Spring Street, SW., Atlanta, Georgia 30303.

The Norfolk Southern Corporation seeks approval of the proposed discontinuance and removal of the automatic block signal system, on the two main tracks between Clair, New Jersey, milepost 11.7 and DB-Junction, New Jersey, milepost 4.3, on the Orange Running Track, Harrisburg Division. The proposal includes retention of the interlocking signals at DB-Junction.

The reason given for the proposed changes is to eliminate facilities no longer needed for present day operation. Both tracks are only used for local access to the Orange Industry Track.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

All communications concerning this proceeding should be identified by the docket number and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by the FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the internet at the docket facility's Web site at *http://dms.dot.gov*.

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov*.

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC on June 11, 2003.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 03–15396 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection abstracted below has been forwarded to the Office of management and Budget (OMB) for review and approval. The nature of the information collection is described as well as its expected burden. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 4, 2003. No comments were received.

DATES: Comments must be submitted on or before July 18, 2003.

FOR FURTHER INFORMATION CONTACT: James Zok, maritime Administration (MAR–500), 400 Seventh St., SW., Washington, DC 20590. Telephone: 202–366–0364; FAX: 202–366–9580, or e-mail: *jim.zok@marad.dot.gov.* Copies of this collection also can be obtained from that office.

SUPPLEMENTARY INFORMATION:

Maritime Administration (MARAD)

Title: Customer Service Survey.

OMB Control Number: 2133–0528.

Type of Request: Extension of currently approved collection.

Affected Public: Individuals receiving goods and services from the Maritime Administration.

Forms: MA–1016, MA–1017, and MA–1021.

Abstract: Executive Order 12862 requires agencies to survey customers to determine the kind and quality of services they want and the level of satisfaction with existing services. This collection provides the instruments used to collect the information regarding MARDAD programs and services.

Annual Estimated Burden Hours: 256 hours.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention MARAD Desk Officer.

Comments are Invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents including the use of automated collection techniques or other forms of information technology.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

Issued in Washington, DC on June 13, 2003.

Joel C. Richard,

Secretary Maritime Administration.

[FR Doc. 03–15371 Filed 6–17–03; 8:45 am]

BILLING CODE 4910–81–M

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

June 10, 2003.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before July 18, 2003 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–0139.

Form Number: IRS Form 2106.

Type of Review: Revision.

Title: Employee Business Expenses.

Description: Internal Revenue Code (IRC) section 62 allows employees to deduct their business expenses to the extent of reimbursement in computing ''Adjusted Gross Income''. Expenses in excess of reimbursements are allowed as an itemized deduction. Unreimbursed meals and entertainment are allowed to the extent of 50% of the expense. Form 2106 is used to figure these expenses.

Respondents: Individuals or households.

Estimated Number of Respondents/ Recordkeepers: 5,567,188.

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—2 hr., 11 min.

Learning about the law or the form—27 min.

Preparing and sending the form—1 hr., 27 min.

Copying, assembling, and sending the form to the IRS—34 min.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 22,809,519 hours.

OMB Number: 1545–0890.

Form Number: IRS Form 1120–A.

Type of Review: Extension.

Title: U.S. Corporation Short-Form Income Tax Return.

Description: Form 1120–A is used by small corporations, those with less that $500,000 of income and assets, to compute their taxable income and tax liability. The IRS uses Form 1120–A to determine whether corporations have correctly computed their tax liability.

Respondents: Business or other for-profit, Farms.

Estimated Number of Respondents/ Recordkeepers: 191,769.

Estimated Burden Hours Per Respondent/Recordkeeper:

Form	Recordkeeping	Learning about the law or the form	Preparing the form	Copying, assembling, and sending the form to the IRS
1120	71 hr., 18 min	43 hr., 29 min	75 hr., 24 min	8 hr., 18 min.
1120–A	43 hr., 44 min	23 hr., 6 min	41 hr., 35 min	4 hr., 49 min.
Schedule D (1120)	7 hr., 10 min	4 hr., 6 min	6 hr., 16 min	32 min.
Schedule H (1120)	5 hr., 58 min	35 min	43 min	0 min.
Schedule N (1120)	3 hr., 35 min	1 hr., 7 min	3 hr., 6 min	32 min.
Schedule PH (1120)	15 hr., 18 min	6 hr., 12 min	8 hr., 35 min	32 min.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 19,152,552 hours.

OMB Number: 1545–1057.

Form Number: IRS Form 8800.

Type of Review: Extension.

Title: Application for Additional Extension of Time to File U.S. Return for a Partnership, REMIC, or for Certain Trusts.

Description: Form 8800 is used by partnerships, real estate mortgage investment conduits (REMICs), and by certain trusts to request an additional extension of time (up to 3 months) to file Form 1065, Form 1041, or Form 1066. Form 8800 contains data needed by the IRS to determine whether or not a taxpayer qualifies for such an extension.

Respondents: Business or other for-profit, Farms.

Estimated Number of Respondents/ Recordkeepers: 20,000.

Estimated Burden Hours Per Respondent/Recordkeeper: 11 minutes.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 3,800 hours.

Clearance Officer: Glenn Kirkland, Internal Revenue Service, Room 6411–03, 1111 Constitution Avenue, NW, Washington, DC 20224, (202) 622–3428.

OMB Reviewer: Joseph F. Lackey, Jr., Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, (202) 395–7316.

Mary A. Able,

Departmental Reports Management Officer.

[FR Doc. 03–15382 Filed 6–17–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

June 9, 2003.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before July 18, 2003 to be assured of consideration.

Financial Management Service (FMS)

OMB Number: 1510–0056.

Form Number: SF 3881.

Type of Review: Extension.

Title: ACH Vendor/Miscellaneous Payment Enrollment Form.

Description: Payment data will be collected from vendors doing business with the Federal Government. FMS/ Treasury will use the information to electronically transmit payments to vendors' financial institutions. The affected public includes (but not limited to) business, state/local governments, corporations, educational institutions, and other organizations.

Respondents: Business or other for-profit, not-for-profit institutions, State, Local or Tribal Government.

Estimated Number of Respondents: 70,000.

Estimated Burden Hours Per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 17,500 hours.

Clearance Officer: Juanita Holder, Financial Management Service, 3700 East West Highway, Room 135, PGP II, Hyattsville, MD 20782.

OMB Reviewer: Joseph F. Lackey, Jr., (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Mary A. Able,

Departmental Reports Management Officer.

[FR Doc. 03–15383 Filed 6–17–03; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

President's Commission on the United States Postal Service

AGENCY: Department of the Treasury, Departmental Offices.

ACTION: Notice and request for comments.

SUMMARY: Now that the Commission has concluded the testimonial portion of its work, it will accept final written comments from any party who wishes to submit them for consideration.

The Commission has established three methods by which final comments can be submitted for consideration and review:

1. Transmission by E-mail to the following address: *pcusps_final@do.treas.gov.* Statements can be embedded in the E-mail as ASCII text or sent as a MS Word or ASCII text attachment. Do not include artwork or other graphic elements.

2. Stored on 3½ inch high density computer disk as a MS word or ASCII text document (Windows format only) and mailed or hand-delivered to: President's Commission on the United States Postal Service, 1120 Vermont Avenue, NW., Suite 971, Washington, DC 20005.

3. Typewritten statements may be mailed or hand-delivered to: President's Commission on the United States Postal Service, 1120 Vermont Avenue, NW., Suite 971, Washington, DC 20005.

DATES: E-mail transmissions of all final comments must be received by the Commission no later than 5 p.m. eastern standard time on Tuesday, July 8. Mailed submissions must be postmarked no later than 5 p.m. eastern standard time on Tuesday, July 8.

To be accepted by the Commission, final comments must not exceed a maximum length of 10 pages of double-spaced written text.

SUPPLEMENTARY INFORMATION: Please be aware that the Commission may, at its discretion, post any final comments it receives on the Commission's Web site at *www.treas.gov/offices/domestic-finance/usps.*

FOR FURTHER INFORMATION CONTACT: If you have any questions about this final-comment process, please contact Jana Sinclair White or James Cox of the Commission staff at (202) 622–5930.

Dated: June 12, 2003.

Roger Kodat,

Designated Federal Official.

[FR Doc. 03–15319 Filed 6–17–03; 8:45 am]

BILLING CODE 4811–16–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

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, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Community Development Financial Institutions Fund (the ''Fund'') within the Department of the Treasury is soliciting comments concerning the Fund's conflict of interest reporting requirements for contract readers of applications submitted for funding under the Fund's various programs.

DATES: Written comments should be received on or before August 18, 2003 to be assured of consideration.

ADDRESSES: Direct all comments to Jeffrey C. Berg, Legal Counsel, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, Facsimile Number (202) 622–7754.

FOR FURTHER INFORMATION CONTACT: A copy of the conflict of interest information collection or requests for additional information may be obtained by contacting Jeffrey C. Berg, Legal Counsel, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, Telephone Number (202) 622–8662, Facsimile Number (202) 622–7754.

SUPPLEMENTARY INFORMATION:

Title: The Community Development Financial Institutions Fund—Conflict of Interest Package for Non-Federal Readers.

OMB Number: 1559–0011.

Abstract: Through its programs the Fund supports financial institutions around the country that are specifically dedicated to financing and supporting community and economic development activities. This strategy builds strong institutions that make loans and investments and provide financial services in markets (including economically distressed investments areas and targeted populations) whose needs for loans, investments, and financial services have not been fully met by traditional financial institutions, particularly in the areas of promoting homeownership, developing of affordable housing, and stimulating small business development, as well as providing financial services to those that have not previously accessed financial institutions.

Consistent with the Federal Acquisition Regulations provisions on conflicts of interest, the Fund has applied, and will continue to apply, a conflict of interest policy with respect to its contract (non-Federal employee) readers that avoids a reader's participation in the evaluation or process of selection of applications where such participation creates a conflict of interest or an appearance of a conflict of interest. The conflict of interest review materials are used by the Fund to determine whether or not a contractor's financial interest, or that of the contractor's spouse, parent, dependent child, or member of household, may result in a conflict, or apparent conflict of interest with the individual's duties and responsibilities as a contractor evaluating applications. The completion of the package is mandatory for all contractors prior to their selection as readers.

Current Action: Extension.

Type of Review: Renewal.

Affected Public: Individuals.

Estimated Number of Respondents: 80.

Estimated Annual Time Per Respondent: 0.75 hours.

Estimated Total Annual Burden Hours: 60 hours.

Requests 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 Fund, including whether the information shall have practical utility; (b) the accuracy of the Fund'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 technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Authority: 12 U.S.C. 4703(c); and 48 CFR subpart 9.5.

Dated: June 11, 2003.

Tony T. Brown,

Director, Community Development Financial Institutions Fund.

[FR Doc. 03–15359 Filed 6–17–03; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

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, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Community Development Financial Institutions Fund (the ''Fund'') within the Department of the Treasury is soliciting comments concerning the Community Development Financial Institutions (''CDFI'') Program; Certification/Re-certification Application.

DATES: Written comments should be received on or before August 18, 2003 to be assured of consideration.

ADDRESSES: Direct all comments to Linda G. Davenport, Deputy Director for Policy and Programs, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, Facsimile Number (202) 622–7754.

FOR FURTHER INFORMATION CONTACT: The Certification/Re-certification application will be in the same form as the Eligibility and Certification Materials section of the CDFI Program—Technical Assistance Component application (located at Part II, page 21), except that questions under Subparts A and C will not be included in the stand-alone Certification/Re-certification application and there will be no opportunities for applicants that do not meet a specific certification requirement(s) to provide a narrative describing its proposal to meet such requirement(s).The Technical Assistance Component application may be obtained from the Fund's Web site at *http://www.cdfifund.gov.* Requests for additional information should be directed to Linda G. Davenport, Deputy Director for Policy and Programs, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, or call (202) 622–8662.

SUPPLEMENTARY INFORMATION:

Title: The Community Development Financial Institutions Program—Certification/Re-Certification Application.

OMB Number: 1559–0006.

Abstract: The purpose of the CDFI Program is to promote economic revitalization and community development through investment in and assistance to certified CDFIs. Through the CDFI Program, the Fund makes financial investments in and may provide technical assistance grants to CDFIs that have comprehensive business plans for creating demonstrable community development impact through the deployment of capital within their respective target markets for community development finance purposes. In order to be certified as a CDFI, an entity must submit an application for certification to the Fund.

Type of Review: Extension.

Affected Public: Not-for-profit institutions, businesses or other for-profit institutions and tribal entities.

Estimated Number of Respondents: 215.

Estimated Annual Time Per Respondent: 40 hours.

Estimated Total Annual Burden Hours: 8,600 hours.

Requests 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 Fund, including whether the information shall have practical utility; (b) the accuracy of the Fund'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 technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Authority: 12 U.S.C. 4703, 4703 note, 4704, 4706, 4707, 4717; 12 CFR part 1805.

Dated: June 12, 2003.

Tony T. Brown,

Director, Community Development Financial Institutions Fund.

[FR Doc. 03–15360 Filed 6–17–03; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–103805–99]

Proposed Collection; Comment Request for Regulation Project

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 an existing final regulation, REG–103805–99 (TD 9002), Agent for Consolidated Group (§ 1.1502–77).

DATES: Written comments should be received on or before August 6, 2003 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of regulations should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the internet at *CAROL.A.SAVAGE@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Agent for Consolidated Group.

OMB Number: 1545–1699.

Regulation Project Number: REG–103805–99.

Abstract: The information is needed in order for a terminating common parent of a consolidated group to designate a substitute agent for the group and receive approval of the Commissioner, or for a default substitute agent to notify the Commissioner that it is the default substitute agent, pursuant to Treas. Reg. § 1.1502–77(d). The Commissioner will use the information to determine whether to approve the designation of the substitute agent (if approval is required) and to change the IRS's records to reflect the information about the substitute agent.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 100.

Estimated Time Per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 200.

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: June 11, 2003.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. 03–15284 Filed 6–17–03; 8:45 am]

BILLING CODE 4830–01–M

Federal Register

Wednesday,
June 18, 2003

Part II

Securities and Exchange Commission

17 CFR Parts 210, 228, et al.

Management's Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 210, 228, 229, 240, 249, 270 and 274

[Release Nos. 33–8238; 34–47986; IC–26068; File Nos. S7–40–02; S7–06–03]

RIN 3235–AI66 and 3235–AI79

Management's Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: As directed by Section 404 of the Sarbanes-Oxley Act of 2002, we are adopting rules requiring companies subject to the reporting requirements of the Securities Exchange Act of 1934, other than registered investment companies, to include in their annual reports a report of management on the company's internal control over financial reporting. The internal control report must include: a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the company; management's assessment of the effectiveness of the company's internal control over financial reporting as of the end of the company's most recent fiscal year; a statement identifying the framework used by management to evaluate the effectiveness of the company's internal control over financial reporting; and a statement that the registered public accounting firm that audited the company's financial statements included in the annual report has issued an attestation report on management's assessment of the company's internal control over financial reporting. Under the new rules, a company is required to file the registered public accounting firm's attestation report as part of the annual report. Furthermore, we are adding a requirement that management evaluate any change in the company's internal control over financial reporting that occurred during a fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting. Finally, we are adopting amendments to our rules and forms under the Securities Exchange Act of 1934 and the Investment Company Act of 1940 to revise the Section 302 certification requirements and to require issuers to provide the certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 as exhibits to certain periodic reports.

DATES: *Effective Date:* August 14, 2003.

Compliance Dates: The following compliance dates apply to companies other than registered investment companies. A company that is an ''accelerated filer,'' as defined in Exchange Act Rule 12b–2, as of the end of its first fiscal year ending on or after June 15, 2004, must begin to comply with the management report on internal control over financial reporting disclosure requirements in its annual report for that fiscal year. A company that is not an accelerated filer as of the end of its first fiscal year ending on or after June 15, 2004, including a foreign private issuer, must begin to comply with the annual internal control report for its first fiscal year ending on or after April 15, 2005. A company must begin to comply with the requirements regarding evaluation of any material change to its internal control over financial reporting in its first periodic report due after the first annual report required to include a management report on internal control over financial reporting. Companies may voluntarily comply with the new disclosure requirements before the compliance dates. A company must comply with the new exhibit requirements for the certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 and changes to the Section 302 certification requirements in its quarterly, semi-annual or annual report due on or after August 14, 2003. To account for the differences between the compliance date of the rules relating to internal control over financial reporting and the effective date of changes to the language of the Section 302 certification, a company's certifying officers may temporarily modify the content of their Section 302 certifications to eliminate certain references to internal control over financial reporting until the compliance date, as further explained in Section III.E. below.

Registered investment companies must comply with the rule and form amendments applicable to them on and after August 14, 2003, except as follows. Registered investment companies must comply with the amendments to Exchange Act Rules 13a–15(a) and 15d–15(a) and Investment Company Act Rule 30a–3(a) that require them to maintain internal control over financial reporting with respect to fiscal years ending on or after June 15, 2004. In addition, a registered investment company's certifying officers may temporarily modify the content of their Section 302 certifications to eliminate certain references to internal control over financial reporting, as further explained in Section II.I. below. Registered investment companies may voluntarily comply with the rule and form amendments before the compliance dates.

FOR FURTHER INFORMATION CONTACT: N. Sean Harrison, Special Counsel, or Andrew D. Thorpe, Special Counsel, Division of Corporation Finance, at (202) 942–2910, or with respect to registered investment companies, Christian Broadbent, Senior Counsel, Division of Investment Management, at (202) 942–0721, or with respect to attestation and auditing issues, Edmund Bailey, Assistant Chief Accountant, Randolph P. Green, Professional Accounting Fellow, or Paul Munter, Academic Accounting Fellow, Office of the Chief Accountant, at (202) 942–4400, U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are revising Items 307, 401 and 601 of Regulations S–B [1] and S–K; [2] adding new Item 308 to Regulations S–B and S–K; amending Form 10–K,[3] Form 10–KSB,[4] Form 10–Q,[5] Form 10–QSB,[6] Form 20–F,[7] Form 40–F,[8] Rule 12b–15,[9] Rule 13a–14,[10] Rule 13a–15,[11] Rule 15d–14 [12] and Rule 15d–15 [13] under the Securities Exchange Act of 1934 (the ''Exchange Act''); [14] amending Rules 1–02 and 2–02 [15] of Regulation S–X; [16] amending Rules 8b–15,[17] 30a–2 [18] and 30a–3 [19] under the Investment Company Act of 1940 (''Investment Company Act''); [20] and amending Forms N–CSR [21] and N–SAR [22] under the Exchange Act and the Investment Company Act.

Table of Contents

[1] 17 CFR 228.10 *et seq.*
[2] 17 CFR 229.10 *et seq.*
[3] 17 CFR 249.310.
[4] 17 CFR 249.310b.
[5] 17 CFR 249.308a.
[6] 17 CFR 249.308b.
[7] 17 CFR 249.220f.
[8] 17 CFR 249.240f.
[9] 17 CFR 240.12b–15.
[10] 17 CFR 240.13a–14.
[11] 17 CFR 240.13a–15.
[12] 17 CFR 140.15d–14.
[13] 17 CFR 240.15d–15.
[14] 15 U.S.C. 78a *et seq.*
[15] 17 CFR 210.1–02 and 2–02.
[16] 17 CFR 210.1–01 *et seq.*
[17] 17 CFR 270.8b–15.
[18] 17 CFR 270.30a–2.
[19] 17 CFR 270.30a–3.
[20] 15 U.S.C. 80a–1 *et seq.*
[21] 17 CFR 249.331; 17 CFR 274.128.
[22] 17 CFR 249.330; 17 CFR 274.101.

I. Background

A. Management's Report on Internal Control Over Financial Reporting

In this release, we implement Section 404 of the Sarbanes-Oxley Act of 2002 (the ''Sarbanes-Oxley Act''),[23] which requires us to prescribe rules requiring each annual report that a company, other than a registered investment company,[24] files pursuant to Section 13(a) or 15(d) of the Exchange Act to contain an internal control report: (1) Stating management's responsibility for establishing and maintaining an adequate internal control structure and procedures for financial reporting; and (2) containing an assessment, as of the end of the company's most recent fiscal year, of the effectiveness of the company's internal control structure and procedures for financial reporting. Section 404 also requires every registered public accounting firm that prepares or issues an audit report on a company's annual financial statements to attest to, and report on, the assessment made by management. The attestation must be made in accordance with standards for attestation engagements issued or adopted by the Public Company Accounting Oversight Board (''PCAOB'').[25] Section 404 further stipulates that the attestation cannot be the subject of a separate engagement of the registered public accounting firm.

We received over 200 comment letters in response to our release proposing requirements to implement Sections 404, 406 and 407 of the Sarbanes-Oxley Act.[26] Of these, 61 respondents commented on the Section 404 proposals.[27] These comment letters came from corporations, professional associations, accountants, law firms, consultants, academics, investors and others. In general, the commenters supported the objectives of the proposed new requirements. Investors supported the manner in which we proposed to achieve these objectives and, in some cases, urged us to require additional disclosure from companies. Other commenters, however, thought that we were requiring more disclosure than necessary to fulfill the mandates of the Sarbanes-Oxley Act and suggested modifications to the proposals. We have reviewed and considered all of the comments that we received on the proposals. The adopted rules reflect many of these comments—we discuss our conclusions with respect to each topic and related comments in more detail throughout the release.

B. Certifications

We also are adopting amendments to require companies to file the certifications mandated by Sections 302 and 906 of the Sarbanes-Oxley Act as exhibits to annual, semi-annual and quarterly reports. Section 302 required the Commission to adopt final rules that were to be effective by August 29, 2002, under which the principal executive and principal financial officers, or persons performing similar functions, of a company filing periodic reports under Section 13(a) or 15(d) of the Exchange Act[28] must provide a certification in

[23] Pub. L. 107–204, 116 Stat. 745 (2002).

[24] Section 404 of the Sarbanes-Oxley Act does not apply to any registered investment company due to an exemption in Section 405 of the Sarbanes-Oxley Act. See sec. 405 of Pub. L. 107–204, 116 Stat. 745 (2002).

[25] On April 25, 2003, the Commission approved the PCAOB's adoption of the auditing and attestation standards in existence as of April 16, 2003 as interim auditing and attestation standards. See Release No. 33–8222 (Apr. 25, 2003) [68 FR 23335].

[26] Release No. 33–8138 (Oct. 22, 2002) [67 FR 66208] (''Proposing Release''). The public comments we received can be viewed in our Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549, in File No. S7–40–02. Public comments submitted by electronic mail are available on our Web site, *http://www.sec.gov*.

[27] The commenters on File No. S7–40–02 are as follows: *Academics* Paul Walker, Ph.D., CPA; *Accounting Firms* BDO Seidman, LLP; Deloitte & Touche LLP; Ernst & Young LLP; KPMG LLP; PricewaterhouseCoopers LLP; *Associations* America's Community Bankers; American Bankers Association; American Bar Association; American Corporate Counsel Association; American Institute of Certified Public Accountants; Association for Financial Professionals; the Association of the Bar of the City of New York; Association for Investment Management and Research; the Business Roundtable; Community Bankers Association of New York State; Edison Electric Institute; Financial Executives International; Independent Community Bankers of America; the Institute of Internal Auditors; Maine Bankers Association; Manufacturers Alliance/MAPI Inc.; Massachusetts Bankers Association; National Association of Real Estate Investment Trusts; New York Bankers Association; New York County Lawyers' Association; New York State Bar Association; Software & Information Industry Association; Software Finance and Tax Executives Council; Wisconsin Bankers Association; *Corporations* Cardinal Health, Inc.; Compass Bancshares, Inc.; Computer Sciences Corporation; Eastman Kodak Company; Eli Lilly and Company; Emerson Electric Co.; Executive Responsibility Advisors, LLC; Greif Bros.; Intel Corporation; International Paper Company; Protiviti; *Government Entities* Federal Reserve Bank of Atlanta; Small Business Administration; *Law Firms* Dykema Gossett PLLC; Karr Tuttle Campbell; Fried, Frank, Harris, Shriver and Jacobson; Sutherland, Asbill & Brennan LLP; *Individuals* Thomas Damman; D. Scott Huggins; Tim J. Leech; Simon Lorne; Ralph Saul; Lee Squire; Robert J. Stuckey; *Foreign Companies* Siemens Aktiengesellcraft; *International Entities* British Bankers Association; British Embassy; Canadian Bankers Association; Confederation of British Industry; European Commission; Institute of Chartered Accountants of England and Wales.

[28] 15 U.S.C. 78m(a) or 78o(d). Section 13(a) of the Exchange Act requires every issuer of a security registered pursuant to Section 12 of the Exchange Act [15 U.S.C. 78*l*] to file with the Commission such annual reports and such quarterly reports as the Commission may prescribe. Section 15(d) of the Exchange Act requires each issuer that has filed a registration statement that has become effective pursuant to the Securities Act of 1933 [15 U.S.C. 77a *et seq.*] (the ''Securities Act'') to file such supplementary and periodic information, documents and reports as may be required pursuant

Continued

each quarterly and annual report filed with the Commission. Section 906 of the Sarbanes-Oxley Act added new Section 1350 to Title 18 of the United States Code,[29] which contains a certification requirement subject to specific federal criminal provisions and that is separate and distinct from the certification requirement mandated by Section 302.[30] On August 28, 2002, we adopted Exchange Act Rules 13a-14 and 15d-14 and Investment Company Act Rule 30a-2 and amended our periodic report forms to implement the statutory directive in Section 302.[31] These rules and amendments became effective on August 29, 2002. On January 27, 2003, we adopted Form N–CSR to be used by registered management investment companies to file certified shareholder reports with the Commission.[32] The provisions added to Title 18 by Section 906 were by their terms effective on enactment of the Sarbanes-Oxley Act.

To enhance the ability of interested parties to effectively access the certifications through our Electronic Data Gathering, Analysis and Retrieval (''EDGAR'') system and thereby enhance compliance with the certification requirements, we proposed to amend our rules and forms to require a company to file the certifications as an exhibit to the periodic reports to which they relate.[33] The proposals addressed both Section 302 and 906 certifications. After discussions with the Department of Justice, we concluded that, in light of the inconsistent methods that companies have been employing to fulfill their obligations under Section 906,[34] an exhibit requirement would consistently enable investors and the Commission staff, as well as the Department of Justice, to more effectively monitor compliance with this certification requirement.

II. Discussion of Amendments Implementing Section 404

A. Definition of Internal Control

1. Proposed Rule

The proposed rules would have defined the term ''internal controls and procedures for financial reporting'' [35] to mean controls that pertain to the preparation of financial statements for external purposes that are fairly presented in conformity with generally accepted accounting principles as addressed by the Codification of Statements on Auditing Standards § 319 or any superseding definition or other literature that is issued or adopted by the Public Company Accounting Oversight Board.

As noted in the Proposing Release, there has been some confusion over the exact meaning and scope of the term ''internal control,'' because the definition of the term has evolved over time. Historically, the term ''internal control'' was applied almost exclusively within the accounting profession.[36] As the auditing of financial statements evolved from a process of detailed testing of transactions and account balances towards a process of sampling and testing, greater consideration of a company's internal controls became necessary in planning an audit.[37] If an internal control component had been adequately designed, then the auditor could limit further consideration of that control to procedures to determine whether the control had been placed in operation. Accordingly, the auditor could rely on the control to serve as a basis to reduce the amount, timing or extent of substantive testing in the execution of an audit. Conversely, if an auditor determined that an internal control component was inadequate in its design or operation, then the auditor could not rely upon that control. In this instance, the auditor would conduct tests of transactions and perform additional analyses in order to accumulate sufficient, competent audit evidence to support its opinion on the financial statements.

From the outset, it was recognized that internal control is a broad concept that extends beyond the accounting functions of a company. Early attempts to define the term focused primarily on clarifying the portion of a company's internal control that an auditor should consider when planning and performing an audit of a company's financial statements.[38] However, this did not improve the level of understanding of the term, nor satisfactorily provide the guidance sought by auditors. Successive definitions and formal studies of the concept of internal control followed.

In 1977, based on recommendations of the Commission, Congress enacted the Foreign Corrupt Practices Act (''FCPA'').[39] The FCPA codified the accounting control provisions contained in Statement of Auditing Standards No. 1 (codified as AU § 320 in the Codification of Statements on Auditing Standards). Under the FCPA, companies that have a class of securities registered under Section 12 of the Exchange Act, or that are required to file reports under Section 15(d) of the Exchange Act, are required to devise and maintain a

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to Section 13 in respect of a security registered pursuant to Section 12, unless the duty to file under Section 15(d) has been suspended for any fiscal year. See Exchange Act Rule 12h-3 [17 CFR 240.12h-3].

[29] 29 18 U.S.C. 1350.

[30] See Release No. 34–46300 (Aug. 2, 2002) [67 FR 51508] at n. 11, containing supplemental information on the Commission's original certification proposal in light of the enactment of the Sarbanes-Oxley Act of 2002.

[31] See Release No. 33–8124 (Aug. 28, 2002) [67 FR 57276].

[32] See Release No. IC–25914 (Jan. 27, 2003) [68 FR 5348].

[33] See Release No. 33–8212 (Mar. 21, 2003) [68 FR 15600].

[34] These methods have included: (1) Submitting the statement as non-public paper correspondence; (2) submitting the statement as non-public electronic correspondence with the EDGAR filing of the periodic report; (3) submitting the statement under (1) or (2) above supplemented by an Item 9 Form 8-K report so that the statement is publicly available; (4) submitting the statement as an exhibit to the periodic report; and (5) submitting the statement in the text of the periodic report (typically, below the signature block for the report).

[35] We proposed to use this term throughout the rules implementing the annual internal control report requirements of Section 404 of the Sarbanes-Oxley Act, as well as the revised Sarbanes-Oxley Section 302 certification requirements, to complement the defined term ''disclosure controls and procedures'' referred to in the Section 302 requirements. Congress used the term ''internal controls'' in Section 302 and ''internal control structure and procedures for financial reporting'' in Section 404.

[36] For a history of the development of internal control standards, see Steven J. Root, *Beyond COSO—Internal Control to Enhance Corporate Governance* (1998).

[37] In 1941, the Commission adopted amendments to Rules 2–02 and 3–07 of Regulation S-X that formally codified this practice. See Accounting Series Release No. 21 (Feb. 5, 1941) [11 FR 10921].

[38] An early definition for the term appeared in *Internal Control—Elements Of a Coordinated System and Its Importance to Management and the Independent Public Accountant,* a report published in 1949 by the American Institute of Accountants, the predecessor to the American Institute of Certified Public Accountants (''AICPA''). The report defined internal control to mean ''the plan of organization and all of the coordinate methods and measures adopted within a business to safeguard its assets, check the accuracy and reliability of its accounting data, promote operational efficiency, and encourage adherence to prescribed managerial policies.'' Subsequent definitions of the term attempted to clarify the distinction by labeling the controls relevant to an audit as ''internal accounting controls'' and the non-accounting controls as ''administrative controls.'' The AICPA officially dropped these distinctions in 1988. See Root, at p. 76.

[39] Title I of Pub. L. 95–213 (1977). Beginning in 1973, as a result of the work of the Office of the Watergate Special Prosecutor, the Commission became aware of a pattern of conduct involving the use of corporate funds for illegal domestic political contributions. A subsequent Commission investigation revealed that instances of undisclosed questionable or illegal corporate payments—both domestic and foreign—were widespread. On May 12, 1976, the Commission submitted to the Senate Banking, Housing and Urban Affairs Committee a report entitled *Report on Questionable and Illegal Corporate Payments and Practices.* The report described and analyzed the Commission's investigation concerning improper corporate payments and outlined legislative and other responses that the Commission recommended to remedy these problems. One of the Commission's recommendations was that Congress enact legislation aimed expressly at enhancing the accuracy of the corporate books and records and the reliability of the audit process.

system of internal accounting controls sufficient to provide reasonable assurances that:

- transactions are executed in accordance with management's general or specific authorization;
- transactions are recorded as necessary (1) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (2) to maintain accountability for assets;
- access to assets is permitted only in accordance with management's general or specific authorization; and
- the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.[40]

In 1985, a private-sector initiative known as the National Commission on Fraudulent Financial Reporting, also known as the Treadway Commission, was formed to study the financial reporting system in the United States. In 1987, the Treadway Commission issued a report recommending that its sponsoring organizations work together to integrate the various internal control concepts and definitions and to develop a common reference point.

In response, the Committee of Sponsoring Organizations of the Treadway Commission (''COSO'') [41] undertook an extensive study of internal control to establish a common definition that would serve the needs of companies, independent public accountants, legislators and regulatory agencies, and to provide a broad framework of criteria against which companies could evaluate the effectiveness of their internal control systems. In 1992, COSO published its *Internal Control—Integrated Framework*.[42] The COSO Framework defined internal control as ''a process, effected by an entity's board of directors, management and other personnel, designed to provide reasonable assurance regarding the achievement of objectives'' in three categories—effectiveness and efficiency of operations; reliability of financial reporting; and compliance with applicable laws and regulations. COSO further stated that internal control consists of: the control environment, risk assessment, control activities, information and communication, and monitoring. The scope of internal control therefore extends to policies, plans, procedures, processes, systems, activities, functions, projects, initiatives, and endeavors of all types at all levels of a company.

In 1995, the AICPA incorporated the definition of internal control set forth in the COSO Report in Statement on Auditing Standards No. 78 (codified as AU § 319 in the Codification of Statements on Auditing Standards).[43] Although we recognized that the AU § 319 definition was derived from the COSO definition, our proposal referred to AU § 319 because we thought that the former constituted a more formal and widely-accessible version of the definition than the latter.

2. Comments on the Proposal

We received comments from 25 commenters on the proposed definition of ''internal control and procedures for financial reporting.'' Eleven commenters stated that the proposed definition of internal control was appropriate or generally agreed with the proposal.[44] Two of these noted that the definition in AU § 319 had been adopted by the bank regulatory agencies for use by banking institutions.[45] Fourteen of the 25 commenters opposed the proposed definition. Two of these asserted that the proposed definition was too complex and would not resolve the confusion that existed over the meaning or scope of the term.

Several of the commenters that were opposed to the proposed definition thought that we should refer to COSO for the definition of internal control, rather than AU § 319.[46] Some of these commenters noted that the objective of AU § 319 is to provide guidance to auditors regarding their consideration of internal control in planning and performing an audit of financial statements. The common concern of these commenters was that AU § 319 does not provide any measure or standard by which a company's management can determine that internal control is effective, nor does it define what constitutes effective internal control. One commenter believed that absent such evaluative criteria or definition of effectiveness, the proposed rules could not be implemented effectively.[47] In addition, several of the commenters opposed to the proposed definition suggested that we use the term ''internal control over financial reporting'' rather than the term ''internal controls and procedures for financial reporting,''[48] on the ground that the former is more consistent with the terminology currently used within the auditing literature.

A few of the commenters urged us to adopt a considerably broader definition of internal control that would focus not only on internal control over financial reporting, but also on internal control objectives associated with enterprise risk management and corporate governance. While we agree that these are important objectives, the definition that we are adopting retains a focus on financial reporting, consistent with our position articulated in the Proposing Release. We are not adopting a more expansive definition of internal control for a variety of reasons. Most important, we believe that Section 404 focuses on the element of internal control that relates to financial reporting. In addition, many commenters indicated that even the more limited definition related to financial reporting that we proposed will impose substantial reporting and cost burdens on companies. Finally, independent accountants traditionally have not been responsible for reviewing and testing, or attesting to an assessment by management of, internal controls that

[40] See Exchange Act Section 13(b)(2) [15 U.S.C. 78m(b)(2)].

[41] The Treadway Commission was sponsored by the AICPA, the American Accounting Association, the Financial Executives International (formerly Financial Executives Institute), the Institute of Internal Auditors and the Institute of Management Accountants (formerly the National Association of Accountants). The Treadway Commission's report, the Report of the National Commission on Fraudulent Financial Reporting (Oct. 1987), is available at *www.coso.org*.

[42] See COSO, *Internal Control—Integrated Framework* (1992) (''COSO Report''). In 1994, COSO published an addendum to the *Reporting to External Parties* volume of the COSO Report. The addendum discusses the issue of, and provides a vehicle for, expanding the scope of a public management report on internal control to address additional controls pertaining to safeguarding of assets. In 1996, COSO issued a supplement to its original framework to address the application of internal control over financial derivative activities.

[43] Auditing Standards Board, AICPA, Statement on Auditing Standards No. 78, *Consideration of Internal Control in a Financial Statement Audit: An Amendment to Statement on Auditing Standards No. 55* (1995).

[44] See letters regarding File No. S7–40–02 of: America's Community Bankers (''ACB''); American Corporate Counsel Association (''ACCA''); American Institute of Certified Public Accountants (''AICPA''); Compass Bancshares, Inc. (''Compass''); Computer Sciences Corporation (''CSC''); the Edison Electric Institute (''EEI''); the Independent Community Bankers of America (''ICBA''); the Institute of Internal Auditors (''IIA''); the Association of the Bar of the City of New York, Committee on Corporate Law (''NYCB–CCL''); Protiviti; and Siemens AG.

[45] See letters regarding File No. S7–40–02 of ACB and ICBA.

[46] See letters regarding File No. S7–40–02 of: the American Bar Association, Committee on the Federal Regulation of Securities and the Committee on Law and Accounting (''ABA''); the Federal Reserve Bank of Atlanta (''FED''); IIA; Simon Lorne (''Lorne''); and Pricewaterhouse Coopers LLP (''PwC'').

[47] See ABA letter regarding File No. S7–40–02.

[48] See letters regarding File No. S7–40–02 of: AICPA; Compass; Deloitte & Touche LLP (''D&T''); IIA; KPMG LLP (''KPMG''); and PwC.

are outside the boundary of financial reporting.

3. Final Rules

After consideration of the comments, we have decided to make several modifications to the proposed amendments. We agree that we should use the term ''internal control over financial reporting'' in our amendments to implement Section 404, as well as our revisions to the Section 302 certification requirements and forms of certification.[49] Rapidly changing terminology has been one obstacle in the development of an accepted understanding of internal control. The term ''internal control over financial reporting'' is the predominant term used by companies and auditors and best encompasses the objectives of the Sarbanes-Oxley Act. In addition, by using this term, we avoid having to familiarize investors, companies and auditors with new terminology, which should lessen any confusion that may exist about the meaning and scope of internal control.

The final rules define ''internal control over financial reporting'' as:

A process designed by, or under the supervision of, the registrant's principal executive and principal financial officers, or persons performing similar functions, and effected by the registrant's board of directors,[50] management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the registrant;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the registrant are being made only in accordance with authorizations of management and directors of the registrant; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the registrant's assets that could have a material effect on the financial statements.[51]

We recognize that our definition of the term ''internal control over financial reporting'' reflected in the final rules encompasses the subset of internal controls addressed in the COSO Report that pertains to financial reporting objectives. Our definition does not encompass the elements of the COSO Report definition that relate to effectiveness and efficiency of a company's operations and a company's compliance with applicable laws and regulations, with the exception of compliance with the applicable laws and regulations directly related to the preparation of financial statements, such as the Commission's financial reporting requirements.[52] Our definition is consistent with the description of internal accounting controls in Exchange Act Section 13(b)(2)(B).[53]

Following the general language defining internal control over financial reporting, clauses (1) and (2) include the internal control matters described in Section 103 of the Sarbanes-Oxley Act that the company's registered public accounting firm is required to evaluate in its audit or attestation report.[54] This language is included to make clear that the assessment of management in its internal control report as to which the company's registered public accounting firm will be required to attest and report specifically covers the matters referenced in Section 103. A few commenters believed that it would cause confusion if the definition of internal control did not acknowledge the objectives set forth in Section 103 of the Sarbanes-Oxley Act. As discussed in Section II.G below, the PCAOB is responsible for establishing the Section 103 standards.

Our definition also includes, in clause (3), explicit reference to assurances regarding use or disposition of the company's assets. This provision is specifically included to make clear that, for purposes of our definition, the safeguarding of assets is one of the elements of internal control over financial reporting and it addresses the supplementation of the COSO Framework after it was originally promulgated. In the absence of our change to the definition, the determination of whether control regarding the safeguarding of assets falls within a company's internal control over financial reporting currently could be subject to varying interpretation.

Safeguarding of assets had been a primary objective of internal accounting control in SAS No. 1. In 1988, the ASB issued Statement of Auditing Standards No. 55 (codified as AU § 319 in the Codification of Statements on Auditing Standards), which replaced AU § 320. SAS No. 55 revised the definition of ''internal control'' and expanded auditors' responsibilities for considering internal control in a financial statement audit. The prior classification of internal control into the two categories of ''internal accounting control'' and ''administrative control'' was replaced with the single term ''internal control structure,'' which consisted of three interrelated components—control environment, the accounting system and control procedures. Under this new

[49] See new Item 308 of Regulations S–K and S–B, amended Items 1–02 and 2–02 of Regulation S–X; amended Items 307and 401 of Regulations S–K and S–B; amended Exchange Act Rules 13a–14, 13a–15, 15d–14 and 15d–15; and amended Forms 20–F and 40–F.

[50] The COSO Report states that the composition of a company's board and audit committee, and how the directors fulfill their responsibilities related to the financial reporting process, are key aspects of the company's control environment. An important element of the company's internal control over financial reporting ''* * * is the involvement of the board or audit committee in overseeing the financial reporting process, including assessing the reasonableness of management's accounting judgments and estimates and reviewing key filings with regulatory agencies.'' See COSO Report at 130. The Commission similarly has stated in the past that both a company's management and board have important roles to play in establishing a supportive control environment. In its 1981 Statement of Policy regarding the FCPA, the Commission stated, ''In the last analysis, the key to an adequate 'control environment' is an approach on the part of the board and top management which makes clear what is expected and that conformity to these expectations will be rewarded while breaches will be punished.'' See Release No. 34–17500 (Jan. 29, 1981) [46 FR 11544].

[51] See amended Exchange Act Rules 13a–14(d) and 15d–14(d). The scope of the term ''preparation of financial statements in accordance with generally accepted accounting principles'' in the definition encompasses financial statements prepared for regulatory reporting purposes.

[52] Codification of Statements on Auditing Standards Section 317 requires auditors to consider a company's compliance with laws and regulations that have a direct and material effect on the financial statements.

[53] 15 U.S.C. 78m(b)(2)(B).

[54] Section 103 of the Sarbanes-Oxley Act requires the PCAOB to establish by rule standards to be used by registered public accounting firms in the preparation and issuance of audit reports. In carrying out this responsibility, the PCAOB must include in the auditing standards that it adopts, among other things: a requirement that each registered public accounting firm describe in each audit report the scope of its testing of the company's internal control structure and procedures performed in fulfilling its internal control evaluation and reporting required by Section 404(b) of the Sarbanes-Oxley Act; present in the audit report (or attestation report) its findings from such testing; and an evaluation of whether the company's internal control structure and procedures: (1) Include maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the company's assets; and (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with the authorization of management and directors of the company. In the audit report (or attestation report), the registered public accounting firm also must describe, at a minimum, material weaknesses in such internal controls and any material noncompliance found on the basis of such testing. See Sections 103(a)(2)(A)(iii)(I), (II) and (III) of the Sarbanes-Oxley Act. See also, Interim Professional Attestation Standards Rule 3300T, adopted in PCAOB Release No. 2003–006 (Apr. 18, 2003), and approved by the Commission on April 25, 2003.

definition, the safeguarding of assets was no longer a primary objective, but a subset of the control procedures component.[55] The COSO Report followed this shift in the iteration of safeguarding of assets. The COSO Report states that operations objectives ''pertain to effectiveness and efficiency of the entity's operations, including performance and profitability goals and safeguarding resources against loss.'' [56] However, the report also clarifies that safeguarding of assets can fall within other categories of internal control.[57]

In 1994, COSO published an addendum to the *Reporting to External Parties* volume of the COSO Report. The addendum was issued in response to a concern expressed by some parties, including the U.S. General Accounting Office, that the management reports contemplated by the COSO Report did not adequately address controls relating to safeguarding of assets and therefore would not fully respond to the requirements of the FCPA.[58] In the addendum, COSO concluded that while it believed its definition of internal control in its 1992 report remained appropriate, it recognized that the FCPA encompasses certain controls related to safeguarding of assets and that there is a reasonable expectation on the part of some readers of management's internal control reports that the reports will cover such controls. The addendum therefore sets forth the following definition of the term ''internal control over safeguarding of assets against unauthorized acquisition, use or disposition'':

> Internal control over safeguarding of assets against unauthorized acquisition, use or disposition is a process, effected by an entity's board of directors, management and other personnel, designed to provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the entity's assets that could have a material effect on the financial statements.

As indicated above, to achieve the desired result and to provide consistency with COSO's 1994 addendum, we have incorporated this definition into our definition of ''internal control over financial reporting.'' We are persuaded that this is appropriate given the fact that our definition will be used for purposes of public management reporting, and that the companies that will be subject to the Section 404 requirements also are subject to the FCPA requirements. So, under the final rules, safeguarding of assets as provided is specifically included in our definition of ''internal control over financial reporting.''

B. Management's Annual Assessment of, and Report on, the Company's Internal Control Over Financial Reporting

1. Proposed Rule

We proposed to amend Item 307 of Regulations S–K and S–B, as well as Forms 20–F and 40–F, to require a company's annual report to include an internal control report of management containing:

- A statement of management's responsibility for establishing and maintaining adequate internal controls and procedures for financial reporting;
- The conclusions of management about the effectiveness of the company's internal controls and procedures for financial reporting based on management's evaluation of those controls and procedures; and
- A statement that the registered public accounting firm that prepared or issued the company's audit report relating to the financial statements included in the company's annual report has attested to, and reported on, management's evaluation of the company's internal controls and procedures for financial reporting.

The proposed amendments did not list any additional disclosure requirements for the management report, but rather would have afforded management the flexibility to tailor the report to fit its company's particular circumstances.

2. Comments on the Proposal

We received comments from 17 commenters on our proposed annual internal control report requirements. All of these commenters believed, in varying degrees, that we should set forth additional disclosure criteria or standards for the management report. Nine commenters stated that we should provide guidance as to the topics to be addressed in the management report, or specify standards or a common set of internal control objectives to be considered by management when assessing the effectiveness of its company's internal control over financial reporting to ensure that control objectives are addressed in a consistent fashion.[59] These commenters believed that consistent standards for management's report on internal control would help investors to understand and compare the quality of various management internal control reports.

Several commenters also thought that we should require management's internal control report to include certain recitations that would parallel recitations that the registered public accounting firm would have to make in its report attesting to management's assessment.[60] Additional commenters believed that the management report on internal control should specifically reference the objectives contained in Section 103 of the Sarbanes-Oxley Act.[61] Furthermore, although Section 404(b) of the Sarbanes-Oxley Act does not explicitly direct us to require companies to file the registered public accounting firms' attestation reports as part of the companies' annual report filings, we proposed a filing

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[55] Control procedures were described as policies and procedures in addition to the control environment and accounting system that management established to provide reasonable assurance that specific entity objectives will be achieved. SAS 55 also states that control procedures may generally be categorized as procedures that include, among other things, ''adequate safeguards over access to and use of assets and records, such as secured facilities and authorization for access to computer programs and data files.'' See Statement on Auditing Standards No. 55, paragraph no. 11.

[56] See COSO ''Addendum to Reporting to External Parties,'' *Internal Control—Integrated Framework*, (1994) (''1994 Addendum'') at p. 154.

[57] The COSO Report states: ''Although these [objectives relating to safeguarding of resources] are primarily operations objectives, certain aspects of safeguarding can fall under other categories * * * [T]he goal of ensuring that any such asset losses are properly reflected in the entity's financial statements represents a financial reporting objective.'' The category in which an objective falls can sometimes depend on the circumstances. Continuing the discussion of safeguarding of assets, controls to prevent theft of assets—such as maintaining a fence around inventory and a gatekeeper verifying proper authorization of requests for movement of goods—fall under the operations category. These controls normally would not be relevant to the reliability of financial statement preparation, because any inventory losses would be detected pursuant to periodic physical inspection and recorded in the financial statements. However, if for financial reporting purposes management relies solely on perpetual inventory records, as may be the case for interim reporting, the physical security controls would then also fall within the financial reporting category. This is because these physical security controls, along with other controls over the perpetual inventory records, would be needed to ensure reliable financial reporting. *Id.* at 37.

[58] As stated in n. 1 to the 1994 Addendum, the FCPA requires companies, among other things, to ''devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary * * * to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.''

[59] See letters regarding File No. S7–40–02 of: ABA; CSC; EEI; FED; Eastman Kodak Co. (''Kodak''); KPMG; Protiviti; and PwC.

[60] See letters regarding File No. S7–40–02 of: ACCA and Financial Executives Institute (''FEI'').

[61] See letters regarding File No. S7–40–02 of: AICPA; BDO Seidman, LLP (''BDO''); D&T; Ernst & Young LLP (''E&Y''); KPMG; and PwC.

requirement that most of those commenting on this aspect of the proposal supported.

3. Final Rules

After evaluating the comments received, we are adopting the proposals with several modifications. The final rules require a company's annual report to include an internal control report of management that contains:

- A statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the company;
- A statement identifying the framework used by management to conduct the required evaluation of the effectiveness of the company's internal control over financial reporting;
- Management's assessment of the effectiveness of the company's internal control over financial reporting as of the end of the company's most recent fiscal year, including a statement as to whether or not the company's internal control over financial reporting is effective.[62] The assessment must include disclosure of any ''material weaknesses'' [63] in the company's internal control over financial reporting identified by management. Management is not permitted to conclude that the company's internal control over financial reporting is effective if there are one or more material weaknesses in the company's internal control over financial reporting; and
- A statement that the registered public accounting firm that audited the financial statements included in the annual report has issued an attestation report on management's assessment of the registrant's internal control over financial reporting.[64]

As proposed, our final rules also require a company to file, as part of the company's annual report, the attestation report of the registered public accounting firm that audited the company's financial statements.

a. Evaluation of Internal Control Over Financial Reporting

In the Proposing Release, we requested comment on whether we should establish specific evaluative criteria for management's report on internal control. All of the commenters responding to this request supported the establishment of such evaluative criteria in order to improve comparability among the standards used by companies to conduct their annual internal control evaluations.[65] Several commenters believed that we either should adopt the COSO Framework as the means by which management must evaluate its company's internal control over financial reporting or, alternatively, simply acknowledge the COSO Framework as being suitable for purposes of management's evaluation. Other commenters suggested that we require management to evaluate the effectiveness of a company's internal control over financial reporting using suitable control criteria established by a group that follows due process procedures.

After consideration of the comments, we have modified the final requirements to specify that management must base its evaluation of the effectiveness of the company's internal control over financial reporting on a suitable, recognized control framework that is established by a body or group that has followed due-process procedures, including the broad distribution of the framework for public comment.[66]

The COSO Framework satisfies our criteria and may be used as an evaluation framework for purposes of management's annual internal control evaluation and disclosure requirements. However, the final rules do not mandate use of a particular framework, such as the COSO Framework, in recognition of the fact that other evaluation standards exist outside of the United States,[67] and that frameworks other than COSO may be developed within the United States in the future, that satisfy the intent of the statute without diminishing the benefits to investors. The use of standard measures that are publicly available will enhance the quality of the internal control report and will promote comparability of the internal control reports of different companies. The final rules require management's report to identify the evaluation framework used by management to assess the effectiveness of the company's internal control over financial reporting.[68]

Specifically, a suitable framework must: be free from bias; permit reasonably consistent qualitative and quantitative measurements of a company's internal control; be sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of a company's internal controls are not omitted; and be relevant to an evaluation of internal control over financial reporting.[69]

b. Auditor Independence Issues

Because the auditor is required to attest to management's assessment of internal control over financial reporting, management and the company's independent auditors will need to coordinate their processes of documenting and testing the internal controls over financial reporting. However, we remind companies and their auditors that the Commission's rules on auditor independence prohibit an auditor from providing certain nonaudit services to an audit client.[70] As the Commission stated in its auditor independence release, auditors may assist management in documenting internal controls. When the auditor is engaged to assist management in documenting internal controls, management must be actively involved in the process. We understand the need for coordination between management and the auditor, however, we remind companies and auditors that management cannot delegate its responsibility to assess its internal controls over financial reporting to the auditor.[71] The rules adopted today do

[62] Management must state whether or not the company's internal control over financial reporting is effective. A negative assurance statement indicating that nothing has come to management's attention to suggest that the company's internal control over financial reporting is not effective will not be acceptable.

[63] A ''material weakness'' is defined in Statement on Auditing Standards No. 60 (codified in Codification of Statements on Auditing Standards AU § 325) as a reportable condition in which the design or operation of one or more of the internal control components does not reduce to a relatively low level the risk that misstatements caused by errors or fraud in amounts that would be material in relation to the financial statements being audited may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions. See discussion in Section II.B.3.b. below.

[64] See new Item 308 of Regulations S–B and S–K, Item 15 of Form 20–F and General Instruction B(6) of Form 40–F.

[65] Many commenters cited the absence of evaluative criteria in AU § 319 in their arguments against the reference to AU § 319 in our proposed definition of ''internal controls and procedures for financial reporting.''

[66] See amended Exchange Act Rule 13a–15(c) or 15d–15(c), amended Item 15 of Form 20–F and amended General Instruction (B) to Form 40–F.

[67] The *Guidance on Assessing Control* published by the Canadian Institute of Chartered Accountants and the *Turnbull Report* published by the Institute of Chartered Accountants in England & Wales are examples of other suitable frameworks.

[68] We are aware that some of the evaluation frameworks used to assess a foreign company's internal controls in its home country do not require a statement regarding whether the company's system of internal control has been effective. Under our final rules, management of a foreign reporting company who relies on such an evaluation framework used in its home country is nevertheless under an obligation to state affirmatively whether its company's internal controls are, or are not, effective.

[69] See AT § 101, paragraph 24.

[70] *See* Release No. 33–8183 (Jan. 28, 2003) [68 FR 6006].

[71] Management's acceptance of responsibility for the documentation and testing performed by the auditor does not satisfy the auditor independence rules.

not amend the Commission's rules on auditor independence.

c. Material Weaknesses in Internal Control Over Financial Reporting

In the Proposing Release, we did not propose any specific standard on which management would base its conclusion that the company's internal control over financial reporting is effective. We requested comment on whether we should prescribe specific standards upon which an effectiveness determination would be based, and also what standards we should consider. Several commenters agreed that the final rules should specify standards, and all believed that the existence of a material weakness in internal control over financial eporting should preclude a conclusion by management that a registrant's internal control over financial reporting is effective. We have considered these comments, and agree that the rules should set forth this threshold for concluding that a company's internal control over financial reporting is effective.

The final rules therefore preclude management from determining that a company's internal control over financial reporting is effective if it identifies one or more material weaknesses in the company's internal control over financial reporting.[72] For purposes of the final rules, the term ''material weakness'' has the same meaning as in the definition under GAAS and attestation standards.[73] The final rules also specify that management's report must include disclosure of any ''material weakness'' in the company's internal control over financial reporting identified by management in the course of its evaluation.[74]

d. Method of Evaluating

Many commenters addressed the method of evaluating internal control over financial reporting, and some sought additional precision or guidance regarding the extent of evaluation, including the documentation required.[75] The methods of conducting evaluations of internal control over financial reporting will, and should, vary from company to company. Therefore, the final rules do not specify the method or procedures to be performed in an evaluation. However, in conducting such an evaluation and developing its assessment of the effectiveness of internal control over financial reporting, a company must maintain evidential matter, including documentation, to provide reasonable support for management's assessment of the effectiveness of the company's internal control over financial reporting. Developing and maintaining such evidential matter is an inherent element of effective internal controls.[76] An instruction to new Item 308 of Regulations S–K and S–B and Forms 20–F and 40–F reminds registrants to maintain such evidential matter.[77]

The assessment of a company's internal control over financial reporting must be based on procedures sufficient both to evaluate its design and to test its operating effectiveness. Controls subject to such assessment include, but are not limited to: controls over initiating, recording, processing and reconciling account balances, classes of transactions and disclosure and related assertions included in the financial statements; controls related to the initiation and processing of non-routine and non-systematic transactions; controls related to the selection and application of appropriate accounting policies; and controls related to the prevention, identification, and detection of fraud. The nature of a company's testing activities will largely depend on the circumstances of the company and the significance of the control. However, inquiry alone generally will not provide an adequate basis for management's assessment.[78]

An assessment of the effectiveness of internal control over financial reporting must be supported by evidential matter, including documentation, regarding both the design of internal controls and the testing processes. This evidential matter should provide reasonable support: for the evaluation of whether the control is designed to prevent or detect material misstatements or omissions; for the conclusion that the tests were appropriately planned and performed; and that the results of the tests were appropriately considered. The public accounting firm that is required to attest to, and report on, management's assessment of the effectiveness of the company's internal control over financial reporting also will require that the company develop and maintain such evidential matter to support management's assessment.[79]

e. Location of Management's Report

Although the final rules do not specify where management's internal control report must appear in the company's annual report, we think it is important for management's report to be in close proximity to the corresponding attestation report issued by the company's registered public accounting firm. We expect that many companies will choose to place the internal control report and attestation report near the companies' MD&A disclosure or in a portion of the document immediately preceding the companies' financial statements.

C. Quarterly Evaluations of Internal Control Over Financial Reporting

1. Proposed Rule

We proposed to require a company's certifying officers to evaluate the effectiveness of the company's internal controls and procedures for financial reporting as of the end of the period covered by each annual and quarterly

[72] This is consistent with interim attestation standards. *See* AT § 501.

[73] The term ''significant deficiency'' has the same meaning as the term ''reportable condition'' as used in AU § 325 and AT § 501. The terms ''material weakness'' and ''significant deficiency'' both represent deficiencies in the design or operation of internal control that could adversely affect a company's ability to record, process, summarize and report financial data consistent with the assertions of management in the company's financial statements, with a ''material weakness'' constituting a greater deficiency than a ''significant deficiency.'' Because of this relationship, it is our judgment that an aggregation of significant deficiencies could constitute a material weakness in a company's internal control over financial reporting.

[74] *See* new Item 308(d) of Regulations S–B and S–K.

[75] *See,* for example, letters re: File No. S7–40–02 of: ABA; AICPA; BDO; Intel; and Eli Lilly and Company.

[76] Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. 78m(b)(2)(A)] requires companies to ''make and keep books, records, and accounts, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer.'' *See* also Section 13(b)(2)(B) of the Exchange Act [15 U.S.C. 78m(b)(2)(B)] and *In re Microsoft Corp.,* Administrative Proceeding File No. 3–10789 (June 3, 2002). In the *Microsoft* order, the Commission stated that such books and records include not only general ledgers and accounting entries, but also memoranda and internal corporate reports. We have previously stated, as a matter of policy, that under Section 13(b)(2) ''every public company needs to establish and maintain records of sufficient accuracy to meet adequately four interrelated objectives: appropriate reflection of corporate transactions and the disposition of assets; effective administration of other facets of the issuer's internal control system; preparation of its financial statements in accordance with generally accepted accounting principles; and proper auditing.'' Statement of Policy Regarding the Foreign Corrupt Practices Act of 1977, Release No. 34–17500 (Jan. 29, 1981) [46 FR 11544].

[77] *See* Instruction 1 to new Item 308 of Regulations S–K and S–B, Instruction 1 to Item 15 of Form 20–F and Instruction 1 to paragraphs (b), (c), (d) and (e) of General Instruction B.6 to Form 40–F.

[78] This statement should not be interpreted to mean that management personally must conduct the necessary activities to evaluate the design and test the operating effectiveness of the company's internal control over financial reporting. Activities, including those necessary to provide management with the information on which it bases its assessment, may be conducted by non-management personnel acting under the supervision of management.

[79] *See* Statements on Standards for Attestation Engagements No. 10.

report that the company is required to file under the Exchange Act. The company's certifying officers already are required to evaluate the effectiveness of the company's disclosure controls and procedures on a quarterly basis.[80] We noted that a quarterly evaluation requirement with respect to internal controls would create symmetry between our requirements for periodic evaluations of both the company's disclosure controls and procedures and its internal controls and procedures for financial reporting, and give effect to the language in the Section 302 certification requirements regarding quarterly internal control evaluations.

2. Comments on the Proposal

We received responses from 25 commenters on the proposed amendments. Of the 25 commenters, four supported the proposal to require quarterly evaluations of internal controls and procedures for financial reporting.[81] One commenter specifically concurred with our objective of creating symmetry between the requirements to conduct periodic evaluations of both the company's disclosure controls and procedures and its internal controls and procedures for financial reporting.[82]

Twenty-one commenters opposed quarterly evaluations of internal controls.[83] Many of these believed that quarterly evaluations would impose substantial additional costs on companies without producing any incremental benefit to investors. One individual stated that the proper evaluation of a company's system of internal controls is a weighty and time-consuming process.[84] Twelve of the commenters opposed to quarterly evaluations indicated that quarterly evaluations of all aspects of internal controls and procedures would be extremely burdensome, expensive and difficult to perform under the time constraints of quarterly reporting, particularly as the accelerated filing deadlines for quarterly reports take effect.[85] Several other commenters argued that we should not go beyond the requirements of Section 404 of the Sarbanes-Oxley Act with respect to the frequency of internal control reporting without an adequate basis for doing so.[86] These commenters remarked that such a decision would be better made after we have had sufficient experience with the Section 302 certification requirements adopted in August of 2002.

Several commenters suggested alternatives to quarterly evaluations. Five commenters stated that it would be more appropriate and desirable if companies were required to make quarterly disclosure only of material changes to their internal control that occurred subsequent to management's most recent annual internal control evaluation.[87] Two other commenters similarly recommended that the quarterly evaluation be less rigorous than the annual evaluation.[88] One commenter stated that we should instead adopt an approach that requires less effort and assurance for purposes of quarterly reports, such as permitting companies to test compliance with controls relating to major applications on a rotating basis throughout the year.[89] This commenter further stated that the objective of the quarterly evaluation should be to identify changes in controls during the quarter and evaluate whether they would change the certifying officers' conclusions about disclosure controls and internal controls as stated in the most recent annual report. The other commenter, although opposed to any quarterly evaluation requirement, believed that if we did require it, the quarterly evaluation should be viewed as an update of the annual evaluation, just as the quarterly report on Form 10–Q is an update of the annual report on Form 10–K.[90] One commenter stated that if we require some form of quarterly certification, it should be limited to negative assurance that nothing has come to the certifying officers' attention since the prior year's evaluation to suggest that the controls are no longer effective.[91]

3. Final Rules

After consideration of the comments received, we have decided not to require quarterly evaluations of internal control over financial reporting that are as extensive as the annual evaluation. We recognize that some controls operate continuously while others operate only at certain times, such as the end of the fiscal year. We believe that each company should be afforded the flexibility to design its system of internal control over financial reporting to fit its particular circumstances. The management of each company should perform evaluations of the design and operation of the company's entire system of internal control over financial reporting over a period of time that is adequate for it to determine whether, as of the end of the company's fiscal year, the design and operation of the company's internal control over financial reporting are effective.

Accordingly, we are adopting amendments that require a company's management, with the participation of the principal executive and financial officers, to evaluate any change in the company's internal control over financial reporting that occurred during a fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting. We also have adopted a modification to the Section 302 certification requirement and our disclosure requirements to adopt this approach, as discussed below.

The management of a foreign private issuer that has Exchange Act reporting obligations must also, like its domestic counterparts, report any material changes to the issuer's internal control over financial reporting. However, because foreign private issuers are not required to file quarterly reports under Section 13(a) or 15(d) of the Exchange Act, the final rules clarify that a foreign private issuer's management need only disclose in the issuer's annual report the material changes to its internal control over financial reporting that have occurred in the period covered by the annual report.[92]

D. Differences Between Internal Control Over Financial Reporting and Disclosure Controls and Procedures

Many of the commenters on the Proposing Release indicated that they

[80] *See* Exchange Act Rules 13a–15(b) and 15d–15(b) [17 CFR 240.13a–15(b) and 240.15d–15(b)].

[81] *See* letters regarding File No. S7–40–02 of: AICPA; Executive Responsibility; FED; and Protiviti.

[82] *See* Protiviti letter regarding File No. S7–40–02.

[83] *See* letters regarding File No. S7–40–02 of: ABA; ACB; ACCA; Association for Financial Professionals (''AFP''); Am. Bankers Assoc.; BDO; Business Roundtable (''BRT''); Computer Sciences Corporation (''CSC''); Compass; Thomas Damman (''Damman''); EEI; Emerson Electric Co. (''Emerson''); FEI; Fried, Frank, Harris, Shriver and Jacobson (''Fried Frank''); International Paper Company (''IPC''); ICBA; NYCB–CCL; New York State Bar Association (''NYSBA''); Siemens AG (''Siemens''); Software & Information Industry Association (''SIIA''); and Software Finance and Tax Executives Council (''SOFTEC'').

[84] *See* Damman letter regarding File No. S7–40–02.

[85] *See* letters regarding File No. S7–40–02 of: ABA; ACB; ACCA; BRT; CSC; Emerson; Fried Frank; ICBA; IPC; NYCB–CCL; SIIA; and SOFTEC.

[86] *See* letters regarding File No. S7–40–02 of: Am. Bankers Assoc.; CSC; Fried Frank.

[87] *See* letters regarding File No. S7–40–02 of: Damman; Compass; EEI; Executive Responsibility Advisors, LLC (''Executive Responsibility''); and Siemens.

[88] *See* letters regarding File No. S7–40–02 of: ABA and BDO.

[89] 89 *See* BDO letter regarding File No. S7–40–02.

[90] *See* ABA letter regarding File No. S7–40–02.

[91] *See* Emerson letter regarding File No. S7–40–02.

[92] See Exchange Act Rules 13a–15(d) and 15d–15(d) [17 CFR 240.13a–15(d) and 240.15d–15(d)].

were confused as to the differences between a company's disclosure controls and procedures and a company's internal control over financial reporting. Exchange Act Rule 13a–15(d) defines ''disclosure controls and procedures'' to mean controls and procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The definition further states that disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

While there is substantial overlap between a company's disclosure controls and procedures and its internal control over financial reporting, there are both some elements of disclosure controls and procedures that are not subsumed by internal control over financial reporting and some elements of internal control that are not subsumed by the definition of disclosure controls and procedures.

With respect to the latter point, clearly, the broad COSO description of internal control, which includes the efficiency and effectiveness of a company's operations and the company's compliance with laws and regulations (not restricted to the federal securities laws), would not be wholly subsumed within the definition of disclosure controls and procedures. A number of commenters suggested that the narrower concept of internal control, involving internal control over financial reporting, is a subset of a company's disclosure controls and procedures, given that the maintenance of reliable financial reporting is a prerequisite to a company's ability to submit or file complete disclosure in its Exchange Act reports on a timely basis. This suggestion focuses on the fact that the elements of internal control over financial reporting requiring a company to have a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles can be viewed as a subset of disclosure controls and procedures.

We agree that some components of internal control over financial reporting will be included in disclosure controls and procedures for all companies. In particular, disclosure controls and procedures will include those components of internal control over financial reporting that provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles. However, in designing their disclosure controls and procedures, companies can be expected to make judgments regarding the processes on which they will rely to meet applicable requirements. In doing so, some companies might design their disclosure controls and procedures so that certain components of internal control over financial reporting pertaining to the accurate recording of transactions and disposition of assets or to the safeguarding of assets are not included. For example, a company might have developed internal control over financial reporting that includes as a component of safeguarding of assets dual signature requirements or limitations on signature authority on checks. That company could nonetheless determine that this component is not part of disclosure controls and procedures. We therefore believe that while there is substantial overlap between internal control over financial reporting and disclosure controls and procedures, many companies will design their disclosure controls and procedures so that they do not include all components of internal control over financial reporting.

E. Evaluation of Disclosure Controls and Procedures

The rules in place starting in August 2002 requiring quarterly evaluations of disclosure controls and procedures and disclosure of the conclusions regarding effectiveness of disclosure controls and procedures have not been substantively changed since their adoption, including in the rules that we adopt today. These evaluation and disclosure requirements will continue to apply to disclosure controls and procedures, including the elements of internal control over financial reporting that are subsumed within disclosure controls and procedures.

With respect to evaluations of disclosure controls and procedures, companies must, under our rules and consistent with the Sarbanes-Oxley Act, evaluate the effectiveness of those controls and procedures on a quarterly basis. While the evaluation is of effectiveness overall, a company's management has the ability to make judgments (and it is responsible for its judgments) that evaluations, particularly quarterly evaluations, should focus on developments since the most recent evaluation, areas of weakness or continuing concern or other aspects of disclosure controls and procedures that merit attention. Finally, the nature of the quarterly evaluations of those components of internal control over financial reporting that are subsumed within disclosure controls and procedures should be informed by the purposes of disclosure controls and procedures.[93]

The rules adopted in August 2002 required the management of an Exchange Act reporting foreign private issuer to evaluate and disclose conclusions regarding the effectiveness of the issuer's disclosure controls and procedures only in its annual report and not on a quarterly basis. The primary reason for this treatment is because foreign private issuers are not subject to mandated quarterly reporting requirements under the Exchange Act. The rules adopted today continue this treatment.[94]

F. Periodic Disclosure About the Certifying Officers' Evaluation of the Company's Disclosure Controls and Procedures and Disclosure About Changes to its Internal Control Over Financial Reporting

1. Existing Disclosure Requirements

The rules that we adopted in August 2002 to implement the certification requirements of Section 302 of the Sarbanes-Oxley Act included new Item 307 of Regulations S-B and S-K. Paragraph (a) of Item 307 requires companies, in their quarterly and annual reports, to disclose the conclusions of the company's principal executive and financial officers (or persons performing similar functions) about the effectiveness of the company's disclosure controls and procedures as of a date within 90 days of the filing date of the quarterly or annual report. This disclosure enables the certifying officers to satisfy the representation made in

[93] For example, where a component of internal control over financial reporting is subsumed within disclosure controls and procedures, even where systems testing of that component would clearly be required as part of the annual evaluation of internal control over financial reporting, management could make a different determination of the appropriate nature of the evaluation of that component for purposes of a quarterly evaluation of disclosure controls and procedures.

[94] See Exchange Act Rules 13a–15(b) and 15d–15(b).

their certifications that they have ''presented in the quarterly or annual report their conclusions about the effectiveness of the disclosure controls and procedures based on their evaluation.''

Paragraph (b) of Item 307 requires the company to disclose in each quarterly and annual report whether or not there were significant changes in the company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses. This disclosure enables the certifying officers to satisfy the representation made in their certifications that they have ''indicated in the quarterly or annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of their most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.''

2. Proposed Amendments to the Disclosure Requirements

In the Proposing Release, we proposed several revisions to the existing disclosure requirements regarding: (1) The certifying officers' evaluation of the company's disclosure controls and procedures; and (2) changes to the company's internal control over financial reporting. We also proposed to require quarterly disclosure regarding the conclusions of the certifying officers about the effectiveness of the company's internal control over financial reporting.

Moreover, we proposed to require evaluations of both types of controls as of the end of the period covered by the quarterly or annual report, rather than ''as of a date within 90 days of the filing date'' of the quarterly or annual report, as currently required with respect to disclosure controls. With respect to the disclosure about changes to the company's internal control over financial reporting, we proposed to require a company to disclose ''any significant changes made during the period covered by the quarterly or annual report'' rather than ''whether or not there were significant changes in the company's internal control over financial reporting that could significantly affect these controls subsequent to the date of their evaluation.''

The commenters were mixed in their reaction to these proposed changes. A couple of the commenters remarking on the point at which a company must undertake an evaluation of its controls ''strongly agreed'' with the proposed change to require evaluations as of the end of the period. Several other commenters preferred the existing ''90 days within the filing date'' evaluation point, noting that it provides more flexibility than the fixed point. Some of these commenters expressed concern that it would be hard to conduct evaluations on the last day of the period. One of the commenters suggested that the proposed requirement that a company disclose changes to its internal control over financial reporting that occurred at any time during a fiscal quarter was inconsistent with the proposed requirement that management evaluate such changes ''as of the end of each fiscal quarter.''[95] An additional commenter asserted that it was critical that we offer companies some guidance as to the types of changes that constitute ''significant changes.''[96] Finally, a few commenters noted that while we had proposed to delete the words ''or other factors'' from Exchange Act Rules 13a–14(b)(6) and 15d–14(b)(6) regarding disclosure of ''significant changes in internal controls or in other factors that could significantly affect internal controls, * * *'' we had not likewise proposed to delete those words from the actual certification language.

3. Final Disclosure Requirements

After consideration of the comments, we are adopting the proposals with several modifications. We are adopting as proposed the change of the evaluation date for disclosure controls to ''as of the end of the period'' covered by the quarterly or annual report. We are not specifying the point at which management must evaluate changes to the company's internal control over financial reporting. Given that the final rules do not require a company to state the conclusions of the certifying officers regarding the effectiveness of the company's internal control over financial reporting as of a particular date on a quarterly basis as proposed, as the company must with respect to disclosure controls and procedures, it is unnecessary to specify a date for the quarterly evaluation of changes in internal control over financial reporting. We believe that this change is consistent with the new accelerated reporting deadlines.[97]

We are amending the proposal that would have required companies to disclose any significant changes in its internal controls. Under the final rules, a company must disclose any change in its internal control over financial reporting that occurred during the fiscal quarter covered by the quarterly report, or the last fiscal quarter in the case of an annual report, that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.[98] Furthermore, we have deleted the phrase ''or in other factors'' from Exchange Act Rules 13a–14 and 15d–15 and the form of certification. Although the final rules do not explicitly require the company to disclose the reasons for any change that occurred during a fiscal quarter, or to otherwise elaborate about the change, a company will have to determine, on a facts and circumstances basis, whether the reasons for the change, or other information about the circumstances surrounding the change, constitute material information necessary to make the disclosure about the change not misleading.[99]

While an evaluation of the effectiveness of disclosure controls and procedures must be undertaken on a quarterly basis, we expect that for purposes of disclosure by domestic companies, the traditional relationship between disclosure in annual reports on Form 10–K and intervening quarterly reports on Form 10–Q will continue. Disclosure in an annual report that continues to be accurate need not be repeated. Rather, disclosure in quarterly reports may make appropriate reference to disclosures in the most recent annual report (and, where appropriate, intervening quarterly reports) and disclose subsequent developments required to be disclosed in the quarterly report.

We note that, as required by the Sarbanes-Oxley Act, the quarterly certification regarding disclosure that the certifying officers must make to the company's auditors and audit committee provides:[100]

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[95] 95 See ABA letter regarding File No. S7–40–02.

[96] See Intel letter regarding File No. S7–40–02.

[97] See Release No. 33–8128 (Sept. 16, 2002) [67 FR 58480]. The final rule amendments do not require that the evaluation take place on the last day of the period, but that the statement of effectiveness of the issuer's disclosure controls and internal control over financial reporting be as of the end of the period.

[98] 98 We have also made conforming changes to Forms 20–F and 40–F to clarify that the management of a foreign private issuer must disclose in the issuer's annual report filed on Form 20–F or 40–F any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report and that materially affected, or is reasonably likely to affect, this internal control. See Item 15(d) of Form 20–F and General Instruction B(6)(e) of Form 40–F.

[99] *See* Exchange Act Rules 10b–5 and 12b–20 [17 CFR 240.10b–5 and 17 CFR

[100] This is the disclosure required by paragraph 5 of the certification form.

The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

We expect that if a certifying officer becomes aware of a significant deficiency, material weakness or fraud requiring disclosure outside of the formal evaluation process or after the management's most recent evaluation of internal control over financial reporting, he or she will disclose it to the company's auditors and audit committee.

4. Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

In disclosures required under current Item 307 of Regulations S–K and S–B, Item 15 of Form 20–F and General Instruction B(6) to Form 40–F, some companies have indicated that disclosure controls and procedures are designed only to provide ''reasonable assurance'' that the controls and procedures will meet their objectives. In reviewing those disclosures, the Commission staff generally has not objected to that type of disclosure. The staff has, however, requested companies including that type of disclosure to set forth, if true, the conclusions of the principal executive and principal financial officer that the disclosure controls and procedures are, in fact, effective at the ''reasonable assurance'' level. Other companies have included disclosure that there is ''no assurance'' that the disclosure controls and procedures will operate effectively under all circumstances. In these instances, the staff has requested companies to clarify that the disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives and to set forth, if true, the conclusions of the principal executive and principal financial officers that the controls and procedures are, in fact, effective at the ''reasonable assurance'' level.

The concept of reasonable assurance is built into the definition of internal control over financial reporting that we are adopting. This conforms to the standard contained in the internal accounting control provisions of Section 13(b)(2) of the Exchange Act [101] and current auditing literature.[102] If management decides to include a discussion of reasonable assurance in the internal control report, the discussion must be presented in a manner that neither makes the disclosure in the report confusing nor renders management's assessment concerning the effectiveness of the company's internal control over financial reporting unclear.

G. Attestation to Management's Internal Control Report by the Company's Registered Public Accounting Firm

In the Proposing Release, we proposed to amend Rules 210.1–02 and 210.2–02 of Regulation S–X to make conforming revisions to Regulation S–X to reflect the registered public accounting firm attestation requirements mandated by Section 404(b) of the Sarbanes-Oxley Act. Under the proposals, we set forth a definition for the new term ''attestation report on management's evaluation of internal control over financial reporting'' and certain requirements for the accountant's attestation report. We are adopting the proposals substantially as proposed. However, the final rules define the expanded term ''attestation report on management's evaluation of internal control over financial reporting.'' Several commenters suggested that we use this more specific term, noting that auditors currently perform attestation engagements on a broad variety of subjects. Amended Rule 2–02 requires every registered public accounting firm that issues an audit report on the company's financial statements that are included in its annual report required by Section 13(a) or 15(d) of the Exchange Act containing an assessment by management of the effectiveness of the registrant's internal control over financial reporting must attest to, and report on, such assessment.

At the time of the enactment of the Sarbanes-Oxley Act, the applicable standard for attestation by auditors of internal control over financial reporting was set forth in Statements on Standards for Attestation Engagements No. 10 (''SSAE No. 10''). That standard was used by auditors providing attestations on a voluntary basis to companies, as well as by auditors whose financial institution clients are required to obtain attestations under Federal Deposit Insurance Corporation Improvement Act of 1991,[103] as discussed below. Under the Sarbanes-Oxley Act, the PCAOB has become the body that sets auditing and attestation standards generally for registered public accounting firms to use in the preparation and issuance of audit reports on the financial statements of issuers, and under Section 404(b) of the Sarbanes-Oxley Act, the PCAOB is required to set standards for the registered public accounting firms' attestations to, and reports on, management's assessment regarding its internal control over financial reporting.

On April 16, 2003, the PCAOB designated Statements on Standards for Attestation Engagements as existed on April 16 as the standard for attestations of management's assessment of the effectiveness of internal control over financial reporting pending further PCAOB standard-setting in the area (and subject to our approval of the PCAOB's actions), and on April 25, we approved the PCAOB's action. SSAE No. 10 is thus the standard applicable on a transition basis for attestations required under Section 404 of the Act and the rules we are adopting today, again pending further PCAOB standard-setting (and our approval). We expect that the PCAOB will assess the appropriateness of those standards and modify them as needed, and any future standards adopted by the PCAOB will apply to registered public accounting firms in connection with the preparation and issuance of attestation reports on management's assessment of the effectiveness of internal control over financial reporting.

H. Types of Companies Affected

Section 404 of the Sarbanes-Oxley Act states that the Commission must prescribe rules that require each annual report required by Section 13(a) or 15(d) of the Exchange Act to contain an internal control report. The Act exempts registered investment companies from this requirement.[104]

1. Foreign Private Issuers

Section 404 of the Sarbanes-Oxley Act makes no distinction between domestic and foreign issuers and, by its terms, clearly applies to foreign private issuers. These amendments, therefore, apply the management report on internal control over financial reporting requirement to foreign private issuers that file reports under Section 13(a) or 15(d) of the Exchange Act. We have, however, adopted a later compliance date for

[101] 101 15 U.S.C. 78m(b)(2).

[102] *See* Codification of Statement on Auditing Standards AU § 319.18.

[103] Pub. L. 102–242, 105 Stat. 2242 (1991).

[104] *See* Section 405 of the Sarbanes-Oxley Act.

foreign private issuers than for accelerated filers.

2. Asset-Backed Issuers

In the Proposing Release, we proposed to exclude issuers of asset-backed securities from the proposed rules implementing Section 404 of the Act. We noted that because of the unique nature of asset-backed issuers, such issuers are subject to substantially different reporting requirements. Most significantly, asset-backed issuers are generally not required to file the types of financial statements that other companies must file. Also, such entities typically are passive pools of assets, without a board of directors or persons acting in a similar capacity. We did not receive any comments on the proposed exclusion of asset-backed issuers from the internal control reporting requirements, and we are excluding asset-backed issuers from the new disclosure requirements as proposed.

3. Small Business Issuers

Our proposed rules implementing Section 404 of the Act did not distinguish between large and small issuers. Similarly, Section 404 of the Act directs that the management report on internal control over financial reporting apply to any company filing periodic reports under Section 13(a) or 15(d) of the Exchange Act. Accordingly, these amendments apply to all issuers that file Exchange Act periodic reports, except registered investment companies, regardless of their size. However, we are sensitive that many small business issuers may experience difficulty in evaluating their internal control over financial reporting because these issuers may not have as formal or well-structured a system of internal control over financial reporting as larger companies. Accordingly, we are providing an extended compliance period for small business issuers and other companies that are not accelerated filers.[105] In addition, our approach of not mandating specific criteria to be used by management to evaluate a company's internal control over financial reporting should provide small issuers some flexibility in meeting these disclosure requirements.

4. Bank and Thrift Holding Companies

In the Proposing Release, we stated that we were coordinating with the Federal Deposit Insurance Corporation (the ''FDIC'') and the other federal banking regulators to eliminate, to the extent possible, any unnecessary duplication between our proposed internal control report and the FDIC's internal control report requirements. Under regulations adopted by the FDIC implementing Section 36 of the Federal Deposit Insurance Act,[106] a federally insured depository institution with total assets of $500 million or more (''institution''), is required, among other things, to prepare an annual management report that contains:

- A statement of management's responsibility for preparing the institution's annual financial statements, for establishing and maintaining an adequate internal control structure and procedures for financial reporting, and for complying with designated laws and regulations relating to safety and soundness;[107] and
- Management's assessment of the effectiveness of the institution's internal control structure and procedures for financial reporting as of the end of the fiscal year and the institution's compliance with the designated safety and soundness laws and regulations during the fiscal year.[108]

The FDIC's regulations additionally require the institution's independent accountant to examine, and attest to, management's assertions concerning the effectiveness of the institution's internal control structure and procedures for financial reporting.[109] The institution's management report and the accountant's attestation report must be filed with the FDIC, the institution's primary federal regulator (if other than the FDIC), and any appropriate state depository institution supervisor and must be available for public inspection.[110]

Although bank and thrift holding companies are not required under the FDIC's regulations to prepare these internal control reports, many of these holding companies do so under a provision of Part 363 of the FDIC's regulations[111] that permits an insured depository institution that is the subsidiary of a holding company to satisfy its internal control report requirements with an internal control report of the consolidated holding company's management if:

- Services and functions comparable to those required of the subsidiary by Part 363 are provided at the holding company level;[112] and
- The subsidiary has, as of the beginning of its fiscal year, (i) total assets of less than $5 billion or (ii) total assets of $5 billion or more and a composite rating of 1 or 2 under the Uniform Financial Institutions Rating System.[113]

Section 404 of the Sarbanes-Oxley Act does not contain an exemption for insured depository institutions that are both subject to the FDIC's internal control report requirements and required to file Exchange Act reports. In fact, it makes no distinction whatsoever between institutions subject to the FDIC's requirements and other types of Exchange Act filers. Accordingly, regardless of whether an insured depository institution is subject to the FDIC's requirements, insured depository institutions or holding companies that are required to file periodic reports under Section 13(a) or 15(d) of the Exchange Act are subject to the internal control reporting requirements that we are adopting today.

Although our final rules are similar to the FDIC's internal control report requirements, the rules differ in a few significant respects. Most notably, our final rules do not require a statement of compliance with designated laws and regulations relating to safety and soundness. Conversely, the following

[105] *See* Section II. J. below.

[106] 12 U.S.C. 1831m.

[107] The designated laws and regulations are federal laws and regulations concerning loans to insiders and federal and state laws and regulations concerning dividend restrictions. See 12 CFR part 363, Appendix A, Guideline 12.

[108] See 12 CFR 363.2, adopted in 58 FR 31332. These requirements only apply to an insured depository institution with total assets of $500 million or more. We recognize that the FDIC's regulations use the term ''internal control structure and procedures for financial reporting'' rather than the term ''internal control over financial reporting'' used in our rules. We think the differences in the meaning of the two terms are insignificant because both Section 36(b)(2) of the Federal Deposit Insurance Act and Section 404(a) of the Sarbanes-Oxley Act refer to ''internal control structure and procedures for financial reporting.'' Nevertheless, the FDIC has defined the term ''financial reporting'' to include financial statements prepared in accordance with generally accepted accounting principles (''GAAP'') and those prepared for regulatory reporting purposes (see FDIC Financial Institution Letter FIL–86–94, dated December 23, 1994).

[109] 12 CFR 363.3.

[110] 12 CFR 363.4(a) and (b).

[111] 12 CFR Part 363.

[112] Services and functions are considered ''comparable'' if the holding company prepares and submits the management assessment of the effectiveness of the internal control structure and procedures for financial reporting and compliance with the designated safety and soundness laws and regulations based on information concerning the relevant activities and operations of those subsidiary institutions subject to Part 363. See 12 CFR Part 363, Appendix A, Guideline 4.

[113] This rating is more commonly known as the CAMELS rating, which addresses Capital adequacy, Asset quality, Management, Earnings, Liquidity and Sensitivity to market risk. See 12 CFR 363.1(b)(2). The appropriate federal banking agency may determine that an insured depository institution with total assets in excess of $9 billion that is a subsidiary of a holding company may not satisfy its FDIC internal control report requirement with an internal control report of the consolidated holding company's management if the agency determines that there could be a significant risk to the affected deposit insurance fund if the institution were allowed to satisfy its requirements in this manner. See 12 CFR 363.1(b)(3).

provisions in our rules are not included in the FDIC's regulations:

- The requirement that the report include a statement identifying the framework used by management to evaluate the effectiveness of the company's internal control over financial reporting;[114]
- The requirement that management disclose any material weakness that it has identified in the company's internal control over financial reporting (and related stipulation that management is not permitted to conclude that the company's internal control over financial reporting is effective if there are one or more material weaknesses);
- The requirement that the company state that the registered public accounting firm that audited the financial statements included in the annual report has issued an attestation report on management's assessment of the company's internal control over financial reporting; and
- The requirement that the company must provide the registered public accounting firm's attestation report on management's assessment of internal control over financial reporting in the company's annual report filed under the Exchange Act.[115]

Several commenters generally supported our goal to eliminate or reduce duplicative reporting requirements. Some of these commenters asserted that we should recognize the substantial protections to depositors and investors provided by the federal laws that govern depository institutions and their holding companies. They suggested that our final rules should state that compliance with the FDIC's internal control report requirements satisfies the internal control report requirements that we are adopting under Section 404. A number of these commenters also thought that if we did not exempt insured depository institutions already filing internal control reports under the FDIC's requirements, we should provide an exemption in our rules mirroring the FDIC's exemption that excludes insured depository institutions or their holding companies with less than $500 million in assets from the internal control report requirements.

After consultation with the staffs of the FDIC, the Federal Reserve Board, the Office of Thrift Supervision and the Office of the Comptroller of Currency, we have determined that insured depository institutions that are subject to Part 363 of the FDIC's regulations (as well as holding companies permitted to file an internal control report on behalf of their insured depository institution subsidiaries in satisfaction of these regulations) and also subject to our new rules implementing Section 404 of the Sarbanes-Oxley Act[116] should be afforded considerable flexibility in determining how best to satisfy both sets of requirements. Therefore, they can choose either of the following two options:

- They can prepare two separate management reports to satisfy the FDIC's and our new requirements; or
- They can prepare a single management report that satisfies both the FDIC's requirements and our new requirements.

If an insured depository institution or its holding company chooses to prepare a single report to satisfy both sets of requirements, the report of management on the institution's or holding company's internal control over financial reporting (as defined in Exchange Act Rule 13a–15(f) or 15d–15(f)) will have to contain the following:[117]

- A statement of management's responsibility for preparing the registrant's annual financial statements, for establishing and maintaining adequate internal control over financial reporting for the registrant, and for the institution's compliance with laws and regulations relating to safety and soundness designated by the FDIC and the appropriate federal banking agencies;
- A statement identifying the framework used by management to evaluate the effectiveness of the registrant's internal control over financial reporting as required by Exchange Act Rule 13a–15 or 15d–15;
- Management's assessment of the effectiveness of the registrant's internal control over financial reporting as of the end of the registrant's most recent fiscal year, including a statement as to whether or not management has concluded that the registrant's internal control over financial reporting is effective, and of the institution's compliance with the designated safety and soundness laws and regulations during the fiscal year. This discussion must include disclosure of any material weakness in the registrant's internal control over financial reporting identified by management;[118] and
- A statement that the registered public accounting firm that audited the financial statements included in the registrant's annual report has issued an attestation report on management's assessment of the registrant's internal control over financial reporting.

Additionally, the institution or holding company will have to provide the registered public accounting firm's attestation report on management's assessment in its annual report filed under the Exchange Act.[119] For purposes of the report of management and the attestation report, financial reporting must encompass both financial statements prepared in accordance with GAAP and those prepared for regulatory reporting purposes.

I. Registered Investment Companies

Section 404 of the Sarbanes-Oxley Act does not apply to registered investment

[114] The FDIC's regulations do not specifically require that management identify the control framework used to evaluate the effectiveness of the institution's internal control over financial reporting. However, given the requirements of Sections 101 and 501 of the American Institute of Certified Public Accountants' attestation standards, the FDIC believes that the framework used must be disclosed or otherwise publicly available to all users of reports that institutions file with the FDIC pursuant to Part 363 of the FDIC's regulations.

[115] The FDIC's regulations do require an independent public accountant to examine, attest to, and report separately on, the assertion of management concerning the institution's internal control structure and procedures for financial reporting, but these regulations do not require the accountant to be a registered public accounting firm. See 12 CFR 363.3(b).

[116] Our rules do not provide an exemption that parallels the FDIC's exemption for insured depository institutions with less than $500 million in assets. It would be incongruous to provide an exemption in our rules for small depository institutions and not other small, non-depository Exchange Act reporting companies.

[117] An insured depository institution subject to both the FDIC's requirements and our new requirements choosing to file a single report to satisfy both sets of requirements will file the report with its primary federal regulator under the Exchange Act and the FDIC, its primary federal regulator (if other than the FDIC), and any appropriate state depository institution supervisor under Part 363 of the FDIC's regulations. A holding company choosing to prepare a single report to satisfy both sets of requirements will file the report with the Commission under the Exchange Act and the FDIC, the primary federal regulator of the insured depository institution subsidiary subject to the FDIC's requirements, and any appropriate state depository institution supervisor under Part 363.

[118] Management will not be permitted to conclude that the registrant's internal control over financial reporting is effective if there are one or more material weaknesses in the registrant's internal control over financial reporting.

[119] An insured depository institution subject to both the FDIC's requirements and our new requirements choosing to file a single management report to satisfy both sets of requirements will file the attestation report with its primary federal regulator under the Exchange Act and the FDIC, its primary federal regulator (if other than the FDIC), and any appropriate state depository institution supervisor under Part 363 of the FDIC's regulations. A holding company choosing to prepare a single management report to satisfy both sets of requirements will file the attestation report with the Commission under the Exchange Act and the FDIC, the primary federal regulator of the insured depository institution subsidiary subject to the FDIC's requirements, and any appropriate state depository institution supervisor under Part 363.

companies, and we are not extending any of the requirements that would implement section 404 to registered investment companies.[120] Several commenters objected to the proposed requirement that the Section 302 certification include a statement of the officers' responsibility for internal controls.[121] These commenters argued that this requirement would contradict Section 405 of the Sarbanes-Oxley Act and represent a ''back-door'' application of Section 404, from which registered investment companies are exempt.[122] We disagree. The certification requirements implement Section 302 of the Sarbanes-Oxley Act, from which registered investment companies are not exempt.[123] We are not subjecting registered investment companies to the requirements implementing Section 404 of the Sarbanes-Oxley Act, including the annual and quarterly evaluation requirements with respect to internal control over financial reporting and the requirements for an annual report by management on internal control over financial reporting and an attestation report on management's assessment.

We are adopting the following technical changes to our rules and forms implementing Section 302 of the Sarbanes-Oxley Act for registered investment companies in order to conform to the changes that we are adopting for operating companies.[124]

- *Paragraph (d) of Investment Company Act Rule 30a–3.* The amendments use the same term ''internal control over financial reporting'' that we are using in the rules for operating companies and include the same definition of ''internal control over financial reporting'' that we are adopting in Exchange Act Rules 13a–15(f) and 15d–15(f).
- *Paragraph (a) of Investment Company Act Rule 30a–3.* The amendments require every registered management investment company, other than a small business investment company, to maintain internal control over financial reporting. These amendments parallel those that we are adopting for operating companies in Exchange Act Rules 13a–15(a) and 15d–15(a).
- *Introductory text and sub–paragraph (b) of paragraph 4 of the certification in Item 10(a)(2) of Form N–CSR.* The amendments require the signing officers to state that they are responsible for establishing and maintaining internal control over financial reporting, and that they have designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
- *Paragraph (4)(d) of the certification of Item 10(a)(2), and Item 9(b) of Form N–CSR.* The amendments require disclosure of any change in the investment company's internal control over financial reporting that occurred during the most recent fiscal half-year that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.
- *Paragraph (5) of the certification of Item 10(a)(2) of Form N–CSR.* The amendments require the signing officers to state that they have disclosed to the investment company's auditors and the audit committee all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the investment company's ability to record, process, summarize, and report financial information.

We are not, however, adopting proposed amendments that would have required the evaluation by an investment company's management of the effectiveness of its disclosure controls and procedures to be as of the end of the period covered by each report on Form N–CSR, rather than within 90 days prior to the filing date of the report, as our certification rules currently require.[125] Commenters noted that this would require investment company complexes that have funds with staggered fiscal year ends to perform evaluations of their disclosure controls and procedures as many as twelve times per year. They argued that requiring such frequent evaluations would be extremely costly, inefficient, and operationally disruptive, and would not provide any benefits to shareholders.[126] We agree that the costs of requiring investment company complexes to perform evaluations of their disclosure controls and procedures twelve times per year would outweigh the benefits to investors. The certification rules we are adopting will require an investment company complex to perform at most four such evaluations per year.[127]

Transition Period for Registered Investment Companies

Registered investment companies must comply with the rule and form amendments applicable to them on and after August 14, 2003, except as follows. Registered investment companies must comply with the amendments to Exchange Act Rules 13a–15(a) and 15d–15(a) and Investment Company Act Rule 30a–3(a) that require them to maintain internal control over financial reporting with respect to fiscal years ending on or after June 15, 2004. In addition, registered investment companies must comply with the portion of the introductory language in paragraph 4 of the certification in Item 10(a)(2) of Form N–CSR that refers to the certifying officers' responsibility for establishing

[120] *See* Section 405 of the Sarbanes-Oxley Act (''Nothing in section 401, 402, or 404, the amendments made by those sections, or the rules of the Commission under those sections shall apply to any investment company registered under section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8).''). The provisions that would not extend to registered investment companies include amendments to Exchange Act rules 13a–15(c) and 15d–15(c) (requiring annual evaluation of the effectiveness of internal control over financial reporting); Exchange Act rules 13a–15(d) and 15d–15(d) (requiring quarterly evaluation of any change in internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting); and Items 308(a) and (b) of Regulations S–K and S–B (requiring annual report by management on internal control over financial reporting and attestation report on management's evaluation of internal control over financial reporting).

[121] Proposed paragraph 4 of the certification section of proposed Form N–CSR. Proposing Release, note 26 above, 67 FR at 66250. We received 7 comment letters on the proposed changes to the certification rules with respect to investment companies in the Proposing Release. See letters regarding File No. S7–40–02 of: the Investment Company Institute (''ICI''); Protiviti; OppenheimerFunds, Inc. (''Oppenheimer''); The Association of the Bar of the City of New York; Leslie Ogg of Board Services Corporation (''Ogg''); Federated Funds; and D&T.

[122] *See* letters regarding File No. S7–40–02 of: Association of the Bar of the City of New York; ICI; and Oppenheimer.

[123] *See* Section 302(a)(4)(A) and (B) of the Sarbanes-Oxley Act (requiring signing officers to certify that they are responsible for establishing and maintaining internal controls and have designed the internal controls to ensure that material information relating to the issuer is made known to the signing officers).

[124] For a discussion of changes to the form of the Section 302 certification for operating companies, *see* Section III.D. below.

[125] Proposed Exchange Act Rules 13a–15(c) and 15d–15(c), proposed Investment Company Act Rule 30a–2(b)(4)(iii), and proposed Investment Company Act Rule 30a–3(b).

[126] *See* letters regarding File No. S7–40–02 of: D&T; ICI; Ogg; and Oppenheimer.

[127] *See* Release No. IC–25914 (Jan. 27, 2003) [68 FR 5348, 5352 n. 43] (noting that in the case of a series fund or family of investment companies in which the disclosure controls and procedures for each fund in the series or family are the same, a single evaluation of the effectiveness of the disclosure controls and procedures for the series or family could be used in multiple certifications for the funds in the series or family, as long as the evaluation has been performed within 90 days of the report on Form N–CSR).

and maintaining internal control over financial reporting, as well as paragraph 4(b) of the certification, beginning with the first annual report filed on Form N–CSR for a fiscal year ending on or after June 15, 2004.

J. Transition Period

We received a number of comments urging us to adopt an extended transition period for compliance with the new disclosure requirements.[128] We have decided to delay the compliance date of the requirement to provide a management report assessing the effectiveness of internal control over financial reporting and an auditor's attestation to, and report on, that assessment beyond that in the Proposing Release so that companies and their auditors will have time to prepare and satisfy the new requirements. These compliance dates do not apply to registered investment companies, which are not required to provide the management report assessing the effectiveness of internal control over financial reporting and the related auditor's attestation.[129] A company that is an ''accelerated filer,'' as defined in Exchange Act Rule 12b–2, as of the end of its first fiscal year ending on or after June 15, 2004, must begin to comply with the management report on internal control over financial reporting disclosure requirements promulgated under Section 404 of the Sarbanes-Oxley Act in its annual report for that fiscal year. We recognize that non-accelerated filers, including smaller companies and foreign private issuers, may have greater difficulty in preparing the management report on internal control over financial reporting. Therefore, these types of companies must begin to comply with the disclosure requirements in annual reports for their first fiscal year ending on or after April 15, 2005. A company must begin to comply with the quarterly evaluation of changes to internal control over financial reporting requirements for its first periodic report due after the first annual report that must include management's report on internal control over financial reporting. We believe that the transition period is appropriate in light of both the substantial time and resources needed to properly implement the rules[130] and the corresponding benefit to investors that will result. In addition, the transition period will provide additional time for the PCAOB to consider relevant factors in determining and implementing any new attestation standard as it finds appropriate, subject to our approval.

Consistent with this extended compliance period for management's internal control report and the related attestation, and for the subsequent evaluation of changes in internal control over financial reporting, the following provisions of the rules adopted today are subject to the extended compliance period:

- The provisions of Items 308(a) and (b) of Regulations S–K and S–B and the comparable provisions of Forms 20–F and 40–F requiring management's internal control report and the related attestation;
- The amendments to Rules 13a–15(a) and 15d–15(a) under the Exchange Act relating to maintenance of internal control over financial reporting; and
- The provisions of Rules 13a–15(c) and (d) and 15d–15(c) and (d) under the Exchange Act requiring evaluations of internal control over financial reporting and changes thereto.

The extended compliance period does not in any way affect the provisions of our other rules and regulations regarding internal controls that are in effect, including, without limitation, Rule 13b–2 under the Exchange Act.

Other rules relating to evaluation and disclosure adopted today are effective on August 14, 2003. These other rules include amendments to Items 308(c) of Regulations S–K and S–B and the comparable provisions of Forms 20–F and 40–F requiring disclosure regarding certain changes in internal control over financial reporting. These amendments modify existing requirements regarding disclosure of changes in internal control over financial reporting, are related to statements made in the Section 302 certifications of principal executive and financial officers, and provide clarifications that are beneficial and whose implementation need not be delayed. These other rules that are effective on August 14, 2003 also include amendments relating to disclosure controls and procedures.

III. Discussion of Amendments Related to Certifications

A. Proposed Rules

We proposed to amend our rules and forms to require companies to file the certifications required by Section 302 of the Sarbanes-Oxley Act as an exhibit to the periodic reports to which they relate. Specifically, we proposed to amend the exhibit requirements of Forms 20–F and 40–F and Item 601 of Regulations S–B and S–K to add the Section 302 certifications to the list of required exhibits. In addition, we proposed to amend Exchange Act Rules 13a–14 and 15d–14 to require that Section 906 certifications accompany the periodic reports to which they relate, and to amend Forms 20–F and 40–F and Item 601 of Regulations S–B and S–K to add Section 906 certifications to the list of required exhibits. We also proposed to amend Investment Company Act Rule 30a–2 to require that Section 906 certifications accompany the periodic reports on Form N–CSR to which they relate and Item 10 of Form N–CSR to add the Section 906 certifications as a required exhibit.

We received eight comment letters in response to the proposals.[131] The primary topic addressed by the commenters was whether Section 906 of the Sarbanes-Oxley Act applied to annual reports filed on Form 11–K. Most of the commenters believed that issuers required to file annual reports on Form 11–K should be exempt from the requirement to furnish a Section 906 certification as an exhibit.[132] Two commenters noted that the language of Section 906 that requires certification of the chief executive officer and chief financial officer (or equivalent thereof) is inconsistent with the actual administration of employee benefit plans because such plans do not have individuals acting as chief executive officer and chief financial officer.[133] Those commenters noted that employee benefit plans are typically administered through one or more committees that are appointed as the plan's named fiduciaries to administer the plan and oversee investments.[134] In addition, some commenters believed that we should provide an exemption for Form 11–K because employee benefit plans are already subject to extensive regulation under the Employee Retirement Income Security Act of 1974 (''ERISA''),[135] which includes a requirement for the plan administrator to certify, under penalties of perjury and other criminal and administrative

[128] *See,* for example, the letters regarding File No. S7–40–02 of: AICPA; D&T; CSC; E&Y; and Association of the Bar of the City of New York, Committee on Securities Regulation (''NYCB–CSR'').

[129] *See* Section II. I., above, for compliance dates applicable to registered investment companies.

[130] *See* Section V. below.

[131] *See* letters regarding File No. S7–06–03 of: ABA; Cleary, Gottlieb, Steen & Hamilton (''Cleary''); Prof. Paul A. Griffin (''Griffin''); Intel Corporation (''Intel''); ICI; PwC; John Stalnaker and Patrick Derksen (''Stalnaker''); and Rooks Pitts (''Rooks'').

[132] *See* letters regarding File No. S7–06–03 of: ABA; Cleary; Intel; and PwC.

[133] *See* letters File No. S7–06–03 of ABA and Cleary.

[134] *Id.*

[135] Pub. L. No. 83–406, 88 Stat. 129 (1974).

penalties, the accuracy of the plan's disclosures under ERISA.[136]

Commenters also addressed other topics related to Section 906. One commenter requested that the Commission allow Section 906 certifications to remain confidential.[137] That commenter expressed concern that a plaintiff could use a Section 906 certification to create a basis for liability that did not otherwise exist.[138] One commenter objected to the proposal to deem Section 906 certifications as ''furnished,'' rather than as ''filed.''[139] After considering all of the comments, we are adopting the proposals substantially as proposed.

On April 11, 2003, U.S. Senator Joseph Biden introduced a statement into the Congressional Record that discusses Section 906.[140] The statement asserts that Section 906 ''is intended to apply to any financial statement filed by a publicly-traded company, upon which the investing public will rely to gauge the financial health of the company,'' which includes financial statements included in current reports on Forms 6–K and 8–K and annual reports on Form 11–K.[141] The language added to Title 18 by Section 906 refers to ''periodic reports containing financial statements,'' and our proposals to require companies to furnish Section 906 certifications as exhibits applied to periodic (annual, semi-annual and quarterly) reports but did not address current reports on Forms 6–K and 8–K.[142] One commenter addressed the statement in the Congressional Record, indicating that the suggested requirements would create substantial practical burdens for companies to provide Section 906 certifications in current reports filed on Forms 6–K or 8–K.[143] We are also concerned that extending Section 906 certifications to Forms 6–K or 8–K could potentially chill the disclosure of information by companies. As noted above, four commenters argued that Section 906 should not apply to Form 11–K.[144] In light of these developments, we are considering, in consultation with the Department of Justice, the application of Section 906 to current reports on Forms 6–K and 8–K and annual reports on Form 11–K and the possibility of taking additional action.

B. Final Rules

We are amending the exhibit requirements of Forms 20–F and 40–F and Item 601 of Regulations S–B and S–K to add the Section 302 certifications to the list of required exhibits.[145] In the final rules, the specific form and content of the required certifications is set forth in the applicable exhibit filing requirement.[146] To coordinate the rules requiring an evaluation of ''disclosure controls and procedures'' and ''internal control over financial reporting,'' we are moving the definition of the term ''disclosure controls and procedures'' from Exchange Act Rules 13a–14(c) and 15d–14(c) and Investment Company Act Rule 30a–2(c) to new Exchange Act Rules 13a–15(c) and 15d–15(c) and Investment Company Act Rule 30a–3(c), respectively.

We are amending Exchange Act Rules 13a–14 and 15d–14 and Investment Company Act Rule 30a–2 to require the Section 906 certifications to accompany periodic reports containing financial statements as exhibits. We also are amending the exhibit requirements in Forms 20–F, 40–F and Item 601 of Regulations S–B and S–K to add the Section 906 certifications to the list of required exhibits to be included in reports filed with the Commission. In addition, we are amending Item 10 of Form N–CSR to add the Section 906 certifications as a required exhibit. Because the Section 906 certification requirement applies to periodic reports containing financial statements that are filed by an issuer pursuant to Section 13(a) or 15(d) of the Exchange Act, the exhibit requirement will only apply to reports on Form N–CSR filed under these sections and not to reports on Form N–CSR that are filed under the Investment Company Act only.[147] A failure to furnish the Section 906 certifications would cause the periodic report to which they relate to be incomplete, thereby violating Section 13(a) of the Exchange Act.[148] In addition, referencing the Section 906 certifications in Exchange Act Rules 13a–14 and 15d–14 and Investment Company Act Rule 30a–2 subjects these certifications to the signature requirements of Rule 302 of Regulation S–T.[149]

Section 906 requires that the certifications ''accompany'' the periodic report to which they relate. This is in contrast to Section 302, which requires the certifications to be included ''in'' the periodic report. In recognition of this difference, we are permitting companies to ''furnish,'' rather than ''file,'' the Section 906 certifications with the Commission.[150] Thus, the certifications would not be subject to liability under Section 18 of the Exchange Act.[151] Moreover, the certifications would not be subject to automatic incorporation by reference into a company's Securities Act registration statements, which are subject to liability under Section 11 of the Securities Act,[152] unless the issuer takes steps to include the certifications in a registration statement.

Although Section 906 does not explicitly require the certifications to be made public, we believe that it is appropriate to require certifications that ''accompany'' a publicly filed periodic report to be provided publicly in this manner. We believe that Congress intended for Section 906 certifications

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[136] *See* letters regarding File No. S7–06–03 of: ABA; Cleary; and PwC.

[137] *See* ABA letter regarding File No. S7–06–03.

[138] *Id.*

[139] *See* Stalnaker letter regarding File No. S7–06–03.

[140] *See* 149 Cong. Rec. S5325 (daily ed. Apr. 11, 2003).

[141] *Id.* at S5331.

[142] *See* Release No. 33–8212 (Mar. 21, 2003) [68 FR 15600] at fn. 37.

[143] *See* ABA letter regarding File No. S7–06–03.

[144] *See* letters regarding File No. S7–06–03 of: ABA; Cleary; Intel; and PwC.

[145] We recently adopted Form N–CSR, to be used by registered management investment companies to file certified shareholder reports with the Commission. *See* Release No. IC–25914 (Jan. 27, 2003) [68 FR 5348]. As adopted, Form N–CSR requires the Section 302 certifications to be filed as an exhibit to a report on Form N–CSR. Item 10(b) of Form N–CSR.

[146] Accordingly, we are revising Exchange Act Rules 13a–14 and 15d–14 to delete from those rules the detailed description of the contents of the required certifications and to revise the instructions to Forms 10–Q, 10–QSB, 10–K, and 10–KSB to delete the references to the Section 302 certification requirements. We are also adopting similar changes to Investment Company Act Rule 30a–2 and Form N–CSR.

[147] *See* General Instruction A of Form N–CSR (Form N–CSR is a combined reporting form to be used for reports of registered management investment companies under Section 30(b)(2) of the Investment Company Act and Sections 13(a) or 15(d) of the Exchange Act); n. 28 above (discussing issuers covered by Sections 13(a) and 15(d) of the Exchange Act). Registered management investment companies that are required to file reports on Form N–CSR pursuant to Section 13(a) or 15(d) of the Exchange Act will be required to provide the Section 906 certifications under Exchange Act Rules 13a–14(b) and 15d–14(b) as well as Investment Company Act Rule 30a–2(b). By contrast, registered management investment companies that are required to file reports on Form N–CSR are required to provide the Section 302 certifications solely under Investment Company Act Rule 30a–2(a), which was adopted under Sections 13(a) and 15(d) of the Exchange Act as well as the Investment Company Act. Release No. 33–8124 (Aug. 28, 2002) [67 FR 57276, 57295]; Release No. IC–25914 (Jan. 27, 2003) [68 FR 5348, 5365].

[148] *See also* Section 3(b)(1) of the Sarbanes-Oxley Act, which provides that ''[a] violation by any person of this Act * * * shall be treated for all purposes in the same manner as a violation of the Securities Exchange Act of 1934 * * * and any such person shall be subject to the same penalties, and to the same extent, as for a violation of that Act* * *.''

[149] *See* Rule 302(b) of Regulation S–T [17 CFR 232.302(b)]. Among other things, this rule requires that an issuer maintain manually signed certifications or other authenticating documents.

[150] *See*, for example, Item 601(b)(32)(ii) of Regulation S–K.

[151] 15 U.S.C. 78r.

[152] 15 U.S.C. 77k.

to be publicly provided. Civil liability already exists under our signature requirements and the Section 302 certifications. In addition, any Section 906 certification submitted to the Commission as correspondence is subject to the Freedom of Information Act.[153] Finally, the requirement to furnish Section 906 certifications as exhibits serves a number of important functions. First, the exhibit requirement enhances compliance by allowing the Commission, the Department of Justice and the public to monitor the certifications effectively. Second, by subjecting the Section 906 certifications to the signature requirements of Regulation S–T, companies are required to retain a manually signed signature page or other authenticating document for a five-year period. This requirement helps to preserve evidential matter in the event of prosecution.

There are important distinctions to be made between Sections 302 and 906 of the Sarbanes-Oxley Act. Unlike the Section 302 certifications, the Section 906 certifications are required only in periodic reports that contain financial statements. Therefore, amendments to periodic reports that do not contain financial statements would not require a new Section 906 certification, but would require a new Section 302 certification to be filed with the amendment.[154] In addition, unlike the Section 302 certifications, the Section 906 certifications may take the form of a single statement signed by a company's chief executive and financial officers.[155]

C. Effect on Interim Guidance Regarding Filing Procedures

We provided interim guidance regarding voluntary filing procedures for Section 906 certifications.[156] That guidance encouraged issuers to submit their Section 906 certifications as exhibits to the periodic reports to which they relate.[157] For issuers that are not investment companies, that interim voluntary guidance shall remain in effect until the rules become effective. In the event that the EDGAR system is not updated by the effective date, companies should submit the required certifications as Exhibit 99.[158] For registered investment companies, the interim guidance shall remain in effect until the rules become effective.[159]

D. Form of Section 302 Certifications

We proposed several amendments to the form of certifications to be provided pursuant to Section 302 of the Sarbanes-Oxley Act. In particular, we proposed the following:

- The addition of a statement that principal executive and financial officers are responsible for designing internal controls and procedures for financial reporting or having such controls and procedures designed under their supervision;
- The clarification that disclosure controls and procedures may be designed under the supervision of principal executive and financial officers; and
- The revision of the statement as to the effectiveness of disclosure controls and procedures and internal controls and procedures for financial reporting would be as of the end of the period.

We have adopted the proposals referred to above substantially as proposed. In addition, we have made the following changes:

- We have incorporated the term ''internal control over financial reporting'' into the certification;
- We have amended the provision of the certification relating to changes in internal control over financial reporting, consistent with the final rules discussed above regarding evaluation and disclosure, so that it refers to changes that have materially affected or are reasonably likely to materially affect internal control over financial reporting;
- We have clarified that the statement as effectiveness of disclosure controls and procedures be as of the end of the period, but that the date of the evaluation is not specified; and
- We have made minor changes in the organization of the certification.

E. Transition Period

The final rules regarding filing of certifications under Sections 302 and 906, for companies other than registered investment companies, will be effective on August 14, 2003. The compliance dates applicable to registered investment companies are described in Section II. I., above.

We believe that changes in the form of Section 302 certification described above are beneficial to both registrants and investors because they clarify the provisions of the certification. With one exception, discussed below, the changes are also not related to our new requirements regarding management's internal control report. With that one exception, appropriateness of the modified certification is thus not affected by the extended compliance period we are providing in connection with management's internal control report and the related attestation. Our rules adopted today also therefore provide that the form of Section 302 certification will be modified, with that one exception, in accordance with these rules effective on August 14, 2003.

We are applying the extended compliance period to the portion of the introductory language in paragraph 4 of the Section 302 certification that refers to the certifying officers' responsibility for establishing and maintaining internal control over financial reporting for the company, as well as paragraph 4(b), which must be provided in the first annual report required to contain management's internal control report and thereafter. As noted above, this extended compliance period does not in any way affect the provisions of our other rules and regulations regarding internal controls that are in effect.

IV. Paperwork Reduction Act

A. Background

Certain provisions of our final amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[160] We published a notice requesting comment on the collection of information requirements in the proposing release for the rule amendments, and we submitted these requirements to the Office of

[153] 5 U.S.C. 552 *et seq.*

[154] *See* Exchange Act Rule 12b–15 [17 CFR 240.12b–15] and Investment Company Act Rule 8b–15 [17 CFR 270.8b–15]. Depending on the contents of the amendment, the form of certification required to be included may be subject to modification.

[155] *See* Exchange Act Rules 13a–14(b) and 15d–14(b) [17 CFR 240.13a–14(b) and 240.15d–14(b)] and Investment Company Act Rule 30a–2(b) [17 CFR 270.30a–2(b)].

[156] *See* Release No. 33–8212 (Mar. 21, 2003) [68 FR 15600] at Section III.

[157] We are modifying that interim guidance, however, to more closely parallel the provisions of Section 302 of Regulation S–T that require retention of manual signatures for electronically filed signed statements. Issuers furnishing Section 906 certifications to the Commission as an exhibit to the periodic reports to which they relate during the period covered by the interim guidance should insert the following legend after the text of each certification: ''A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to [name of issuer] and will be retained by [name of issuer] and furnished to the Securities and Exchange Commission or its staff upon request.''

[158] Use of Exhibit 99 for this purpose will remain in effect until we announce that our EDGAR system permits registrants to file or furnish exhibits 31 and 32 for Section 302 and 906 certifications. We will issue a statement and post it on the Commission's website to announce this date as soon as it becomes known.

[159] For a registered management investment company filing reports on Form N–CSR, the EDGAR document type should be EX–99.906CERT for the Section 906 certifications.

[160] 44 U.S.C. 3501 *et seq.*

Management and Budget (''OMB'') for review in accordance with the PRA.[161] The titles for the collection of information are:

(1) ''Form 10–Q'' (OMB Control No. 3235–0070);

(2) ''Form 10–QSB'' (OMB Control No. 3235–0416);

(3) ''Form 10–K'' (OMB Control No. 3235–0063);

(4) ''Form 10–KSB'' (OMB Control No. 3235–0420);

(5) ''Form 20–F'' (OMB Control No. 3235–0288);

(6) ''Form 40–F'' (OMB Control No. 3235–0381);

(7) ''Regulation S–X'' (OMB Control No. 3235–0009);

(8) ''Regulation S–K'' (OMB Control No. 3235–0071);

(9) ''Regulation S–B'' (OMB Control No. 3235–0417); and

(10) ''Form N–CSR'' (OMB Control No. 3235–0570).

The forms are periodic reports adopted under the Exchange Act and the Investment Company Act. The regulations set forth the disclosure requirements for periodic reports, registration statements and proxy and information statements filed by companies to ensure that investors are informed. The hours and costs associated with preparing, filing and sending these forms constitute reporting and cost burdens imposed by each collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Compliance with the requirements is mandatory. Under our rules for the retention of manual signatures,[162] companies must retain, for a period of five years, an original signature page or other document authenticating, acknowledging or otherwise adopting the certifying officers' signatures that appear in their electronically filed periodic reports. Responses to the information collections are not kept confidential.

B. Summary of the Final Rules

The final rules require the annual report of every company that files periodic reports under Section 13(a) or 15(d) of the Exchange Act, other than reports by registered investment companies, to contain a report of management that includes:

- A statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the company;
- A statement identifying the framework used by management to evaluate the effectiveness of the company's internal control over financial reporting;
- Management's assessment of the effectiveness of the company's internal control over financial reporting, as of the end of the most recent fiscal year; and
- A statement that the registered public accounting firm that audited the financial statements included in the annual report has issued an attestation report on management's evaluation of the company's internal control over financial reporting.

We are adding these requirements pursuant to the legislative mandate in Section 404 of the Sarbanes-Oxley Act. Under our final rules, a company also will be required to evaluate and disclose any change in its internal control over financial reporting that occurred during the fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.

We are also adopting amendments to require companies to file the certifications mandated by Sections 302 and 906 of the Sarbanes-Oxley Act as exhibits to their annual, semi-annual and quarterly reports. These amendments will enhance the ability of investors, the Commission staff, the Department of Justice and other interested parties to easily and efficiently access the certifications through our Electronic Data Gathering, Analysis and Retrieval (''EDGAR'') system and facilitate better monitoring of a company's compliance with the certification requirements.

C. Summary of Comment Letters and Revisions to Proposals

We requested comment on the PRA analysis contained in the proposing releases addressing Section 404 and Sections 302 and 906 of the Sarbanes-Oxley Act.[163] We received no comments on our PRA estimates for the certification requirements. With respect to our PRA estimates for the rules implementing Section 404 of the Sarbanes-Oxley Act, eight commenters thought that our PRA estimates significantly understated the actual time and costs that companies would have to expend evaluating and reporting on their internal control over financial reporting.[164] However, few of these commenters provided actual alternative cost estimates, and none provided estimates that could be applied generally to all types and sizes of companies. One commenter believed that, based on its experience, we understated the burden estimate by at least a factor of 100.[165] In response to these commenters, and based on follow-up conversations with several of the commenters who expressed a view on our burden and cost estimates, we have revised our estimates as discussed more fully in Section IV.D below.

We have made a substantive modification to the proposed rules in response to the cost concerns expressed by commenters. Specifically, the final rules require companies to undertake a quarterly evaluation only of any change occurring during the fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting. This change should substantially mitigate some of the costs and burdens associated with the proposed requirements.

We have made additional substantive changes to the proposed rule as well. First, the final rules require management to evaluate the company's internal control over financial reporting using a suitable framework, such as the COSO Framework. Second, the final rules expand the list of information that must be included in the management report and specify that management cannot conclude that a company's internal control over financial reporting is effective if there are one or more material weaknesses in such control. Under the final rules, management must identify the framework used to evaluate the company's internal control over financial reporting and disclose any material weaknesses in the company's internal control over financial reporting discovered through the evaluation. We do not believe that these changes significantly alter the burdens imposed on companies resulting from the required assessment of internal control over financial reporting.

D. Revisions to PRA Reporting and Cost Burden Estimates

As discussed above, in consideration of commenters' remarks, we are revising our PRA burden and cost estimates for the rules pertaining to Section 404 that we originally submitted to the OMB in connection with the proposed rules.

[161] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[162] *See* Rule 302 of Regulation S–T [17 CFR 232.302].

[163] See Release No. 33–8138 (Oct. 22, 2002) [67 FR 66208] and Release No. 33–8212 (Mar. 21, 2003) [68 FR 15600].

[164] 164 See letters regarding File No. S7–40–02 of: AICPA; BDO; D&T; Emerson; E&Y; IPC; Intel; and NYCB–CCL.

[165] See Intel letter regarding File No. S7–40–02.

We derived our new burden hour estimates for the annual report forms by estimating the total amount of time that it will take a company's management to conduct the annual evaluation of its internal control over financial reporting and to prepare the required management report.[166] Our annual burden estimate is based on several assumptions. First, we assumed that the annual number of responses for each form would be consistent with the number of filings that we received in fiscal year 2002.[167] Second, we assumed that there is a direct correlation between the extent of the burden and the size of the reporting company, with the burden increasing commensurate with the size of the company. We believe that there will be a marked disparity of burdens and costs resulting from the new internal control requirements between the largest and smallest reporting companies. Our estimates reflect an average burden for all sizes of companies. Third, we assumed that the first-year burden would be greater than that for subsequent years, as a portion of the costs will reflect one-time expenditures associated with complying with the rule, such as compiling documentation, implementing new processes, and training staff. We also adjusted the second and third year estimates to account for the fact that management should become more efficient at conducting its internal control assessment and preparing the disclosure after the first year as the process becomes more routine.[168] Under these assumptions, we estimate that the average incremental burden for an annual filing will be 383 hours per company and the portion of that burden that is reflected as the cost associated with outside professionals is approximately $34,300 per company. For large corporations, we expect that this burden will be substantially higher. Indeed, we received estimates in the thousands of hours for some large and complex companies. Conversely, we expect small companies to find their burden to be less than this average. We also believe that many companies will experience costs well in excess of this average in the first year of compliance with the final rules. We believe that costs will decrease in subsequent years. This burden will also vary among companies based on the complexity of their organization and the nature of their current internal control procedures. We therefore calculated our estimates by averaging the estimated burdens over a three-year period.

We derived our burden estimates for the quarterly report forms by estimating the total amount of time that it will take a company's management to conduct the quarterly evaluation of material changes to the company's internal control over financial reporting and for the company to prepare the required disclosure about such changes. We believe that these quarterly evaluations will impose little additional burden, as much of the structure to conduct these evaluations will be established in connection with the annual evaluations. We estimate that the quarterly reporting will impose an additional burden of five hours per company in connection with each quarterly report. Accordingly, we did not revise our original burden hour estimates for the quarterly report forms.

We estimate the total annual incremental burden (for annual and quarterly reports) associated with the new internal control evaluation and disclosure requirements for all companies to be approximately 3,792,888 hours of company personnel time and a cost of $481,013,550 for the services of outside professionals.[169]

Table 1 below presents these burdens and costs for each form affected by the final rules implementing Section 404 of Sarbanes-Oxley. We calculated the burden by multiplying the estimated number of affected responses by the estimated average number of hours that management will spend conducting its assessment of the company's internal control over financial reporting and preparing the related disclosure. For Exchange Act annual reports, we estimate that 75% of the burden of preparation is carried by the company internally and that 25% of the burden of preparation is carried by outside professionals retained by the company at an average cost of $300 per hour.[170] The portion of the burden carried by outside professionals is reflected as a cost, while the portion of the burden carried by the company internally is reflected in hours. There is no change to the estimated burden of the collections of information entitled ''Regulation S–K,'' ''Regulation S–B'' and ''Regulation S–X'' because the burdens that these regulations impose are reflected in our revised estimates for the forms.

TABLE 1.—INCREMENTAL PAPERWORK BURDEN FOR THE RULES IMPLEMENTING SECTION 404

	Annual responses (A)	Incremental hours/form (B)	Total burden (C)=(A)*(B)	75% Company (D)=(C)*0.75	25% Professional (E)=(C)*0.25	Professional costs (F)=(E)*$300
10–K	8,484	383	3,249,372	2,437,029	812,343	243,702,900
10–KSB	3,820	383	1,463,606	1,097,295	365,765	109,729,500
20–F	1,194	383	457,302	114,326	342,977	102,892,950
40–F	134	383	51,322	12,831	37,989	11,547,450
10–Q	23,743	5	118,715	89,036	29,679	8,903,625
10–QSB	11,299	5	56,495	42,371	14,124	4,237,125
Reg. S–K	N/A	1	1	N/A	N/A	N/A
Reg. S–B	N/A	1	1	N/A	N/A	N/A
Reg. S–X	N/A	1	1	N/A	N/A	N/A
Total	.....	.....	.....	3,792,888	.....	$481,013,550

[166] Our estimates are based on information from with several large and small firms, accounting firms and trade and professional associations.

[167] The estimates used in the releases proposing these rules were based on the number of filings that we received in fiscal year 2001.

[168] We assumed the estimated burdens in the second and third years would decline by 75% from the first year estimate.

[169] Our PRA estimates do not include any additional burdens or costs that a company will incur as a result of having to obtain an auditor's attestation report on management's internal control report because the PCAOB, rather than the Commission, is responsible for establishing the attestation standards and the Sarbanes-Oxley Act itself requires companies to obtain such an attestation. We have, however, included an estimated 0.5 hour burden in our revised annual burden estimates to account for the filing by the company of the attestation report.

[170] The burden allocation for Forms 20–F and 40–F, however, use a 25% internal to 75% outside professional allocation to reflect the fact that foreign private issuers rely more heavily on outside professionals for the preparation of these forms.

We do not believe that the amendments with respect to the Section 302 certifications result in a need to alter the burden estimates that we previously submitted to OMB because they merely relocate the certifications from the text of quarterly and annual reports filed or submitted under Section 13(a) or 15(d) of the Exchange Act to the ''Exhibits'' section of the reports. We are, however, revising the burden estimates for quarterly and annual reports and for Form N–CSR based on the amendment with respect to the Section 906 certification.[171] The PRA estimates for these amendments do not reflect a cost because we believe that the entire burden will be borne by company personnel. With respect to semi-annual reports on Form N–CSR, because the financial statements of registered management investment companies are not as complex as those of operating companies, we estimate that the amendments relating to the Section 906 certifications would result in an increase of one burden hour per portfolio.[172] We estimate that there are approximately 3,700 registered management investment companies that are required to file reports on Form N–CSR, containing 9,850 portfolios. The following table illustrates the incremental PRA estimates for the new Section 906 certification [173] requirements:

TABLE 2.—INCREMENTAL PAPERWORK BURDEN FOR CERTIFICATION REQUIREMENTS

Form	Annual responses	Hours/form	Total hours added
20–F	1,194	2	2,388
40–F	134	2	268
10–K	8,484	2	16,968
10–KSB	3,820	2	7,640
10–Q	23,743	2	47,486
10–QSB	11,299	2	22,598
N–CSR	7,400	[173] 2.66	19,700
Total	.....	.....	117,048

V. Cost-Benefit Analysis

The amendments implementing Section 404 of the Sarbanes-Oxley Act are congressionally mandated. We recognize that implementation of the Sarbanes-Oxley Act will likely result in costs and benefits to the economy. We are sensitive to the costs and benefits imposed by our rules, and we have considered costs and benefits of our amendments.

A. Benefits

One of the main goals of the Sarbanes-Oxley Act is to enhance the quality of reporting and increase investor confidence in the financial markets. Recent market events have evidenced a need to provide investors with a clearer understanding of the processes that surround the preparation and presentation of financial information. These amendments are intended to accomplish the Act's goals by improving public company disclosure to investors about the extent of management's responsibility for the company's financial statements and internal control over financial reporting and the means by which management discharges its responsibility. The establishment and maintenance of internal control over financial reporting has always been an important responsibility of management. An effective system of internal control over financial reporting is necessary to produce reliable financial statements and other financial information used by investors. By requiring a report of management stating management's responsibility for the company's financial statements and internal control over financial reporting and management's assessment regarding the effectiveness of such control, investors will be able to better evaluate management's performance of its stewardship responsibilities and the reliability of a company's financial statements and other unaudited financial information.

The required annual evaluation of internal control over financial reporting will encourage companies to devote adequate resources and attention to the maintenance of such control. Additionally, the required evaluation should help to identify potential weaknesses and deficiencies in advance of a system breakdown, thereby facilitating the continuous, orderly and timely flow of information within the company and, ultimately, to investors and the marketplace. Improved disclosure may help companies detect fraudulent financial reporting earlier and perhaps thereby deter financial fraud or minimize its adverse effects. All of these benefits will increase market efficiency by improving investor confidence in the reliability of a company's financial disclosure and system of internal control over financial reporting. These benefits are not readily quantifiable. Commenters overwhelmingly supported the benefits of the amendments.

The amendments related to Section 302 of the Sarbanes-Oxley Act relocate the certifications required by Exchange Act Rules 13a-14 and 15d-14 from the text of quarterly and annual reports filed or submitted under Section 13(a) or 15(d) of the Exchange Act to the ''Exhibits'' section of these reports. The amendments related to Section 906 of the Sarbanes-Oxley Act require that the certifications required by Section 1350 of Title 18 of the United States Code, added by Section 906 of the Act, accompany the periodic reports to which they relate as exhibits. These changes will enhance the ability of investors and the Commission staff to verify that the certifications have, in fact, been submitted with the Exchange Act reports to which they relate and to review the contents of the certifications to ensure compliance with the

[171] While Section 906 of the Sarbanes-Oxley Act requires that certifications must accompany a periodic report, we are increasing our PRA burdens in view of the fact that the amendments explicitly require companies to furnish Section 906 certifications as exhibits to these reports. To date, companies have used various methods to fulfill their obligations under Section 906, and have not consistently submitted the certifications as part of the report.

[172] Many registered management investment companies have multiple portfolios. However, they prepare separate financial statements for each portfolio. Thus, the burden of the Section 906 certifications is estimated on a portfolio basis rather than a registered management investment company basis.

[173] This number represents the burden associated with the average number of portfolios per form. This number will vary for each registered management investment company depending on the number of portfolios. We estimate that the paperwork burden for each portfolio is one hour.

applicable requirements. In addition, the changes will enable the Department of Justice, which has responsibility for enforcing Section 906, to review effectively the form and content of the certifications required by that section.

B. Costs

The final rules related to Section 404 of the Sarbanes-Oxley Act require companies, other than registered investment companies, to include in their annual reports a report of management on the company's internal control over financial reporting. The management report on internal control over financial reporting must include: a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting; a statement identifying the framework used to evaluate the effectiveness of the company's internal control over financial reporting; management's assessment of the effectiveness of the company's internal control over financial reporting as of the end of the company's most recent fiscal year; and a statement that the registered public accounting firm that audited the company's financial statements included in the annual report has issued an attestation report on management's evaluation of the company's internal control over financial reporting. The final rules will increase costs for all reporting companies. These costs are mitigated somewhat because companies have an existing obligation to maintain an adequate system of internal accounting control under the FCPA. Moreover, one commenter noted that some companies already voluntarily include management reports on their internal controls in their annual reports. The preparation of the management report on internal control over financial reporting will likely involve multiple parties, including senior management, internal auditors, in-house counsel, outside counsel and audit committee members.

Many commenters believed that our proposal to require quarterly evaluations of a company's internal control over financial reporting would significantly increase the costs of preparing periodic reports. Several commenters also were concerned that the proposals would result in increased audit fees. We have limited data on which to base cost estimates of the final rules.

Using our PRA burden estimates, we estimate the aggregate annual costs of implementing Section 404(a) of the Sarbanes-Oxley Act to be around $1.24 billion (or $91,000 per company).[174] We recognize the magnitude of the cost burdens and we are making several accommodations to address commenters' concerns and to ease compliance, including:

- Requiring quarterly disclosure only of any change that has materially affected, or is reasonably likely to materially affect, a company's internal control over financial reporting; and
- An extended transition period for the new internal control reporting requirements.

We originally proposed to require a company to include an internal control report in its annual report for fiscal years ending on or after September 15, 2003. Under the final rules, a company that is an ''accelerated filer'' under the definition in Exchange Act Rule 12b-2 must begin to comply with the internal control report requirement in its annual report for its first fiscal year ending on or after June 15, 2004. All other companies must begin to comply with the requirement in their annual reports for their first fiscal year ending on or after April 15, 2005.

A longer transition period will help to alleviate the immediate impact of any costs and burdens imposed on companies. A longer transition period may even help to reduce costs as companies will have additional time to develop best practices, long-term processes and efficiencies in preparing management reports. Also, a longer transition period will expand the period of availability of outside professionals that some companies may wish to retain as they prepare to comply with the new requirements.

The PRA burden estimate, however, excludes several costs attributable to Section 404. The estimate does not include the costs associated with the auditor's attestation report, which many commenters have suggested might be substantial. It also excludes estimates of likely ''indirect'' costs of the final rules. For instance, the final rules increase the cost of being a public company; therefore the final rules may discourage some companies from seeking capital from the public markets. Moreover, the final rules may also discourage non-U.S. firms from seeking capital in the United States.

The incremental costs of the amendments related to Section 302 of the Sarbanes-Oxley Act are minimal. Since companies must already include the certifications required by Exchange Act Rules 13a-14 and 15d-14 in their quarterly and annual reports, there should be no incremental cost to relocating the certifications from the text of the reports to the ''Exhibits'' section of these reports. Requiring the Section 906 certifications to be included as an exhibit to the periodic reports to which they relate will lead to some additional costs for companies that currently are submitting the certifications to the Commission in some other manner. While these costs are difficult to quantify, we estimate that the annual paperwork burden of the amendments will be approximately $23.4 million.[175]

One commenter has expressed concern that companies may assume greater legal risk by making their Section 906 certifications publicly available.[176] To the extent that companies may assume greater legal risk by including the Section 906 certifications as part of their periodic reports filed pursuant to the Exchange Act where these reports are incorporated by reference into Securities Act registration statements, we address this risk by requiring companies to ''furnish,'' rather than ''file,'' the certifications with the Commission for purposes of Section 18 of the Exchange Act or incorporation by reference into other filings. Thus, the amendments should mitigate this potential indirect cost of compliance. We believe that it is appropriate to require the certifications that accompany a periodic report to be publicly available. We believe that Congress intended for Section 906 certifications to be publicly available. Civil liability already exists by virtue of the pre-existing signature requirements and Section 302 certifications. In addition, any Section 906 certification submitted to the Commission as correspondence is subject to the Freedom of Information Act.[177]

[174] This estimate is based on the estimated total burden hours of 5,396,266, an assumed 75%/25% split of the burden hours between internal staff and external professionals, and an hourly rate of $200 for internal staff time and $300 for external professionals. The hourly cost estimate is based on consultations with several registrants and law firms and other persons who regularly assist registrants in preparing and filing periodic reports with the Commission. Our PRA estimate does not reflect any additional cost burdens that a company will incur as a result of having to obtain an auditor's attestation on management's internal control report.

[175] This calculation is based on an estimate of burden hours multiplied by a cost of $200.00 per hour. (117,048 hours multiplied by $200.00 per hour). The hourly cost estimate is based on consultations with several registrants and law firms and other persons who regularly assist registrants in preparing and filing periodic reports with the Commission.

[176] 176 *See* ABA letter regarding File No. S7–06–03.

[177] 5 U.S.C. 552 *et seq.*

VI. Effect on Efficiency, Competition and Capital Formation

Section 23(a)(2) of the Exchange Act [178] requires us to consider the anti-competitive effects of any rules that we adopt under the Exchange Act. In addition, Section 23(a)(2) prohibits us from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. The amendments related to Section 404 of the Sarbanes-Oxley Act represent the implementation of a congressional mandate. The final rules require management reports that improve investors' understanding of management's responsibility for the preparation of reliable financial information and maintaining adequate internal control over financial reporting. We anticipate that these requirements will enhance the proper functioning of the capital markets by increasing the quality and accountability of financial reporting and restoring investor confidence.

Section 2(b) of the Securities Act,[179] Section 3(f) of the Exchange Act [180] and Section 2(c) of the Investment Company Act [181] require us, when engaging in rulemaking to consider or determine whether an action is necessary or appropriate in the public interest, and consider whether the action will promote efficiency, competition, and capital formation. The amendments related to Section 404 are designed to enhance the quality and accountability of the financial reporting process and may help increase investor confidence, which implies increased efficiency and competitiveness of the U.S. capital markets. Increased market efficiency and investor confidence also may encourage more efficient capital formation. We requested comments on the effect of these amendments on efficiency, competition and capital formation analyses in the proposing release addressing Section 404. We received no comments in response to these requests.

The amendments related to Section 302 of the Sarbanes-Oxley Act would relocate the certifications required by Exchange Act Rules 13a–14 and 15d–14 from the text of quarterly and annual reports filed or submitted under Section 13(a) or 15(d) of the Exchange Act to the ''Exhibits'' section of these reports. This relocation will enhance the ability of investors and the Commission staff to verify that the certifications have, in fact, been submitted with the Exchange Act reports to which they relate and to review the contents of the certifications to ensure compliance with the applicable requirements. The amendments related to Section 906 of the Sarbanes-Oxley Act also will streamline compliance with Section 1350 of Title 18 of the United States Code, added by Section 906 of the Act, and will enable investors, the Commission staff and the Department of Justice, which has responsibility for enforcing Section 1350, to verify submission and efficiently review the form and content of the certifications required by that provision.

We do not believe that the amendments related to certifications will impose any burden on competition, nor are we aware of any impact on capital formation that would result from the amendments. Depending on how an issuer's principal executive and principal financial officers presently satisfy the Section 906 certification requirements, issuers may incur some additional costs in submitting these certifications as an exhibit to their periodic reports. While these costs are difficult to quantify, we believe that they would be nominal. We requested comment on whether the amendments would affect competition, efficiency and capital formation. We received no comments in response to this request.

VII. Final Regulatory Flexibility Analysis

This Final Regulatory Flexibility Analysis (''FRFA'') has been prepared in accordance with the Regulatory Flexibility Act.[182] This FRFA relates to new rules and amendments that require Exchange Act companies, other than registered investment companies, to include in their annual reports a report of management on the company's internal control over financial reporting. The management report on internal control over financial reporting must include: a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting; a statement identifying the framework used to evaluate the effectiveness of the company's internal control over financial reporting; management's assessment of the effectiveness of the company's internal control over financial reporting as of the end of the company's most recent fiscal year; and a statement that the registered public accounting firm that audited the company's financial statements included in the annual report has issued an attestation report on management's evaluation of the company's internal control over financial reporting. This FRFA also addresses new rules and amendments that require companies to file the certifications mandated by Sections 302 and 906 of the Sarbanes-Oxley Act as exhibits to their periodic reports. An Initial Regulatory Flexibility Analysis (''IRFA'') was prepared in accordance with the Regulatory Flexibility Act in conjunction with each of the releases proposing these rules.[183] The proposing releases solicited comments on these analyses.

A. Need for the Amendments

We are adopting these disclosure requirements to comply with the mandate of, and to fulfill the purposes underlying the provisions of, the Sarbanes-Oxley Act of 2002. The new evaluation and disclosure requirements regarding a company's internal control over financial reporting are intended to enhance the quality of reporting and increase investor confidence in the fairness and integrity of the securities markets by making it clear that a company's management is responsible for maintaining and annually assessing such controls. The amendments related to Sections 302 and 906 of the Sarbanes-Oxley Act will enhance the ability of investors and the Commission staff to verify that the certifications have, in fact, been submitted with the Exchange Act reports to which they relate and to review the contents of the certifications to ensure compliance with the applicable requirements. The amendments also will streamline compliance with Section 1350 of Title 18 of the United States Code and will enable investors, the Commission staff and the Department of Justice, which has responsibility for enforcing Section 1350, to verify a company's submission of the Section 906 certification and efficiently review the form and content of the certifications.

B. Significant Issues Raised by Public Comment

In the Proposing Releases, we requested comment on any aspect of the IRFA, including the number of small entities that would be affected by the proposals, and both quantitative and qualitative nature of the impact. Several commenters expressed concern that small business issuers, including small entities, would be particularly disadvantaged by our proposal to require quarterly evaluations of internal control over financial reporting. We received no commentary on the impact

[178] 15 U.S.C. 78w(a)(2).

[179] 15 U.S.C 77b(b).

[180] 15 U.S.C. 78c(f).

[181] 15 U.S.C. 80a–2(c).

[182] 5 U.S.C. 601.

[183] 5 U.S.C. 603.

on small entities of the new certification requirements.

C. Small Entities Subject to the Amendments

The new disclosure items affect issuers that are small entities. Exchange Act Rule 0–10(a) [184] defines an issuer, other than an investment company, to be a ''small business'' or ''small organization'' if it had total assets of $5 million or less on the last day of its most recent fiscal year. We estimate that there are approximately 2,500 issuers, other than investment companies, that may be considered small entities. For purposes of the Regulatory Flexibility Act, an investment company is a ''small entity'' if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[185] We estimate that there are approximately 190 registered management investment companies that, together with other investment companies in the same group of related investment companies, have net assets of $50 million or less as of the end of the most recent fiscal year.[186]

The new disclosure items with respect to management's report on internal control over financial reporting and the registered public accounting firm's attestation report apply to any small entity, other than a registered investment company, that is subject to Exchange Act reporting requirements. The new certification requirements apply to any small entity that is subject to Exchange Act reporting requirements.

D. Reporting, Recordkeeping and Other Compliance Requirements

The amendments require a company's management to disclose information regarding the company's internal control over financial reporting, including management's assessment of the effectiveness of the company's internal control over financial reporting. All small entities that are subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act, other than registered investment companies, are subject to these evaluation and disclosure requirements. Because reporting companies already file the forms being amended, no additional professional skills beyond those currently possessed by these filers necessarily are required to prepare the new disclosure, although some companies may choose to engage outside professionals to assist them in complying with the new requirements. We expect that these new disclosure items will increase compliance costs incurred by small entities. We have calculated for purposes of the Paperwork Reduction Act that each company would be subject to an added annual reporting burden of approximately 398 hours and the portion of that burden that is reflected as the cost associated with outside professionals is approximately $35,286.[187] We believe, however, that the annual average burden and costs for small issuers are much lower.[188] For the new certification requirements, we estimate that a company, including a small entity, will be subject to an additional reporting burden of eight hours per year.[189] These burden estimates reflect only the burden and cost of the required collection of information.

E. Agency Action to Minimize Effect on Small Entities

The Regulatory Flexibility Act directs us to consider alternatives that would accomplish our stated objectives, while minimizing any significant adverse impact on small entities. In connection with the amendments, we considered the following alternatives:

- Establishing different compliance or reporting requirements or timetables that take into account the resources available to small entities;
- Clarifying, consolidating or simplifying compliance and reporting requirements under the rules for small entities;
- Using performance rather than design standards; and
- Exempting small entities from all or part of the requirements.

Several of these alternatives were considered but rejected, while other alternatives were taken into account in the final rules. We believe the final rules fulfill the intent of the Sarbanes-Oxley Act of enhancing the quality of reporting and increasing investor confidence in the fairness and integrity of the securities markets.

Sections 302, 404 and 906 of the Sarbanes-Oxley Act make no distinction based on a company's size. We think that improvements in the financial reporting process for all companies are important for promoting investor confidence in our markets. For example, a 1999 report commissioned by the organizations that sponsored the Treadway Commission found that the incidence of financial fraud was greater in small companies.[190] However, we are sensitive to the costs and burdens that small entities will face. The final rules require only a quarterly evaluation of material changes to a company's internal control over financial reporting, unlike the proposed rules that would have required management to evaluate the effectiveness of a company's internal control over financial reporting on a quarterly basis. In response to comments, including comments submitted by the Small Business Administration, we have decided not to adopt this proposal.

We believe that a blanket exemption for small entities from coverage of the requirements is not appropriate and would be inconsistent with the policies underlying the Sarbanes-Oxley Act. However, we have provided an extended transition period for companies that do not meet the definition in Exchange Act Rule 12b–2 [191] of an ''accelerated filer'' for the rules implementing Section 404 of the Sarbanes-Oxley Act. Under the adopted rules, non-accelerated filers, including small business issuers, need not prepare the management report on internal control over financial reporting until they file their annual reports for fiscal years ending on or after April 15, 2005. This deferral provides non-accelerated filers more time to develop structured and formal systems of internal control over financial reporting.

We believe that the new disclosure and certification requirements are clear and straightforward. The amendments require only brief disclosure. An effective system of internal control over financial reporting has always been necessary to produce reliable financial statements and other financial information. Our amendments do not specify any particular controls that a company's internal control over financial reporting should include. Each company is afforded the flexibility to design its internal control over financial reporting according to its own set of circumstances. This flexibility should

[184] 17 CFR 240.0–10(a).

[185] 17 CFR 270.0–10.

[186] This estimate is based on figures compiled by the Commission staff regarding investment companies registered on Forms N–1A, N–2 and N–3, which are required to file reports on Form N–CSR.

[187] This estimate includes the burden for one annual report and three quarterly reports.

[188] Under the method we used to estimate the PRA burdens associated with the Section 404 rules, we estimated that companies with less than $100 million in revenues would be subject to an added annual reporting burden of approximately 100 hours.

[189] The estimated burden for one annual report and three quarterly reports.

[190] *See* Beasley, Carcello and Hermanson, Fraudulent Financial Reporting: 1987–1997, *An Analysis of U.S. Public Companies* (Mar. 1999) (study commissioned by the Committee of Sponsoring Organizations of the Treadway Commission).

[191] 17 CFR 240.12b–2.

enable companies to keep costs of compliance as low as possible. Therefore, it does not seem necessary to develop separate requirements for small entities.

The final rules impose both design and performance standards regarding disclosure of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the company and management's assessment of the effectiveness of such controls. The rules do, however, afford a company the flexibility to design its internal control over financial reporting to fit its particular circumstances. We believe that it would be inconsistent with the purposes of the Sarbanes-Oxley Act to specify different requirements for small entities.

VIII. Statutory Authority and Text of Rule Amendments

The amendments described in this release are being adopted under the authority set forth in Sections 5, 6, 7, 10, 17 and 19 of the Securities Act, as amended, Sections 12, 13, 15, 23 and 36 of the Exchange Act, Sections 8, 30, 31 and 38 of the Investment Company Act, as amended and Sections 3(a), 302, 404, 405 and 906 of the Sarbanes-Oxley Act.

List of Subjects

17 CFR Part 210

Accountants, Accounting, Reporting and recordkeeping requirements, Securities.

17 CFR Part 228

Reporting and recordkeeping requirements, Securities, Small businesses.

17 CFR Parts 229, 240 and 249

Reporting and recordkeeping requirements, Securities.

17 CFR Parts 270 and 274

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Amendments

■ For the reasons set out in the preamble, the Commission amends title 17, chapter II, of the Code of Federal Regulations as follows:

PART 210—FORM AND CONTENT OF AND REQUIREMENTS FOR FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, INVESTMENT COMPANY ACT OF 1940, INVESTMENT ADVISERS ACT OF 1940, AND ENERGY POLICY AND CONSERVATION ACT OF 1975

■ 1. The authority citation for Part 210 is revised to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 78c, 78j–1, 78l, 78m, 78n, 78o(d), 78q, 78u–5, 78w(a), 78ll, 78mm, 79e(b), 79j(a), 79n, 79t(a), 80a–8, 80a–20, 80a–29, 80a–30, 80a–31, 80a–37(a), 80b–3, 80b–11, 7202 and 7262, unless otherwise noted.

■ 2. Section 210.1–02 is amended by:
■ a. Removing the authority citation following § 210.1–02;
■ b. Redesignating paragraph (a) as paragraph (a)(1); and
■ c. Adding paragraph (a)(2).

The revisions read as follows:

§ 210.1–02 Definitions of terms used in Regulation S–X (17 CFR part 210).

* * * * *

(a)(1) * * *

(2) *Attestation report on management's assessment of internal control over financial reporting.* The term *attestation report on management's assessment of internal control over financial reporting* means a report in which a registered public accounting firm expresses an opinion, or states that an opinion cannot be expressed, concerning management's assessment of the effectiveness of the registrant's internal control over financial reporting (as defined in § 240.13a–15(f) or 240.15d–15(f) of this chapter) in accordance with standards on attestation engagements. When an overall opinion cannot be expressed, the registered public accounting firm must state why it is unable to express such an opinion.

* * * * *

■ 3. Amend § 210.2–02 by:
■ a. Revising the section heading;
■ b. Revising the headings of paragraphs (a), (b), (c) and (d); and
■ c. Adding paragraph (f).

The addition and revisions read as follows.

§ 210.2–02 Accountants' reports and attestation reports on management's assessment of internal control over financial reporting.

(a) *Technical requirements for accountants' reports.* * * *

(b) *Representations as to the audit included in accountants' reports.* * * *

(c) *Opinions to be expressed in accountants' reports.* * * *

(d) *Exceptions identified in accountants' reports.* * * *

* * * * *

(f) *Attestation report on management's assessment of internal control over financial reporting.* Every registered public accounting firm that issues or prepares an accountant's report for a registrant, other than an investment company registered under section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8), that is included in an annual report required by section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) containing an assessment by management of the effectiveness of the registrant's internal control over financial reporting must attest to, and report on, such assessment. The attestation report on management's assessment of internal control over financial reporting shall be dated, signed manually, identify the period covered by the report and clearly state the opinion of the accountant as to whether management's assessment of the effectiveness of the registrant's internal control over financial reporting is fairly stated in all material respects, or must include an opinion to the effect that an overall opinion cannot be expressed. If an overall opinion cannot be expressed, explain why. The attestation report on management's assessment of internal control over financial reporting may be separate from the accountant's report.

PART 228—INTEGRATED DISCLOSURE SYSTEM FOR SMALL BUSINESS ISSUERS

■ 4. The general authority citation for Part 228 is revised to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77jjj, 77nnn, 77sss, 78*l*, 78m, 78n, 78o, 78u–5, 78w, 78*ll*, 78mm, 80a–8, 80a–29, 80a–30, 80a–37, 80b–11, 7202, 7241, and 7262; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 5. Revise § 228.307 to read as follows:

§ 228.307 (Item 307) Disclosure controls and procedures.

Disclose the conclusions of the small business issuer's principal executive and principal financial officers, or persons performing similar functions, regarding the effectiveness of the small business issuer's disclosure controls and procedures (as defined in § 240.13a-15(e) or 240.15d-15(e) of this chapter) as of the end of the period covered by the report, based on the evaluation of these

controls and procedures required by paragraph (b) of § 240.13a-15 or 240.15d-15 of this chapter.

■ 6. Add § 228.308 to read as follows:

§ 228.308 (Item 308) Internal control over financial reporting.

(a) *Management's annual report on internal control over financial reporting.* Provide a report of management on the small business issuer's internal control over financial reporting (as defined in § 240.13a-15(f) or 240.15d-15(f) of this chapter) that contains:

(1) A statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the small business issuer;

(2) A statement identifying the framework used by management to evaluate the effectiveness of the small business issuer's internal control over financial reporting as required by paragraph (c) of § 240.13a-15 or 240.15d-15 of this chapter;

(3) Management's assessment of the effectiveness of the small business issuer's internal control over financial reporting as of the end of the small business issuer's most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective. This discussion must include disclosure of any material weakness in the small business issuer's internal control over financial reporting identified by management. Management is not permitted to conclude that the small business issuer's internal control over financial reporting is effective if there are one or more material weaknesses in the small business issuer's internal control over financial reporting; and

(4) A statement that the registered public accounting firm that audited the financial statements included in the annual report containing the disclosure required by this Item has issued an attestation report on management's assessment of the small business issuer's internal control over financial reporting.

(b) *Attestation report of the registered public accounting firm.* Provide the registered public accounting firm's attestation report on management's assessment of the small business issuer's internal control over financial reporting in the small business issuer's annual report containing the disclosure required by this Item.

(c) *Changes in internal control over financial reporting.* Disclose any change in the small business issuer's internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of § 240.13a-15 or 240.15d-15 of this chapter that occurred during the small business issuer's last fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting.

Instructions to Item 308

1. The small business issuer must maintain evidential matter, including documentation, to provide reasonable support for management's assessment of the effectiveness of the small business issuer's internal control over financial reporting.

2. A small business issuer that is an Asset-Backed Issuer (as defined in § 240.13a-14(g) and § 240.15d-14(g) of this chapter) is not required to disclose the information required by this Item.

§ 228.401 [Amended]

■ 7. Amend § 228.401 by removing the phrase ''internal controls and procedures for financial reporting'' in paragraph (e)(2)(iv) of Item 401 and adding, in its place, the phrase ''internal control over financial reporting''.

■ 8. Amend § 228.601 by:

■ a. Removing the last sentence of paragraph (a)(1);

■ b. Revising the Exhibit Table;

■ c. Revising paragraph (b)(7) to read ''No exhibit required.'';

■ d. Revising the heading in paragraph (b)(11) to read ''Statement re: computation of per share earnings''; and

■ e. Revising paragraphs (b)(27) through (b)(98).

■ The revisions read as follows.

§ 228.601 (Item 601) Exhibits.

* * * * *

EXHIBIT TABLE

	Securities act forms						Exchange act forms		
	SB–2	S–2	S–3	S–4 [3]	S–8	10–SB	8–K	10–QSB	10–KSB
(1) Underwriting agreement	X	X	X	X			X		
(2) Plan of purchase, sale, reorganization, arrangement, liquidation or succession	X	X	X	X		X	X	X	X
(3) (i) Articles of Incorporation	X			X		X		X	X
(ii) By-laws	X			X		X		X	X
(4) Instruments defining the rights of security holders, including indentures	X	X	X	X	X	X	X	X	X
(5) Opinion on legality	X	X	X	X	X				
(6) No exhibit required	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
(7) No exhibit required	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
(8) Opinion on tax matters	X	X	X	X					
(9) Voting trust agreement and amendments	X			X		X			X
(10) Material contracts	X	X		X		X		X	X
(11) Statement re: computation of per share earnings	X	X		X		X		X	X
(12) No exhibit required	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
(13) Annual report to security holders for the last fiscal year, Form 10-Q or 10-QSB or quarterly report to security holders [1]	X	X		X					X
(14) Code of ethics									X
(15) Letter on unaudited interim financial information	X	X	X	X	X			X	

EXHIBIT TABLE—Continued

	Securities act forms						Exchange act forms		
	SB–2	S–2	S–3	S–4 [3]	S–8	10–SB	8–K	10–QSB	10–KSB
(16) Letter on change in certifying accountant [4]	X	X	.....	X	.....	X	X	.....	X
(17) Letter on director resignation	.....	.....	.....	.....	.....	.....	X	.....	.....
(18) Letter on change in accounting principles	.....	.....	.....	.....	.....	.....	.....	X	X
(19) Reports furnished to security holders	.....	.....	.....	.....	.....	.....	.....	X	.....
(20) Other documents or statements to security holders or any document incorporated by reference	.....	.....	.....	.....	.....	.....	.....	X	X
(21) Subsidiaries of the small business issuer	X	.....	.....	X	.....	X	.....	.....	X
(22) Published report regarding matters submitted to vote of security holders	.....	.....	.....	.....	.....	.....	.....	X	X
(23) Consents of experts and counsel	X	X	X	X	X	.....	X [2]	X [2]	X [2]
(24) Power of attorney	X	X	X	X	X	X	X	X	X
(25) Statement of eligibility of trustee	X	X	X	X	.....	.....	.....	.....	.....
(26) Invitations for competitive bids	.....	X	X	X	X	.....	.....	.....	.....
(27) through (30) [Reserved]	.....	.....	.....	.....	.....	.....	.....	.....	.....
(31) Rule 13a-14(a)/15d-14(a) Certifications	.....	.....	.....	.....	.....	.....	.....	X	X
(32) Section 1350 Certifications	.....	.....	.....	.....	.....	.....	.....	X	X
(33) through (98)[Reserved]	.....	.....	.....	.....	.....	.....	.....	.....	.....
(99) Additional exhibits	X	X	X	X	X	X	X	X	X

[1] Only if incorporated by reference into a prospectus and delivered to holders along with the prospectus as permitted by the registration statement; or in the case of a Form 10-KSB, where the annual report is incorporated by reference into the text of the Form 10-KSB.

[2] Where the opinion of the expert or counsel has been incorporated by reference into a previously filed Securities Act registration statement.

[3] An issuer need not provide an exhibit if: (1) an election was made under Form S–4 to provide S–2 or S–3 disclosure; and (2) the form selected (S–2 or S–3) would not require the company to provide the exhibit.

[4] If required under Item 304 of Regulation S-B.

(b) *Description of exhibits.* * * *

(27) through (30) [Reserved]

(31) *Rule 13a-14(a)/15d-14(a) Certifications.* The certifications required by Rule 13a-14(a) (17 CFR 240.13a-14(a)) or Rule 15d-14(a) (17 CFR 240.15d-14(a)) exactly as set forth below:

*Certifications **

I, [identify the certifying individual], certify that:

1. I have reviewed this [specify report] of [identify small business issuer];

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the small business issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or

persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date:

_____

[Signature]

[Title]

* Provide a separate certification for each principal executive officer and principal financial officer of the small business issuer. See Rules 13a–14(a) and 15d–14(a)

(32) *Section 1350 Certifications.*

(i) The certifications required by Rule 13a–14(b) (17 CFR 240.13a–14(b)) or Rule 15d–14(b) (17 CFR 240.15d–14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

(ii) A certification furnished pursuant to this Item will not be deemed ''filed'' for purposes of section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the small business issuer specifically incorporates it by reference.

(33) through (98) [Reserved]

* * * * *

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

■ 9. The general authority citation for Part 229 is revised to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78l, 78m, 78n, 78o, 78u–5, 78w, 78ll, 78mm, 79e, 79j, 79n, 79t, 80a–8, 80a–9, 80a–20, 80a–29, 80a–30, 80a–31(c), 80a–37, 80a–38(a), 80a–39, 80b–11, 7202, 7241, and 7262; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 10. By revising § 229.307 to read as follows:

§ 229.307 (Item 307) Disclosure controls and procedures.

Disclose the conclusions of the registrant's principal executive and principal financial officers, or persons performing similar functions, regarding the effectiveness of the registrant's disclosure controls and procedures (as defined in § 240.13a–15(e) or 240.15d–15(e) of this chapter) as of the end of the period covered by the report, based on the evaluation of these controls and procedures required by paragraph (b) of § 240.13a–15 or 240.15d–15 of this chapter.

■ 11. By adding § 229.308 to read as follows:

§ 229.308 (Item 308) Internal control over financial reporting.

(a) *Management's annual report on internal control over financial reporting.* Provide a report of management on the registrant's internal control over financial reporting (as defined in § 240.13a–15(f) or 240.15d–15(f) of this chapter) that contains:

(1) A statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the registrant;

(2) A statement identifying the framework used by management to evaluate the effectiveness of the registrant's internal control over financial reporting as required by paragraph (c) of § 240.13a–15 or 240.15d–15 of this chapter;

(3) Management's assessment of the effectiveness of the registrant's internal control over financial reporting as of the end of the registrant's most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective. This discussion must include disclosure of any material weakness in the registrant's internal control over financial reporting identified by management. Management is not permitted to conclude that the registrant's internal control over financial reporting is effective if there are one or more material weaknesses in the registrant's internal control over financial reporting; and

(4) A statement that the registered public accounting firm that audited the financial statements included in the annual report containing the disclosure required by this Item has issued an attestation report on management's assessment of the registrant's internal control over financial reporting.

(b) *Attestation report of the registered public accounting firm.* Provide the registered public accounting firm's attestation report on management's assessment of the registrant's internal control over financial reporting in the registrant's annual report containing the disclosure required by this Item.

(c) *Changes in internal control over financial reporting.* Disclose any change in the registrant's internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of § 240.13a–15 or 240.15d–15 of this chapter that occurred during the registrant's last fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

Instructions to Item 308

1. The registrant must maintain evidential matter, including documentation, to provide reasonable support for management's assessment of the effectiveness of the registrant's internal control over financial reporting.

2. A registrant that is an Asset-Backed Issuer (as defined in § 240.13a–14(g) and § 240.15d–14(g) of this chapter) is not required to disclose the information required by this Item.

§ 229.401 [Amended]

■ 12. By amending § 229.401 by removing the phrase ''internal controls and procedures for financial reporting'' in paragraph (h)(2)(iv) of Item 401 and adding, in its place, the phrase ''internal control over financial reporting''.

■ 13. By amending § 229.601 by:

■ a. Removing the second and third sentences of paragraph (a)(1);

■ b. Revising the Exhibit Table which follows the Instructions to the Exhibit Table; and

■ c. Revising paragraphs (b)(27) through (b)(98).

■ The revisions read as follows:

§ 229.601 (Item 601) Exhibits.

(a) *Exhibits and index required.* * * *

Instructions to the Exhibit Table

* * * * *

EXHIBIT TABLE

	Securities act forms										Exchange act forms			
	S–1	S–2	S–3	S–4[3]	S–8	S–11	F–1	F–2	F–3	F–4[3]	10	8–K	10–Q	10–K
(1) Underwriting agreement	X	X	X	X	.....	X	X	X	X	X	.....	X	.....	.....
(2) Plan of acquisition, reorganization, arrangement, liquidation or succession	X	X	X	X	.....	X	X	X	X	X	X	X	X	X
(3) (i) Articles of incorporation	X	.....	.....	X	.....	X	X	.....	.....	X	X	.....	X	X
(ii) By-laws	X	.....	.....	X	.....	X	X	.....	.....	X	X	.....	X	X
(4) Instruments defining the rights of security holders, including indentures	X	X	X	X	X	X	X	X	X	X	X	X	X	X
(5) Opinion re legality	X	X	X	X	X	X	X	X	X	X	.....	.....	.....	.....
(6) [Reserved]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
(7) [Reserved]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
(8) Opinion re tax matters	X	X	X	X	.....	X	X	X	X	X	.....	.....	.....	.....
(9) Voting trust agreement	X	X	X	X	X	X	X	X	X	X	X	X	X	X
(10) Material contracts	X	X	.....	X	.....	X	X	X	.....	X	X	.....	X	X
(11) Statement re computation of per share earnings	X	X	.....	X	.....	X	X	X	.....	X	X	.....	X	X
(12) Statements re computation of ratios	X	X	X	X	.....	X	X	X	.....	X	X	.....	.....	X
(13) Annual report to security holders, Form 10–Q and 10–QSB, or quarterly report to security holders[1]	.....	X	.....	X	.....	.....	.....	.....	.....	.....	.....	.....	.....	X
(14) Code of Ethics	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X
(15) Letter re unaudited interim financial information	X	X	X	X	X	X	X	X	X	X	.....	.....	X	.....
(16) Letter re change in certifying accountant[4]	X	X	.....	X	.....	X	.....	.....	.....	.....	X	X	.....	X
(17) Letter re director resignation	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	.....	.....
(18) Letter re change in accounting principles	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	X
(19) Report furnished to security holders	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	.....
(20) Other documents or statements to security holders	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	.....	.....
(21) Subsidiaries of the registrant	X	.....	.....	X	.....	X	X	.....	.....	X	X	.....	.....	X
(22) Published report regarding matters submitted to vote of security holders	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	X
(23) Consents of experts and counsel	X	X	X	X	X	X	X	X	X	X	.....	X[2]	X[2]	X[2]
(24) Power of attorney	X	X	X	X	X	X	X	X	X	X	X	X	X	X
(25) Statement of eligibility of trustee	X	X	X	X	.....	X	X	X	X	X	.....	.....	.....	.....
(26) Invitations for competitive bids	X	X	X	X	.....	.....	X	X	X	X	.....	.....	.....	.....
(27) through (30) [Reserved]	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
(31) Rule 13a–14(a)/15d–14(a) Certifications	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	X
(32) Section 1350 Certifications	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	X
(33) through (98) [Reserved]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
(99) Additional exhibits	X	X	X	X	X	X	X	X	X	X	X	X	X	X

[1] Where incorporated by reference into the text of the prospectus and delivered to security holders along with the prospectus as permitted by the registration statement; or, in the case of the Form 10–K, where the annual report to security holders is incorporated by reference into the text of the Form 10–K.

[2] Where the opinion of the expert or counsel has been incorporated by reference into a previously filed Securities Act registration statement.

[3] An exhibit need not be provided about a company if: (1) With respect to such company an election has been made under Form S–4 or F–4 to provide information about such company at a level prescribed by Forms S–2, S–3, F–2 or F–3 and (2) the form, the level of which has been elected under Forms S–4 or F–4, would not require such company to provide such exhibit if it were registering a primary offering.

[4] If required pursuant to Item 304 of Regulation S–K.

(b) *Description of exhibits.* * * *

(27) through (30) [Reserved]

(31) *Rule 13a–14(a)/15d–14(a) Certifications.* The certifications required by Rule 13a–14(a) (17 CFR 240.13a–14(a)) or Rule 15d–14(a) (17 CFR 240.15d–14(a)) exactly as set forth below:

*Certifications**

I, [identify the certifying individual], certify that:

1. I have reviewed this [specify report] of [identify registrant];

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such

disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:

_____

_____

_____

[Signature]

_____

[Title]

*Provide a separate certification for each principal executive officer and principal financial officer of the registrant. See Rules 13a–14(a) and 15d–14(a).

(32) *Section 1350 Certifications.*

(i) The certifications required by Rule 13a–14(b) (17 CFR 240.13a–14(b)) or Rule 15d–14(b) (17 CFR 240.15d–14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

(ii) A certification furnished pursuant to this item will not be deemed ''filed'' for purposes of Section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

(33) through (98) [Reserved]

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 14. The general authority citation for Part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78ll, 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7202, 7241, 7262, and 7263; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 15. By revising § 240.12b–15 to read as follows:

§ 240.12b–15 Amendments.

All amendments must be filed under cover of the form amended, marked with the letter ''A'' to designate the document as an amendment, *e.g.*, ''10–K/A,'' and in compliance with pertinent requirements applicable to statements and reports. Amendments filed pursuant to this section must set forth the complete text of each item as amended. Amendments must be numbered sequentially and be filed separately for each statement or report amended. Amendments to a statement may be filed either before or after registration becomes effective. Amendments must be signed on behalf of the registrant by a duly authorized representative of the registrant. An amendment to any report required to include the certifications as specified in § 240.13a–14(a) or § 240.15d–14(a) must include new certifications by each principal executive and principal financial officer of the registrant, and an amendment to any report required to be accompanied by the certifications as specified in § 240.13a–14(b) or § 240.15d–14(b) must be accompanied by new certifications by each principal executive and principal financial officer of the registrant. The requirements of the form being amended will govern the number of copies to be filed in connection with a paper format amendment. Electronic filers satisfy the provisions dictating the number of copies by filing one copy of the amendment in electronic format. See § 232.309 of this chapter (Rule 309 of Regulation S–T).

■ 16. By amending § 240.13a–14 by:
■ a. Revising paragraphs (a) and (b);
■ b. Removing paragraph (c);
■ c. Redesignating paragraphs (d), (e) and (f) as paragraphs (c), (d) and (e);
■ d. Revising newly redesignated paragraph (c), the introductory text of newly redesignated paragraph (d) and newly redesignated paragraph (e); and
■ e. Adding and reserving new paragraph (f).

The revisions read as follows:

§ 240.13a–14 Certification of disclosure in annual and quarterly reports.

(a) Each report, including transition reports, filed on Form 10–Q, Form 10–QSB, Form 10–K, Form 10–KSB, Form 20–F or Form 40–F (§§ 249.308a, 249.308b, 249.310, 249.310b, 249.220f or 249.240f of this chapter) under section 13(a) of the Act (15 U.S.C. 78m(a)), other than a report filed by an Asset-Backed Issuer (as defined in paragraph (g) of this section), must include certifications in the form specified in the applicable exhibit filing requirements of such report and such certifications must be filed as an exhibit to such report. Each principal executive and principal financial officer of the issuer, or persons performing similar functions, at the time of filing of the report must sign a certification.

(b) Each periodic report containing financial statements filed by an issuer pursuant to section 13(a) of the Act (15 U.S.C. 78m(a)) must be accompanied by the certifications required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) and such certifications must be furnished as an exhibit to such report as specified in the applicable exhibit requirements for such report. Each principal executive and principal financial officer of the issuer (or equivalent thereof) must sign a certification. This requirement may be satisfied by a single certification signed by an issuer's principal executive and principal financial officers.

(c) A person required to provide a certification specified in paragraph (a) or (b) of this section may not have the certification signed on his or her behalf pursuant to a power of attorney or other form of confirming authority.

(d) Each annual report filed by an Asset-Backed Issuer (as defined in paragraph (g) of this section) under

section 13(a) of the Act (15 U.S.C. 78m(a)) must include a certification addressing the following items: * * *

(e) With respect to Asset-Backed Issuers, the certification required by paragraph (d) of this section must be signed by the trustee of the trust (if the trustee signs the annual report) or the senior officer in charge of securitization of the depositor (if the depositor signs the annual report). Alternatively, the senior officer in charge of the servicing function of the master servicer (or entity performing the equivalent functions) may sign the certification.

(f) [Reserved]

* * * * *

■ 17. Section 240.13a–15 is revised to read as follows:

§ 240.13a–15 Controls and procedures.

(a) Every issuer that has a class of securities registered pursuant to section 12 of the Act (15 U.S.C. 78l), other than an Asset-Backed Issuer (as defined in § 240.13a–14(g)), a small business investment company registered on Form N–5 (§§ 239.24 and 274.5 of this chapter), or a unit investment trust as defined by section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4(2)), must maintain disclosure controls and procedures (as defined in paragraph (e) of this section) and internal control over financial reporting (as defined in paragraph (f) of this section).

(b) Each such issuer's management must evaluate, with the participation of the issuer's principal executive and principal financial officers, or persons performing similar functions, the effectiveness of the issuer's disclosure controls and procedures, as of the end of each fiscal quarter, except that management must perform this evaluation:

(1) In the case of a foreign private issuer (as defined in § 240.3b–4) as of the end of each fiscal year; and

(2) In the case of an investment company registered under section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8), within the 90-day period prior to the filing date of each report requiring certification under § 270.30a–2 of this chapter.

(c) The management of each such issuer, other than an investment company registered under section 8 of the Investment Company Act of 1940, must evaluate, with the participation of the issuer's principal executive and principal financial officers, or persons performing similar functions, the effectiveness, as of the end of each fiscal year, of the issuer's internal control over financial reporting. The framework on which management's evaluation of the issuer's internal control over financial reporting is based must be a suitable, recognized control framework that is established by a body or group that has followed due-process procedures, including the broad distribution of the framework for public comment.

(d) The management of each such issuer, other than an investment company registered under section 8 of the Investment Company Act of 1940, must evaluate, with the participation of the issuer's principal executive and principal financial officers, or persons performing similar functions, any change in the issuer's internal control over financial reporting, that occurred during each of the issuer's fiscal quarters, or fiscal year in the case of a foreign private issuer, that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

(e) For purposes of this section, the term *disclosure controls and procedures* means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act (15 U.S.C. 78a *et seq.*) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(f) The term *internal control over financial reporting* is defined as a process designed by, or under the supervision of, the issuer's principal executive and principal financial officers, or persons performing similar functions, and effected by the issuer's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the issuer;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the financial statements.

■ 18. Amending § 240.15d–14 by:

■ a. Revising paragraphs (a) and (b);

■ b. Removing paragraph (c);

■ c. Redesignating paragraphs (d), (e) and (f) as paragraphs (c), (d) and (e);

■ d. Revising newly redesignated paragraph (c), the introductory text of newly redesignated paragraph (d) and newly redesignated paragraph (e); and

■ e. Adding and reserving new paragraph (f).

The revisions read as follows:

§ 240.15d–14 Certification of disclosure in annual and quarterly reports.

(a) Each report, including transition reports, filed on Form 10–Q, Form 10–QSB, Form 10–K, Form 10–KSB, Form 20–F or Form 40–F (§§ 249.308a, 249.308b, 249.310, 249.310b, 249.220f or 249.240f of this chapter) under section 15(d) of the Act (15 U.S.C. 78o(d)), other than a report filed by an Asset-Backed Issuer (as defined in paragraph (g) of this section), must include certifications in the form specified in the applicable exhibit filing requirements of such report and such certifications must be filed as an exhibit to such report. Each principal executive and principal financial officer of the issuer, or persons performing similar functions, at the time of filing of the report must sign a certification.

(b) Each periodic report containing financial statements filed by an issuer pursuant to section 15(d) of the Act (15 U.S.C. 78o(d)) must be accompanied by the certifications required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) and such certifications must be furnished as an exhibit to such report as specified in the applicable exhibit requirements for such report. Each principal executive and principal financial officer of the issuer (or equivalent thereof) must sign a certification. This requirement may be satisfied by a single certification signed by an issuer's principal executive and principal financial officers.

(c) A person required to provide a certification specified in paragraph (a) or (b) of this section may not have the

certification signed on his or her behalf pursuant to a power of attorney or other form of confirming authority.

(d) Each annual report filed by an Asset-Backed Issuer (as defined in paragraph (g) of this section) under section 15(d) of the Act (15 U.S.C. 78o(d)), must include a certification addressing the following items: * * *

(e) With respect to Asset-Backed Issuers, the certification required by paragraph (d) of this section must be signed by the trustee of the trust (if the trustee signs the annual report) or the senior officer in charge of securitization of the depositor (if the depositor signs the annual report). Alternatively, the senior officer in charge of the servicing function of the master servicer (or entity performing the equivalent functions) may sign the certification.

(f) [Reserved]

* * * * *

■ 19. Section 240.15d–15 is revised to read as follows:

§ 240.15d–15 Controls and procedures.

(a) Every issuer that files reports under section 15(d) of the Act (15 U.S.C. 78o(d)), other than an Asset-Backed Issuer (as defined in § 240.15d–14(g) of this chapter), a small business investment company registered on Form N–5 (§§ 239.24 and 274.5 of this chapter), or a unit investment trust as defined in section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4(2)), must maintain disclosure controls and procedures (as defined in paragraph (e) of this section) and internal control over financial reporting (as defined in paragraph (f) of this section).

(b) Each such issuer's management must evaluate, with the participation of the issuer's principal executive and principal financial officers, or persons performing similar functions, the effectiveness of the issuer's disclosure controls and procedures, as of the end of each fiscal quarter, except that management must perform this evaluation:

(1) In the case of a foreign private issuer (as defined in § 240.3b–4) as of the end of each fiscal year; and

(2) In the case of an investment company registered under section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8), within the 90-day period prior to the filing date of each report requiring certification under § 270.30a–2 of this chapter.

(c) The management of each such issuer, other than an investment company registered under section 8 of the Investment Company Act of 1940, must evaluate, with the participation of the issuer's principal executive and principal financial officers, or persons performing similar functions, the effectiveness, as of the end of each fiscal year, of the issuer's internal control over financial reporting. The framework on which management's evaluation of the issuer's internal control over financial reporting is based must be a suitable, recognized control framework that is established by a body or group that has followed due-process procedures, including the broad distribution of the framework for public comment.

(d) The management of each such issuer, other than an investment company registered under section 8 of the Investment Company Act of 1940, must evaluate, with the participation of the issuer's principal executive and principal financial officers, or persons performing similar functions, any change in the issuer's internal control over financial reporting, that occurred during each of the issuer's fiscal quarters, or fiscal year in the case of a foreign private issuer, that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

(e) For purposes of this section, the term disclosure controls and procedures means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act (15 U.S.C. 78a *et seq.*) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(f) The term *internal control over financial reporting* is defined as a process designed by, or under the supervision of, the issuer's principal executive and principal financial officers, or persons performing similar functions, and effected by the issuer's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the issuer;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the financial statements.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 20. The general authority citation for Part 249 and the subauthority citation for ''Section 249.331'' are revised to read as follows:

Authority: 15 U.S.C. 78a *et seq.*, 7202, 7233, 7241, 7262, 7264, and 7265; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

Section 249.331 is also issued under 15 U.S.C. 78j-1, 7202, 7233, 7241, 7264, 7265; and 18 U.S.C. 1350.

* * * * *

■ 21. By amending Form 10-Q (referenced in § 249.308a) by:
■ a. Removing the last sentence of General Instruction G;
■ b. Revising Item 4 to ''Part I—Financial Information;'' and
■ c. Removing the ''Certifications'' section after the ''Signatures'' section.
■ The revision reads as follows.

Note: The text of Form 10–Q does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 10–Q

* * * * *

Part I—Financial Information

* * * * *

Item 4. Controls and Procedures.

Furnish the information required by Items 307 of Regulation S-K (17 CFR 229.307) and 308(c) of Regulation S-K (17 CFR 229.308(c)).

* * * * *

■ 22. By amending Form 10-QSB (referenced in § 249.308b) by:
■ a. Removing the last sentence of paragraph 2 of General Instruction F;
■ b. Revising Item 3 to ''Part I—Financial Information;'' and
■ c. Removing the ''Certifications'' section after the ''Signatures'' section.

■ The revision reads as follows.

Note: The text of Form 10-QSB does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 10–QSB

* * * * *

Part I—Financial Information

* * * * *

Item 3. Controls and Procedures.

Furnish the information required by Items 307 of Regulation S–B (17 CFR 228.307) and 308(c) of Regulation S–B (17 CFR 228.308(c)).

* * * * *

■ 23. By amending Form 10–K (referenced in § 249.310) by:
■ a. Removing the phrase ''(who also must provide the certification required by Rule 13a–14 (17 CFR 240.13a–14) or Rule 15d–14 (17 CFR 240.15d–14) exactly as specified in this form)'' each time it appears in the first sentence of paragraph (2)(a) of General Instruction D.;
■ b. Removing the phrase ''(Items 1 through 9 or any portion thereof)'' and adding, in its place, the phrase ''(Items 1 through 9A or any portion thereof)'' in the first sentence of paragraph (2) of General Instruction G.;
■ c. Removing the phrase ''(Items 10, 11, 12 and 13)'' and adding, in its place, the phrase ''(Items 10, 11, 12, 13 and 14)'' in the first sentence of paragraph (3) of General Instruction G.;
■ d. Removing the phrase ''(Items 1 through 9)'' in the third sentence of paragraph (4) of General Instruction G and adding, in its place, the phrase ''(Items 1 through 9A)'';
■ e. Removing the phrase ''(Items 10 through 13)'' in the third sentence of paragraph (4) of General Instruction G and adding, in its place, the phrase ''(Items 10 through 14)'';
■ f. Redesignating Item 14 of Part III as Item 9A of Part II and revising newly redesignated Item 9A;
■ g. Redesignating Item 15 in Part III as Item 14;
■ h. ''Instruction to Item 15'' is corrected to read ''Instruction to Item 14'';
■ i. Redesignating Item 16 in Part IV as Item 15;
■ j. Removing the ''Certifications'' section after the ''Signatures'' section and before the reference to ''Supplemental Information to be Furnished With Reports Filed Pursuant to Section 15(d) of the Act by Issuers Which Have Not Registered Securities Pursuant to Section 12 of the Act.''
■ The revision reads as follows.

Note: The text of Form 10-K does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 10-K

* * * * *

Part II

* * * * *

Item 9A. Controls and procedures.

Furnish the information required by Items 307 and 308 of Regulation S-K (17 CFR 229.307 and 229.308).

■ 24. By amending Form 10-KSB (referenced in § 249.310b) by:
■ a. Removing the phrase ''(who also must provide the certification required by Rule 13a-14 (17 CFR 240.13a-14) or Rule 15d-14 (17 CFR 240.15d-14) exactly as specified in this form)'' each time it appears in the first sentence of paragraph 2 of General Instruction C.;
■ b. Redesignating Item 14 of Part III as Item 8A of Part II and revising newly redesignated Item 8A;
■ c. Redesignating Item 15 of Part III as Item 14;
■ d. ''Instruction to Item 15'' is corrected to read ''Instruction to Item 14'';
■ e. Revising Item 2 of Part III of ''INFORMATION REQUIRED IN ANNUAL REPORT OF TRANSITIONAL SMALL BUSINESS ISSER''; and
■ f. Removing the ''Certifications'' section after the ''Signatures'' section and before the reference to ''Supplemental Information to be Furnished With Reports Filed Pursuant to Section 15(d) of the Exchange Act By Non-reporting Issuers.''

Note: The text of Form 10-KSB does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 10–KSB

* * * * *

PART II

* * * * *

Item 8A. Controls and Procedures

Furnish the information required by Items 307 of Regulation S-B (17 CFR 228.307) and 308 of Regulation S-B (17 CFR 228.308).

* * * * *

Information Required in Annual Report of Transitional Small Business isser

* * * * *

PART III

* * * * *

Item 2. Description of Exhibits.

As appropriate, the issuer should file those documents required to be filed as Exhibit Number 2, 3, 5, 6, and 7 in Part III of Form 1-A. The registrant also shall file:

(12) *Additional exhibits*—Any additional exhibits which the issuer may wish to file, which shall be so marked as to indicate clearly the subject matters to which they refer.

(13) *Form F-X*—Canadian issuers shall file a written irrevocable consent and power of attorney on Form F-X.

(31) The exhibit described in paragraph (b)(31) of Item 601 of Regulation S-B.

(32) The exhibit described in paragraph (b)(32) of Item 601 of Regulation S-B.

■ 25. By amending Form 20–F (referenced in § 249.220f) by:
■ a. Revising paragraph (e) to General Instruction B;
■ b. Revising Item 15 of Part II;
■ c. Removing the phrase ''internal controls and procedures for financial reporting'' in paragraph (b)(4) of Item 16A of Part II and adding, in its place, the phrase ''internal control over financial reporting'';
■ d. Removing the ''Certifications'' section after the ''Signatures'' section and before the section referencing ''Instructions as to Exhibits''; and
■ e. In the ''Instruction as to Exhibits'' section, redesignate paragraph 12 as paragraph 14 and add new paragraph 12 and paragraph 13.
■ The revisions and addition read as follows.

Note: The text of Form 20–F does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 20–F

* * * * *

General Instructions

* * * * *

B. General Rules and Regulations That Apply to this Form.

* * * * *

(e) Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act, provide the certifications required by Rule 13a-14 (17 CFR 240.13a-14) or Rule 15d-14 (17 CFR 240.15d-14).

* * * * *

Part II

* * * * *

Item 15. Controls and Procedures.

(a) *Disclosure Controls and Procedures.* Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act, disclose the conclusions of the issuer's principal executive and principal financial officers, or persons performing similar functions, regarding the effectiveness of the issuer's disclosure controls and procedures (as

defined in 17 CFR 240.13a-15(e) or 240.15d-15(e)) as of the end of the period covered by the report, based on the evaluation of these controls and procedures required by paragraph (b) of 17 CFR 240.13a-15 or 240.15d-15.

(b) *Management's annual report on internal control over financial reporting.* Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act, provide a report of management on the issuer's internal control over financial reporting (as defined in 17 CFR 240.13a–15(f) or 240.15d–15(f)) that contains:

(1) A statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the issuer;

(2) A statement identifying the framework used by management to evaluate the effectiveness of the issuer's internal control over financial reporting as required by paragraph (c) of 17 CFR 240.13a–15 or 240.15d–15;

(3) Management's assessment of the effectiveness of the issuer's internal control over financial reporting as of the end of the issuer's most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective. This discussion must include disclosure of any material weakness in the issuer's internal control over financial reporting identified by management. Management is not permitted to conclude that the issuer's internal control over financial reporting is effective if there are one or more material weaknesses in the issuer's internal control over financial reporting; and

(4) A statement that the registered public accounting firm that audited the financial statements included in the annual report containing the disclosure required by this Item has issued an attestation report on management's assessment of the issuer's internal control over financial reporting.

(c) *Attestation report of the registered public accounting firm.* Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act, provide the registered public accounting firm's attestation report on management's assessment of the issuer's internal control over financial reporting in the issuer's annual report containing the disclosure required by this Item.

(d) *Changes in internal control over financial reporting.* Disclose any change in the issuer's internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of 17 CFR 240.13a–15 or 240.15d–15 that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Instructions to Item 15.

1. The issuer must maintain evidential matter, including documentation, to provide reasonable support for management's assessment of the effectiveness of the issuer's internal control over financial reporting.

2. An issuer that is an Asset-Backed Issuer (as defined in 17 CFR 240.13a–14(g) and 17 CFR 240.15d–14(g)) is not required to disclose the information required by this Item.

* * * * *

Instructions as to Exhibits

* * * * *

12. The certifications required by Rule 13a–14(a) (17 CFR 240.13a–14(a)) or Rule 15d–14(a) (17 CFR 240.15d–14(a)) exactly as set forth below:

Certifications*

I, [identify the certifying individual], certify that:

1. I have reviewed this annual report on Form 20–F of [identify company];

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date:

_____

_____

_____

[Signature]

_____

[Title]

*Provide a separate certification for each principal executive officer and principal financial officer of the company. See Rules 13a–14(a) and 15d–14(a).

13. (a) The certifications required by Rule 13a–14(b) (17 CFR 240.13a–14(b)) or Rule 15d–14(b) (17 CFR 240.15d–14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

(b) A certification furnished pursuant to Rule 13a–14(b) (17 CFR 240.13a–14(b)) or Rule 15d–14(b) (17 CFR 240.15d–14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) will not be deemed ''filed'' for purposes of Section 18 of the Exchange Act [15 U.S.C. 78r], or otherwise subject to the liability of

that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the company specifically incorporates it by reference.

■ 26. By amending Form 40–F (referenced in § 249.240f) by:

■ a. Revising paragraph (6) to General Instruction B; and

■ b. Removing the phrase ''internal controls and procedures for financial reporting'' and adding, in its place, the phrase ''internal control over financial reporting'' in paragraph (8)(b)(4) of General Instruction B; and

■ c. Removing the ''Certifications'' section after the ''Signatures'' section.

■ The revision reads as follows.

Note: The text of Form 40–F does not, and this amendment will not, appear in the Code of Federal Regulations.

FORM 40–F

* * * * *

General Instructions

* * * * *

B. Information To Be Filed on this Form

* * * * *

(6) Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act:

(a) (1) Provide the certifications required by Rule 13a–14(a) (17 CFR 240.13a–14(a)) or Rule 15d–14(a) (17 CFR 240.15d–14(a)) as an exhibit to this report exactly as set forth below.

Certifications*

I, [identify the certifying individual], certify that:

1. I have reviewed this annual report on Form 40–F of [identify issuer];

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date:

_____

_____

_____

[Signature]

_____

[Title]

*Provide a separate certification for each principal executive officer and principal financial officer of the issuer. See Rules 13a–14(a) and 15d–14(a).

(2) (i) Provide the certifications required by Rule 13a–14(b) (17 CFR 240.13a–14(b)) or Rule 15d–14(b) (17 CFR 240.15d–14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) as an exhibit to this report.

(ii) A certification furnished pursuant to Rule 13a–14(b) (17 CFR 240.13a–14(b)) or Rule 15d–14(b) (17 CFR 240.15d–14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) will not be deemed ''filed'' for purposes of Section 18 of the Exchange Act [15 U.S.C. 78r], or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the issuer specifically incorporates it by reference.

(b) *Disclosure Controls and Procedures.* Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act, disclose the conclusions of the issuer's principal executive and principal financial officers, or persons performing similar functions, regarding the effectiveness of the issuer's disclosure controls and procedures (as defined in 17 CFR 240.13a-15(e) or 240.15d-15(e)) as of the end of the period covered by the report, based on the evaluation of these controls and procedures required by paragraph (b) of 17 CFR 240.13a-15 or 240.15d-15.

(c) *Management's annual report on internal control over financial reporting.* Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act, provide a report of management on the issuer's internal control over financial reporting (as defined in 17 CFR 240.13a-15(f) or 240.15d-15(f)) that contains:

(1) A statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the issuer;

(2) A statement identifying the framework used by management to evaluate the effectiveness of the issuer's internal control over financial reporting as required by paragraph (c) of 17 CFR 240.13a-15 or 240.15d-15;

(3) Management's assessment of the effectiveness of the issuer's internal control over financial reporting as of the end of the issuer's most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective. This discussion must include disclosure of any material weakness in the issuer's internal control over financial reporting identified by management. Management is not permitted to conclude that the

issuer's internal control over financial reporting is effective if there are one or more material weaknesses in the issuer's internal control over financial reporting; and

(4) A statement that the registered public accounting firm that audited the financial statements included in the annual report containing the disclosure required by this Item has issued an attestation report on management's assessment of the issuer's internal control over financial reporting.

(d) *Attestation report of the registered public accounting firm.* Where the Form is being used as an annual report filed under Section 13(a) or 15(d) of the Exchange Act, provide the registered public accounting firm's attestation report on management's assessment of internal control over financial reporting in the annual report containing the disclosure required by this Item.

(e) *Changes in internal control over financial reporting.* Disclose any change in the issuer's internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of 17 CFR 240.13a-15 or 240.15d-15 that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

Instructions to paragraphs (b), (c), (d) and (e) of General Instruction B. 6.

1. The issuer must maintain evidential matter, including documentation, to provide reasonable support for management's assessment of the effectiveness of the issuer's internal control over financial reporting.

2. An issuer that is an Asset-Backed Issuer (as defined in 17 CFR 240.13a-14(g) and 240.15d-14(g)) is not required to disclose the information required by this Item.

* * * * *

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 27. The authority citation for Part 270 is amended by revising the subauthority citation for ''Section 270.30a-2'' to read as follows:

Authority: 15 U.S.C. 80a-1 *et seq.*, 80a-34(d), 80a-37, and 80a-39, unless otherwise noted.

* * * * *

Section 270.30a-2 is also issued under 15 U.S.C. 78m, 78o(d), 80a-8, 80a-29, 7202, and 7241; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 28. By revising the last sentence of § 270.8b-15 to read as follows:

§ 270.8b-15 Amendments.

* * * An amendment to any report required to include the certifications as specified in § 270.30a-2(a) must include new certifications by each principal executive and principal financial officer of the registrant, and an amendment to any report required to be accompanied by the certifications as specified in § 240.13a-14(b) or § 240.15d-14(b) and § 270.30a-2(b) must be accompanied by new certifications by each principal executive and principal financial officer of the registrant.

■ 29. Section 270.30a-2 is revised to read as follows:

§ 270.30a-2 Certification of Form N–CSR.

(a) Each report filed on Form N-CSR (§§ 249.331 and 274.128 of this chapter) by a registered management investment company must include certifications in the form specified in Item 10(a)(2) of Form N–CSR and such certifications must be filed as an exhibit to such report. Each principal executive and principal financial officer of the investment company, or persons performing similar functions, at the time of filing of the report must sign a certification.

(b) Each report on Form N–CSR filed by a registered management investment company under Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)) and that contains financial statements must be accompanied by the certifications required by Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) and such certifications must be furnished as an exhibit to such report as specified in Item 10(b) of Form N–CSR. Each principal executive and principal financial officer of the investment company (or equivalent thereof) must sign a certification. This requirement may be satisfied by a single certification signed by an investment company's principal executive and principal financial officers.

(c) A person required to provide a certification specified in paragraph (a) or (b) of this section may not have the certification signed on his or her behalf pursuant to a power of attorney or other form of confirming authority.

■ 30. By revising § 270.30a-3 to read as follows:

§ 270.30a-3 Controls and procedures.

(a) Every registered management investment company, other than a small business investment company registered on Form N–5 (§§ 239.24 and 274.5 of this chapter), must maintain disclosure controls and procedures (as defined in paragraph (c) of this section) and internal control over financial reporting (as defined in paragraph (d) of this section).

(b) Each such registered management investment company's management must evaluate, with the participation of the company's principal executive and principal financial officers, or persons performing similar functions, the effectiveness of the company's disclosure controls and procedures, within the 90-day period prior to the filing date of each report on Form N–CSR (§§ 249.331 and 274.128 of this chapter).

(c) For purposes of this section, the term *disclosure controls and procedures* means controls and other procedures of a registered management investment company that are designed to ensure that information required to be disclosed by the investment company on Form N–CSR (§§ 249.331 and 274.128 of this chapter) is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an investment company in the reports that it files or submits on Form N–CSR is accumulated and communicated to the investment company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(d) The term *internal control over financial reporting* is defined as a process designed by, or under the supervision of, the registered management investment company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the investment company;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the investment company are being made only in accordance with authorizations

of management and directors of the investment company; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the investment company's assets that could have a material effect on the financial statements.

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 31. The authority citation for Part 274 is amended by revising the authority citation for ''Section 274.128'' to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l*, 78m, 78n, 78o(d), 80a-8, 80a-24, 80a-26, and 80a-29, unless otherwise noted.

* * * * *

Section 274.128 is also issued under 15 U.S.C. 78j-1, 7202, 7233, 7241, 7264, and 7265; and 18 U.S.C. 1350.

■ 32. Form N–SAR (referenced in §§ 249.330 and 274.101) is amended by revising the reference ''internal controls and procedures for financial reporting'' in paragraph (b)(6)(iv) of the Instruction to Sub-Item 102P3 to read ''internal control over financial reporting''.

■ 33. Form N–CSR (referenced in §§ 249.331 and 274.128) is amended by:

■ a. In General Instruction D, revising the reference ''Items 4, 5, and 10(a)'' to read ''Items 4, 5, and 10(a)(1)'';

■ b. Revising paragraph 2.(a) of General Instruction F;

■ c. In paragraph (c) of Item 2, revising the reference ''Item 10(a)'' to read ''Item 10(a)(1)'';

■ d. In paragraph (f)(1) of Item 2, revising the reference ''Item 10(a)'' to read ''Item 10(a)(1)'';

■ e. In paragraph (b)(4) of Item 3, revising the reference ''internal controls and procedures for financial reporting'' to read ''internal control over financial reporting'';

■ f. Revising Item 9; and

■ g. In Item 10:

■ (i) The introductory text and paragraphs (a) and (b) are redesignated as paragraphs (a), (a)(1) and (a)(2), respectively;

■ (ii) Revising newly redesignated paragraph (a) and newly redesignated paragraph (a)(2); and

■ (iii) Adding new paragraph (b) and an Instruction to Item 10.

The revisions and additions read as follows.

Note: The text of Form N-CSR does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM N–CSR

* * * * *

General Instructions

* * * * *

F. Signature and Filing of Report.

* * * * *

2. (a) The report must be signed by the registrant, and on behalf of the registrant by its principal executive and principal financial officers.

* * * * *

Item 9. Controls and Procedures.

(a) Disclose the conclusions of the registrant's principal executive and principal financial officers, or persons performing similar functions, regarding the effectiveness of the registrant's disclosure controls and procedures (as defined in Rule 30a-3(c) under the Act (17 CFR 270.30a-3(c))) as of a date within 90 days of the filing date of the report that includes the disclosure required by this paragraph, based on the evaluation of these controls and procedures required by Rule 30a-3(b) under the Act (17 CFR 270.30a-3(b)) and Rules 13a-15(b) or 15d-15(b) under the Exchange Act (17 CFR 240.13a-15(b) or 240.15d-15(b)).

(b) Disclose any change in the registrant's internal control over financial reporting (as defined in Rule 30a-3(d) under the Act (17 CFR 270.30a-3(d)) that occurred during the registrant's last fiscal half-year (the registrant's second fiscal half-year in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

Item 10. Exhibits.

(a) File the exhibits listed below as part of this Form.

* * * * *

(a)(2) A separate certification for each principal executive and principal financial officer of the registrant as required by Rule 30a-2(a) under the Act (17 CFR 270.30a-2(a)), exactly as set forth below:

Certifications

I, [identify the certifying individual], certify that:

1. I have reviewed this report on Form N-CSR of [identify registrant];

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, changes in net assets, and cash flows (if the financial statements are required to include a statement of cash flows) of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rule 30a-3(c) under the Investment Company Act of 1940) and internal control over financial reporting (as defined in Rule 30a-3(d) under the Investment Company Act of 1940) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of a date within 90 days prior to the filing date of this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal half-year (the registrant's second fiscal half-year in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:

_____

_____

[Signature]

_____

[Title]

(b) If the report is filed under Section 13(a) or 15(d) of the Exchange Act, provide the certifications required by Rule 30a-2(b) under the Act (17 CFR 270.30a-2(b)), Rule 13a-14(b) or Rule 15d-14(b) under the Exchange Act (17 CFR 240.13a-14(b) or 240.15d-14(b)), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) as an exhibit. A certification furnished pursuant to this paragraph will not be deemed ''filed'' for purposes of Section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

Instruction to Item 10.

Letter or number the exhibits in the sequence that they appear in this item.

* * * * *

By the Commission.

Dated: June 5, 2003.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 03–14640 Filed 6–13–03; 8:45 am]

BILLING CODE 8010–01–P

Federal Register

Wednesday,
June 18, 2003

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 314

Applications for FDA Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 02N–0417]

RIN 0910–AC48

Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its patent submission and listing requirements for new drug applications (NDAs). The final rule clarifies the types of patents that must and must not be submitted and revises the declaration that NDA applicants must provide regarding their patents to help ensure that NDA applicants submit only appropriate patents. The final rule also revises the regulations regarding the effective date of approval for certain abbreviated new drug applications (ANDAs) and certain other new drug applications, known as 505(b)(2) applications, submitted under the Federal Food, Drug, and Cosmetic Act (the act). In certain situations, Federal law bars FDA from making the approval of certain ANDA and 505(b)(2) applications effective for 30 months if the applicant has certified that the patent claiming a drug is invalid or will not be infringed, and the patent owner or NDA holder then brings suit for patent infringement. The final rule also states that there is only one opportunity for a 30-month stay in the approval date of each ANDA and 505(b)(2) application. The final rule will make the patent submission and listing process more efficient as well as enhance the ANDA and 505(b)(2) application approval processes.

DATES: *Effective Date*: This final rule is effective on August 18, 2003.

Compliance Date: The compliance date is December 18, 2003, for the submission of information on polymorph patents.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy and Planning (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Introduction

This final rule revises implementing regulations in part 314 (21 CFR part 314) for certain statutory amendments to the act, 21 U.S.C. 301 *et seq.*, relating to new drug applications and generic drug approvals. The statutory provisions were added to the act through the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417 (21 U.S.C. 355, 360cc; 35 U.S.C. 156, 271, 282) (''Hatch-Waxman Amendments'')). These statutory provisions reflect an attempt to balance two competing interests: Promoting competition between ''brand-name'' or ''innovator drugs'' and ''generic'' drugs, and encouraging research and innovation. The act promotes competition by creating a process to expedite the filing and approval of ANDA and 505(b)(2) drug applications (applications submitted under the provisions of section 505(b)(2) of the act) and for resolving challenges to patents in court before marketing begins. At the same time, the act encourages research and innovation by protecting the patent interests of the patent owner and innovator drug company.

The final rule maintains a balance between the innovator companies' intellectual property rights and the desire to get generic drugs on the market in a timely fashion. The final rule limits to one per ANDA or 505(b)(2) application the maximum number of statutory 30-month stays of approval to which an innovator will be entitled when it submits multiple patents for the same NDA. Eliminating multiple 30-month stays will speed up the approval and market entry of generic drugs. The final rule also clarifies patent submission and listing requirements, which will reduce confusion and help curb attempts to take advantage of this process. Specifically, patents claiming packaging, intermediates, or metabolites must not be submitted for listing. Patents claiming a different polymorphic form of the active ingredient described in the NDA must be submitted if the NDA holder has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.

A. What Are the Statutory Provisions Which Affect Patent Submissions and the Approval of New Drugs?

To explain why we (FDA) issued the proposal, we first describe how Federal law requires NDA applicants to file patent information and how that patent information can affect the approval of ANDA and 505(b)(2) applications. (We will refer to these as ''ANDA and 505(b)(2) applicants'' or ''ANDA or 505(b)(2) applicants'' and refer to their applications as ''ANDA and 505(b)(2) applications'' or ''ANDA or 505(b)(2) applications'' throughout the remainder of the preamble of this document.)

Section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) requires all NDA applicants to file, as part of the NDA, ''the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'' Section 505(c)(2) of the act (21 U.S.C. 355(c)(2)) imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application.

Under section 505(b)(1) of the act, we publish patent information after approval of an NDA application in our approved drug products list entitled ''Approved Drug Products With Therapeutic Equivalence Evaluations.'' This list is known popularly as the ''Orange Book'' because of its orange-colored cover. If patent information is submitted after NDA approval, section 505(c)(2) of the act directs us to publish the information upon its submission.

The act also requires ANDA or 505(b)(2) applicants to make certifications regarding each of the listed patents pertaining to the drug they intend to reference (see sections 505(b)(2)(A)(i) through (b)(2)(A)(iv) and 505(j)(2)(A)(vii)(I) through (j)(2)(A)(vii)(IV) of the act (21 U.S.C. 355(b)(2)(A)(i) through (b)(2)(A)(iv) and 21 U.S.C. 355(j)(2)(A)(vii)(I) through (j)(2)(A)(vii)(IV)). In brief, these certifications state that:

- Patent information has not been filed,
- The patent has expired,
- The patent will expire on a specific date, or
- The patent is invalid or will not be infringed.

If the ANDA or 505(b)(2) applicant certifies that the patent is invalid or will not be infringed (a certification known as a ''paragraph IV'' certification because it is the fourth type of patent certification described in the act[1]), the act requires the applicant to notify the

[1] Paragraph IV throughout also refers to paragraph iv, the comparable provision in section 505(b)(2)(A) of the act.

NDA holder and patent owner (see sections 505(b)(3) and 505(j)(2)(B) of the act (21 U.S.C. 355(b)(3) and 355(j)(2)(B)). The notice states that an ANDA or 505(b)(2) application containing a paragraph IV certification to a listed patent has been submitted for the NDA holder's approved drug product (known as the ''listed drug''). The notice also includes a ''detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed'' (*id.*). If the NDA holder or patent owner brings an action for patent infringement within 45 days after notice of the paragraph IV certification has been received, then we may not make the approval of an ANDA or 505(b)(2) application effective for 30 months, or such shorter or longer period as a court may order, or until the date of a court decision (see sections 505(c)(3)(C) and 505(j)(5)(B)(iii) of the act (21 U.S.C. 355(c)(3)(C) and 355(j)(5)(B)(iii)). (We will refer to the date the approval of an ANDA or 505(b)(2) application is made effective as the ''approval date'' throughout the remainder of this preamble.)

B. What Did the Proposed Rule Say?

In the **Federal Register** of October 24, 2002 (67 FR 65448), we published a proposed rule (proposed rule) that would address:

- The types of patents that must and must not be submitted by NDA applicants and NDA holders or patent owners (for purposes of this preamble, an NDA applicant is someone who is seeking FDA approval of a specific new drug application or supplement, whereas an NDA holder is someone whose NDA we have approved);
- The types of patents that we will list in the Orange Book;
- The patent declaration that NDA applicants must submit as part of an NDA, an amendment, a supplement, or when submitting information on a newly issued patent; and
- The 30-month stay of the effective date of approval for an ANDA or 505(b)(2) application.

The preamble to the proposed rule noted that, on occasion, we have seen NDA holders submit new patents for listing shortly before other listed patents for the same drug were to expire (see 67 FR 65448 at 65449). We explained that, in some disputes over recently listed patents, the parties had questioned whether particular patents met the regulatory requirements for submission and listing in the Orange Book. These disputes sometimes resulted in judicial decisions that are inconsistent with our regulatory policies or our interpretation of our own regulations (*id.*). We proposed to clarify our regulatory policies regarding patent submission, listing, certification, and notice. We also issued the proposal to respond, in part, to concerns raised by the Bureau of Competition and the Policy Planning Staff of the Federal Trade Commission (FTC). On May 16, 2001, the FTC submitted a citizen petition to FDA (FDA docket number 01P–0248) (''FTC Citizen Petition'') asking for guidance concerning the criteria that a patent must meet before it is listed in the Orange Book. The FTC Citizen Petition asked us to clarify several patent listing issues and indicated that the FTC was conducting an extensive study of generic drug competition.

In July 2002, the FTC published the results of the study in a report entitled ''Generic Drug Entry Prior to Patent Expiration: An FTC Study'' (''FTC Report''). The FTC Report focused on the procedures used to facilitate a generic drug's entry into the market before the expiration of a patent or patents that claim the brand-name drug product. The FTC also recommended changing Federal law to ''permit only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA'' (see FTC Report at page ii). The FTC Report explained ''To permit only one 30-month stay per drug product per ANDA should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays'' (*id.* at page v (footnote omitted)). In an appendix to its report, the FTC asked us to issue a regulation or guidance clarifying whether an NDA holder could submit various types of patents for listing in the Orange Book. The types of patents for which the FTC sought clarification were patents that claimed metabolites, polymorphs, intermediates, product-by-process patents, and double patents (see FTC Report at pages A–39–A–45).

C. What Does This Final Rule Do?

The comments received expressed both support for, and opposition to, various provisions of the proposed rule. After careful review of these comments, we are making final most of the provisions of the proposed rule with certain modifications. The final rule:

- Allows a full opportunity for only one 30-month stay per ANDA or 505(b)(2) application;
- Prohibits the submission of patents claiming packaging, intermediates, or metabolites;
- Requires the submission of certain patents claiming a different polymorphic form of the active ingredient described in the NDA;
- Adds a requirement that for submission of polymorph patents the NDA holder must have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA;
- Makes changes to the patent information required to be submitted and provides declaration forms for submitting that information to FDA, both with the NDA and after NDA approval; and
- Does not require claim-by-claim listing on the declaration form except for method-of-use patents claiming approved methods of use.

II. Comments on the Proposed Rule

We received over 35 comments on the proposed rule. The comments represented a diverse range of interests such as: Health insurance programs, brand name pharmaceutical companies, generic pharmaceutical companies, law firms, consumer organizations, pharmacy associations, the FTC, the New York Department of Health, large corporations, and individuals. In general, most comments supported the rule, either in whole or in part, and believed that the rule would help reduce prescription drug costs by making generic drugs available more quickly. However, other comments opposed the rule because they felt we had misinterpreted the act or because they felt that new legislation, rather than a regulation, was necessary. We describe the comments, and our responses to the comments, in this section. To make it easier to identify the comments and our responses, the word ''Comment'' in parentheses, will appear before the description of the comment, and the word ''Response'' in parentheses, will appear before our response. We also have numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is only for organizational purposes. It does not signify the comment's value, importance, or the order in which we received it.

A. Comments on Specific Aspects of the Proposed Rule

1. What Patents Must and Must Not Be Submitted? (Section 314.53(b))

Proposed § 314.53(b) would require NDA applicants and holders or patent owners to submit information on the following types of patents for listing in the Orange Book. In brief, the proposed

rule would clarify that we would list only patents that claim:

- The drug substance (ingredient);
- The drug product (formulation and composition); and
- Method of use.

Proposed § 314.53(b) would not allow listing of process patents and patents claiming packaging, metabolites, or intermediates.

a. *Patents Claiming a Drug Substance—Must Patents that Claim the ''Same'' Active Ingredient Be Submitted and Listed*? For patents that claim a drug substance, the proposal stated that an applicant ''shall submit information only on those patents that claim the form of the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application.'' We explained that an NDA applicant or holder would determine whether the drug substance was the ''same'' as the active ingredient in the NDA by considering ''whether the drug substances can be expected to perform the same with respect to such characteristics as dissolution, solubility, and bioavailability'' (see 67 FR 65448 at 65452).

Drug substances that are the same active ingredient, but that are in different physical forms, are often called ''polymorphs.'' For example, the different crystalline forms of a drug substance are sometimes known collectively as polymorphs, and drug substances with different waters of hydration are sometimes referred to as ''polymorphs'' as well. (For purposes of this final rule, polymorphs include chemicals with different crystalline structures, different waters of hydration, solvates, and amorphous forms.) Under the proposed rule, an NDA applicant or holder would be required to submit a patent claiming a different polymorph from that of the drug substance described in the NDA if a drug product containing the polymorph will perform the same as the drug product described in the NDA with respect to dissolution, solubility, and bioavailability.

The proposed rule would make the patent listing standards generally consistent with the ANDA approval standards. For ANDA approval purposes, the active ingredient in a generic drug product can be the ''same'' as that in the reference listed drug notwithstanding differences in the physical forms of their active ingredient if the drug product performs the same. Thus, we stated that it would be consistent to interpret ''drug substance'' for patent submission and listing purposes as including certain drug substances having different physical forms if they would be considered the same active ingredient for ANDA approval purposes (*id.*).

We invited comment on whether we should revise the codified language to require an NDA holder to submit additional information regarding the basis for its assertion that the drug substances are the ''same'' active ingredient. We also invited comment on the potential impact of the change (allowing the submission of patents claiming different polymorphs) on the submission of ANDA and 505(b)(2) applications.

(Comment 1) Several comments disagreed with our proposal to allow listing of patents claiming different polymorphs of the active ingredient in the listed drug. Some comments stated that section 505(b)(1) of the act requires the patent to claim the drug substance that is the subject of the NDA. Several comments asserted that a patent claiming a polymorph that was not the subject of an NDA did not satisfy section 505(b)(1) of the act. Other comments argued that ''sameness'' for ANDA approval purposes differed from ''sameness'' in patent law, so we did not have to develop an identical interpretation of the two concepts. Several comments maintained that no such patents could exist if the active ingredients were truly the ''same'' because a subsequent patent for the ''same'' active ingredient should not have been issued. Some comments agreed that patents claiming different polymorphs of the same active ingredient should be listed, but only with submission of additional information such as clinical trial data required for FDA approval or proof that ''sameness'' is beneficial. A few comments maintained that the proposal did not change our pre-existing position because we have permitted NDA holders and applicants to submit patents claiming different polymorphs of the active ingredient. In response to our request for comment on the impact on ANDA and 505(b)(2) applications, one comment expressed the belief that listing patents claiming different polymorphs of the active ingredient would reduce the ability of generic manufacturers to ''design around'' the existing patents, an option which was contemplated by the Hatch-Waxman Amendments.

(Response) We decline to modify our position taken in the proposed rule which would require patents to be submitted for listing that claim different polymorphs of the active ingredient described in the NDA. If the NDA applicant or holder is able to establish that a polymorph claimed in a patent is the ''same'' active ingredient (i.e., that a drug product containing the polymorph will perform the same as the drug product described in the NDA with respect to such characteristics as dissolution, solubility, and bioavailability), the NDA applicant or holder must submit the patent to us for listing. We acknowledge that there may be some legitimate confusion regarding our prior position concerning submission of such patents for listing, which resulted in the listing of some polymorph patents in the Orange Book. The uncertainty over our policy resulted from certain court decisions, our response to those court decisions, and other public statements. The FTC Citizen Petition highlighted the need for clarification and is one reason we decided to implement this final rule and clarify our position. For the reasons explained in the preamble to the proposed rule (see 67 FR 65448 at 65452 to 65453), it is appropriate to have a consistent interpretation of the ''sameness'' principle in the patent listing and ANDA approval contexts. Accordingly, we will not treat polymorphs differently for patent submission and listings and ANDA approval. The argument that certain polymorph patents should never have been issued is not a matter for us to address. The Patent and Trademark Office (PTO) is responsible for reviewing and issuing patents. We will not question whether the PTO should have issued a particular patent, nor will we conduct a ''patent law'' or other analysis to determine ''sameness.''

We agree with the comments that suggested we needed to take additional steps to help ensure that the submitted patents claim the ''same'' active ingredient as that described in the NDA. A polymorph patent must claim the drug substance (active ingredient) to meet the statutory requirements for submission. We have modified the declaration requirement and created forms to help ensure that the NDA applicant or holder or patent owner confirms that the patent does claim the ''same'' active ingredient. The final rule and the declaration forms require that the NDA applicant or holder or patent owner certify that test data exist demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. If a patent claims more than one polymorph, each polymorph for which the required test data are available must be identified by claim or description in the declaration forms.

The final rule does not require these tests to be submitted to FDA at the time of patent submission, nor does it require the NDA applicant or holder to conduct the tests itself. The testing requirements, however, will ensure that only relevant polymorphs are submitted for listing.

Whether two different polymorphs are the ''same'' active ingredient for purposes of drug approval is a scientific determination based upon the specific characteristics of the forms of the drug substance involved. Only with testing can the scientific determination be made that the drug product containing the polymorph will perform the same as the drug product described in the NDA. The test data that the NDA applicant or holder or patent owner must certify exist at the time of patent submission are similar to the type of information required under §§ 314.50 and 314.94. The following explains more fully the required tests or data that would support the statement in the declaration forms:

• A full description of the polymorphic form of the drug substance, including its physical and chemical characteristics and stability; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the polymorphic form of the drug substance;

• The executed batch record for a drug product containing the polymorphic form of the drug substance and documentation that the batch was manufactured under current good manufacturing practice requirements;

• Demonstration of bioequivalence between the executed batch of the drug product that contains the polymorphic form of the drug substance and the drug product as described in the NDA;

• A list of all components used in the manufacture of the drug product containing the polymorphic form and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; a description of the manufacturing and packaging procedures and in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including release and stability data complying with the approved product specifications to demonstrate pharmaceutical equivalence and comparable product stability; and

• Comparative in vitro dissolution testing on 12 dosage units each of the executed test batch and the NDA product.

This test data requirement corresponds to the test data required of ANDA applicants to demonstrate the drug product containing the polymorph described in the ANDA will perform the same as the drug product described in the NDA. In addition to the data requirements described in our regulations cited above (§§ 314.50 and 314.94), we have published guidance documents describing the test data ANDA applicants may use to demonstrate that the drug product will perform the same as the drug product described in the NDA. (See ''Guidance for Industry: Changes to an Approved NDA or ANDA'' (November 1999) and ''Guidance for Industry: Immediate Release Solid Oral Dosage Forms CMS 5'' (November 1995); these guidances are available at www.fda.gov/opacom/morechoices/industry/guidedc.htm.)

The stringency of these requirements regarding ''sameness'' also should address the concerns that the submission of polymorph patents might lead to submission of other patents claiming components which are not, but might be, included in a drug described in an NDA. Given the narrow legal and scientific basis for submission of polymorph patents, the final rule does not open the door to submission of any patents claiming formulations or inactive ingredients not contained in the drug product described in the NDA.

We believe that these changes will help deter submission of inappropriate polymorph patents. The assumption that a product containing a polymorph will perform the same as the product containing a different polymorph and described in the NDA will have to be substantiated.

b. *Product-by-Process Patents—Should These Patents Be Listed?* Proposed § 314.53(b) would allow an NDA applicant or holder or patent owner to submit information on product-by-process patents. The act requires that NDA holders submit patents that claim the drug product. However, NDA applicants or holders must not submit patents that claim a process for making that product.

We explained that a product-by-process patent claims a product by describing or listing process steps to wholly or partially define the claimed product. In a product-by-process patent, the patented, novel invention is the product and not the process that is used to make the product. We recognized that the distinction between a product-by-process patent and a process patent might not be readily apparent to persons who are unfamiliar with patent law. We sought comment on ways to ensure that only appropriate product-by-process patents are listed in the Orange Book.

(Comment 2) Several comments argued that product-by-process patents must not be listed. Some comments stated that product-by-process patents ''closely resemble'' process patents and that the act does not allow listing of process patents. One comment asserted that listing product-by-process patents would have a ''profound negative effect'' on generic drug approvals because NDA applicants and holders or patent owners would attempt to list any product-by-process patent, whether or not the process defined in the patent was actually used to manufacture the drug product approved in the NDA.

Similarly, other comments sought to limit the type of product-by-process patents that could be listed. Several comments would revise the rule to require the product-by-process patent to claim a ''novel'' product, so that if the drug product described by the product-by-process patent was a ''known'' drug product or the product already had been listed in the Orange Book, we would not list the product-by-process patent. In other words, the comments sought to ensure that the product-by-process patent covered a product that was ''new and patentably distinct'' from previously-approved drug products. One comment suggested adding a new paragraph to the patent declaration to read as follows:

F. For each drug substance or drug product claim that was (1) identified as listable in subparts B and C and (2) is drafted in product-by-process format, please provide the following information:

1. Is the product of the recited process novel? [If the answer to question F.1 is ''no,'' stop. The patent cannot be listed. If yes, please identify the claim(s) by number.]

Another comment thought that few drugs would be the subject of a product-by-process patent. The comment recommended that we investigate any product-by-process patents that were listed in the Orange Book to see if these related to the NDA drug product. Yet another comment would amend the patent declaration to identify the product-by-process claims in the patent, the effective filing date of the patent application, whether the product has been previously sold, and, if the product had been previously sold, whether such sales occurred more than 1 year before the effective filing date of the patent application. The comment explained that if the drug's active ingredient has been previously sold for more than 1 year before the effective filing date of the product-by-process patent

application, the patent would be ineligible for listing because the patent would violate a specific provision in patent law.

In contrast, three comments supported listing product-by-process patents. These comments agreed that product-by-process patents are a form of a product patent. Two comments stated that we did not need to revise the rule to distinguish between product-by-process patents (which must be listed) and process patents (which must not be listed). The comment suggested revising § 314.53(b) to replace its mention of product-by-process patents with ''patents that claim the drug substance or drug product at least in part in terms of its method of manufacture (product-by-process patents).''

(Response) We agree that, to be submitted for listing, the product-by-process patent must claim the drug product that is the subject of the NDA. We explained in the proposed rule why a product-by-process patent is a type of product patent (see 67 FR 65448 at 65452). We also agree that the declaration should be clear enough to ensure that the patents that are submitted for listing are product-by-process patents and not process patents. In the response to comment 12 in section II.A of this document we detail the changes we have made to the declaration (including declaration forms) to help ensure that the patents submitted for listing are patents that claim the drug product that is the subject of the NDA and do not claim the process that is used to manufacture the drug product.

The declaration forms include a question which requires the NDA applicant or holder or patent owner to certify whether the patent being submitted is a product-by-process patent in which the product claimed is novel. Although we do not adopt the wording suggested by several comments, we agree that a requirement to identify the product as novel will help ensure that the patent is a product-by-process patent. We acknowledge that when the PTO issues a patent, the PTO necessarily determines that some aspect of the patent claims is ''novel.'' We want to make sure that the NDA applicant or holder or patent owner is identifying the product claim as the novel aspect. This clarification should eliminate the submission of patents that may be mistakenly identified as product-by-process patents but, in reality, are process patents which cannot be submitted for listing.

We expect that product-by-process patents will not be submitted often. Drug products approved under section 505 of the act typically are capable of being described by their chemical formula. Most such drug products approved are not of the type that can be described only in terms of the process used to produce the product. We decline to add any additional questions to the declaration relating to the patented product's length of time in the commercial market or other related questions, as we believe that the declaration questions we have added will accomplish the clarification necessary to prevent the submission of process patents.

c. *Patents Claiming Packaging—Do We Consider Containers and Delivery Systems to be ''Packaging*?'' Proposed § 314.53(b) would not have allowed an applicant to list a patent that claimed packaging.

(Comment 3) Most comments agreed that patents claiming packaging should not be submitted for listing. However, some comments stated that patents claiming devices or containers that are ''integral'' to the drug product or require prior FDA approval should be submitted and listed. These comments distinguished between packaging and devices such as metered dose inhalers and transdermal patches, which are drug delivery systems used and approved in combination with a drug.

(Response) We agree that patents claiming a package or container must not be submitted. Such packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission. However, we have clarified the rule to ensure that if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing.

Section 314.3 defines a ''drug product'' as ''* * * a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.'' The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems. The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product. Patents must not be submitted for bottles or containers and other packaging, as these are not ''dosage forms.'' The revised declaration requirements, described in the response to comment 12 in section II.A of this document, detail the information required for submission.

d. *Patents Claiming Metabolites—Are Any Patents Claiming Metabolites Eligible for Submission and Listing*? The proposed rule would prohibit submission and listing of a patent claiming a metabolite of the approved drug. A metabolite is the chemical compound that results after the active ingredient of the drug has broken down inside the body. We explained that a patent claiming a metabolite does not claim the approved drug, as required by the act, because the metabolite exists only after the approved drug has been broken down inside the body (see 67 FR at 65451).

(Comment 4) Most comments agreed with our exclusion of patents claiming a metabolite. One comment, however, asked whether we would list ''a patent that claims a method of using an approved drug to administer a metabolite.'' The comment distinguished a method-of-use patent from a patent that claimed the metabolite.

(Response) The final rule prohibits submission of patents claiming metabolites when the metabolite is not the active ingredient described in the NDA. The submission of a metabolite patent does not meet the legal requirements for patent submissions as discussed in the proposed rule (see 67 FR 65448 at 65451). By contrast, if a patent submitted for listing claimed an approved method of using an approved drug to administer a metabolite, the submission of the patent would be permissible as long as all the conditions for submitting ''method-of-use'' patents are met. We describe the requirements for submission of method-of-use patents in the response to comment 7 in section II.A of this document. Briefly, if a method of use is described in the labeling for the drug product, and there is a patent claiming that method of use, the patent must be submitted for listing in the Orange Book, the method-of-use claim must be identified in the declaration forms, and the labeling language related to the method-of-use claim must be provided in the declaration forms.

e. *Patents Claiming Intermediates—Must We Allow Them to Be Submitted*? The proposed rule would not allow the submission of patents that claimed an intermediate. We explained that intermediates are materials that are produced during preparation of the active ingredient and are not present in the finished drug product. We consider intermediates to be ''in-process materials'' rather than drug substances or components in the finished drug product (see 67 FR 65448 at 65451 to 65452).

(Comment 5 and Response) The comments that addressed this issue agreed with the proposal. Consequently,

the final rule does not allow submission of patents that claim intermediates for the reasons explained in the proposal.

f. *''Double'' Patents—What Are They, and Must We Allow Them to Be Submitted*? The proposal did not discuss ''double'' patents.

(Comment 6) One comment suggested that we prohibit the listing of patents that contain a terminal disclaimer over a patent that had already been listed. The comment explained that patent law generally prevents an inventor from double patenting—that is, extending the term of the patent ''by the subsequent patenting of variations that are not patentably distinct from the first-patented invention.'' The comment stated that this ''double patenting'' can be cured if the patent holder files a ''terminal disclaimer'' which ''acts to disclaim the term of the later patent that extends beyond the term of the original patent, so that both patents expire on the same day.'' The comment expressed concern that NDA holders could list a later patent and have an opportunity to obtain a 30-month stay even if the later listed patent had a terminal disclaimer. In other words, the terminal disclaimer would prevent the inventor from enjoying a longer term of patent protection, but it would not prevent the imposition of another 30-month stay if the NDA holder or patent owner sued to enforce the later patent. The comment noted that, for the drugs PAXIL and FOSAMAX, the NDA holder had submitted earlier patents and a later-issued patent that had a terminal disclaimer. The patents were listed in the Orange Book, paragraph IV certifications were required for both patents and the NDA holder sued ANDA applicants on both patents, triggering 30-month stays.

(Response) We acknowledge that the ''double patenting'' described by the comment may, indeed, provide an NDA holder an opportunity to obtain an additional 30-month stay under the prior interpretation of the act. Under the final rule, there is no opportunity for multiple 30-month stays if patents with terminal disclaimers are submitted for listing. If such a patent is submitted after an ANDA applicant has filed a paragraph IV certification to a previously filed patent, and one full opportunity was provided for the 30-month stay, no notice need be given for a subsequent paragraph IV certification and no additional 30-month stay for that ANDA applicant can result under the final rule.

The act expressly contemplates listing of patents after NDA approval. It does not prevent an NDA holder or patent owner from submitting a patent with a terminal disclaimer. As long as the patent meets the statutory requirements, the patent must be submitted, even if it contains a terminal disclaimer. Again, we note that the PTO is responsible for the issuance of such patents. We defer to the PTO on matters of patent issuance.

g. *Method-of-Use Patents—Must the ''Use'' Be Approved in the Approved Drug Product*? The preamble to the proposed rule mentioned that patents claiming a method of use would be able to be submitted, but did not address such patents except to confirm our position that patents may not be submitted for listing if they claim methods of use that are not approved for the listed drug or are not the subject of a pending application.

(Comment 7) Comments disagreed as to whether the method-of-use claim in a patent submitted for listing must be a use approved in the NDA. Several comments urged us to list only those patents claiming methods of use approved in the NDA or that required clinical trials. One comment argued that listing only patents for approved uses was the only way to stop NDA holders from claiming broad uses or indications not in the approved labeling. In contrast, other comments argued that the act did not prevent NDA applicants or holders or patent owners from submitting patents for listing that claimed uses not approved by FDA. Some comments stated that patent infringement is not limited to approved uses. Other comments stated that section 505(b)(1) of the act contemplates the listing of patents claiming unapproved uses if a claim of patent infringement could reasonably be asserted, citing *Purepac Pharm. Co.* v. *Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002) (*Purepac*).

(Response) If an NDA applicant or holder or patent owner intends to submit information on a patent that claims a method of use, the patent must claim a use that is described in the NDA. If we have already approved the NDA, the patent must claim a method of use that is in the labeling of the approved NDA. This has been our position since before we issued the final patent information rule in 1994 (see 59 FR 50338, 50363–50364 (Oct. 3, 1994)). The pre-existing requirement can be found at § 314.53(b) and (c)(2).

Sections 505(b) and (c) of the act support our position that only patents claiming approved methods of use be submitted for listing. Section 505(b)(1) of the act provides that the NDA applicant ''shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug * * * .'' The corresponding language in section 505(c)(2) of the act is nearly identical. Only method-of-use patents ''which claim the drug for which the applicant submitted the application'' must be listed. ''Drug'' is an ambiguous term, one which, for many years, we have consistently interpreted in the Hatch-Waxman Amendments to refer to the drug product. One court has said that:

> The meaning of the word ''drug'' in 21 U.S.C.§ 355(b)(1) cannot be determined apart from its context. Neither the FDA nor this court disputes that the definition of drug in § 321(g) covers both drug products and active ingredients. The relevant statutory section in this case, however, modifies the word ''drug'' by attaching the phrase ''for which the applicant submitted the application.'' In that context the FDA's interpretation of drug as meaning drug product is consistent with and indeed required by the statute.

(See *Pfizer, Inc.* v. *FDA*, 753 F. Supp. 171, 176 (D. Md. 1990).) All of the benefits afforded NDA holders under the Hatch-Waxman Amendments, such as the 30-month stay, derive from obtaining our approval of a particular drug product. Accordingly, only method-of-use patents that claim a use of the drug product in the pending or approved application must be submitted. Method-of-use patents for uses that the NDA holder ''has not chosen to make available to the public'' (*id.* at 177) must not be submitted for listing.

This construction of the statute is also supported by the more recent case law. Since we issued the proposed rule, there have been several judicial opinions discussing method-of-use patents. In *Purepac Pharm. Co.* v. *Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), and in the related case *TorPharm, Inc.* v. *Thompson*, Civ. No. 03–0254 (D.D.C. April 25, 2003) (appeal pending for both *Purepac* and *TorPharm*), the district court held that, where a patent did not claim a use approved in the NDA, an ANDA applicant could not be required to certify to that patent, and the agency could properly find that no ANDA applicant was entitled to 180-day exclusivity on that patent. In *Warner-Lambert Co.* v. *Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), the Federal Circuit held that an ANDA applicant does not need to certify to a patent claiming a use not covered by the applicable NDA, and there is no cause of action against an ANDA applicant for patent infringement under 35 U.S.C. 271(e)(2)(A) for patents that claim an unapproved use. In *Allergan, Inc.* v. *Alcon Labs., Inc.*, 324 F.3d 1322 (Fed.

Cir. 2003), the Federal Circuit issued a per curium opinion that held that a method-of-use patent holder does not have an infringement action against an ANDA applicant when the use claimed in the patent is not FDA approved and the ANDA applicant is not seeking approval of that use. These decisions are consistent with our position that sponsors must not submit method-of-use patents that do not claim an approved use for listing in the Orange Book. They also highlight the need for an improved declaration that will clarify the claimed scope of the method-of-use patents being submitted.

We have modified the required declaration relating to method-of-use patents submitted. Although we agree, as discussed in the response to comment 11 of section II.A of this document, that each individual claim of a patent does not need to be listed on the declaration forms for drug substance and drug product patents, we do require identification of individual claims for method-of-use patents. The declarant must describe each individual method of use for which a patent is submitted for listing, and identify the corresponding language found in the labeling of the approved NDA that corresponds to that method of use. This information will expedite our review of ANDA and 505(b)(2) applications that do not seek approval for all the approved uses. In determining whether an ANDA applicant can ''carve out'' the method of use, rather than certify to the listed patent, we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book.

The need for accurate and detailed information related to the approved methods of use claimed in the patent being submitted for listing is underscored by the decision in *Purepac Pharm. Co.* v. *Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002). In that case, the NDA holder submitted information on a patent claiming what was later determined to be an unapproved use of the approved drug product. This submission was accompanied by the required signed declaration from the NDA holder that the patent covered the method of use for the approved product. Accordingly, we listed the patent and the use code information submitted with the patent. Years later, well after litigation over this patent was underway, the NDA holder clarified to FDA that the patent did not, in fact, claim the use for which the NDA was approved.

This submission of inappropriate patent information led to confusion and then to litigation over an ANDA applicant's obligation to submit either a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the act or a ''section viii'' statement under section 505(j)(2)(A)(viii) of the act. The section viii statement, which is also applicable to 505(b)(2) applications, permits the ANDA or 505(b)(2) applicant to avoid certifying to a patent by stating that it is not seeking approval for the use claimed in the listed patent. A section viii statement does not carry the requirement for notice to the NDA holder and patent owner, and the related opportunity for a 30-month stay.

We have implemented the section viii provisions of the act by deferring to the NDA holder's or patent owner's assertion that the method-of-use patent claims an approved use of the drug product. When the NDA holder or patent owner submits a method-of-use patent for an approved NDA, we rely upon the requirements in the regulations and the required declaration as the evidence that the patent claims an approved use. Therefore, when an ANDA applicant has sought to duplicate the labeling for which the innovator has submitted the patent, and not to specifically omit, or ''carve out'' labeling, we require the ANDA applicant to submit a certification to that patent. A section viii statement would not be appropriate because the ANDA applicant is seeking approval for exactly the same labeling as that in the NDA for which the patent was submitted.

Our position has been that, for an ANDA applicant to file a section viii statement, it must ''carve out'' from the proposed ANDA labeling, the labeling protected by the listed patent. Unless the ANDA applicant can show that it is carving out certain method-of-use labeling, a section viii statement is not a correct submission for the listed patent. In *Purepac*, the court rejected our reliance on the regulations and the general declaration as a reasonable basis for this approach to implementation. The court specifically pointed to the patent submissions in the case, and noted that the NDA holder had not complied with the requirement that NDA holders submit only those patents claiming an approved use for the drug. Although the court noted that the facts in *Purepac* were unique (the NDA holder later admitted that it made its submission ''without regard'' to FDA's regulations), there may be other cases in which NDA holders have submitted patents claiming unapproved uses of approved drug products.

Following the *Purepac* decision, we have two options for implementing the section viii statement provisions under sections 505(b)(2)(B) and 505(j)(2)(A)(viii) of the act that intersect with the patent submission considerations described in the proposed rule. One approach would be to permit each ANDA and 505(b)(2) applicant to make its own independent decision on whether a listed method-of-use patent claims the use for which the ANDA applicant seeks approval, and then to submit a paragraph IV certification or section viii statement as the applicant sees fit. The second approach would be to require the NDA applicant or holder to identify specifically the approved uses claimed by the method-of-use patent, with reference to the approved labeling, and declare under penalty of perjury that the patent claims an approved use. This would permit ANDA and 505(b)(2) applicants, and us, to assess whether the ANDA or 505(b)(2) applicant is seeking approval for a use the sponsor states is claimed in the listed patent, and thus determine whether the applicant must submit a patent certification or may submit a section viii statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the act.

In the absence of explicit statutory language, we believe an approach that requires the NDA applicant or holder or patent owner to identify the approved methods of use protected by the patent is most consistent with the general balance adopted in Hatch-Waxman. This approach permits the NDA applicant or holder to determine which patents claim its approved drug product and then, when appropriate, to resolve disputes over infringement of those patents through patent litigation. If ANDA and 505(b)(2) applicants could always avoid the possibility of a 30-month stay by asserting in a section viii statement that certain labeling for which the applicant is seeking approval is not protected by a listed method-of-use patent—despite the NDA holder's assertion to the contrary—there would be little reason for any applicant to submit a paragraph IV certification for a method-of-use patent. This approach would essentially eliminate the certification, notice, and litigation process as to any listed method-of-use patent, producing an outcome that is inconsistent with the act.

To effectively implement the certification and section viii statement provisions set out in the statute, we must have adequate information concerning method-of-use patents. Since 1994, we have requested, but not required, that NDA applicants submit to FDA information on the approved use claimed by the patent. Since the

Purepac case and other instances have raised questions about what aspects of the approved drug are claimed by a listed use patent, we believe that it is necessary that an NDA holder submit more specific information on the approved methods of use protected by a submitted patent. Only with this information can we determine what submission is required of the ANDA and 505(b)(2) applicants referencing the approved drug.

We further note that we list methods of use for approved products in the Orange Book in the section on use codes. Due to the limitations of our database system and software constraints, we are limited to using 240 total characters for the use code description in the Orange Book. Traditionally, we have created the use code description for the Orange Book from the information submitted by the NDA applicant or holder. After considering the comments, and in light of the previously described litigation, we have determined that it is more efficient and accurate to ask the NDA holder to give us the exact use code description to be published in the Orange Book. Use codes are intended to alert ANDA and 505(b)(2) applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling. We understand that in some cases 240 characters may not fully describe the use as claimed in the patent. The declaration, which includes the complete description of the method-of-use claim and the corresponding language in the labeling of the approved drug, will be publicly available after NDA approval.

h. *Miscellaneous Patent Listing Comments.* i. *Should We Create an Administrative Process to Challenge Patent Listings or to De-List Patents or to Review the Listability of Patents*? The proposed rule did not propose an administrative process for challenging patent listings or for seeking removal of a patent from the Orange Book, nor did we propose a new process to internally review the patents for listability.

(Comment 8) Several comments stated that parties, such as generic drug companies and even third parties, need a method for challenging patent listings or for de-listing patents in the Orange Book. Some comments explained that the lack of an administrative procedure for challenging patent listings either encouraged NDA applicants to submit inappropriate patent information, or did not deter the practice, to delay generic competition. A number of comments maintained that FDA has more than a ministerial role and should review patents to determine if they meet the requirements for listing. Several comments contend that we have the authority to determine the attributes of the approved drug and thus to determine the appropriate patent listings. Various administrative mechanisms were suggested through which FDA could conduct a review of patents. These suggestions ranged from hiring patent lawyers to review submitted patents to development of a full administrative hearing process.

One comment stated that patent owners need an administrative process to enforce the listing of their patents because an NDA holder might ''fail'' to list eligible patents.

(Response) A fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents. The courts have the experience, expertise, and authority to address complex and important issues of patent law. This final rule supports that assumption in two ways. First, the final rule clarifies what patents must and must not be submitted for listing. This will make it easier for NDA applicants and holders and patent owners to avoid inadvertently submitting patents that do not meet the statutory and regulatory requirements. The clarification will reduce the pressure on us to intercede in patent listing disputes and will allow the courts and parties to focus on the ultimate issue of patent invalidity or non-infringement. Second, the final rule requires NDA applicants or holders or patent owners to submit detailed information and to certify to its correctness. This should further ensure that only patents meeting the statutory requirements will be submitted for listing.

We decline to create an additional administrative process for challenging patent listings beyond that already established in § 314.53(f). We also decline to create a new process for de-listing patents or for internal FDA review of patents beyond the limited review of the patent declaration described in this final rule. Section 505(b)(1) of the act directs NDA applicants to submit certain patent information. It requires that ''[u]pon approval of the application, the Secretary shall publish'' the patent information (emphasis added). In section 505(j)(7)(A)(ii) and (iii) the statute mandates that we publish revisions to this information every 30 days. These short time frames do not contemplate a substantive agency review of the scope of the patent and its application to the approved drug product. Indeed, the requirement of prompt publication (''upon submission''), combined with the 30-day timeframe for updating the Orange Book, are strong evidence that Congress did not intend us to undertake anything other than a ministerial action.

In addition to the absence of any statutory basis for a substantive agency review of patents, we have long observed that we lack expertise in patent matters. An administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are outside both our expertise and our authority. Although we will continue to relay questions about the accuracy of a patent submission to the NDA holder (see § 314.53(f)), our patent listing role remains ministerial. Courts have upheld our determination that our role with respect to patent listing is ministerial. (See *aai Pharma* v. *Thompson*, 296 F.3d 227, 242–43 (4th Cir. 2002), cert. denied, 123 S. Ct. 1582 (2003); *American Biosci., Inc.* v. *Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001); *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002); *Watson Pharm., Inc.* v. *Henney*, 194 F. Supp. 2d 442, 445–446 (D. Md. 2001); *Mylan Pharm., Inc.* v. *Thompson*, 139 F. Supp. 2d 1, 10–11 (D.D.C.), *rev'd on other grounds*, 268 F.3d 1323 (Fed. Cir. 2001).) We recognize that one court has held that parties have no private right of action to seek de-listing of patents (see *Mylan Pharmaceuticals, Inc.* v. *Thompson*, 268 F.3d 1323 (Fed. Cir. 2001)). Nevertheless, it would be inappropriate and impractical for us to create regulatory mechanisms for reviewing patent listings or permitting third parties to submit patents for listing. We lack both the resources and the expertise to resolve such matters.

Furthermore, even if we were to establish an administrative process for patent review, our decisions on these patent listing matters would inevitably lead to disputes and increased litigation against us. This litigation could question whether such an administrative process was within our legal authority. Even if the courts were to decide that we may review submitted patents, there would be repeated litigation over individual patent listing decisions. Given the uncertainty of the listing status of the challenged patent during the litigation, there is no assurance that, if we reviewed submitted patents, ANDAs or 505(b)(2) applications would be approved sooner and generic drugs would enter the market any more rapidly.

We agree that there have been a few cases in which legitimate concerns have been raised about whether specific submitted patents meet the statutory requirements for submission and listing. We believe that these concerns will be adequately and efficiently addressed by the clarification of the types of patents that must and must not be submitted and by improvements to the patent information required. We further believe that even if legally permissible, it is not necessary for us to develop a patent review mechanism. The final rule permits us to allocate our limited resources to public health activities, while leaving questions of patent law to the courts, which are better able to handle such questions. This division of responsibility is fully consistent with the process established in the Hatch-Waxman Amendments.

(Comment 9) One comment suggested that we create an administrative mechanism to ensure timely patent infringement litigation if no statutory notice is provided to the NDA holder.

(Response) We decline to amend the proposed rule as suggested by the comment. The act does not contemplate that we will play an active role in determining the timing of patent infringement litigation. In the absence of the 45-day timetable imposed when notice is given for a paragraph IV certification, a decision on whether and when to file suit for patent infringement may depend on multiple variables. For example, did the NDA holder or patent owner have sufficient information to decide whether to sue the ANDA or 505(b)(2) applicant for patent infringement? An ANDA applicant and the NDA holder may disagree on when the NDA holder had sufficient information to decide to file suit. The parties may also disagree as to what constitutes ''timely'' litigation. For example, an NDA holder who defers filing a lawsuit on a later-filed patent until a 30-month stay has elapsed may feel that the subsequent litigation is still ''timely,'' given the information available to the NDA holder. The ANDA or 505(b)(2) applicant may view this latter lawsuit as an obstacle to marketing its drug product. Given the limits of our statutory authority as well as complex issues of patent litigation strategy that lie outside our expertise, we decline to create a mechanism to ensure ''timely'' patent litigation in situations where the NDA holder and patent owner did not receive notice of subsequent paragraph IV certifications.

ii. *Should There Be Time Limits on Patent Submissions or Certifications*? The proposed rule did not specify when patent information would need to be submitted, or whether ANDA or 505(b)(2) applicants would need to provide certifications for patents listed after they had filed an ANDA or 505(b)(2) application.

(Comment 10) Several comments suggested revising the rule to create time limits relating to the submission of patent information or patent certifications. For example, one comment asserted that ''abuse'' occurs when NDA holders submit non-meritorious patent information to us shortly before an earlier-submitted patent is to expire. Another comment suggested that we limit the time during which NDA holders can submit patent information to a defined time period after we have approved their NDAs. Another comment said we should not require ANDA applicants to submit amended patent certifications if the patent was submitted after the first ANDA had been filed.

Similarly, one comment asserted that a patent submitted after NDA approval cannot claim the approved drug product because the later-submitted patent would be invalid. The comment explained that, under patent law, a person cannot obtain a patent if the subject of the patent is known and therefore ''anticipated'' under patent law.

(Response) We decline to amend the proposed rule as suggested by the comments. The act clearly contemplates the submission of additional patent information after an NDA has been filed. For example, section 505(b)(1) of the act instructs applicants to amend their NDAs to include information on a patent issued after the NDA has been filed, but before the NDA has been approved, which claims the drug or a method of using the drug that is the subject of the application. Section 505(c)(2) of the act directs NDA holders to submit patent information if the patent issued after we have approved the NDA. We do not interpret the act as permitting us to refuse to accept submissions of new patents either after an NDA has been filed or approved, or after an ANDA has been submitted.

Section 505(c)(2) of the act also instructs NDA holders to submit information on patents issued after NDA approval no later than 30 days after the date the patent issued. This deadline ensures prompt public notice that the NDA holder believes the patent claims the approved drug product and permits legal issues regarding these later-issued patents to be resolved as early as possible. Under § 314.94(a)(12)(vi), we do not require an ANDA or 505(b)(2) applicant with a pending application to certify to a patent issued after NDA approval but not submitted to us within 30 days after issuance. However, the patent will be listed in the Orange Book upon submission of a complete declaration, and ANDA and 505(b)(2) applications filed after the patent is listed will be required to contain a certification to the patent. This longstanding interpretation is consistent with the statutory language describing patent submission deadlines, the notice concept inherent in patent publication, and early judicial resolution of patent disputes. We are not persuaded by the comments that we should change our interpretation.

We believe that removing the possibility of multiple 30-month stays per ANDA will diminish the incentive to obtain additional patents late in the patent life of the product described in the NDA. As described in the FTC Report, of the patents reviewed by FTC, many of the patents submitted well after NDA approval, and usually after an ANDA application was filed, were ultimately found to be invalid. Therefore, in the absence of the 30-month stay, these patents would have been unlikely to serve as a basis for a preliminary injunction precluding market entry of generic drugs.

We also decline to amend the proposed rule to exempt ANDA applicants from submitting patent certifications if the patent was listed after the ANDA was filed. Our pre-existing regulations do not require ANDA applicants to amend their patent certifications if:

- The NDA holder failed to provide the required patent information within 30 days after the issuance of the patent; and
- The ANDA had already been submitted and had contained an appropriate patent certification before the submission of new patent information (see § 314.94(a)(12)(vi)).

However, if the NDA holder has submitted patent information in a timely manner, consistent with section 505(c)(2) of the act, then section 505(j)(2)(A)(vii) of the act requires the ANDA applicant to certify to that patent. Section 505(j)(2)(A)(vii) of the act requires ANDA applicants to provide a certification with respect to ''each patent which claims the listed drug,'' not only patents that are listed at the time the ANDA is submitted. The act contemplates the submission of patent certifications even if the patent was listed after the ANDA or 505(b)(2) application had been submitted.

We do not have the authority to declare any patent to be invalid. We leave questions regarding the issuance

and validity of patents to the PTO and the courts.

iii. *What Should the Patent Declaration Say*? (Proposed § 314.53(c)). Proposed § 314.53(c) would require a patent declaration for NDA applicants and holders and patent owners to complete as part of the NDA, an amendment, a supplement, or for information on a later-issued patent. The proposed revised declaration in the proposal was a ''checklist'' that focused on individual patent claims. The proposed declaration required information on each claim to help ensure that applicants submit only appropriate patent information, and that they stand behind the accuracy of the information. The proposed requirement to identify claims was intended to help all parties focus on the same claim and help prevent arguments as to whether a particular claim claimed the approved drug product.

(1) *Should the Declaration Identify Individual Patent Claims*?

(Comment 11) Several comments objected to identifying patent claims as part of the declaration. The comments stated that a claim-by-claim listing:

• Would be ''unnecessarily onerous'' because patents may contain many claims;

• Could threaten the patent holder's legitimate rights if the NDA applicant failed to list a patent claim because the failure to list that claim could be used as an admission against the NDA holder's or patent owner's interests in litigation;

• Could expose the NDA holder to criminal and civil liability if the claim cited in the declaration is later found not to claim the drug; or,

• Is irrelevant to patent listing because the patent, and not the patent claims, is what we must list in the Orange Book.

Other comments supported the claim-by-claim listing. Some comments requested that we impose a 30-month stay only if the specific claims submitted in the patent declaration were the subject of the patent litigation filed within the 45-day time period.

(Response) We have re-examined our rationale for proposing a claim-by-claim listing and have concluded that submission of a claim-by-claim declaration for all patents is not warranted. Such detailed information is not explicitly required by the act and is not necessary for a patent to be listed in the Orange Book. Section 505(b)(1) of the act requires that the patent be one that ''claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted * * *.'' The number of claims contained within a particular patent does not affect the ability of the patent to be listed as long as there is at least one claim that meets the two required elements.

Individual patent claims are relevant for purposes of the Orange Book only in the context of method-of-use patents. The specific method-of-use claims are essential to our review because sections 505(j)(2)(A)(viii) and 505(b)(2)(B) of the act allow ANDA and 505(b)(2) applicants to file statements which assert that the method-of-use patent does not claim a use for which the applicant is seeking approval. The ANDA or 505(b)(2) applicant does not have to seek approval for all uses approved for the reference listed drug. Thus, the claim-by-claim listing of method-of-use patents will permit ANDA and 505(b)(2) applicants to assess whether they are seeking approval for a use claimed in the listed patent, and thus determine whether to submit a patent certification or a section viii statement. Additionally, we can verify that the certification or statement is correct, and that only the appropriate methods of use are included in the proposed labeling for the ANDA or 505(b)(2) drug product.

We decline to adopt the recommendation made in some comments to require all claims to be listed and then provide a 30-month stay only for litigation involving a claim listed in the Orange Book. This suggestion would require us to significantly exceed our ministerial responsibility in listing patents because we would be obliged to evaluate patent lawsuits and their relation to individual patent claims. We discuss our ministerial role in the response to comment 8. Removing the proposed requirement of a claim-by-claim listing in the final rule should not be detrimental to ANDA or 505(b)(2) applicants. In fact, several generic companies, the FTC and the Generic Pharmaceutical Association (GPhA), stated in their comments that no ''prudent generic company'' would rely solely on Orange Book listings to evaluate patent information for litigation exposure, particularly when all patents cannot be listed in the Orange Book. Thus, we believe that identification of the relevant patent(s), as opposed to the individual patent claims (other than for method-of-use patents), satisfies the act's explicit requirements, provides sufficient information to potential applicants to determine if a more thorough patent search or analysis is warranted, and will help to ensure appropriate patent submissions.

(2) *Should the Declaration Be Expanded or Modified*? The proposed rule would revise § 314.53(c)(2) and would replace the existing, general declaration with a more detailed declaration. The proposed declaration would be a ''checklist'' that required information on the approved drug product including trade name, active ingredient(s), strength(s), dosage form(s), and approval date. For each patent submitted, each claim of a patent which applied to the drug substance (active ingredient), drug product (formulation or composition), and method of use would need identification. A ''yes'' or ''no'' check-off would be required as to each individual applicable patent claim. The proposed § 314.53 would require the NDA applicant or holder or patent owner to state in the declaration that the information was provided for an NDA submitted under section 505 of the act.

(Comment 12) Several comments supported our proposed changes to the declaration but also suggested additions to the declaration. These comments would add the following information to the declaration:

• Specific exclusions of patents for forms of the active ingredient not marketed, such as acids, freebases, salts, and isomers;

• Exclusion of patents claiming labeling matters such as business methods, registries, titration/dosing schedules, or ornamental designs;

• Exclusion of a patent claiming a drug substance claimed in conjunction with another active ingredient or method of using the combination which is not the claimed drug substance;

• Various forms of statements indicating or certifying the submitter has filed accurate information;

• Identification of the NDA applicant's pending patent applications; and

• Additional information for product-by-process patents.

The comments suggested that it was necessary to identify each of the excluded patents in the declaration form and the codified text. Several comments suggested requiring a sworn statement and an acknowledgement that a false statement was subject to criminal penalties. For example, one comment suggested that the declaration include the statement: ''The undersigned declares that all of the above information has been provided in accordance with Title 28, section 1746, entitled 'Unsworn declarations under penalty of perjury','' followed by the signature, date, title, and telephone

number. The comment also would require additional information on patents in the declaration form to identify that the product in the product-by-process patent was a novel product.

(Response) We agree, in part, with the comments that the information that would be required in the declaration should be modified. Also, we have created standardized declaration forms which will encompass the required patent declaration information.

The final rule changes the general requirements in pre-existing § 314.53(c)(1) by requiring that the patent information which must be submitted must be provided on the declaration forms in full. In final § 314.53(c)(2), we substitute declaration forms which must be used in place of the checklist described in the proposed rule. Each declaration form is a standard form that must be used by all NDA applicants or holders or patent owners for submission of patent information at the time of initial NDA or supplement filing, and upon and after NDA or supplement approval.

For several years our Internet Web site has included a sample format which can be used in submitting patent information required under pre-existing regulations. Although use of the sample format is purely voluntary, it is used extensively to submit patent information to us. Based on this experience, and given the additional information required in the final rule, we concluded that mandatory declaration forms are appropriate to obtain the patent information. We, thus, require use of forms in the final rule. Since we determined that forms are appropriate, we have consolidated information currently required by pre-existing regulations with the new required information. For example, we require a response on whether there are relevant patents related to the drug product, information currently required under pre-existing § 314.53(c)(3). This was not contained in the proposal but, for administrative efficiency, and to lessen the burden on NDA applicants or holders or patent owners, we have included in the declaration forms all of the required information relating to the patent submission.

The NDA applicant must provide a declaration form when an NDA, amendment, or supplement to an NDA is filed. The NDA holder must also submit another declaration form after NDA or supplement approval to provide information on all patents relevant to the approved NDA or supplement, whether or not information on any such patent was previously submitted. The declaration forms filed with us must be attested to as to the accuracy of the patent information being submitted. Examples of the two declaration forms, FDA Form 3542 and 3542a, are provided in the Appendix found at the end of this document. The declaration forms will be available on the Internet at http://www.fda.gov by searching for the word ''forms''.

The final rule also revises pre-existing § 314.53(c)(2)(ii) and (c)(3) to conform to the changes we made to the patent information required on the declaration forms. The final rule requires a declaration form to be filed with us within 30 days after NDA approval; this is consistent with the pre-existing requirement. This form must also be used to file patent information on any patents submitted or issued after NDA approval. This declaration form requires the NDA holder or patent owner to provide the patent information applicable to the approved NDA. It is similar to the declaration form filed upon the filing of an NDA, supplement, or amendment. However, the declaration form filed upon or after NDA approval requires information on the approved product and a description of the approved methods of use for the use code listing in the Orange Book. This description will be limited to 240 characters as discussed in the response to comment 7.

The final rule describes other information required for the declaration forms not identified in the proposed rule. Some of the additional information will allow us to more easily determine the eligibility of the patent for listing, while other information will provide more complete information related to the responsibilities of the NDA holders or ANDA applicants. For example, we require the issue date of the patent in order to determine whether the patent has been submitted to us within the required 30 days. We require information on whether the patent being submitted has been submitted previously for the NDA or supplement referenced in the declaration. For example, an earlier listed patent may have included several method-of-use claims but only one method of use previously approved and submitted. A second method of use may be approved in a supplement and must be submitted for listing. Such information will assist the Orange Book staff with its administrative listing responsibilities. The address and contact information of the patent owner required in the declaration forms will assist in the required notification to the patent owner of a paragraph IV certification. We have elaborated on the requirement for asserting that the polymorph is the ''same'' as the active ingredient approved in the NDA. We require information on whether the patents submitted claim metabolites or intermediates to help ensure that the patents prohibited from submission under final § 314.53(b) are not submitted. Similarly, we require information on patents claiming the drug product to prevent the submission of patents claiming packaging.

The final rule also requires information on product-by-process patents as discussed in the response to comment 2 of section II.A of this document. We have added a requirement that the NDA applicant or holder or patent owner state whether the patent being submitted is a product-by-process patent in which the product claimed is novel. This is to help ensure that process patents are not submitted for listing.

We agree that the attestation in the declaration form should be revised in the final rule. In the proposal, we stated that we had revised the declaration so that applicants would ''make careful and well-considered representations'' and ''stand behind the accuracy of that information'' (see 67 FR 65448 at 65453). In the final rule, we revise the statement to be more specific about the need to ensure the information is accurate. We adopt the attestation statement contained in 28 U.S.C. 1746 for unsworn declarations and include attestations in the declaration forms. The attestation statements in the declaration forms read as follows:

(Declaration Form 3542a submitted with NDA, amendment or supplement.)

The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.

(Declaration Form 3542 submitted upon or after NDA approval.)

The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.

We also include a warning statement in the declaration forms to alert the submitter that a willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

We decline to revise the proposed rule to list every excluded type of patent as requested by some comments. Based on our experience, we believe that if we attempted to include questions on all types of patents, such as ''business method'' or ''registry'' patents, or specifically list all exclusions in the final rule, there would be disagreements over whether the examples are all-inclusive or whether other types of patents were excluded as well. We believe the patent information requested is sufficient to ensure only eligible patents are submitted for listing.

We also decline to revise the declaration to require identification of an NDA applicant or NDA holder's patent applications that are under review by the PTO. The act does not contain any references to pending patents. In contrast, sections 505(b) and 505(c)(2) of the act contain requirements for patent information to be submitted after the patent is issued. Section 505(b) of the act requires that the information submitted on any patent claiming the drug include the patent number and expiration date of the patent. We publish that information when we list the patent in the Orange Book. A patent number and expiration date are available only when the PTO issues a patent and are not available for pending patent applications. Accordingly, we will not require submission of information regarding pending patent applications.

Although we do not require submission of information concerning pending patent applications, we understand that pending patent applications are generally publicly disclosable by the PTO if pending for more than 18 months at the PTO or foreign patent offices. In addition, information concerning pending patents would not provide any useful information if the PTO never issued the patent.

We note that we will not evaluate a patent to assess whether the declaration is accurate or whether the patent has been appropriately submitted for listing (see our response to comment 8). We will, however, review the declaration for completeness and to determine that the information given by the NDA applicant or holder or patent owner indicates that the patent is eligible for listing.

Although section 505(b)(1) of the act requires submission of patent information upon the filing of an NDA, we will rely only on the declaration form filed upon or after NDA approval under § 314.53(c)(2)(ii) to list patent information in the Orange Book. Patent information for newly approved NDAs, NDA supplements, or newly issued patents will not be published in the Orange Book unless and until we receive a complete declaration submitted post-NDA approval indicating the patent is eligible for listing.

We interpret the statute to permit listing of only those patents claiming the approved drug product and its approved uses. Even though the NDA applicant must submit patent information prior to NDA approval, it is not until the NDA or supplement has been approved that the scope of that approval is known. For example, we might approve only one of two indications proposed in an NDA and, thus, patents on an unapproved indication or use, although submitted with the original NDA, could not be listed. Therefore, as a way of confirming or amending the original patent information, a declaration form must be submitted after approval. If the declaration form submitted after NDA approval is incomplete or indicates a patent is not eligible for listing, we will notify the NDA holder and indicate the reason. The NDA holder must resubmit the declaration form with complete information indicating that the patent is eligible for listing. If the declaration form is incomplete or indicates the patent is not eligible for listing, we will refuse to list the patent until an appropriate declaration form has been submitted.

For patents newly issued by the PTO after the NDA is approved, section 505(c)(2) of the act requires that the NDA holder submit the patent information to us within 30 days to be considered timely filed. All such patent information must be contained in a complete declaration submitted post-NDA approval indicating that the patent is eligible for listing. A patent is considered listed in the Orange Book as of the date it is received in the Central Document Room as required in § 314.53(d)(4) and (d)(5), if it is accompanied by a declaration form that is both complete and contains information indicating that the patent is eligible for listing. If we must notify an NDA holder that a declaration form is incomplete or the patent is not eligible for listing, and the NDA holder then submits an acceptable declaration within 15 calendar days, we will consider the patent timely filed. So, for example, suppose an NDA holder submits information on a new patent to us 20 days after the patent is issued by PTO, and we notify the NDA holder 5 days later that the declaration is incomplete. If the NDA holder submits an adequate declaration within 15 calendar days of the notification, we will consider the patent information to have been submitted as of the date we originally received it, that is, within the 30 day period allowed by the statute. If the NDA holder submits the adequate declaration more than 15 calendar days after notification, we will consider the patent information to have been submitted on the day the revised declaration form is received, which may be more than 30 days after the date of patent issuance. Such patents will be subject to patent certification only as described in § 314.94(a)(12)(vi). If the NDA holder does not submit an adequate declaration for the newly issued patent, we will not list the patent in the Orange Book. This approach is appropriate because it gives the NDA holder who promptly submits information on a newly-issued patent a reasonable period of time to correct a mistake in a patent declaration, while at the same time ensuring that there are adequate declarations and minimal delays for listed patents. We will accept certifications to any patent only from the date an acceptable declaration is submitted.

The process established in § 314.53(f) for patent listing challenges is not altered by our requirements for patent information and declaration forms. Interested parties may still rely on that process if they believe a patent has been submitted and listed in error.

We are aware of NDA holders that have submitted patents for listing that have been listed in the Orange Book and then, at a later time, been removed from the Orange Book at the NDA holder's request. If, after the patent has been removed from the Orange Book, the NDA holder again seeks to submit the patent for listing, we will require resubmission of the patent information and the filing of an accompanying patent declaration before the patent will be relisted. Such resubmission will be governed under the final rule. If the resubmission of a previously listed patent takes place after the effective date of this rule, the final rule applies as described in section IV of this document.

The final rule does not require us to review or evaluate patents, but will simplify and clarify the submission process for NDA applicants and holders and patent owners, and will promote administrative efficiency. The additional information required by the declaration form will help ensure that only appropriate patents are submitted for listing.

2. How Many Times Can an ANDA or § 505(b)(2) Application's Approval Date Be Delayed by 30-Month Stays?

The proposed rule offered an interpretation of the act that would limit the number of 30-month stays to only one possible stay per ANDA or 505(b)(2) application. The proposed interpretation in the proposed rule differed from our previous interpretation of the act (which allowed for multiple 30-month stays). Under our proposed interpretation, the ANDA or 505(b)(2) applicant would continue to file the appropriate certifications as required under section 505(j)(2)(A)(vii)(I) through (j)(2)(A)(vii)(IV) or section 505(b)(2)(A)(i) through (b)(2)(A)(iv) of the act. However, under the proposed interpretation in the proposed rule, the notice to the NDA holder and patent holder of the paragraph IV certification is required only when a paragraph IV certification is included in the initial ANDA or 505(b)(2) application or when such an application is amended to include, for the first time, a paragraph IV certification. Notice to the NDA holder and patent owner is one of the requirements for a 30-month stay; if the ANDA or 505(b)(2) applicant is not obliged to provide a subsequent notice to the patent owner and NDA holder, no successive 30-month stay is possible.

a. *When Must Notice Be Provided and What Is a Full Opportunity for a 30-Month Stay*? The proposed rule would require an ANDA or 505(b)(2) applicant to provide notice to NDA holders and patent owners only when the applicant files a paragraph IV certification with the initial application or amends the application to include a paragraph IV certification for the first time. If the application were amended to add additional paragraph IV certifications, no notice to the NDA holder and patent owner would be required.

(Comment 13) Several comments claimed that the lack of notice for subsequent paragraph IV certifications would delay initiation of patent litigation. To avoid this ''delay,'' the comments suggested that, if we retained our proposed interpretation allowing only one 30-month stay per ANDA or 505(b)(2) application, we should amend the rule to:

• Give the ANDA applicant the ''option'' to provide voluntary notification;

• Give the ANDA applicant the ''option'' to provide notification and be subject to an ''optional'' additional 30-month stay;

• Require us to notify the NDA holder as to a subsequent paragraph IV certification.

Similarly, several comments expressed concerns that ANDA and 505(b)(2) applicants could manipulate the rule to avoid even a single 30-month stay. The comments explained that in the absence of notice for all paragraph IV certifications, there could be several scenarios in which an ANDA or 505(b)(2) applicant could take advantage of the regulations to avoid a meaningful 30-month stay under our revised interpretation. For example, an ANDA or 505(b)(2) applicant could file a paragraph IV certification on a narrow patent or a narrow patent claim and provide notice to the NDA holder and patent owner on that certification, thereby satisfying the regulatory requirements, while providing a paragraph III certification on broader patents or claims. The NDA holder or patent owner could bring a patent infringement suit within the 45 days, triggering a 30-month stay, or decide not to bring suit on the narrow claim or patent. The comments argued that, after suit was filed, or after the 45 days expired with no suit initiated, the ANDA or 505(b)(2) applicant could change the paragraph IV certification to a paragraph III. If suit had been filed, the applicant could seek dismissal of the patent infringement suit and avoid the 30-month stay. At a later date, the ANDA or 505(b)(2) applicant could change its paragraph III certification on the broader patent or claim to a paragraph IV certification, but because there had already been an opportunity for a 30-month stay, no further 30-month stay would be possible.

The comments maintained that we should not allow such manipulation and that it could be avoided by treating the new or revised certification as though it relates back to, and substitutes for, the original certification so that the notification requirements for original applications, and not those for amendments, apply. Under this suggested approach, the changed paragraph III certification would be treated as if the original application had contained the paragraph IV certification. The new certification, thus, would require notice to the NDA holder and patent owner and have the potential to trigger a 30-month stay. The comment cited § 314.94(a)(12)(viii) which relates to amended certifications to support this approach. In this instance, it was argued that there should be the opportunity for at least one 30-month stay when the ANDA or 505(b)(2) applicant ''alters or amends'' a patent certification for reasons other than the listing of a patent subsequent to the filing of an ANDA.

(Response) We decline to modify the proposed rule as suggested. We conclude, however, that clarification of the proposed rule is required in the final rule to ensure that our revised interpretation allows for one full opportunity for a 30-month stay after notice of a paragraph IV certification.

Our long experience with administering the Hatch-Waxman Amendments convinces us that any regulatory scheme in this area will be complex, and that any advantage that a party can find in manipulating the regulatory program will be pursued. Despite our conviction that the final rule will substantially reduce such manipulation, we do not believe we can completely prevent attempts at ''creative compliance'' by the parties.

Our revised interpretation of the statute reads all three subparagraphs of section 505(j)(2)(B) of the act as a coherent whole. We believe that Congress considered the first paragraph IV certification, notice and the opportunity for a single 30-month stay, to be part of an inter-connected process. In the final rule we keep these provisions operating together, as much as possible, requiring that certifications be made and notification provided in such a way that there always will be one full opportunity for a 30-month stay.

The notice requirement in the final rule depends on whether the ANDA or 505(b)(2) application contained a paragraph IV certification before the submission of an amendment containing a paragraph IV certification. We note three potentially confusing situations concerning applicability of that principle and describe how these will be treated under the final rule.

First, an ANDA or 505(b)(2) applicant who filed a paragraph IV certification could change to a paragraph III certification after notice is given but before the 45 days for filing suit has run and before a suit is filed. In this situation, because the opportunity for a 30-month stay has not vested (the 45 days has not expired or patent litigation has not yet been initiated), under the final rule, this ANDA or 505(b)(2) application will not be considered to have ever included a paragraph IV certification. If a paragraph IV certification is submitted later, the notice obligation and one full opportunity for a 30-month stay will attach. This ensures that, consistent with the statute, for at least one paragraph IV certification, the NDA holder or patent owner has a full 45 days to determine whether to exercise the right to sue for patent infringement

and to obtain a 30-month stay on ANDA or 505(b)(2) approval. The phrase ''one full opportunity for a 30-month stay'' used throughout this preamble means a notice of a paragraph IV certification followed by either the full 45 day period, or notice followed by the initiation of patent litigation before the 45 days expire.

Only where both the 45 days have not run and the ANDA or 505(b)(2) applicant has not been sued for patent infringement will this exception apply. If the NDA holder brings suit before the 45 days, and the ANDA or 505(b)(2) applicant then changes its application to omit any paragraph IV certifications, the court where suit is pending can determine how to proceed.

For effective enforcement of this provision of the regulations, notice of the first paragraph IV certification(s) must be given by the ANDA or 505(b)(2) applicant either: (1) When the applicant receives from us an acknowledgement that the ANDA or 505(b)(2) application is sufficiently complete to permit substantive review, or (2) at the same time that the amendment to the ANDA or 505(b)(2) application is submitted to us. These requirements are already contained in our regulations at § 314.95(b) and (d) and § 314.52(b) and (d). (These also apply to a second notice of a paragraph IV certification when the first notice did not result in a full opportunity for a 30-month stay.) The importance of ANDA and 505(b)(2) applicants providing this notice was recently reaffirmed in *TorPharm, Inc.* v. *Thompson*, Civ. No. 03–0254 (D.D.C. April 25, 2003) (appeal pending). ANDA and 505(b)(2) applicants shall submit proper documentation of notice to us as required by §§ 314.95(e) and 314.52(e).

Second, an applicant who filed a paragraph IV certification with its original ANDA or 505(b)(2) application could change its paragraph IV certification (generally to a paragraph III certification) after a patent infringement suit is filed and after the 30-month stay has commenced. Such a change could occur, for example, as a result of a court order after a finding of infringement in the patent litigation. In this circumstance, an application that previously contained a paragraph IV certification would no longer do so. If such an application is subsequently amended to add a new paragraph IV certification, the notice obligation will not be triggered for the new certification. The notice requirement and one full opportunity for 30-month stay will have been exhausted when the first patent lawsuit was filed and a 30-month stay was imposed.

The third situation could occur when an applicant withdraws an ANDA or 505(b)(2) application that contained a paragraph IV certification after it has provided notification to the NDA holder and patent owner. If an ANDA or 505(b)(2) applicant were to reactivate its withdrawn application, it might contend that the notice that it provided prior to withdrawal of the ANDA or 505(b)(2) application was the only notice that could trigger a 30-month stay, regardless of whether the 45 day period had run, whether patent infringement litigation was initiated, or whether that litigation was terminated because of withdrawal of the application.

Our pre-existing regulations prevent an applicant from using withdrawal to defeat the opportunity for one 30-month stay. Under §§ 314.52(b) and 314.95(b), the applicant is not to give notice until it receives an acknowledgement letter from us stating that its application is sufficiently complete to permit review. Any notice sent prior to receipt of such letter will not constitute the notice that creates the full opportunity for the single 30-month stay.

Once the review period begins, an application may not be withdrawn and then ''reactivated.'' If the ANDA or 505(b)(2) application is withdrawn during the review period, we ''will treat the resubmission as a new application or abbreviated application'' under § 314.100(b). If the applicant wishes to have the withdrawn ANDA or 505(b)(2) application reviewed, it must submit it as a new ANDA or 505(b)(2) application. The ''decision to withdraw the application is without prejudice to refiling'' as noted in § 314.65. However, we will treat the new ANDA or 505(b)(2) application in the same manner as any other original application. The applicant will be required to provide notice for paragraph IV certifications contained in the new ANDA or 505(b)(2) application, with the possibility of a single 30-month stay. If the new ANDA or 505(b)(2) application contains no paragraph IV certification, notice must be provided if it is later amended to include such a certification. In short, withdrawal of an ANDA or 505(b)(2) application will not defeat the opportunity for a 30-month stay of approval for the resubmitted ANDA or 505(b)(2) application.

We do not agree that § 314.94(a)(12)(viii) supports a ''relation back'' theory. The provision does provide that when an ANDA or 505(b)(2) applicant changes a certification in its application, ''the application will no longer be considered to contain the prior certification,'' but it cannot be read to suggest that the application will be considered to have contained only the changed certification retroactively to the date that the original certification was filed. If interpreted in that manner, an ANDA or 505(b)(2) applicant could amend certifications to other patents and make them paragraph IV certifications. Among other difficulties, an applicant could then argue that, by virtue of relating back, such a paragraph IV certification was the ''first'' application with a paragraph IV certification, potentially entitling the applicant to exclusivity under section 505(j)(5)(B)(iv) of the act. This theory would lead to absurd results in the application of 180-day exclusivity.

Furthermore, we note that ANDA applicants have substantial incentives to avoid manipulation of the patent certification process. The 180-day marketing exclusivity provided in section 505(j)(5)(B)(iv) of the act is a significant incentive for ANDA applicants to file legitimate paragraph IV certifications. Exclusivity as to each listed patent is available only to the first ANDA applicant filing a paragraph IV certification. Frequently, there is a race to submit the first paragraph IV certification. Consequently, given this incentive, we do not anticipate that ANDA applicants will manipulate their patent certification filings, because they could jeopardize their chances of obtaining the valuable 180-day exclusivity.

We encourage ANDA and 505(b)(2) applicants to resolve their concerns about commencing litigation quickly by providing voluntary notice to the NDA holder and patent owner as they wish. There is nothing in the final rule to prevent ANDA or 505(b)(2) applicants from providing notice on their own initiative, nothing to prevent NDA holders or patent owners from responding with patent litigation, and nothing to prevent ANDA or 505(b)(2) applicants from not marketing during the litigation. To the extent that ANDA or 505(b)(2) applicants seek resolution of outstanding patent issues before entering the market, we note that the applicant can file a declaratory judgment action (as discussed below) and enter into a stipulated preliminary injunction pursuant to which the ANDA or 505(b)(2) applicant will not enter the market during the course of the litigation. Such a stipulation, of course, must be consistent with FTC precedent and established antitrust requirements. Information on pertinent FTC consent orders may be obtained from the FTC or its Internet Web site.

The interpretation we are adopting in the final rule allows only one 30-month stay per ANDA or 505(b)(2) application;

it does not permit multiple 30-month stays. Revising the rule to impose additional 30-month stays would be contrary to our interpretation of the act and the reasons for the rulemaking. Furthermore, requiring notice and imposing a second full opportunity for an additional 30-month stay under the circumstances described would be inconsistent with our legal basis for a single 30-month stay since we permit notice and one full opportunity for a 30-month stay per ANDA or 505(b) application. Multiple 30-month stays increase the delay in approval of generic drugs and result in increased costs to consumers because the cost of individual drugs is reduced when generic drugs enter the marketplace and compete with the NDA drug.

b. *Should All Paragraph IV Certifications Be Made Public and Should the Notice Requirements Be Modified*? The proposed rule would limit when a notice of a paragraph IV certification is provided to NDA holders and patent owners but did not address the content or format of the notice. The proposed rule did not address whether or not paragraph IV certifications were subject to public disclosure. We invited comment on whether our regulations regarding the notice by ANDA and 505(b)(2) applicants to the NDA holder and patent owner could and should be amended (67 FR 65454).

(Comment 14) Several comments suggested that we should post all paragraph IV certifications on our Web site because, these comments argued, there is no basis to exempt the paragraph IV certifications from public disclosure. The comments also suggested that we disclose all paragraph IV certifications.

(Response) We decline to amend the proposed rule to make public all paragraph IV certifications or otherwise provide notice of paragraph IV certifications to NDA holders and patent owners. Under current practice, paragraph IV certifications are subject to public disclosure under the Freedom of Information Act (FOIA) and FDA's public disclosure regulations once the notice of the paragraph IV certification has been provided to the NDA holder and patent owner. Because the notice to the NDA holder or patent owner of the paragraph IV certification is considered a public disclosure after notice has been given, the certification is available under FOIA. The final rule requires notice only for the first paragraph IV certification of an ANDA or 505(b)(2) application if that notice results in a full opportunity for a 30-month stay. Notice for a subsequent paragraph IV certification will be required only if the full opportunity did not result. Only the paragraph IV certifications for which notice is required will be routinely subject to public disclosure prior to approval. All other certifications in an application would be considered confidential, commercial information. Unless the ANDA or 505(b)(2) applicant makes the subsequent certification public on its own accord, we are prohibited from any disclosure that would reveal the applicant's identity, contents of the application, or the timing of the application (see §§ 20.61(b) and 314.430). We do not believe that amending our FOIA regulations to permit the release of information typically considered confidential, commercial information, i.e. information that could cause competitive harm is appropriate, without deciding at this time that we could even do so.

Although parties are free to make paragraph IV certifications public themselves, we will continue to adhere to our pre-existing FOIA and public disclosure requirements as applicable to paragraph IV certifications. We also intend to publish on our Internet Web site, for each drug, the number of paragraph IV certifications filed to patents submitted after the effective date of this final rule, if it can be done in a manner that is consistent with FOIA. To avoid any inappropriate public identification, we will not publish the number of subsequent paragraph IV certifications if there is only one ANDA or 505(b)(2) application containing a paragraph IV certification because such publication would be tantamount to a public disclosure of that applicant's confidential, commercial information.

The NDA holder and patent owner also have other means to determine whether subsequent paragraph IV certifications have been filed. If a lawsuit is filed after notice of the paragraph IV certification, the NDA holder or patent owner can use the litigation process to discover the ANDA or 505(b)(2) applicant's certifications to subsequent patents. Furthermore, additional public information is available if we issue a tentative approval letter to the ANDA or 505(b)(2) applicant with a paragraph IV certification. These letters are publicly available before the ANDA or 505(b)(2) applicant receives an approval and note the applicable patents, patent certifications, and exclusivities affecting the timing of the approval of the ANDA or 505(b)(2) application.

We note that comments concerning public disclosure of paragraph IV certifications and the need for quick resolution of patent issues were submitted both by brand name or innovator firms and their trade associations and by generic drug firms or related interests. We believe such mutual interests will encourage the voluntary disclosure of paragraph IV certifications.

(Comment 15) Several comments responded to our request for comments on whether our regulations concerning the certifications filed by ANDA and 505(b)(2) applicants and the notice to NDA holders and patent owners could or should be modified. Most comments agreed that we had the authority to modify both the certifications and the notice. One comment suggested that we ''clarify the elements of a proper paragraph IV notification'' to ''ensure that paragraph IV notifications communicate meaningful information regarding the basis for an assertion that a listed patent is invalid or not infringed'' and that ''adequate'' information is provided. Another comment suggested that the notice provided to the NDA holder and patent owner of a paragraph IV certification should include an explanation of the relationship between the patent claims as construed by the ANDA or 505(b)(2) applicant and the drug product. Another comment said we should require the NDA holder and patent owner to identify an ''agent for service'' and require service by registered mail to ensure that the notice will reach its ''proper location within the corporation in a timely manner.''

(Response) In reviewing the current notification requirements at § 314.95(c), we do not believe that the suggested solutions for clarification or more detailed explanations would improve upon the current regulation. The current regulation requires specific information in a notice that explains in full, and in detail, the nature of the claim that the listed patent is invalid or, unenforceable or will not be infringed. Our regulations, at §§ 314.52(a) and 314.95(a), require notification by registered or certified mail, return receipt requested. Our regulations also require documentation of a receipt establishing that the notice was received by the listed NDA holder and patent owner (see § 314.52(e) and § 314.95(e)). A receipt other than a return receipt or a letter from the recipient acknowledging receipt can be provided only with advance FDA agreement.

We do not believe it would be appropriate to further limit delivery of the notice, nor do we believe it is appropriate to require ''agents for service.'' We are not persuaded that such agents would solve the comment's problem that ''notice is not reaching its

proper location within the corporation in a timely manner.'' In addition, the individual listed as the ''agent for service'' could change, resulting in confusion and delay in providing notice.

(Comment 16) Another comment suggested we require ANDA and 505(b)(2) applicants to file a new complete application for every drug product listed separately in the Orange Book rather than allow applicants to file supplements to approved applications. This comment would require new applications for each drug strength listed in the Orange Book as a separate product.

(Response) We decline to adopt the comment's suggestions. Our current policies regarding supplements to ANDA and 505(b)(2) applications allow for significant administrative efficiencies and reduced application review times. Requiring separate ANDA or 505(b)(2) applications would substantially increase costs for applicants, as well as the agency, to accommodate the burden of creating, submitting, processing, and reviewing multiple, complete applications. Our policy regarding supplemental ANDAs for multiple strengths of a drug has been a major factor in reducing ANDA review times. Before 1991 (when applicants had to submit separate ANDAs for different strengths of a drug), the median approval time for an ANDA was 33 months. Today it is approximately 18 months. A key purpose of this final rule is to help expedite the approval of generic products so that they can more quickly be introduced to the marketplace. If we adopted the suggestion, the probable effect would be to delay the introduction of generic drugs into the market because the review times would increase. Requiring multiple applications would not provide any additional value to our review of ANDA applications. Consequently, we decline to require separate applications as suggested by the comment.

c. *Should the Single 30-Month Stay Be Further Limited*?

(Comment 17) Many comments agreed with our determination that the delay in approval of ANDA or 505(b)(2) applications could be limited to one 30-month stay per application. Other comments agreed with the limitation but stated that the single 30-month limitation was or should be:

- Per drug;
- Per ANDA, for all patents submitted before any ANDA filing; or
- Limited only to patents submitted within 30 days of NDA approval.

(Response) We decline to adopt the additional limitations as suggested by the comments. The act requires a certification for each listed patent for each application filed under sections 505(b)(2) or 505(j) of the act. We construe section 505(c)(2) of the act to require submission of patent information after NDA approval, without regard to when an ANDA or 505 (b)(2) application has been filed. We decline to limit the 30-month stay resulting from a paragraph IV certification to only those patents submitted before any ANDA or 505(b)(2) filing, or those filed only within 30 days of NDA approval, or per listed drug instead of per application.

d. *Will the Application of Only One 30-Month Stay Affect Declaratory Judgment Actions Under the Act*?

(Comment 18) Several comments supported the single 30-month stay but expressed concern that limiting the notice requirement and 30-month stays to the first paragraph IV certification could affect the ability of ANDA and 505(b)(2) applicants to file a declaratory judgment action to resolve patent infringement issues. Some comments believed that in the absence of both notice to the NDA holder and patent owner and the ensuing 45-day period within which a patent infringement suit could be initiated, a declaratory judgment action could not be brought. Other comments opposed the single 30-month stay and also expressed concern about the ability to pursue a declaratory judgment action under the proposal. Some comments questioned whether a declaratory judgment action could be filed under other statutory provisions; the comments explained that the Hatch-Waxman Amendments created the act of patent infringement and, if litigation were bought ''outside'' the act, there would be no ''case or controversy'' required by those provisions. One comment cited *Cordis Corp.* v. *Medtronic, Inc.*, 835 F.2d 859, 862 (Fed. Cir. 1987), noting that ''when the generic cannot meet the subjective standard of proving a reasonable apprehension of a suit by the brand company,'' the case may be dismissed because there was no ''case or controversy.'' Another comment cited *Teva Pharmaceuticals, USA, Inc.* v. *FDA*, 182 F.3d 1003 (D.C. Cir. 1999), to claim that if no notification were received, arguably no declaratory action could be brought. Other comments suggested that limiting NDA holders to a single 30-month stay per ANDA or 505(b)(2) application would encourage the delay of litigation designed to resolve patent issues and thus would reduce ''certainty'' for ANDA applicants.

(Response) We appreciate the desire to resolve patent issues quickly, but believe the concerns expressed about the ability to pursue declaratory judgment actions are unwarranted. Section 505(j)(5)(B)(iii) of the act provides: ''Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent.'' We interpret this particular section as creating an exception to the general right of a party to bring a declaratory judgment action at any time that jurisdictional requirements are satisfied under title 28, United States Code. The general rule allowing declaratory judgments under 28 U.S.C. 2201 would be applicable as long as a party can satisfy the ''case or controversy'' requirement that is necessary to file a declaratory judgment action. The exception created in section 505(j) of the act restricts the timing when a declaratory judgment action may be filed under certain limited circumstances. Under the act, if notice of a paragraph IV certification is required, no declaratory judgment action can be filed until 45 days after that notice is given to the NDA holder and patent owner. However, if no notice is required to be provided to the NDA holder and patent owner, the exception created in section 505(j) of the act no longer applies, and the general rule permitting declaratory judgments to be filed at any time under 28 U.S.C. 2201 would apply.

We also disagree with the conclusions drawn from the cases cited in the comments that, in the absence of the notice of subsequent paragraph IV certifications, there would be no case or controversy on which to base a declaratory judgment action. A case or controversy can exist where first, there is reasonable fear of a lawsuit and, second, the plaintiff has actually produced the product in question or is prepared to produce the product. (See *Cordis Corp.* v. *Medtronic, Inc.*, 835 F.2d 859 (Fed. Cir. 1987)). In *Vanguard Research, Inc.* v. *PEAT, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002), the court found that fear of a lawsuit existed when the competitor was engaged in activity subject to a patent infringement charge, and the patent holder already had sued the competitor to protect its technology. The court noted that: ''[f]iling a lawsuit for patent infringement would be just another logical step in its quest to protect its technology.'' This is similar to the

situation in which an ANDA or 505(b)(2) applicant has filed an initial paragraph IV certification and the NDA holder or patent owner has filed a lawsuit to protect the patent and obtain a 30-month stay. There is little reason to doubt that an NDA holder or patent owner who had submitted a second patent to us for listing would bring another lawsuit to protect the second patent if an ANDA or 505(b)(2) applicant were to manufacture the drug, even if no notice of a subsequent paragraph IV certification was provided. In other words, the NDA holder or patent owner should have an incentive to protect the patented invention regardless of whether the ANDA or 505(b)(2) applicant provided notice.

We acknowledge that the court in *Jervis B. Webb Co.* v. *Southern Systems, Inc.*, 742 F.2d 1388 (Fed. Cir. 1984), found that a case or controversy did not exist when the plaintiff had not produced a product (a device) at the time of the declaratory judgment counterclaim. However, an ANDA or 505(b)(2) applicant is engaged in ''producing'' a product at the time the ANDA or 505(b)(2) application is filed. Although 35 U.S.C. 271(e)(1) makes it an act of non-infringement to use a patented invention for uses related to submitting an ANDA or 505(b)(2) application (such as testing and producing sample batches of drug product), 35 U.S.C. 271(e)(2) expressly makes it an act of infringement to submit an ANDA or 505(b)(2) application seeking approval of the drug product before a patent expires. This statutory provision does not require that the NDA holder or patent owner receive formal notice of a paragraph IV certification for the submission of the application to be an act of infringement. Thus, unlike the plaintiff in *Jervis B. Webb Co.* v. *Southern Systems, Inc.*, the second element of the case or controversy test would be satisfied.

In another case cited in the comments, *Teva Pharmaceuticals, USA, Inc.* v. *FDA*, 182 F.3d 1003 (D.C. Cir. 1999), the court explained that a case or controversy did not exist in the underlying declaratory judgment action. There was no reasonable apprehension of suit—the first element of the case or controversy test—because the patent owner had disavowed an intent to sue. A disavowal of the intent to sue is an unusual circumstance that we do not expect to occur in many cases. In any event, the availability of a declaratory judgment action is less important when the innovator or patent owner disavows an intent to sue because the ANDA applicant will face less risk in marketing its competing product. We are not aware of any other Hatch-Waxman patent infringement case in which a court has found no reasonable apprehension of suit.

In response to the comments arguing that a single 30-month stay would create uncertainty regarding litigation and later-submitted patents, we note that a firm's inability to predict whether it will or will not be sued for patent infringement is a matter outside the scope of this final rule. A decision by the NDA holder or patent owner on whether to file suit for patent infringement may depend on many factors. For example, litigation decisions could be affected by the strength of the underlying patent, the party's resources, licensing agreements if the patented invention is made under a license, or other factors. We also note that some patent infringement suits may be initiated after the 45 day period available to obtain a 30-month stay has expired. The act only requires the initiation of a patent infringement suit within a specific time if the NDA holder or patent owner wishes to get the benefit of a 30-month stay in the approval of an ANDA or 505(b)(2) application; the NDA holder or patent owner can bring suit at a later time, but loses the opportunity to obtain a 30-month stay of approval.

In addition, there are various types of patents which must not be submitted for listing in the Orange Book. These patents are not subject to the certification, notice, and 30-month stay provisions. The fact that such patents must not be listed does not prevent the NDA holder or patent owner from defending those patents in litigation as it deems appropriate.

e. *Is the Correct Legal Interpretation Applied to Provide Only One 30-Month Stay*?

(Comment 19) Numerous comments challenged our proposed interpretation of the act to permit only one 30-month stay per ANDA or 505(b)(2) application. Some comments advanced a legal analysis different than the one we described in the preamble to the proposal to support a single 30-month stay. The comments asserted that their legal theories were either better than ours or were the only appropriate legal arguments possible.

In contrast, other comments maintained that section 505(j)(2)(B)(iii) of the act requires that notice be provided to the NDA holder and patent owner each time a new paragraph IV certification is added to an ANDA. These comments maintained that multiple 30-month stays are clearly required if the notices result in patent litigation. Several comments contended that the plain meaning of ''include'' or ''amended to include'' is to ''contain'' or ''comprise as part of a whole,'' and that our interpretation of section 505(j)(2)(B)(iii) of the act is not reasonable. The comments also argued that our interpretation of ''include'' in this provision differs from its use elsewhere in section 505 of the act. One comment stated that the meaning of ''include'' in sections 505(j)(7)(A)(ii) and (iii) of the act cannot be reconciled with our interpretation of that term in section 505(j)(2)(B)(iii) of the act. Section 505(j)(2)(B)(iii) of the act states that ''If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.'' The comment noted that section 505(j)(7)(A)(ii) of the act provides that the Secretary ''shall revise the list [Orange Book] to include each drug which has been approved . . . during the [intervening] thirty-day period'' and, when that updated drug information is recorded ''in revisions made under clause (ii), [shall] include such [patent] information for such drug.''

Several comments questioned whether the legislative history of the Hatch-Waxman Amendments supported our proposed interpretation of section 505(j)(2)(B)(iii) of the act. One comment contended that House Report language (see 67 FR 65448 at 65456) we had cited should be read as supporting multiple 30-month stays. The comments also argued that our interpretation failed to consider the importance of the final compromise that led to a 30-month, rather than 18-month, stay to ensure that patent litigation was resolved before a generic drug was approved. Finally, other comments criticized our failure to consider other language from a House Report that allegedly shows that Congress intended the availability of multiple 30-month stays. This language, found at H. Rept. 98–857, Part 1, 98th Cong., 2d Sess. at 28, states: ''In the case where the patent certification is amended in an ANDA to allege invalidity or non-infringement of a patent, the FDA may not make the approval effective within the 45 day period that an action for patent infringement may be brought.''

(Response) We agree that section 505(j)(2)(B)(iii) of the act can be read to permit multiple 30-month stays. Indeed, this has been our position since the enactment of the Hatch-Waxman Amendments. The proposal put forth a different interpretation, one that we believe is equally reasonable and more in line with the intent of the Hatch-

Waxman Amendments—to maintain a balance between the rights of the NDA holders and patent owners, and the desire to have more rapid availability of generic drugs. Our revised interpretation of section 505(j)(2)(B)(iii) of the act accomplishes two statutory objectives: (1) It closes a possible loophole that would have allowed ANDA applicants to avoid any 30-month stay and (2) it prevents multiple 30-month stays per ANDA application. A similar conclusion applies to the parallel provisions of section 505(b)(2) of the act.

We based our change in position on a reevaluation of the statutory text and concluded that the act is ambiguous on this issue of multiple 30-month stays. We note that certain other legal interpretations or theories may support a single 30-month stay, but we believe that the position we have taken in the final rule is the most appropriate.

The preamble to the proposed rule explained the rationale for our different interpretation (see 67 FR 65448 at 65454 to 65456). In brief, after reviewing the text of section 505(j)(2)(B)(i) through (iii) of the act, we believe that these provisions may be reasonably interpreted so that notice and the opportunity for a 30-month stay do not flow from all paragraph IV certifications. However, one notice of a paragraph IV certification and one full opportunity for a 30-month stay will always be required. This outcome—the opportunity for one 30-month stay during which patent rights can be litigated, but no multiple 30-month stays per ANDA or 505(b)(2) application to unreasonably delay approvals of competitor drugs—is a reasonable and balanced interpretation of the act.

We disagree with the comments that claimed that notice and 30-month stays are required only for paragraph IV certifications contained in original ANDAs because the notice provision at section 505(j)(2)(B)(ii) references only section 505(j)(2)(B)(i) of the act. This interpretation would eliminate the opportunity for a 30-month stay in any situation where an ANDA applicant waits until an amendment to submit a paragraph IV certification. As we explained in the proposed rule (see 67 FR 65448 at 65455 to 65456), section 505(j)(2)(B)(iii) of the act specifically requires ANDA applicants to give notice if they amend their applications to include their first paragraph IV certification. For these reasons, we do not interpret the act to require that only paragraph IV certifications contained in original ANDA applications will trigger the notice requirements and the possibility of a 30-month stay.

Our interpretation ensures that the NDA holder and patent owner will receive notice of at least one paragraph IV certification and have one full opportunity for a 30-month stay. However, we also disagree that every paragraph IV certification requires notice and an opportunity for a 30-month stay. We will require notice to the NDA holder and patent owner of a later paragraph IV certification if: (1) The ANDA or 505(b)(2) application did not previously contain a paragraph IV certification, but is amended to include a paragraph IV certification; or (2) a previous notice of a paragraph IV certification did not result in one full opportunity for the 30-month stay under the act.

This approach is consistent with the statutory language. By its terms, section 505(j)(2)(B)(i) of the act, and the nearly identical language applicable to 505(b)(2) applicants, requires that the ANDA applicant submitting a paragraph IV certification in its original ANDA ''include in the application'' that it will provide the required notice. Section 505(j)(2)(B)(ii) of the act sets forth the required content of the notice referred to in clause (i). Under section 505(j)(5)(B)(iii) of the act, we are prohibited from approving an application with a paragraph IV certification if an action has been brought within 45 days of the date the notice under section 505(j)(2)(B)(i) is received. The text of section 505(j)(5)(B)(iii) refers multiple times to ''the notice provided [or made] under paragraph (2)(B)(i).'' Thus, at a minimum, it cannot be said the statute clearly applies the notice requirement to all paragraph IV certifications, whether in original or amended ANDAs.

By contrast, section 505(j)(2)(B)(iii) of the act refers to amended, not original, ANDAs. It addresses the question of notice when an ANDA is amended to include a paragraph IV certification. Our interpretation eliminates the possibility that an ANDA applicant could evade any notice that could lead to a 30-month stay by omitting any paragraph IV certification in an original ANDA, and then later amending the application to include such a certification. By providing one full opportunity for the 30-month stay, we reduce the opportunity for intentional manipulation of the filing of paragraph IV certifications.

We do not agree that the act's language governing the operation of paragraph IV certifications, notice, and 30-month stays is clear and unambiguous. As the multiple interpretations advanced by the comments demonstrate, the statutory language may plausibly be read in different ways. It is certainly reasonable to interpret ''include'' as used in the act to mean ''contain.'' That is the meaning we understood the word to have when we issued the proposed rule (see 67 FR 65448 at 65455). Thus, it is a reasonable construction of the act to conclude that when an application is amended to contain a paragraph IV certification (when it did not previously contain such a certification), it is thus amended to include such a certification; and, that once an application contains such a certification, adding a new one does not amend or change the application to include or contain one, since it already contained such a certification. In any event, reliance on words in isolation is misplaced. As Judge Learned Hand observed, ''Words are not pebbles in alien juxtaposition; they have only a communal existence; and not only does the meaning of each interpenetrate the other, but all in their aggregate take their purport from the setting in which they are used * * *.'' *NLRB* v. *Federbush Co.*, 121 F.2d 954, 957 (2d Cir. 1941). Our interpretation of the 30-month stay provision is fully consistent with this principle.

We also reject the view that our interpretation of the statutory language ''amended to include'' is inconsistent with the use of the word ''include'' elsewhere in the statute. We do not agree that the use of ''include'' in section 505(j)(7)(A)(ii) and (j)(7)(A)(iii) of the act cannot be squared with our interpretation of that term in section 505(j)(2)(B)(iii) of the act. Sections 505(j)(7)(A)(ii) and (j)(7)(A)(iii) of the act, which relate to updating the Orange Book every 30 days to take into account drug approvals and patent listings, provide that the Secretary ''shall revise the list to include each drug which has been approved * * * during the [intervening] thirty-day period'' and when that updated drug information is recorded, ''in revisions made under clause (ii), [shall] include such [patent] information for such drug.'' That language requires publication of revisions to include something that was not previously contained in the Orange Book, i.e., approved drugs and patents that were not listed in the version of the Orange Book that existed immediately before the amendments were filed. The Secretary would publish nothing, under this statutory directive, if in the preceding 30 days, no new drugs were approved or patent listings filed. Similarly, when an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, when no such certification is contained in the

application prior to the amendment of the application, section 505(j)(2)(B)(iii) of the act applies. But when an ANDA or 505(b)(2) application contained a paragraph IV certification prior to the amendment and one full opportunity arose for a 30-month stay, no notice obligation is triggered for subsequent paragraph IV certifications.

We do not agree with the comment that the legislative history indicates that Congress changed the 18-month stay to a 30-month stay because it intended that patent litigation be resolved before a generic application could be approved. The House Judiciary Committee rejected an ''amendment [that] would have required that either the patent expire before approval, or that there be a final decision by a Federal District Court that the patent in question was not valid'' (see H. Rept. 98–857, Part 2, 98th Cong. 2d Sess., 9 (1984)). It appears that the amendment was rejected because the effect ''would have been to substantially delay generics from getting onto the market when they seek to challenge the validity of a patent'' (*id.* at 10). Congress explicitly rejected amendments to prohibit generic entry before judicial resolution of the patent issues prior to approval, but accepted a 30-month stay period, whether or not litigation was finally resolved, because, as a practical matter, it was believed the time period would not affect when generic manufacturers would begin to market their drugs (see 130 Congressional Record H9118 (September 6, 1984) (remarks of Rep. Waxman)).

We also believe that the legislative history quoted in the comments is ambiguous at most and can be interpreted in a way that does not undercut our changed interpretation. The report states: ''In the case where the patent certification is amended in an ANDA to allege invalidity or non-infringement of a patent, the FDA may not make the approval effective within the 45 day period that an action for patent infringement may be brought.'' Although this language does not distinguish explicitly between situations when an application already contained a paragraph IV certification and those when it did not, it would not be unreasonable to interpret it to apply only when invalidity or non-infringement of a patent is alleged for the first time. Language describing when an ANDA is ''amended * * * to allege invalidity or non-infringement of a patent'' can be read in another way as ''amended to include'' a paragraph IV certification. When an ANDA or 505(b)(2) application is amended to include an allegation of invalidity or non-infringement of a listed patent for the first time, we cannot approve the application for 45 days, and notification of the paragraph IV certification will be required. For additional paragraph IV certifications, when a patent has already resulted in a paragraph IV certification and a full opportunity for a 30-month stay, no notice is required and we do not need to wait for 45 days to approve an ANDA or 505(b)(2) application if it is otherwise ready for approval.

f. *Is There a Sufficient Basis to Adopt the Change in Legal Interpretation*? In the preamble to the proposed rule, we detailed the factual basis for our decision to reevaluate our legal interpretation of the maximum number of 30-month stays per ANDA or 505(b)(2) application (see 67 FR 65448 at 65455). We noted that our impression that multiple 30-month stays were increasing was confirmed by the FTC Report. In addition, the FTC Report found that there was an increase in submission of later-issued patents, many of which ''do not appear to claim the approved drug product or an approved use of the drug'' (*id.*).

(Comment 20) Several comments questioned the factual basis for what they called our ''dramatic change in position'' and argued that the information used in the FTC Report was already known to us. Since there was no ''new information,'' the comments maintained that the facts did not provide an ''adequate'' basis for our adoption of a single 30-month stay per ANDA or 505(b)(2) application.

(Response) We disagree with the contention that our factual basis underlying our rule was inadequate. At the outset, we note that the comments proceed from a false premise to a flawed conclusion. The ''newness'' of the underlying data is not the appropriate legal standard for evaluating the reasonableness of our different interpretation. An agency must consider ''the wisdom of its policy on a continuing basis'' ''with or without a change in circumstances'' (see *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863, 104 S. Ct. 2778, 2792 (1984); *Motor Vehicle Manufacturers Ass'n* v. *State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 57, 103 S. Ct. 2856, 2873 (1983)). Our pre-existing regulations permitting multiple 30-month stays have led to protracted delays in generic drug approvals and, therefore, need to be changed.

If ''newness'' of the underlying data were the test, the data here would satisfy it. Over the last several years, there has been an increasing number of multiple 30-month stays for a single drug product. These stays have caused significant delays in the approval of generic versions of frequently prescribed drugs. We anticipate that if we do not address the current situation, these multiple 30-month stays and resulting delays in generic drug approvals would continue to increase. There will be an increasing number of patents expiring in the next few years covering innovator drugs currently on the market. According to our records, over 500 drug patents will expire between 2003 and 2009. We have identified 26 top-selling drugs subject to patents with expiration dates between 2003 and 2005. These 26 drugs had combined 2001 retail sales exceeding $38 billion (over 25 percent of all 2001 prescription drug expenditures) and include 7 of the top 10 best selling drugs. The pressure on NDA holders and innovator companies to protect their market share and delay generic competition into the market will continue to increase. We would expect to see an increase in the conduct documented in FTC Report if our regulations remained the same.

The FTC's comprehensive and discerning analyses of the data it collected substantiated the seriousness of the problem. The FTC analyzed the relationship between patent listings and multiple 30-month stays, conducted an extensive review of various lawsuits involving multiple 30-month stays (including lawsuits in which we were not a party) and analyzed the outcome of the litigation. Although we provided some raw data to the FTC to assist its investigations (and thus that information was not ''new'' to us), we did not have all of the data that the FTC collected nor had we analyzed the data in the manner done by the FTC.

We have concluded that our regulations permitting multiple 30-month stays have led to considerable delays in the approval of generic drugs. This consequence was not intended either by Congress or by FDA. Thus, we have changed our regulations to address this problem.

B. Miscellaneous Comments

1. Do We Need Legislation to Accomplish Our Goals?

The preamble to the proposed rule did not discuss any legislative efforts to enhance the availability of generic drugs.

(Comment 21) Several comments said that legislation would be better than rulemaking or that we should support legislation. In general, the comments felt that legislation would:

- Better resolve intellectual property issues than our rule;

• Give us clear legal authority to act or be less vulnerable to judicial review; or,

• Result in timely and predictable access to generic drugs.

One comment noted that Congress had considered several bills to address 30-month stays. The comment declared that such proposed legislative action indicated both that we lacked authority to issue the rule and that new legislation was needed. Another comment suggested that we support legislation to allow only one 30-month stay and only for patents that are listed within 30 days of an NDA's initial approval.

(Response) We believe that, under our existing regulations, there have been delays in generic drugs reaching the market, as well as confusion over certain patent listing requirements. This rule is intended to help ensure that lower cost, safe and effective generic drugs become available to Americans without any inappropriate delays, while still preserving incentives to innovate. These changes can be achieved through rulemaking, using our existing legal authority. We cannot predict whether, if at all, legislation addressing these issues will be enacted. The possibility that there could be legislation to address problems associated with 30-month stays and generic drug approvals cannot, and should not, preclude us from using our existing authority to address these problems. We also note that those comments favoring legislative solutions over regulatory ones apparently assume that legislative changes would necessarily lead to less litigation than a rule. Based on our past experience in defending statutory interpretations, we question whether such a presumption is appropriate here. We recognize that a regulation may not always be a perfect solution due to limits on our statutory authority, but that recognition does not mean that we cannot use our existing legal authority to engage in rulemaking to improve our regulatory approach.

Additionally, we disagree with the comments that claimed we lack authority to issue the rule. The preamble to the proposed rule discussed our legal authority (see 67 FR 65448 at 65457). We will not repeat that discussion here. The fact that Congress has considered, or is currently considering, bills on the 30-month stay issue does not preclude us from exercising our existing authority, nor demonstrate that we presently lack that authority. As the Supreme Court has explained:

> We have stated * * * that failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute. Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that existing legislation already incorporated the offered change.
>
> (See *Central Bank of Denver* v. *First Interstate Bank of Denver*, 511 U.S. 164, 187 (1994).)
>
> (Citations and internal quotation marks omitted.)

Although it would be both inappropriate and premature for us to take a position on any legislative concept without seeing the details of any specific proposed or draft legislation, we are always willing to work with Congress. Until then, we will not take a position on legislation to allow only one 30-month stay for patents filed within 30 days after NDA approval.

2. Will the Different Interpretation Affect Existing Exclusivities?

We stated in the preamble to the proposed rule that the implementation of the final rule would not affect an ANDA's eligibility for 180-day exclusivity under 505(j)(5)(B)(iv) of the act (see 67 FR 65448 at 65457).

(Comment 22) Several comments addressed different aspects of the 180-day and 3 year exclusivity provisions of the Hatch-Waxman Amendments. The comments offered suggestions on changing the exclusivity trigger, requiring the forfeit of the exclusivity if parties agree to delay marketing and expressed concerns about the potential increase in the availability of 180-day exclusivity if we allow additional patents to be filed.

(Response) We appreciate the complexities of the various exclusivities provided by the act. As we noted in the proposed rule, eligibility for 180-day exclusivity will follow the same general principles as before implementation of this final rule. The first ANDA applicant to file a substantially complete ANDA, or supplement, containing a paragraph IV certification to a listed patent will be eligible for exclusivity as to that patent under section 505(j)(5)(B)(iv) of the act. For a paragraph IV certification to be effective for exclusivity purposes, when notice is required, notice must be given as described in the response to comment 13 of section II.A of this document. However, when notice is not required, a paragraph IV certification will be effective for exclusivity purposes without notice. We understand that each patent listed in the Orange Book may form the basis for a claim to 180-day exclusivity. Thus an increase or decrease in listed patents as a result of this final rule could affect the number of exclusivity periods. Other suggestions made in the comments are beyond the scope of the final rule. We are not altering our interpretation of exclusivity in the final rule.

3. Should the Provisions of the Final Rule Be Severable?

The proposed rule did not address whether each provision should be considered independent of other provisions and, thus, severable if any provision were determined to be invalid.

(Comment 23) Although there were no comments that directly addressed severability, one comment suggested that the limitation on multiple 30-months stays was unnecessary because the revised patent listing provisions would prevent improper patents from being submitted for listing in the Orange Book.

(Response) Although we agree that the changes to the patent submission and listing provisions and the information required on the declaration forms will help ensure that improper patents are not submitted for listing, we also believe that eliminating multiple 30-month stays will help maintain the balance intended by the Hatch-Waxman Amendments and is equally important to the final rule. Each of the final rule provisions reinforces interrelated goals. Clarifying that certain patents may not be submitted for listing should lead to the submission of fewer improper patents. Requiring additional patent declaration information from NDA applicants or holders or patent owners also should help ensure that only eligible patents are submitted. Eliminating the opportunity for multiple 30-month stays also should reduce incentives to submit improper patents.

Based on our past experience we acknowledge that the provisions of this final rule will neither completely resolve all issues governing patent submission, nor will they eliminate attempts to manipulate the final rule for market advantage. We also believe that each provision will reduce the opportunities for manipulation and, thus, is independently justified and worthwhile. However, we believe each provision stands on its own as a legal and practical matter.

From the comments we have received to the proposed rule, we believe there is a possibility that we will be challenged on various portions of the final rule. We expect we will prevail in any such challenge, as the final rule and each of its provisions is legally sound. If, however, a court should conclude that any one or more provisions of the final

rule is invalid, we wish to emphasize our intent that the remaining provisions of the final rule be permitted to take effect.

4. Implementation and Effective Date

The preamble to the proposed rule described how a final rule would be applied to pending applications (see 67 FR 65448 at 65457) as follows:

• For patents filed for an NDA that has not been approved by the effective date of a final rule, the rule would apply on the effective date. For example, if the final rule were to become effective 60 days after the date of publication in the **Federal Register**, and an NDA was pending on the 60th day after the final rule's publication date, the NDA applicant would have to comply with the final rule's patent listing and patent declaration requirements. ANDA and 505(b)(2) application applicants would be subject to the revised notice requirement. Each ANDA or 505(b)(2) application referencing that NDA would be subject to the possibility of only one 30-month stay per ANDA or 505(b)(2) application.

• If we have approved the NDA as of the final rule's effective date, and no ANDA has been filed before that date, then any patent listed before that date would be subject to the pre-existing regulation. For example, if the final rule were to become effective 60 days after the date of publication in the **Federal Register**, and we approved the NDA on the 59th day after the date of publication, the NDA applicant would not have to amend its patent listing and patent declaration to comply with the final rule. ANDA and 505(b)(2) applications submitted after the effective date would be subject to the revised notice requirement. Each ANDA or 505(b)(2) application referencing that NDA would be subject to the possibility of only one 30-month stay per ANDA or 505(b)(2) application.

• If we have approved the NDA as of the final rule's effective date, and an ANDA or 505(b)(2) application has been filed before that date, then any patent listed before that date would be subject to the pre-existing regulations, as described in the example immediately above. The ANDA or 505(b)(2) application applicant would have to provide notice to the patent owner and NDA holder if the ANDA or 505(b)(2) application contained a paragraph IV certification. Multiple 30-month stays in the approval date would be possible.

• If the NDA holder or NDA applicant files patent information after the final rule's effective date, then the NDA holder or applicant is subject to the final rule's patent listing and patent declaration requirements, and ANDA or 505(b)(2) application applicants would not have to provide notice if their applications previously contained a paragraph IV certification. Only one 30-month stay per each ANDA's or 505(b)(2) application's approval date would be possible.

We invited comment on how a final rule should be implemented.

(Comment 24) Several comments suggested alternative effective dates including the following:

• Apply the final rule to all ANDAs filed before the effective date of the final rule and cancel any existing multiple 30-month stays;

• Apply the final rule retroactively to all current NDA holders by requiring all NDA holders to be subject to only one 30-month stay and apply the declaration provisions to require all current NDA holders or patent owners to file a new declaration and certification for already listed patents using the declaration statement in the proposal;

• Apply the new declaration requirements retroactively to require the new information on patents currently listed in the Orange Book; if the propriety of a patent listed in Orange Book for a current NDA holder or patent owner is questioned, the NDA holder or patent owner must file a new declaration or FDA should delist the patent.

In contrast, other comments supported the implementation plan as proposed.

(Response) We will implement the final rule on a prospective basis, as we stated in the proposed rule. The fact that we made our intent public in a proposed rule and the time lag between when the rule was proposed and when this final rule is effective provides sufficient time for most parties to adjust their practices and expectations, or to take other steps to suit their business practices.

We do delay the implementation date for submission of information concerning a patent claiming a polymorph that is the active ingredient of the drug product described in the approved NDA. We provide a longer period of implementation to accommodate the tests required to establish that the drug product containing the polymorph will perform the same as the drug product described in the NDA. This test data must exist when a polymorph patent is submitted to us. We recognize that the testing necessary to obtain the data for submission of polymorph patents claiming the active ingredient of the product described in the NDA may take at least 6 months to complete. There will be NDA applicants and holders and patent owners who have not already conducted testing. The 6 months will provide time for NDA applicants and holders and patent owners with patents pending at the PTO to conduct the tests needed to produce the data required for the declaration statement in time to submit any newly issued patent within 30 days of issuance.

We also decline to apply the final rule retroactively. If we canceled all multiple 30-month stays currently applicable to ANDAs and 505(b)(2) applications or applied the declaration requirements to already submitted patents for existing NDAs, we would be applying the provisions retroactively. As we noted in the proposal (67 FR 65448 at 65457): ''If we were to adopt an alternative implementation plan, we would risk upsetting legitimate expectations held by those who had relied on our earlier interpretation of the act.'' As a general matter, a statutory grant of legislative rulemaking does not encompass the power to implement such regulations on a retroactive basis in the absence of express language granting such power (see *Bowen* v. *Georgetown University Hospital*, 488 U.S. 204, 208–09 (1988)). There is no question that this rule ''changes the legal landscape'' (see *National Mining Ass'n* v. *Department of Labor*, 292 F.3d 849, 858 (D.C. Cir. 2002)). Applying this rule retroactively would subject us to potential legal challenge. Thus, adopting these suggestions would lead to even greater uncertainty as to the applicability of the provisions.

After further consideration, however, we believe that the proposed rule's implementation plan will not fully effect our intent to implement the provisions only prospectively. Accordingly, as described in section IV of this document, we have clarified our implementation plan to ensure prospective application of the final rule. Nevertheless, patent owners may voluntarily complete, and NDA holders may voluntarily complete and submit, new patent declarations, using FDA Forms 3542 and 3542a, for patents not subject to the final rule and currently listed in the Orange Book. This course is particularly advisable for method-of-use patents, in light of the *Purepac* decision and concerns about implementation of section 505(j)(2)(A)(viii) of the act. Such voluntary submission of new patent declarations will not bring patents within the scope of the final rule with respect to notice and 30-month stays.

III. Description of the Final Rule

A. Section 314.53(b)—What Patents Must Be Submitted?

1. Which Patents Would the Final Rule Require To Be Submitted?

Section 314.53(b) describes the patents for which information must be submitted. The final rule states, in relevant part, that information must be submitted on the required declaration forms for each patent that claims the drug or a method of using the drug that is the subject of the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. The patents include patents that claim:

- The drug substance (active ingredient),
- The drug product (formulation and composition), and
- A method of use.

Those patents that claim a different polymorphic form of the drug substance that is the active ingredient described in the NDA must be submitted if the applicant has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. The drug product (formulation and composition) patents submitted must claim the specific drug product described in the pending or approved NDA. For patents that claim a method of use, the NDA applicant or holder must submit only those patents that claim indications or other conditions of use that are the subject of a pending or approved application. Each pending or approved method of use and related patent claim must be described.

2. What Patents Must Not Be Submitted?

Section 314.53(b), as finalized, states that information on patents claiming packaging, patents claiming metabolites, and patents claiming intermediates must not be submitted. Process patents also must not be submitted. The final rule clarifies that the prohibition on submission of packaging patents does not apply to patents that claim the drug product as defined in § 314.3. If a patent claims the finished dosage form of the drug product, it must be submitted for listing.

B. Section 314.53(c)—What Does the Patent Declaration Say?

Section 314.53(c)(1) describes the general requirements for submission of patent information and the conditions for acceptance of the patent information. Section 314.53(c)(2)(i) requires a person submitting an NDA, an amendment, or a supplement, to submit an original signed declaration form as part of its submission of patent information. The appropriate declaration form must be used for submitting patent information. The information required to be submitted is described. Each form seeks specific patent information and requires a signed attestation from the NDA applicant or holder or patent owner that the information is accurate and complies with the requirements of the regulations.

Section 314.53(c)(2)(ii) requires that the NDA holder submit a declaration form with information relating to the approved NDA and additional information on use codes within 30 days of NDA approval. The information required to be submitted is described. Each form includes specific patent information and requires a signed attestation from the NDA holder or patent owner that the information is accurate and complies with the requirements of the regulations. This section also requires submission of information on patents submitted for listing after NDA approval. This declaration form is the only declaration form that we will rely on to determine whether a patent is eligible for listing based on the patent information submitted.

C. Section 314.53(c)(3)—What Is Required to Be Filed If There Are No Relevant Patents?

The final rule modifies the statement used to describe the fact that the NDA applicant or holder believes there are no relevant patents to be submitted. The language is changed to conform to the descriptions used for drug substance (active ingredient), drug product (formulation and composition) and method of use to those used in the other regulatory provisions.

D. Sections 314.95(a) and 314.52(a)—When Are Notice and Certification Required?

The final rule modifies §§ 314.95(a) and 314.52(a) to state that, if an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, notice must be provided to the NDA holder and patent owner only if the application did not already contain a paragraph IV certification or there was not a full opportunity for a 30-month stay. If an ANDA or 505(b)(2) applicant changes its paragraph IV certification before the 45-day period after notice to the NDA holder and patent owner has expired, and the NDA holder or patent owner has not initiated patent litigation, such paragraph IV certification and related notice are not considered to have satisfied the requirement of providing one notice of a paragraph IV certification and a full opportunity for a 30-month stay.

IV. Implementation

The final rule will be effective on August 18, 2003.

- Patent information submitted to us (FDA) before the effective date will be subject to our pre-existing regulations governing patent submission, declarations, certifications, notice and availability of 30-month stays;
- Patent information submitted to us on or after the effective date will be subject to the final rule's provisions governing patent submission, accompanying declarations, certifications, notice and availability of 30-month stays;
- Patent information submitted to us on a newly applicable claim, even if the patent was previously submitted to us, will be subject to the final rule's provisions.

The final rule will have a compliance date of December 18, 2003, for patent information submitted to us on patents claiming a polymorph of the same active ingredient of the product described in the NDA.

As a result, within a single same approved or pending NDA, some patents may be subject to our pre-existing regulations while other patents may be subject to the final rule. The date on which the patent information was submitted to us will determine which set of regulations applies.

We believe that the effective dates will provide adequate time for the NDA applicants, NDA holders, and patent owners to adjust their business practices. The patent information required for submission is information readily available to the NDA applicants and holders and patent owners.

We have delayed the implementation date for patent information to be submitted to us on patents claiming a polymorph that is the active ingredient of the drug product described in the approved NDA. NDA applicants and holders and patent owners with patents pending at the PTO will have additional time (i.e., until 6 months after the date of publication in the **Federal Register**) to conduct the tests needed to produce the data required for the declaration statement in time to submit any newly issued patent within 30 days of issuance.

V. Legal Authority

Our principal legal authority for the final rule is section 505 of the act, in

conjunction with our general rulemaking authority in section 701(a) (21 U.S.C. 371) of the act. Section 505(b) and (c) of the act describes the contents of an NDA and 505(b)(2) application, including the patent submission and patent certification requirements. Section 505(j) of the act describes the contents of an ANDA, including patent certification requirements. Sections 505(b)(2)(A) and 505(j)(2)(A)(vii) of the act, respectively, require patent certifications, while sections 505(b)(3) and 505(j)(2)(B) of the act require those applicants who have made a paragraph IV certification to provide notice to the NDA holder and patent owner.

The final rule clarifies the types of patents which NDA applicants and NDA holders must and must not submit to FDA for listing in the Orange Book. It also requires a more detailed patent declaration from NDA applicants and NDA holders or patent owners using declaration forms. The specific legal authority for each provision is set forth in the preamble discussion accompanying it.

For ANDA and 505(b)(2) applicants, the final rule reduces the number of notifications sent to patent owners and NDA holders. The specific legal authority for this action is set forth in the preamble discussion of our changed interpretation.

VI. Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Executive Order 13132: Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this final rule does not contain policies that 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. Accordingly, we have concluded that the final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We describe these provisions below in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed

Description: The final rule clarifies the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment or supplement. The final rule also requires persons submitting an NDA, amendment or supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using required FDA declaration forms. The final rule permits the possibility of only one 30-month stay per each ANDA or 505(b)(2) application's approval date in the event of patent infringement litigation because the final rule does not require ANDA or 505(b)(2) applicants to provide a notice of certification of invalidity or noninfringement of a patent if the application already contains such a certification or if a full opportunity for a 30-month stay resulted after such notice.

Description of Respondents: Persons submitting an NDA, amendment or supplement, or submitting information on a patent after NDA approval, and persons submitting an ANDA or 505(b)(2) application containing a patent certification of invalidity or noninfringement of a patent.

We estimate the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
314.50(a) through (f), (h), and (k) (citing 21 CFR 314.53) FDA Forms 3542 and 3542a	107	2.8	296	1,684	498,464
314.50(i)(1)(i) and 314.94(a)(12)	74	1.5	111	4	444
314.52(a)(3) and 314.95(a)(3)	74	1.01	74	12	897
Total					499,805

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following assumptions. For the years 1998 to 2002, the annual number of original applications we have received containing a paragraph IV certification has been 61, 58, 79, 90, and 82, respectively. The annual average is 74 ((61 certifications + 58 certifications +79 certifications + 90 certifications + 82 certifications) / 5 years = 74 certifications / year). Because the final rule requires notice of a paragraph IV certification filed in the original ANDA or 505(b)(2) application or when the application is amended to include a paragraph IV certification or when such notice did not provide a full opportunity for a 30-month stay, this would mean that these applicants would provide one notice to NDA holders and patent owners, and, in rare instances, a second notice. We increase the frequency of response to account for these rare second notices. There may still be multiple certifications made by ANDA or 505(b)(2) applicants which will not require notice. In previous estimates, we have combined the information collection burden for both the notice and certification. For purposes of the final rule, we assume that the certification information collection burden is 4 hours and the information collection burden for the notice is 12 hours. We also account for the multiple number of certifications that may have to be provided by an ANDA or 505(b)(2) applicant. Under pre-existing regulations, we have had

NDA holders submit two or more patents for a single NDA. While this may continue to occur, we believe that this final rule may reduce the number of patents submitted for listing because we have clarified the type of patents that must be submitted. The number of patents submitted could increase because we allow polymorph patents to be submitted or it could decrease if no test data exist to demonstrate that a drug product containing the polymorph will perform the same as the drug product described in the NDA. We, thus, estimate the number of annual certifications at 1.5 x 74 (the number of original certifications). Thus, the information collection burden for §§ 314.50(i)(1)(i) and 314.94(a)(12) (certifications) would be 444 hours (74 respondents x 1.5 response per respondent x 4 hours per response = 444 hours). The information burden for §§ 314.52(a)(3) and 314.95(a)(3) (notices) would be 897 hours (74 respondents x 1.01 response per respondent x 12 hours per response).

To estimate the number of enhanced patent declarations that will be submitted annually, we referred to historical data on patent submissions. For the years 1998 to 2002, the numbers of patents submitted to us were 159, 205, 321, 280, and 268 respectively, for an annual average of 246.6 ((159 patents +205 patents +321 patents+280 patents+268 patents) / 5 years = 247 patents / year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our review of submissions, we believe the number of duplicate patent listings to be 20 percent of the number of unique patents. Therefore, we estimate 49.2 (246.6 patents x 20 percent) patent declarations will be multiple listings, and there will be 296 (247 declarations + 49 declarations = 296 declarations) total annual patent declarations. As we received 115 and 99 NDAs in 2000 and 2001, respectively, we assume there will be 107 ((115 applications + 99 applications) / 2 years = 80 applications / year) instances where an NDA holder would be affected by the patent declaration requirements and that each of these holders would, on average, submit 2.8 (296 declarations / 107 instances = 2.8 declarations per instance) on FDA Forms 3542 or 3542a.

However, § 314.53(b) and (c) have different impacts on the hours per response. On the one hand, § 314.53(b) might decrease the reporting burden because it would specify certain patents that must not be submitted, and thus NDA applicants and holders and patent owners will not submit information on those patents. On the other hand, § 314.53(b) will require NDA applicants and holders or patent owners to submit patent information on different forms of the active ingredient described in the NDA, and this could result in more patent information being submitted or less patent information if test data do not exist to demonstrate that a drug product containing the polymorph will perform the same as the drug product described in the NDA. We cannot determine whether the potential net effect will increase, decrease, or not change the overall burden associated with submitting patent information, so we have not assigned any change in the total reporting burden for the change in patent information alone.

In contrast, § 314.53(c) makes the patent declaration more detailed. The change in the declaration will increase the burden hours per response under § 314.50(h) (the provision under which we covered patent declarations described in § 314.53(c)) because respondents will be required to be more precise in their declarations. Based on other rules that require respondents to compile and submit information in their possession, we estimate that the information required to be submitted on the patent declaration forms, FDA Forms 3542 or 3542a, will result in an additional information collection burden of 18 hours. However, the previous burden hour estimate of 1,666 hours for § 314.50 covered paragraphs (a) through (f), in addition to paragraphs (h) and (k) (see 66 FR 29143 at 29146, May 29, 2001). We are unable to determine how many of the 1,666 hours were devoted to patent declarations, so, in this table, we simply add 18 hours to the 1,666 hour estimate for § 314.50(a) through (f), (h), and (k), resulting in a burden hour estimate of 1,684 hours (1,666 hours + 18 hours) to account for a respondent's need for more time to make and verify the patent declaration. Thus, the information collection burden for § 314.50(a) through (f), (h), and (k)(citing § 314.53) will increase from the estimate we made in the proposed rule of 209,560 hours to 498,464 hours (296 annual responses x 1,684 hours per response = 498,464 hours).

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

IX. Analysis of Economic Effects

We have examined the impacts of the rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). 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). Unless the agency certifies that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by the Small Business Regulatory Flexibility Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Section 202 of UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in expenditures by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). We have conducted analyses of the rule, and have determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes.

The final rule is a significant regulatory action as defined by the Executive Order. With respect to the Regulatory Flexibility Act, we certify that this final rule is not expected to have a significant impact on a substantial number of small entities. This regulatory action is also a major rule under the Congressional Review Act. The discussion of costs and benefits is consistent with the requirements of the UMRA.

A. Summary

The economic impacts arise from a variety of effects of this rule. The primary effect is the elimination of multiple 30-month stays, which (as explained earlier) will result in earlier market entry by generic drug manufacturers without appreciable effects on pharmaceutical innovation. Earlier generic competition will result in gains for two groups. It will reduce pharmaceutical prices to consumers and increase net revenues of generic drug manufacturers. Earlier competition also

will result in a revenue loss for innovator drug companies, which will be offset slightly by a reduction in associated costs. We believe that the rule will also reduce legal fees associated with disputed patents, although we are unable to provide quantitative estimates of this effect. In addition, innovator drug companies will face a burden of completing revised patent declaration forms. Finally, those NDA holders wishing to submit patents claiming different polymorphs of the active ingredient described in the NDA will need to have test data demonstrating ''sameness.'' Table 2 below provides a summary of our estimates of these effects and overall net benefits. The benefits and costs are annualized at a 7-percent discount rate over 10 years. We have chosen this time period because the Centers for Medicare and Medicaid Services (CMS), the source of the most reliable pharmaceutical expenditure estimates, projects these expenditures only for the next 10 years. We expect that this rule will generate substantial net benefits beyond this time period.

TABLE 2.—ECONOMIC EFFECTS OF THE RULE[1]

Effects	Amount per year (millions of dollars)
Gains	
•Savings to consumers	3,290
• Net revenues to generic manufactures	1,810
•Reduced legal costs	Not quantified
Losses	
• Revenue loss to innovator firms (net of associated costs)	4,870
• Costs of patent declarations and data to support polymorph patent submissions	<10
Net Benefits	220

[1] Gains and Losses include impacts of an economic transfer in addition to changes in resource costs.

These estimates are derived using methods and data similar to those described at more length in the preamble to the proposed rule published in the **Federal Register** on October 24, 2002 (*see* 67 FR 65448 at 65459 to 65464). In that analysis, we found that the increase in revenues to generic drug manufacturers would be $19.117 billion over 10 years, or $1.8 billion per year if annualized assuming a 7-percent discount rate. The benefit to consumers would be $34.822 billion over 10 years or an annualized $3.3 billion. We found that the reduction in revenues to innovator firms would be mitigated somewhat by the reduction in marketing expenses and that the cost would be $51.508 billion over ten years, or an annualized $4.9 billion. The 10-year net benefit is $2.356 billion, and the annualized net benefit is approximately $220 million.

With respect to the changes in market shares, the gains to consumers and generics equal the losses to innovators. An uncertainty estimate on the cost side would equal the uncertainty on the benefit side of such a transfer and would not affect our projection of net benefits. Our projection of net benefits is driven by our estimate of support costs. The primary economic impact of this action is a transfer from innovator drug firms to consumers and generic drug firms. But as innovator drug firms face a decline in revenues, they will save substantial resources used to support their products. These support costs, which include marketing, advertising, and administration, outweigh the costs associated with polymorph testing and completing the revised declaration, so the rule is a net benefit. These support costs are based on a point estimate provided by literature that does not customarily provide confidence intervals. We cannot, therefore, provide confidence intervals about our net benefit estimate, but believe the uncertainty to be small, relative to the projected net benefit.

We received no comment on the analysis published with the proposal. We continue to believe these estimates to be reasonable and include them in the final rule. This final rule, however, contains provisions that differ from what was in the proposed rule. To account for these provisions, we have changed our analysis of the burden of providing the information required for completing the patent declaration and we assess the impact of the requirement that NDA applicants or holders or patent owners submitting patents claiming different polymorphs of the active ingredient described in the NDA. In all other major respects, however, our analysis is unchanged from the proposal, so we do not repeat here some parts of our analysis that were described in detail in the proposal (see 67 FR 65448 at 65459 to 65464).

B. Benefits of the Regulation

We have identified two principal effects from the elimination of 30-month stays. These effects are impacts associated with parties gaining in economic transfer. Generic drug manufacturers gain the market share lost by innovators. Generic revenues, therefore, would be expected to increase. Also, to the extent that these generic drugs are less expensive than innovator drugs, consumers will benefit from saving money as a result of earlier access. Our model, as described in the proposed rule (see 67 FR 65448 at 65460 to 65462), estimates costs and benefits to consumers and innovators and generic drug firms for the first year the rule would be in effect. The projected changes in market shares and prices in the model are based on studies published in the economic literature and by FDA. We then escalate the 1-year estimates by the CMS—projected annual percentage increases in prescription drug expenditures to obtain estimates for 10 years. This 10-year stream is then annualized at a 7-percent discount rate to obtain the annualized estimate.

1. Gains to Consumers

Generic drugs are cheaper than their innovator counterparts. As a generic drug gains market share and its price falls, consumers save more money. The elimination of multiple 30-month stays per ANDA and 505(b)(2) applications and earlier market entry by generic drugs will reduce consumer expenditures on pharmaceuticals. We estimate that the 1-year savings to consumers are projected to be $2.040 billion. We use the CMS pharmaceutical expenditure projections to escalate the base year figure results in a 10-year consumer savings estimate of $34.822 billion for the final rule. Our annualized benefit using a 7-percent discount rate is $3.288 billion, the same as the proposed rule.

2. Gains to the Generic Drug Industry

Innovator market share erosion is accompanied by a gain in generic market share. We estimate the 1-year increase in revenues to be $1.120 billion. Escalating this impact by the annual increases in pharmaceutical expenditures yields a 10-year revenue gain of $19.117 billion. Our annualized impact using a 7-percent discount rate is $1.805 billion. These estimates are the same as in the proposed rule.

3. Benefits Not Quantified

Many important benefits associated with this final rule are difficult to quantify. The benefits to consumers from lower prices also involve favorable secondary benefits from improved access to less expensive drugs. While the economic literature indicates generic competition does not lead to significant overall increases in the quantity of drugs demanded, we nevertheless recognize this rule has favorable distributional effects for consumers who otherwise may not have been able to afford some medications. Such a benefit is consistent with the objective of improving access to affordable quality healthcare. Consumers with better access to affordable safe and effective therapies are healthier and enjoy a higher quality of life.

By addressing multiple 30-month stays, this final rule is removing a barrier to entry for generic drug firms. In principle, the removal of a barrier to entry would imply an increase in economic efficiency. The existing economic literature, however, indicates no significant increase in the quantity of drugs demanded with generic entry, implying no gain in efficiency from the removal of the barrier to entry. Thus, we do not quantify any efficiency gains in our analysis. Nevertheless, this rule encourages more and earlier market entry by generic drug firms and may impact consumption in a way not captured by the economic literature. To that extent, we believe this rule has the potential to increase economic efficiency.

The costs of allocating legal resources to defend patent protections are substantial. We do not know the extent to which this final rule will reduce such costs, but by eliminating multiple 30-month stays per ANDA and 505(b)(2) application, we are reducing the number of instances where innovator and generic drug firms would engage in such litigation. Moreover, we believe that this rule will reduce litigation because it clarifies which patents must and must not be submitted and reduces incentives for submitting patents that may ultimately be found invalid. It logically follows that the reduction in resources devoted to litigation would result in savings to both innovator and generic drug firms.

This final rule reduces the level of uncertainty associated with drug marketing decisions. For example, the final rule diminishes incentives associated with submitting later-issued patents late in the patent life or exclusivity period of the product described in the NDA. Increasing the predictability of the generic drug entry process reduces product introduction costs faced by generic drug firms. In the final rule, we are also addressing a source of confusion over the submission of polymorph patents for listing in the Orange Book. We believe that a more predictable business environment benefits both innovator and generic drug firms.

Another important benefit of the final rule involves the balance between rewarding innovation and the availability of less expensive drugs. In striking this balance, we do not believe that the Hatch-Waxman Amendments intended to create the potential for NDA holders to obtain multiple 30-month stays to unduly delay generic competitors. We believe this balance to be important, yet find the value difficult to quantify. Nevertheless, in addressing the issue of multiple 30-month stays, we believe this action has the very valuable benefit of preserving the balance struck in the Hatch-Waxman Amendments.

4. Total Benefits of the Regulation

The total quantified benefits of this final rule include the gains in generic drug manufacturer revenues and consumer savings from earlier access to less expensive pharmaceuticals. These quantified gains to consumers and generic drug companies are the result of an economic transfer. The 1-year benefits to generic drug manufacturers and consumers are $1.119 billion and $2.040 billion, respectively. Escalating these base year costs over 10 years yields generic drug manufacturer revenue gains of $19.117 billion and consumer savings of $34.822 billion, for a total of $53.940 billion. The 10-year annualized benefits, using a 7-percent discount rate, are $1.805 billion for generic drug manufacturers and $3.288 billion for consumers, for a total of $5.093 billion.

C. Costs of the Regulation

In the proposed rule, we identified two sources of costs. Innovators lose revenues from earlier generic competition and innovators must complete patent declarations. The loss in revenues to innovator drug companies is part of an economic transfer, but is included in this analysis with the resource costs associated with this action. We summarize the revenue loss and we assess the costs associated with the declaration requirement. In addition, we estimate the burden to industry from the requirement that, for submission of patents claiming different polymorphs of the active ingredient described in the NDA, there must be test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.

In the proposed rule, we addressed potential concerns about the effect this action may have on innovation. After considering potential impacts, we concluded that any negative effect would be minimal. As discussed in the proposed rule, while the initial 30-month stay is part of the balance struck in the Hatch-Waxman Amendments to reward innovation, the subsequent stays are not part of this balance. According to the FTC report, most of the court rulings examined by the FTC, which involved a subsequent 30-month stay, found the underlying patent to be either invalid or not infringed. Extending market exclusivity through multiple stays is a strategy that has become popular in the last few years and is not a longstanding source of research funding. Subsequent stays could actually hinder innovation through the replacement effect, in that they provide a disincentive for an NDA holder to improve upon its own product. Moreover, to the extent that subsequent 30-month stays might be associated with increases in spending on research, these increases do not necessarily improve social welfare (see 67 FR 65460). We received no comment on our assessment of the impact on innovation and continue to believe it to be reasonable.

1. Innovator Revenue Loss

As discussed in the analysis of impacts in the proposed rule, the elimination of multiple 30-month stays per ANDA or 505(b)(2) application allows generic drugs to enter the market earlier. Upon entry, generic versions of an innovator drug gradually lower their prices and take market share from the innovator. With the loss of market share, innovator revenues are lower than they would be had the innovator been allowed to use multiple 30-month stays to delay generic entry. In the analysis in the proposed rule, we used data from instances where generics had been blocked with multiple 30-month stays and calculated the impact of a typical

drug being blocked for a typical period of time. We estimated the 1-year loss in innovator revenues to be $3.160 billion. As discussed in the proposed rule, we believe that the negative impact on innovators from earlier generic competition will be mitigated somewhat by a reduction in required innovators' costs. With earlier generic competition, innovators will reduce marketing expenses. In the proposed rule, we estimated the 1-year reduction in support costs to be approximately $142 million. For the final rule, we estimate that the 1-year loss in revenues, after adjusting for the reduction in support costs, is $3.017 billion, the same as in the proposed rule.

2. Declaration Costs

In the proposed rule, we used earlier information collection data to estimate there will be 124 annual patent declarations by innovator firms. We now believe that the number of patents submitted to us each year would better estimate the annual number of patent declarations. For the years 1998 to 2002, the numbers of patents submitted to us were 159, 205, 321, 280, and 268 respectively, for an annual average of 246. We understand that many of these individual patents are included in multiple NDA submissions, so there could be multiple declarations for a single patent and this method could underestimate the number of declarations. From our review of submissions, we believe the number of duplicate patent listings to be 20 percent of the number of unique patents. Therefore, we estimate 49.2 (246.6 x 20 percent) patent declarations will be multiple listings, and there will be 295.8 (246.6 + 49.2) annual patent declarations. We have created patent declaration forms to make the submission of patent information less burdensome. The two forms, for filing with an NDA submission and upon or after NDA approval, will contain more information, but we have simplified the format to make these easier to complete. In simplifying the forms, we believe our initial estimate of 24 additional hours per declaration to complete these forms likely overstates the actual burden. To account for the simplification of the declaration process, we have lowered the expected time required to complete a patent declaration to 18 hours.

A regulatory affairs specialist could perform the tasks associated with this process. Based on the total average hourly compensation of $55.14[2] the estimated cost would be $992 ($55.14 per hour x 18 hours) per event. The burden on individual firms would depend on the number of declarations they submit. We estimate that the 1-year burden for submitting patent declaration forms is $293,000 ($992 per event x 295.8 events).

3. Cost of Submitting Polymorph Patents

We are requiring the submission of patent information for patents that claim different polymorphs of the active ingredient described in the NDA. NDA holders will now be able to submit these polymorph patents for listing in the Orange Book, as long as they have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.

We cannot make a precise estimate of the impact of these requirements, as costs can vary substantially depending on the substance being tested, the number of subjects required, the cost of raw materials, and other factors. As part of an unrelated study in 1998, we commissioned a contractor, Eastern Research Group (ERG) to estimate the cost of bioequivalence testing. We believe the burden of demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA to be similar to that of demonstrating bioequivalence. Our estimates include both the cost of manufacturing the batch and the cost of conducting the bioequivalence testing. ERG found the cost of performing such testing to be between $70,000 and $750,000.[3] We believe the cost of showing ''sameness'' to be at the higher end of this range, and estimate the burden to be between $500,000 and $750,000. The midpoint of this estimate is $625,000. (We did not adjust the ERG estimates for inflation.)

We believe a firm's decision to submit a polymorph patent for listing will depend on whether the expected benefits to the firm from listing exceed the costs of showing ''sameness.'' We recognize that potential benefits from listing polymorph patents may be reduced by the elimination in the final rule of multiple 30-month stays in approval of ANDA or 505(b)(2) applications. Thus, the cost of demonstrating ''sameness'' would deter submitting patents for listing with expected values less than approximately $625,000. We believe the typical value of a deterred polymorph patent to be substantially less than the cost of submission of the patent for listing, as many of the patents have little value without the ability to delay generic entry through multiple 30-month stays. For this analysis, we assume such low value patents to be worth approximately 20 percent of the cost of showing ''sameness,'' or $125,000.

We believe the annual number of polymorph patents that will be submitted for listing to be small, but we do not know with certainty. We reviewed a publicly available listing of NDAs in which an outside party had identified patents it judged to be polymorph patents. Of the 105 NDAs in the sample, there were 13 polymorph patents. Applying that same ratio to the 107 expected NDAs per year, we estimate 13.2 (107 x 13 / 105) potential polymorph patents to be submitted for listing per year. We assume that a polymorph patent will have a high potential value (greater than $625,000—the midpoint of the testing cost estimates) and be submitted, or will have a low potential value ($125,000) and not be submitted. With the elimination of multiple 30-month stays per ANDA or 505(b)(2) application, we believe the number of high-value polymorph patents to be a subset of the number of total polymorph patents, and assume three-fourths of the potential patents will not be submitted for listing. Thus, we assume 3.3 (13.2 potential patents x 0.25 likelihood of being high value) patents will be submitted for listing at a 1-year cost of $2.06 million (3.3 patents x $625,000 cost per patent). Likewise, we assume 9.9 (13.2 potential patents x 0.75 likelihood of being low value) patents will not be submitted each year. We estimate the 1-year cost from the inability to submit these patents for listing to be $1.24 million (9.9 patents x $125,000 value of low-value patent) and the 1-year burden associated with the test data demonstrating ''sameness'' for polymorph patents to be submitted for listing is estimated to be $3.3 million ($2.06 million + $1.24 million).

4. Total Costs of the Regulation

The total costs of the final rule include the lost revenues to innovator firms from the erosion of market share, mitigated by the decrease in support costs, the cost of completing a more detailed patent declaration, and the costs associated with the requirement that test data exist demonstrating ''sameness'' in order to submit a polymorph patent for listing. The estimated 1-year loss in revenues from

[2] The figure of $55.14 represents the hourly rate for ''lawyer'' from the Bureau of Labor Statistics 2003 National Compensation Survey of $38.77, and then adjusted for inflation at 1.58 percent (unadjusted CPI–U) and increased 40 percent to account for benefits.

[3] Pharmaceutical Industry Cost Savings Through Use of the Scale-up and Post-Approval Change Guidance for Immediate Release Solid Oral Dosage Forms (SUPAC–IR), prepared for FDA, 1998, p. 63.

erosion of market share is $3.160 billion and the reduction in support costs would reduce this loss by $142 million. We estimate the 1-year cost of providing the patent declaration information by completing the patent declaration forms is $293,000 and the cost associated with polymorph patents is $3.3 million. Thus, we estimate the 1-year cost to innovator firms is $3.022 billion.

We recognize that in projecting the future impact of this final rule, we must account for changes in the market for pharmaceuticals. The Office of the Actuary at CMS, projects that expenditures on prescription pharmaceuticals will increase dramatically in the near future. As in the proposed rule, we account for the projected growth in pharmaceutical expenditures by escalating our 1-year estimate by the annual CMS projected growth in prescription drug expenditures. We estimate the 10-year costs for the final rule are $51.584 billion. We annualized over the 10-year period at a 7 percent discount rate yields to obtain a cost of $4.871 billion.

D. Summary of Costs and Benefits

We estimate the 10-year cost of this final rule to be $51.584 billion and the annualized cost to be $4.871 billion. The 10-year benefit of this final rule is estimated to be $53.940 billion and the annualized benefit is $5.093 billion. These benefit and cost figures include the estimated impacts of an economic transfer. Thus, the 10-year net benefit is $2.356 billion and the annualized net benefit is $222 million. The quantified benefits exceed the quantified costs.

Moreover, there are benefits that are difficult to quantify. These benefits include reduced costs of litigation and more predictability in the business environment. The benefits to consumers also involve favorable secondary benefits, such as improved access to less expensive drugs. It also preserves the balance struck in the Hatch-Waxman Amendments.

E. Regulatory Alternatives

In creating this final rule, we considered several regulatory alternatives, including not enacting this rule. We rejected the alternative of not enacting this final rule because under the current situation, NDA holders and patent owners are able to use multiple 30-month stays to delay generic entry and frustrate the intent of the Hatch-Waxman Amendments. We considered allowing the submission of polymorph patents for listing in the Orange Book without the required test data demonstrating ''sameness.'' We rejected this alternative as we decided that a patent claiming different polymorphs of the active ingredient described in the NDA needed to have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. This requirement is similar to the requirement of establishing bioequivalence.

We also considered using the current system of patent declarations. This alternative was also rejected because the pre-existing declaration information may be insufficient to prevent NDA applicants and holders and patent owners from submitting patents to us that should not be submitted and listed under the act. The choices to require tests demonstrating ''sameness'' for polymorph patents and the required patent information provided in the patent declarations are particularly important in light of the fact that we lack the authority, expertise and resources to evaluate patents submitted to determine whether they should be listed in the Orange Book.

F. Small Business Impact

Unless the agency certifies that the rule is not expected to have a significant impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by SBREFA, requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. In the proposed rule, we certified that we believed the rule is not expected to have a significant impact on a substantial number of small entities, as we did not know of any small innovator companies that use or would use multiple 30-month stays to block entry from generic competitors. We did not receive comment on this certification and we continue to believe that this final rule will not have a significant impact on a substantial number of small entities.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 2. Section 314.52 is amended by redesignating paragraph (a)(3) as paragraph (a)(4) and by adding new paragraph (a)(3) to read as follows:

§ 314.52 Notice of certification of invalidity or noninfringement of a patent.

(a) * * *

(3) This paragraph does not apply if the applicant amends its application to add a certification under § 314.50(i)(1)(i)(A)(*4*) when the application already contained a certification under § 314.50(i)(1)(i)(A)(*4*) to a patent unless:

(i) The notice of the previous certification under § 314.50(i)(1)(i)(A)(*4*) was withdrawn or changed to a certification other than a certification under § 314.50(i)(1)(i)(A)(*4*); and

(ii) The 45-day period under section 505(c)(3) of the act had not expired; and

(iii) No person receiving notice under paragraphs (a)(1) and (a)(2) of this section had brought an action against the applicant for infringement of the patent that was the subject of the withdrawn or changed certification under § 314.50(i)(1)(i)(A)(*4*).

* * * * *

■ 3. Section 314.53 is amended by revising paragraph (b) and paragraphs (c)(1) through (c)(3) to read as follows:

§ 314.53 Submission of patent information.

* * * * *

(b) *Patents for which information must be submitted and patents for which information must not be submitted*—(1) *General requirements.* An applicant described in paragraph (a) of this section shall submit the required information on the declaration form set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. For patents that claim the drug substance, the applicant shall submit information only on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending

application. For patents that claim a polymorph that is the same as the active ingredient described in the approved or pending application, the applicant shall certify in the declaration forms that the applicant has test data, as set forth in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application. For patents that claim a drug product, the applicant shall submit information only on those patents that claim a drug product, as is defined in § 314.3, that is described in the pending or approved application. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use that are described in the pending or approved application. The applicant shall separately identify each pending or approved method of use and related patent claim. For approved applications, the applicant submitting the method-of-use patent shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted. Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.

(2) *Test Data for Submission of Patent Information for Patents That Claim a Polymorph*. The test data, referenced in paragraph (b)(1) of this section, must include the following:

(i) A full description of the polymorphic form of the drug substance, including its physical and chemical characteristics and stability; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the polymorphic form of the drug substance;

(ii) The executed batch record for a drug product containing the polymorphic form of the drug substance and documentation that the batch was manufactured under current good manufacturing practice requirements;

(iii) Demonstration of bioequivalence between the executed batch of the drug product that contains the polymorphic form of the drug substance and the drug product as described in the NDA;

(iv) A list of all components used in the manufacture of the drug product containing the polymorphic form and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; a description of the manufacturing and packaging procedures and in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including release and stability data complying with the approved product specifications to demonstrate pharmaceutical equivalence and comparable product stability; and

(v) Comparative in vitro dissolution testing on 12 dosage units each of the executed test batch and the new drug application product.

(c) *Reporting requirements*—(1) *General requirements*. An applicant described in paragraph (a) of this section shall submit the required patent information described in paragraph (c)(2) of this section for each patent that meets the requirements described in paragraph (b) of this section. We will not accept the patent information unless it is complete and submitted on the appropriate forms, FDA Forms 3542 or 3542a. These forms may be obtained on the Internet at http://www.fda.gov by searching for ''forms''.

(2) *Drug substance (active ingredient), drug product (formulation or composition), and method-of-use patents*—(i) *Original Declaration*. For each patent that claims a drug substance (active ingredient), drug product (formulation and composition), or method of use, the applicant shall submit FDA Form 3542a. The following information and verification is required:

(A) New drug application number;

(B) Name of new drug application sponsor;

(C) Trade name (or proposed trade name) of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form of new drug;

(G) United States patent number, issue date, and expiration date of patent submitted;

(H) The patent owner's name, full address, phone number and, if available, fax number and e-mail address;

(I) The name, full address, phone number and, if available, fax number and e-mail address of an agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under sections 505(b)(3) and 505(j)(2)(B) of the act and §§ 314.52 and 314.95 (if patent owner or new drug application applicant or holder does not reside or have a place of business within the United States);

(J) Information on whether the patent has been submitted previously for the new drug application;

(K) Information on whether the expiration date is a new expiration date if the patent had been submitted previously for listing;

(L) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(M) Information on the drug substance (active ingredient) patent including the following:

(*1*) Whether the patent claims the drug substance that is the active ingredient in the drug product described in the new drug application or supplement;

(*2*) Whether the patent claims a polymorph that is the same active ingredient that is described in the pending application or supplement;

(*3*) Whether the applicant has test data, described in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application or supplement, and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(N) Information on the drug product (composition/formulation) patent including the following:

(*1*) Whether the patent claims the drug product for which approval is being sought, as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(O) Information on each method-of-use patent including the following:

(*1*) Whether the patent claims one or more methods of using the drug product for which use approval is being sought and a description of each pending method of use or related indication and related patent claim of the patent being submitted; and

(*2*) Identification of the specific section of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted;

(P) Whether there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product;

(Q) A signed verification which states: ''The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.''; and

(R) Information on whether the applicant, patent owner or attorney, agent, representative or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and e-mail address.

(ii) *Submission of patent information upon and after approval.* Within 30 days after the date of approval of its application or supplement, the applicant shall submit FDA Form 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use. FDA will rely only on the information submitted on this form and will not list or publish patent information if the patent declaration is incomplete or indicates the patent is not eligible for listing. Patent information must also be submitted for patents issued after the date of approval of the new drug application as required in paragraph (c)(2)(ii) of this section. As described in paragraph (d)(4) of this section, patent information must be submitted to FDA within 30 days of the date of issuance of the patent. If the applicant submits the required patent information within the 30 days, but we notify an applicant that a declaration form is incomplete or shows that the patent is not eligible for listing, the applicant must submit an acceptable declaration form within 15 days of FDA notification to be considered timely filed. The following information and verification statement is required:

(A) New drug application number;

(B) Name of new drug application sponsor;

(C) Trade name of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form of new drug;

(G) Approval date of new drug application or supplement;

(H) United States patent number, issue date, and expiration date of patent submitted;

(I) The patent owner's name, full address, phone number and, if available, fax number and e-mail address;

(J) The name, full address, phone number and, if available, fax number and e-mail address of an agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under sections 505(b)(3) and 505(j)(2)(B) of the act and §§ 314.52 and 314.95 (if patent owner or new drug application applicant or holder does not reside or have a place of business within the United States);

(K) Information on whether the patent has been submitted previously for the new drug application;

(L) Information on whether the expiration date is a new expiration date if the patent had been submitted previously for listing;

(M) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(N) Information on the drug substance (active ingredient) patent including the following:

(*1*) Whether the patent claims the drug substance that is the active ingredient in the drug product described in the approved application;

(*2*) Whether the patent claims a polymorph that is the same as the active ingredient that is described in the approved application;

(*3*) Whether the applicant has test data, described at paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the approved application and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(O) Information on the drug product (composition/formulation) patent including the following:

(*1*) Whether the patent claims the approved drug product as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(P) Information on each method-of-use patent including the following:

(*1*) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;

(*2*) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; and

(*3*) The description of the patented method of use as required for publication;

(Q) Whether there are no relevant patents that claim the approved drug substance (active ingredient), the approved drug product (formulation or composition) or approved method(s) of use and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product;

(R) A signed verification which states: ''The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.''; and

(S) Information on whether the applicant, patent owner or attorney, agent, representative or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and e-mail address.

(3) *No relevant patents.* If the applicant believes that there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition), or the method(s) of use for which the applicant has received approval, and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product, the applicant will verify this information in the appropriate forms, FDA Forms 3542 or 3542a.

* * * * *

■ 4. Section 314.95 is amended by redesignating paragraph (a)(3) as paragraph (a)(4) and by adding new paragraph (a)(3) to read as follows:

§ 314.95 Notice of certification of invalidity or noninfringement of a patent.

(a) * * *

(3) This paragraph does not apply if the applicant amends its application to add a certification under § 314.94(a)(12)(i)(A)(*4*) when the application already contained a certification under § 314.94(a)(12)(i)(A)(*4*) to a patent unless:

(i) The notice of the previous certification under § 314.94(a)(12)(i)(A)(*4*) was withdrawn or changed to a certification other than a certification under § 314.94(a)(12)(i)(A)(*4*);

(ii) The 45-day period under section 505(j)(5)(B)(iii) of the act had not expired; and

(iii) No person receiving notice under paragraphs (a)(1) and (a)(2) of this section had brought an action against the applicant for infringement of the patent that was the subject of the withdrawn or changed certification under § 314.94(a)(12)(i)(A)(*4*).

* * * * *

Dated: May 23, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

Dated: June 9, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

[This appendix will not appear in the Code of Federal Regulations.]

BILLING CODE 4160–01–S

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use

Form Approved: OMB No. 0910-XXXX
Expiration Date: XX-XX-XX
See OMB Statement on Page 3.

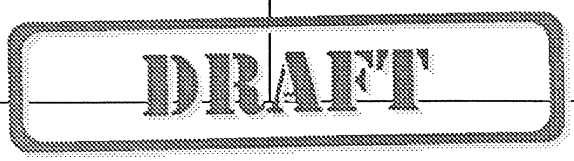
NDA NUMBER

NAME OF APPLICANT / NDA HOLDER

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)

ACTIVE INGREDIENT(S) | STRENGTH(S)



DOSAGE FORM

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).
Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the *only* information relied upon by FDA for listing a patent in the Orange Book.

For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you submit an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
d. Name of Patent Owner	Address *(of Patent Owner)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*
e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States) ☞	Address *(of agent or representative named in 1.e.)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☐ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☐ No

PSC Media Arts (301) 443-1090 EF

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☐ Yes	☐ No
2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the NDA, amendment, or supplement?	☐ Yes	☐ No
2.3 If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No

2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.

2.5 Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)	☐ Yes	☐ No
2.6 Does the patent claim only an intermediate?	☐ Yes	☐ No
2.7 If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

3. Drug Product (Composition/Formulation)

3.1 Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	☐ Yes	☐ No
3.2 Does the patent claim only an intermediate?	☐ Yes	☐ No
3.3 If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☐ Yes	☐ No
4.2 Claim Number (*as listed in the patent*)	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☐ Yes ☐ No	
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the proposed labeling.)*	

5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.	☐ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☐ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name	
Address	City/State
ZIP Code	Telephone Number
FAX Number *(if available)*	E-Mail Address *(if available)*

The public reporting burden for this collection of information has been estimated to average 9 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDER (HFD-007)
5600 Fishers Lane
Rockville, MD 20857

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.

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation or Composition) and/or Method of Use

Form Approved: OMB No. 0910-XXXX
Expiration Date: XX-XX-XX
See OMB Statement on Page 3.

NDA NUMBER

NAME OF APPLICANT / NDA HOLDER

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME

ACTIVE INGREDIENT(S)

STRENGTH(S)

DOSAGE FORM

APPROVAL DATE OF NDA OR SUPPLEMENT

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) within thirty (30) days after approval of an NDA or supplement or within thirty (30) days of issuance of a patent as required by 21 CFR 314.53(c)(2)(ii) at the address provided in 21 CFR 314.53(d)(4). To expedite review of this patent declaration form, you may submit an additional copy of this declaration form to the Center for Drug Evaluation and Research "Orange Book" staff.

For hand-written or typewriter versions of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the approved NDA or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this NDA or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent

d. Name of Patent Owner	Address *(of Patent Owner)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States) ☞	Address *(of agent or representative named in 1.e.)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☐ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☐ No

PSC Media Arts (301) 443-1090 EF

For the patent referenced above, provide the following information on each patent that claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement. FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing. FDA will consider an incomplete patent declaration to be a declaration that does not include a response to all the questions contained within each section below applicable to the patent referenced above.

2. Drug Substance (Active Ingredient)

2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the approved NDA or supplement?	☐ Yes	☐ No
2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the NDA?	☐ Yes	☐ No
2.3 If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5 Does the patent claim only a metabolite of the approved active ingredient? (Complete the information in section 4 below if the patent claims an approved method of using the approved drug product to administer the metabolite.)	☐ Yes	☐ No
2.6 Does the patent claim only an intermediate?	☐ Yes	☐ No
2.7 If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

FDA will not list the patent in the Orange Book as claiming the drug substance if:

- **the answers to 2.1 and 2.2 are "No," or,**
- **the answer to 2.2 is "Yes" and the answer to 2.3 is "No," or,**
- **the answer to 2.3 is "Yes" and there is no response to 2.4, or,**
- **the answer to 2.5 or 2.6 is "Yes."**
- **the answer to 2.7 is "No."**

3. Drug Product (Composition/Formulation)

3.1 Does the patent claim the approved drug product as defined in 21 CFR 314.3?	☐ Yes	☐ No
3.2 Does the patent claim only an intermediate?	☐ Yes	☐ No
3.3 If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

FDA will not list the patent in the Orange Book as claiming the drug product if:

- **the answer to question 3.1 is "No," or,**
- **the answer to question 3.2 is "Yes," or,**
- **the answer to question 3.3 is "No."**

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming an approved method of using the approved drug product. For each method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more approved methods of using the approved drug product?	☐ Yes	☐ No
4.2 Patent Claim Number *(as listed in the patent)* — Does the patent claim referenced in **4.2** claim an approved method of use of the approved drug product?	☐ Yes	☐ No
4.2a If the answer to **4.2** is "Yes," identify the use with specific reference to the approved labeling for the drug product. — Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)*		

4.2b If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use: *(Submit the description of the approved indication or method of use that you propose FDA include as the "Use Code" in the Orange Book, using no more than 240 total characters including spaces.)*

FDA will not list the patent in the Orange Book as claiming the method of use if:

- **the answer to question 4.1 or 4.2 is "No," or**
- **if the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full.**

5. No Relevant Patents

For this NDA or supplement, there are no relevant patents that claim the approved drug substance (active ingredient) or the approved drug product (formulation or composition) or approved method(s) of use with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. ☐ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☐ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official
Name	
Address	City/State
ZIP Code	Telephone Number
FAX Number *(if available)*	E-Mail Address *(if available)*

DRAFT

The public reporting burden for this collection of information has been estimated to average 9 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDER (HFD-007)
5600 Fishers Lane
Rockville, MD 20857

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.

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[FR Doc. 03–15065 Filed 6–12–03; 1:00 pm]
BILLING CODE 4160–01–S

Federal Register

Wednesday,
June 18, 2003

Part IV

Nuclear Regulatory Commission

10 CFR Parts 170 and 171
Revision of Fee Schedules; Fee Recovery for FY 2003; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

RIN 3150–AH14

Revision of Fee Schedules; Fee Recovery for FY 2003

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending the licensing, inspection, and annual fees charged to its applicants and licensees. The amendments are necessary to implement the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), as amended, which requires that the NRC recover approximately 94 percent of its budget authority in fiscal year (FY) 2003, less the amounts appropriated from the Nuclear Waste Fund (NWF). The amount to be recovered for FY 2003 is approximately $526.3 million.

EFFECTIVE DATE: August 18, 2003.

ADDRESSES: The comments received and the agency work papers that support these final changes to 10 CFR Parts 170 and 171 are available electronically at the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, or 301–415–4737, or by email to *pdr@nrc.gov.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR.

Comments received may also be viewed via the NRC's interactive rulemaking Web site (*http://ruleforum.llnl.gov*). This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, 301–415–5905; e-mail *CAG@nrc.gov.*

For a period of 90 days after the effective date of this final rule, the work papers may also be examined at the NRC Public Document Room, Room O–1F22, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738.

FOR FURTHER INFORMATION CONTACT: Ann Norris, telephone 301–415–7807; or Tammy Croote, telephone 301–415–6041; Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Background

For FYs 1991 through 2000, OBRA–90, as amended, required that the NRC recover approximately 100 percent of its budget authority, less the amount appropriated from the U.S. Department of Energy (DOE) administered NWF, by assessing fees. To address fairness and equity concerns raised by the NRC related to charging NRC license holders for agency budgeted costs that do not provide a direct benefit to the licensee, the FY 2001 Energy and Water Development Appropriations Act amended OBRA–90 to decrease the NRC's fee recovery amount by 2 percent per year beginning in FY 2001, until the fee recovery amount is 90 percent in FY 2005. As a result, the NRC is required to recover approximately 94 percent of its FY 2003 budget authority, less the amounts appropriated from the NWF, through fees. In the Energy and Water Development Appropriation Act, 2003, contained in the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), Congress appropriated $584.6 million to the NRC for FY 2003. This sum includes $24.7 million appropriated from the NWF. The total amount NRC is required to recover in fees for FY 2003 is approximately $526.3 million.

The NRC assesses two types of fees to meet the requirements of OBRA–90, as amended. First, license and inspection fees, established in 10 CFR Part 170 under the authority of the Independent Offices Appropriation Act of 1952 (IOAA), 31 U.S.C. 9701, recover the NRC's costs of providing special benefits to identifiable applicants and licensees. Examples of the services provided by the NRC for which these fees are assessed are the review of applications for new licenses, and for certain types of existing licenses, the review of renewal applications, the review of amendment requests, and inspections. Second, annual fees established in 10 CFR Part 171 under the authority of OBRA–90, recover generic and other regulatory costs not otherwise recovered through 10 CFR Part 170 fees.

II. Response to Comments

The NRC published the FY 2003 proposed fee rule on April 3, 2003 (68 FR 16374) to solicit public comment on its proposed revisions to 10 CFR Parts 170 and 171. The NRC received 26 comments dated on or before the close of the comment period (May 5, 2003) and several additional comments thereafter, for a total of 32 comments that were considered in this fee rulemaking. The comments have been grouped by issues, and are addressed in a collective response.

A. Legal Issues

Information Provided by NRC in Support of Proposed Rule

Comment. Several commenters urged the NRC to provide licensees and the public with a more detailed explanation of the activities and associated costs that form the basis for NRC's fees. Some commenters stated that the NRC should provide specific accounting of the major elements that comprise the annual fee, including detailed information on the outstanding major contracts, their purpose, and their costs. Other commenters indicated that this information should also be available for part 170 fees, claiming it is difficult to understand exactly what is included in the hourly rate. One of these commenters also stated that more detailed information on the total costs associated with each component of reactor regulation and all other generic costs would allow stakeholders to provide more effective feedback on the efficiency of NRC's regulatory activities and would propel the Commission to exercise its authority to promote increased fiscal responsibility.

Several commenters raised concerns that the NRC could not specifically identify where resources are being applied, as the agency identified approximately 76 percent of the NRC's budget for recovery under part 171 and only 24 percent under the discrete fee provisions of part 170. These commenters stated this meant that the NRC could only identify 24 percent of its expenditures as directly supporting the licensees, and that neither NRC nor industry management can determine whether applicable resources are being applied to appropriate priorities in such a case. These commenters further stated that the aggregation of a substantial portion of non-discrete expenditures to be recovered through part 171 fees makes it virtually impossible for

licensees to understand and comment on the appropriateness of these expenditures, and that the NRC should revise parts 170 and 171 to discretely allocate generic program costs to individual dockets in order to improve the visibility of management oversight and associated accountability of these programs.

Response. Consistent with the requirements of OBRA–90, as amended, the purpose of this rulemaking is to establish fees necessary to recover 94 percent of the NRC's FY 2003 budget authority, less the amounts appropriated from the NWF, from the various classes of licensees. The efficiencies of NRC's regulatory activities and the manner in which NRC carries out its fiscal responsibilities are outside the scope of this rulemaking. The proposed rule described the types of activities included in the proposed fees and explained how the fees were calculated to recover the budgeted costs for those activities. Therefore, the NRC believes that ample information was available on which to base constructive comments on the proposed revisions to parts 170 and 171 and that its fee schedule development is a transparent process.

In addition to the information provided in the proposed rule, the supporting work papers were available for public examination in the NRC's Agencywide Documents Access and Management System (ADAMS) and, during the 30-day comment period, in the NRC Public Document Room at One White Flint North, 11555 Rockville Pike, Rockville, MD. The work papers show the total budgeted full time equivalent (FTE) and contract costs at the planned accomplishment level for each agency activity. The work papers also include extensive information detailing the allocation of the budgeted costs for each planned accomplishment within each program of each strategic arena to the various classes of licenses, as well as information on categories of costs included in the hourly rate.

The NRC has also made available in the Public Document Room NUREG–1100, Volume 18, ''Budget Estimates and Performance Plan, Fiscal Year 2003'' (February 2002), which discusses the NRC's budget for FY 2003, including the activities to be performed in each strategic arena. This document is also available on the NRC public Web site at *http://www.nrc.gov/reading-rm.html.* The extensive information available to the public meets all legal requirements and the NRC believes it has provided the public with sufficient information on which to base their comments on the proposed fee rule. Additionally, the contacts listed in the proposed fee rule were available during the public comment period to answer any questions that commenters had on the development of the proposed fees. No inquiries were received about the fee development process.

With regard to the comments that expressed concern that too much of the NRC's budget was designated for recovery under part 171, the NRC notes that it has taken action to increase the amount recovered under part 170, consistent with existing Federal law and policy. For example, in FY 1998 the agency began charging part 170 fees for resident inspectors and in FY 1999 the agency started charging part 170 fees for project manager activities associated with oversight of the assigned license or plant. Additionally, in FY 2003 the NRC amended its regulations to allow the agency to recover costs associated with contested hearings on licensing actions involving U.S. Government national security initiatives through part 170 fees assessed to the affected applicant or licensee (67 FR 64033; October 17, 2002). Included under this provision are activities involving the fabrication and utilization of mixed oxide fuel (MOX). The NRC assesses part 170 fees under the IOAA, and consistent with OMB Circular A–25, to recover the costs incurred from each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. Generic costs that do not provide special benefits to identifiable recipients can not be recovered under part 170.

The NRC clearly sets forth the components of these generic costs in its workpapers and how those costs are recovered through annual fees.

B. Specific Part 170 Issues

1. Increase in Hourly Rates

Comment. Several commenters raised concerns with the proposed increase to $158 for the hourly rate for the materials program. One commenter stated that there seems to be no reason that the hourly rate for the materials program is higher than the hourly rate for reactors. This commenter also thought that the rates are out of line with rates paid by industry for safety professionals and managers.

Response. The NRC's hourly rates are based on budgeted costs and must be established at the revised levels each year to meet the fee recovery requirements. The hourly rates include not only average salaries and benefits for professional employees, but also a prorated share of overhead costs, such as supervisory, secretarial, and information technology support, as well as general and administrative costs, such as rent, utilities, supplies, and payroll and human resources staffs. These hourly rates are not developed in relation to one another but are based on budgeted costs for the reactors program and the materials program. Since the budgeted costs are different for each program, different rates result. These rates do not necessarily track with private sector rates, nor should they be used as a benchmark for industry standards. Instead, these rates reflect the budgeted costs of the reactors and materials programs.

A major reason for the four percent increase in the hourly rate for the materials program is the salary and benefits increase resulting primarily from the Government-wide pay raise. While salary and benefits also increase similarly for the reactor program, the increase is offset by a reduction in the average overhead cost per direct FTE for the reactor program. The hourly rates, coupled with the direct contract costs, recover through part 170 fees the full cost to the NRC of providing special services to specifically identifiable beneficiaries as provided by the IOAA. The revised hourly rates plus direct contract costs recover, through part 171 annual fees, the required amount of NRC's budgeted costs for activities not recovered through part 170 fees, as mandated by OBRA–90, as amended. The NRC is establishing in this final rule the revised hourly rates necessary to accomplish the fee recovery requirements. For part 170 activities, the rates will be assessed for professional staff time expended on or after the effective date of this final rule.

2. Project Manager Billing Issues

Comment. Several commenters expressed concern with the increase in charges for Project Manager (PM) time to uranium recovery licensees and other materials licensees. Some of these commenters would like clarification of the status of the NRC's Office of Nuclear Materials Safety and Safeguards (NMSS) policy change that was implemented in July 2001, which states that a PM's costs are not billed to the licensee as part 170 fees if that PM spends 75 percent or less of his/her time in any two-week period on duties to support that licensee. Other commenters said that after an initial drop in part 170 charges for PM duties to uranium recovery licensees, these charges had increased recently even though duties related to the sites had not changed, and stated that PM time should not be charged to part 170 fees, whenever possible. Some commenters thought the Commission should reduce the impact of the hourly rate increase on

uranium recovery licensees by doing everything possible to reduce the amount of time spent by staff working on licensing issues related to uranium recovery licenses. They suggested that this could be accomplished through the streamlining of the regulatory process, including delegating regulation of in-situ leach wellfields to the States through Memoranda of Understanding and more reliance on Safety and Environmental Review Panels and performance based-licensing.

Response. NMSS modified its policy for project management fee billing effective July 29, 2001. The modified policy states that an NRC employee must spend more than 75 percent of his/her time in any two-week period performing duties to support a facility's license or certificate review to be considered a PM for full-cost fee billing purposes (Full-cost fee billing causes a prorated portion of a PM's indirect time to be charged to the licensee. The modified NMSS policy reduced the number of PMs whose indirect time is billed to the licensee.). The NRC has not changed that policy, nor how it is being implemented. The FY 2003 proposed fee rule did not propose to change the NMSS PM fee billing policy, so there was no need for the proposed rule to address its implementation status. If licensees have specific questions about particular invoices, they may request more details from the NRC and the staff will provide additional information. This has always been an option available to licensees and applicants who feel they need more information on the costs billed.

The NRC only charges fees to uranium recovery (or any other) licensees based on its budgeted costs. Regarding the comments suggesting that staff time devoted to regulating uranium recovery facilities should be reduced, the NRC notes that the manner in which NRC carries out its regulatory responsibilities is not addressed in this final rule, since this issue is outside the scope of this rulemaking. Nonetheless, the Commission strives to ensure that all of its efforts are needed to carry out its health, safety, common defense and security responsibilities and frequently modifies its regulatory regime to reduce unnecessary burden on the regulated community. Concerns about specific licensee review efforts conducted by the staff should be directed to the appropriate program office.

3. Fee Waivers for Special Projects

Comment. One commenter raised a number of concerns with NRC's fee waiver policy. This commenter stated that this policy is flawed, unworkable, and counterproductive to regulatory efficiency and effectiveness. In particular, this commenter stated that NRC's fee waiver policy is not consistent with the definitions of part 170 and part 171 fees as described in the FY 2003 proposed fee rule. The commenter stated that the Office of the Chief Financial Officer (OCFO) had been charging part 170 fees for documents that did not fall under the description in the FY 2003 proposed fee rule of documents for which part 170 fees should be assessed. This commenter challenged as flawed various reasons that OCFO had previously given to deny fee waivers in the past. The commenter advocated cooperative efforts between NRC and industry, and expressed concern that OCFO positions blocked this cooperation. The commenter suggested changing NRC's fee waiver policy to eliminate disincentives for industry to be proactive in addressing generic regulatory issues.

Response. The NRC did not propose to revise its policy for those services which part 170 fees are assessed, nor the existing fee waiver policy in this rulemaking. The proposed rule's description of purposes for which part 170 fees would apply is intended to be illustrative, not exhaustive. The NRC clarified its fee waiver policy in the FY 2002 final fee rule (67 FR 42612; June 24, 2002), and responded extensively to comments similar to the one summarized above in the Response to Comments section of that final rule. The Commission's position with respect to its existing fee waiver policy has not changed. In brief, the NRC has consistently applied its policy of waiving the part 170 fees for a special project submitted to the NRC for the purpose of supporting ''NRC's'' generic regulatory improvements, and assessing part 170 fees for the review of a special project that is submitted for other purposes, including those that support ''industry'' generic improvements. The NRC finds no justification for granting a part 170 fee waiver, as the comment suggests, whenever a nuclear industry organization submits a proposal for generic regulatory improvement. Fee waivers will be granted only if the NRC determines the submission will be used for NRC's generic regulatory improvements, and the initiative was submitted specifically for that purpose. Thus, fee waivers are only appropriate where the NRC's review of the industry initiative is part of the process of developing the NRC's generic regulatory program, and the review activities are similar to other NRC generic regulatory activities whose costs are recovered through part 171 annual fees.

The NRC does not believe its fee waiver policy discourages cooperative efforts between the agency and industry, and that its assessment of part 170 fees for a special project is fully consistent with the NRC's policies on industry initiatives. Under the existing fee waiver criteria, NRC will waive the review fees for a special project submitted for the purpose of supporting the agency's regulatory improvements as long as the NRC staff agrees with the applicant at the time of submission that it will be used by the NRC in developing or improving its regulatory framework. The NRC encourages any special project applicant who believes that its proposal will help improve NRC's regulatory process to discuss its proposal with the cognizant NRC program office staff prior to requesting a fee waiver from the Chief Financial Officer.

C. Specific Part 171 Issues

1. Annual Fees vs. Hourly Fees

Comment. One commenter stated that it prefers annual fees to hourly fees, since it is easier to plan and allocate resources related to annual fees, while hourly fees are more unpredictable and more difficult to incorporate into a licensee's financial plan. Some commenters complained, however, that a disproportionate amount of the budget is recovered through annuals fees.

Response. While the NRC appreciates the concerns raised by this commenter, the agency notes that its collection of part 170 fees is consistent with Federal law. The NRC assesses part 170 fees under the IOAA, which allows Federal agencies to assess fees to recover costs incurred in providing special benefits to identifiable recipients. In addition, the Conference Report accompanying OBRA–90 specifically states that the Conference Committee ''* * * expects the NRC to continue to assess fees under the [IOAA] to the end that each licensee or applicant pays the full cost to the NRC of all identifiable regulatory services such licensee or applicant receives'' (136 Cong. Rec. H12692–3, daily ed. October 26 1990). The NRC has received additional direction on this issue in the Office of Management and Budget (OMB) Circular A–25, in which OMB states it is Federal policy that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The NRC abides by this direction in charging part 170 fees to recover the costs of providing special benefits to identifiable recipients.

Further, the NRC notes that, as required by OBRA–90, the part 171 annual fee recovery amounts are offset by the estimated part 170 fee collections. As explained above, the NRC is not at liberty to allocate fees indiscriminately between parts 170 and 171, as statute controls fee allocation. This applies both to comments that more of the budget should be shifted from part 170 fees to part 171 as to the position advocating the reverse.

2. Annual Fees for Materials Users, Including Small Entities

Comment. Two nuclear density gauge users commented that their fees are too high, and create a significant financial burden on small business owners. One of these users indicated only a small fraction of the company's revenues was generated from NRC licensed activities, but that these activities are essential to support projects it designs and monitors. With respect to the NRC's upper fee level for small entities, this commenter stated that the broad revenue range encompassing $350,000 to $5,000,000 in gross annual receipts tends to favor larger firms while burdening smaller businesses. Thus, they urge the NRC to consider adding more tiers for small businesses to reduce the license fee burden on smaller entities. The other commenter stated that license fees make it difficult for small projects to recover expenses, and requested smaller fees.

Response. The NRC stated in the FY 2001 fee rule (66 FR 32452; June 14, 2001), that it would re-examine the small entity fee every two years, in the same years in which it conducts the biennial review of fees as required by the Chief Financial Officer (CFO) Act of 1990 (Pub. L. 101–578, November 15, 1990, 104 Stat. 2838). Accordingly, as discussed in the FY 2003 proposed fee rule, this year the NRC re-examined the small entity fees, and determined that no change to the small entity fee is warranted for FY 2003. The NRC last revised its small entity fees in FY 2000 (65 FR 36936; June 12, 2000), when it increased the small entity annual fee and the lower tier small entity fee by 25 percent. For FY 2003, the NRC has determined that the current small entity fees of $500 and $2,300 continue to meet the objective of providing relief to many small entities while recovering from them some of the NRC costs associated with regulatory activities that benefit them.

The NRC has addressed comments regarding the impact of fees on industry in previous fee rulemakings. The NRC has stated since FY 1991, when the 100 percent fee recovery requirement was first implemented, that it recognizes the assessment of fees to recover the agency's costs may result in a substantial financial hardship for some licensees. However, consistent with the OBRA–90 requirement that annual fees must have, to the maximum extent practicable, a reasonable relationship to the cost of providing regulatory services, the NRC's annual fees for each class of license reflect the NRC's budgeted cost of its regulatory services to the class. The NRC determines the budgeted costs to be allocated to each class of licensee through a comprehensive review of every planned accomplishment in each of the agency's major program areas. Furthermore, a reduction in the fees assessed to one class of licensees would require a corresponding increase in the fees assessed to other classes. Accordingly, the NRC has not based its annual fees on licensees' economic status, market conditions, or the inability of licensees to pass through the costs to its customers. Instead, the NRC has only considered the impacts that it is required to address by law.

Based on the provisions of the Regulatory Flexibility Act (RFA), the NRC provides reduced annual fees for licensees who qualify as small entities under the NRC's size standards. The materials users class has the most licensees who qualify for these reduced fees of any class. As such, the materials users class receives the largest amount of annual fee reductions of any class. About 24 percent of these licensees (approximately 1,200 licensees) have requested small entity certification in the past. The FY 2003 total estimated fee amount that will not be collected from licensees who pay reduced annual fees based on their small entity status is approximately $4.5 million, which must be collected from other NRC licensees in the form of a surcharge. Further reductions in fees for materials users would create an additional fee burden on other licensees, thus raising fairness and equity concerns.

As stated in 10 CFR 2.810, the NRC uses the Small Business Administration's (SBA) definition of receipts. Based on the SBA definition, revenue from all sources, not solely receipts from NRC licensed activities, is considered in determining whether a licensee qualifies as a small entity under the NRC's revenue-based size standards.

The NRC believes that the two tiers of reduced annual fees currently in place provide substantial fee relief for small entities, including those with relatively low annual gross revenues. As noted previously, reductions in fees for small entities must be paid by other NRC licensees in order to comply with the OBRA–90 requirement to recover most of the agency's budget authority through fees. While establishing additional tiers would provide further fee relief to some small entities, it would result in an increase of the small entity subsidy paid by other licensees. The NRC must maintain a reasonable balance between the provisions of OBRA–90 and the RFA requirement that an agency must examine ways to minimize significant impacts that its rules may have on a substantial number of small entities. Therefore, the NRC does not plan to modify its small entity fee structure, nor provide any further reduction in annual fees beyond that already established for small entities. The NRC will re-examine the small entity fees again in FY 2005.

3. Annual Fees for Uranium Recovery Licensees

Comment. The NRC received several comments regarding annual fees for uranium recovery licensees. These comments supported the reduction in annual fees for these facilities that resulted from the decision to rebaseline FY 2003 annual fees. One commenter also supported the continued implementation of last year's determination that the DOE must be assessed one-half of all NRC budgeted costs attributed to generic/other activities for the uranium recovery program. However, despite the proposed reductions, these commenters stated that there continues to be the lack of a reasonable relationship between the cost to uranium recovery licensees of NRC's regulatory program and the benefit derived from such services. These commenters believe there is excessive regulatory oversight by the NRC of the uranium recovery industry, especially in light of the NRC's performance-based licensing approach, which they contend should result in a reduced regulatory effort. The commenters assert that the NRC should consider a more balanced approach to uranium recovery regulation, resulting in less regulatory oversight and lower costs.

Additionally, the commenters stated that the NRC has failed to adequately address the issue of decreasing numbers of uranium recovery licensees. Specifically, as more states become Agreement States and/or additional sites are decommissioned, the number of NRC regulated sites continues to decline, leaving fewer licensees to pay a larger share of the NRC's regulatory costs. These commenters urged NRC to continue its efforts to seek cost efficiencies through its annual reviews conducted as part of the budget process. One commenter stated that uranium recovery licensees continue to be

subject to unnecessary costs due to overlapping Federal or State agency jurisdiction. The commenter stated that in non-Agreement States, the NRC should accept the groundwater quality assessments conducted by the state or the Environmental Protection Agency rather than performing duplicative environmental assessments. Several commenters suggested that the agency proceed expeditiously with extension of the reactor oversight process for these and other facilities as a risk-informed, performance-based oversight process that recognizes the inherent safety of these operations should further reduce unnecessary regulatory burdens.

Response. The NRC has responded to similar concerns raised by commenters in several previous fee rulemakings. First, in response to the specific suggestions about how the NRC should regulate these licensees or operate more efficiently, the NRC again notes that the purpose of this rule is to recover the required percentage of its FY 2003 budget authority, and that the manner in which the NRC carries out its regulatory activities is outside the scope of this rulemaking.

The NRC must assess annual fees to NRC licensees to recover the budgeted costs not recovered through part 170 fees and other receipts. The NRC recognizes that this presents fairness and equity issues as costs must be recovered from licensees for activities that do not directly benefit them. To address these fairness and equity concerns, as previously noted, the FY 2001 Energy and Water Development Appropriations Act amended OBRA–90 to decrease the NRC's fee recovery amount by two percent per year beginning in FY 2001, until the fee recovery amount is 90 percent in FY 2005.

The Commission is concerned about the issue of decreasing numbers of licensees and its implications. Although a decreasing licensee base is only one of several possible factors affecting annual fees, it presents a clear dilemma for both the uranium recovery group in its efforts to maintain a viable industry, and the NRC, which must by statute recover its budgeted costs from the licensees it regulates. Potential remedies to this problem involve establishing arbitrary fee caps or thresholds for certain classes of licensees, or combining fee categories. However, alternatives involving caps or thresholds, and combining fee categories, also raise potential legal and fairness and equity concerns. As noted previously, given the requirements of OBRA–90, as amended, to collect most of NRC's budget authority through fees, failure to fully recover costs from certain classes of licensees due to caps or thresholds would result in other classes of licensees bearing these costs. Combining fee categories would also have the potential to increase the annual fees for certain licensees in the new combined category to cover part of the cost for the licensees whose fees were reduced by this action. At this time, the Commission is not prepared to adopt any of these approaches. The NRC notes that the annual fees for the Uranium Recovery class decreased from FY 2001 to FY 2002, and remained stable for FY 2003 due in part to the concerted efforts by the program offices to reduce budgeted costs associated with this program. However, the NRC recognizes the concerns expressed and will continue its efforts to seek cost efficiencies and reduce regulatory burdens, without compromising its commitment to public health and safety.

4. Annual Fees for Power Reactor Licensees

Comment. One commenter stated that there is insufficient basis to support the required costs to the power reactor licensees for activities not directly attributable or beneficial to their operation. Another commenter expressed concern about the 15 percent increase in the operating power reactor annual fee, despite the two percent drop in the agency's overall recovery rate as mandated by the FY 2001 Energy and Water Appropriations Act. Both commenters raised fairness and equity concerns regarding utilities paying for agency activities that do not provide a direct benefit to them.

Response. The part 171 power reactor annual fees are established to recover the costs for generic activities related to power reactors such as research, rulemakings and guidance development, as well as costs for other activities for the class not recovered through part 170 fees (*e.g.,* allegations, most contested hearings, special projects for which fee waivers are granted, orders issued under 10 CFR 2.202 or responses to such orders). The annual fees for each class also include a share of the total surcharge costs. The surcharge is established to recover the costs for NRC activities that are not attributable to an existing NRC licensee or class of licensees, such as activities that are exempt from part 170 fees by law or Commission policy. The surcharge is required in order for NRC to meet its statutory fee recovery requirements. To address fairness and equity concerns related to charging NRC license holders for these expenses that do not directly benefit them, the FY 2001 Energy and Water Development Appropriations Act amended OBRA–90 to decrease the NRC's fee recovery amount by two percent per year beginning in FY 2001, until the fee recovery amount is 90 percent in FY 2005. This decrease of six percent in FY 2003 is applied to help offset the surcharge amount.

The annual fee for the power reactor class includes the agency's homeland security costs related to power reactors for this fiscal year, which significantly contributed to the 15 percent increase in power reactor fees. Additionally, the increased workload for the new reactor licensing activities contributed to the increase.

The agency workpapers supporting both the proposed and final fee rules show the budgeted costs for each activity at the NRC's planned accomplishment level, and the classes of licenses to which these costs are allocated. Furthermore, the workpapers show by class the total costs allocated, and the estimated part 170 collections. The annual fees are established to recover the difference between the NRC's total recoverable budgeted costs (less the Nuclear Waste Fund) and the estimated part 170 collections, in accordance with OBRA–90, as amended.

5. Annual Fees for Fuel Facilities Licensees

Comment. Several commenters expressed concerns with the annual fees for fuel facilities licensees. One commenter stated that these fees are unreasonably high and not in accord with NRC's Strategic Plan: Fiscal Year 2000–Fiscal Year 2005. Other commenters did not understand why there was a significant discrepancy between the increase in annual fees for fuel fabricators (43 percent) in comparison to power reactors (15 percent), when much of the annual fee increase was attributed to the costs of security-related activities and these activities are similar for both types of facilities. These commenters requested that NRC review this discrepancy and consider revisions to more equitably allocate these costs. Another commenter expressed concerns about the annual fees for gaseous diffusion plants (GDPs), stating that it did not believe that the annual fee for a GDP should be equal to or more than the annual fee for a power reactor. This commenter suggested that NRC reevaluate its methodology to establish the FY 2003 fees with the objective of achieving a fee structure that is fair and equitable when viewed in its entirety. Another commenter stated that low enriched uranium fuel facilities constitute a very small part of the nuclear fuel cycle and pose only

minimal risk, and that their facility operated in a very competitive international market and so the magnitude of the fee increase represents a serious economic burden. The commenter asked that the proposed fees for fuel facilities be reviewed and that the amount of the increase be reduced to a more reasonable level (on the order of 10 percent) to be consistent with other facilities and the general increasing costs of NRC operations.

Response. The part 171 annual fees for each class of licenses are established to recover the costs for generic activities related to that class of licenses, including rulemakings and guidance development, as well as costs for other activities for the class not recovered through part 170 fees. The NRC believes this methodology is consistent with all applicable laws, regulations, and policies. Because the costs for one class of licenses may increase or decrease at different rates than the costs for other classes of licenses, fees for different classes will increase or decrease at different rates accordingly. The NRC has considered capping fee increases for classes of licenses, but has not chosen to do so for potential legal and fairness and equity reasons.

The NRC appreciates the concerns raised about fee predictability and stability. In order to recover its budgeted annual costs in compliance with the OBRA–90, as amended, the NRC annually promulgates a rule establishing licensee fees. In light of concerns about annual fluctuations in these fees, the NRC announced in FY 1995 that annual fees would be adjusted only by the percentage change (plus or minus) in NRC's total budget authority, adjusted for changes in estimated collections for 10 CFR Part 170 fees, the number of licensees paying annual fees, and as otherwise needed to assure the billed amounts resulted in the required collections. The NRC indicated that if there were a substantial change in the total NRC budget authority or the magnitude of the budget allocated to a specific class of licenses, the annual fee base would be recalculated by rebaselining. Commission policy sets the maximum interval between rebaselined fee schedules at three years. Based on the change in the magnitude of the budget to be recovered through fees, the Commission determined that it was appropriate to rebaseline its part 171 annual fees in FY 2003. Rebaselining fees resulted in increased annual fees compared to FY 2002 for four classes of licenses (power reactors, spent fuel storage/reactor decommissioning, fuel facilities, and rare earth facilities), and decreased annual fees for two classes (non-power reactors and uranium recovery). For the small materials users and transportation classes, some categories of licensees will have increased annual fees and others will have decreased annual fees.

Regarding the comment that fees to fuel facilities represent an economic burden, since FY 1991 the Commission has consistently taken the position that it will not consider economic factors when establishing fees, except for reduced fees provided for small entities based on the policies reflected in the Regulatory Flexibility Act. Granting fee relief to the fuel facility licensees on the basis of economic considerations could set an untenable precedent for the NRC with the potential to unravel the stability and viability of the entire fee system. Not only would other classes of licenses be required to subsidize fuel facilities through increased fees, but other categories of licensees may also request similar treatment based on analogous economic considerations. Thus, it would be difficult to develop a rationale for waiving the fees for one class of licenses while denying similar requests from other NRC licensees which may also be experiencing economic downturns.

The annual fees for the fuel facility class reflect increased budgeted costs for activities that are not subject to cost recovery under part 170, primarily homeland security activities related to fuel facilities. Such activities include the issuance and follow-up of orders directing the fuel facility licensees to take interim compensatory measures to increase security, and a series of risk-informed vulnerability assessments the NRC is conducting on fuel facilities.

The NRC initially established a fuel facility ''effort/fee'' matrix in the FY 1995 fee rule (60 FR 32218; June 20, 1995), further revising it in the FY 1999 fee rule (64 FR 31448; June 10, 1999). The purpose of this matrix is to accurately reflect the NRC's current costs of providing generic and other regulatory services to each type of fuel facility. The matrix depicts the categorization of licenses according to their activities, level, scope, depth of coverage, and rigor or generic regulatory programmatic effort applicable to each facility category from a safety and safeguards perspective. The relative weighted factors for each facility type for the various fee subclasses are depicted in Table VII. The matrix has been quite valuable in helping the NRC assign appropriate fees for each type of fuel facility. It is routinely available among the workpapers during the public comment process of each year's rulemaking for revision of fee schedules and the fact that it has withstood this scrutiny for many years continues to lend support to the NRC's confidence in it as a robust tool in the fee development process.

Annual Fees for Spent Fuel Storage/Reactor Decommissioning

Comment. One commenter stated that the proposed 29.3 percent increase in annual fees for spent fuel storage/reactor decommissioning licensees is not equitable and places an undue burden on this particular class of licensees, which do not generate revenue through the sale of electricity and do not have a guarantee of recovering additional costs by petitioning local public utility commissions. The commenter further stated that rapidly rising annual fee increases for spent fuel storage/reactor decommissioning licensees place undue budget constraints that could affect the resources available for performing plant decommissioning activities.

Response. The NRC has responded to similar comments in previous rulemakings. Annual fees for the classes of licenses are based on the budgeted costs for the classes, as well as a surcharge to recover the costs for NRC activities that are not attributable to an existing NRC licensee or class of licensee, including activities that are exempt from part 170 fees by law or Commission policy. Since budgeted costs for one class of licenses may rise or fall at different rates than for other classes of licenses, so will annual fees. The increase in annual fees for the spent fuel storage/reactor decommissioning class of licensees reflects an increase in budgeted costs allocated to this class since FY 2002, including homeland security activities that are on the fee base for FY 2003. Recovering the costs associated with spent fuel storage and reactor decommissioning from operating power reactors, power reactors in decommissioning or possession only status if they have fuel on site, and independent spent fuel storage part 72 licensees who do not hold a part 50 license, is consistent with the intent of OBRA–90 to assess annual fees to licensees or classes of licenses, commensurate with the expenditure of the NRC's resources. The Commission believes it would be inequitable to grant fee relief to one class of licenses (except to address small entity issues in accordance with the Regulatory Flexibility Act) on the basis of economic considerations, since this class would then need to be subsidized by other classes of licenses.

D. Other Issues

1. Security Costs

Comment. The majority of comments did not support the NRC collecting security-related costs from licensees. These commenters noted that the FY 2003 NRC budget includes $29.3 million for homeland security activities, and stated that these activities should be funded through the General Treasury as part of the nation's protection of critical infrastructure. Some of these commenters also stated that significant security costs are being incurred for nuclear vulnerability assessments without due consideration of the evaluated threats or rigor of the methodology for conducting these assessments, which is not the best way to allocate the nation's resources in defending against terrorist attacks. Other commenters noted their belief that there is overlap and duplication of functions in Nuclear Security and Incident Response with those of other Federal agencies, particularly the Department of Homeland Security. One comment suggested that the increased fees for FY 2003 did not appear to reflect a consideration for the substantial work and engineered solutions that have already been implemented in the area of security.

Response. The NRC appreciates the concerns raised by commenters with regard to homeland security costs being funded through licensee fees. The NRC notes that the President's FY 2003 budget requested that NRC's funding for homeland security activities be excluded from the fee base, as was the case in FY 2002. However, the Energy and Water Development Appropriations Act, 2003, contained in the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), included NRC's budget for homeland security activities in the fee base. Therefore, the FY 2003 fees must include the $29.3 million budgeted for NRC's homeland security activities. The Commission agrees there are merits to the arguments that licensees should be treated in the same fashion as other owner/operators of critical infrastructure that do not generally pay user fees for Federal agency homeland security costs. The NRC notes that S. 1043, the ''Nuclear Infrastructure Security Act of 2003,'' recently approved by the Senate Committee on Environment and Public Works, provides that amounts appropriated to the NRC for homeland security activities would be excluded from the fee base except for costs associated with fingerprinting, background checks and security inspections.

In response to the comments that expressed concern regarding how the NRC is expending homeland security funds, as stated previously, the NRC's budget and manner in which the agency carries out its activities are not within the scope of this rulemaking. Nonetheless, the NRC is addressing the issues raised regarding the costs of vulnerability assessments and NRC's relationship with the Department of Homeland Security.

2. NRC Budget

Comment. Many commenters offered suggestions for reducing NRC's budget and for more efficient/different use of NRC's resources. Many of these comments addressed expenditures on homeland security, while others suggested more generally that NRC reduce expenditures, streamline processes, or otherwise perform activities more efficiently. Commenters suggested that changes in NRC's regulatory approach, such as the reactor oversight process and risk-informed changes to inspection, assessment, and enforcement processes, should result in reduced fees. One commenter suggested that increased cooperation between the NRC and industry could increase efficiency and conservation of limited resources.

Response. The NRC's budgets and the manner in which the NRC carries out its activities are not within the scope of this rulemaking. Therefore, this final rule does not address the commenters' suggestions concerning the NRC's budget and the use of NRC resources. The NRC's budget is submitted to the Office of Management and Budget and to Congress for review and approval. The Congressionally-approved budget resulting from this process reflects the resources deemed necessary for NRC to carry out its statutory obligations. In compliance with OBRA–90, the fees are established to recover the required percentage of the approved budget.

3. Cost Recovery for Agreement State Activities

Comment. One commenter stated that it supported the approach to allocate Agreement State Program activities to user fees, rather than the General Fund. Another commenter suggested the opposite approach, and stated that the costs for activities like Agreement State Programs should not be allocated to user fees, but rather paid for from the General Fund.

Response. The FY 2003 proposed fee rule did not propound to change how the NRC recovers costs for Agreement State Program activities, nor does this final rule make any changes with regard to recovery of these costs. The Commission has the authority to, but as a matter of policy does not, assess part 170 fees for specific services rendered to an Agreement State. Agreement States devote significant monetary and staff resources to national radiation control programs, and this effort assists the NRC and other Federal agencies in protecting public health and safety. The NRC costs for these Agreement State activities are funded through a surcharge, which is allocated to the various license classes on a prorated basis.

The surcharge is being funded from the general fund of the U.S. Treasury as a result of the FY 2001 Energy and Water Development Appropriations Act. This act amended OBRA–90 to decrease the NRC's fee recovery amount by 2 percent per year beginning in FY 2001, until the fee recovery amount is 90 percent in FY 2005, to address fairness and equity concerns related to charging NRC license holders for agency budgeted costs that do not provide a direct benefit to the licensee. The 2 percent per year reduction from the fee base accounts for activities such as Agreement State Oversight and Agreement State Regulatory Support.

4. Fee Increase Communication and Timing

Comment. Several commenters suggested that the NRC communicate the potential magnitude of fee increases earlier in the process. The commenters stated that this communication would allow licensees to forecast and mitigate financial impacts. These commenters expressed disappointment that the NRC gave its licensees no warning that significant increases were being contemplated. Several commenters expressed concern that NRC fee increases are seen by licensees almost a year after their budgets have been initially set, and suggested that NRC shift its process by one year (*e.g.,* the 2003 fee collection would be the 2004 fee projection). One commenter specifically requested that NRC review and forecast ongoing costs and fees over the next five years so that licensees can make accurate business forecasts. One commenter stated that NRC's method of collecting retroactive fees during the last government quarter for the previous three quarters will create a significant and unanticipated negative financial impact.

Response. The NRC appreciates the concerns raised by these commenters. However, as a matter of law (OBRA–90, as amended) and policy the NRC must collect the statutorily mandated level of fees by the end of the fiscal year to which they are attributed, in this case,

September 30, 2003. The law also requires that these fees be established through the rulemaking process. The NRC makes every effort to issue its proposed and final fee rules in a timely manner to afford licensees as much time as possible to plan for fee increases. However, the agency must ensure that it fully complies with all applicable legislation, regulations, and policies, as well as perform the required fee calculations, in a relatively short time each year to produce its fee rules. This year Congress did not enact NRC appropriations for FY 2003 until February 20, 2003. Because the NRC does not know in advance what its future budgets will be (*i.e.,* proposed budgets must be submitted to the Office of Management and Budget for its review before the President submits the budget to Congress for enactment), the agency believes it is not practicable to set fees based on future estimated budgets, nor would such an approach be consistent with its statutory mandate. The NRC will continue to strive to issue its fee regulations as early in the process as is practicable in order to give as much time as possible for licensees to plan for changes in fees.

III. Final Action

The NRC is amending its licensing, inspection, and annual fees to recover approximately 94 percent of its FY 2003 budget authority, including the budget authority for its Office of the Inspector General, less the appropriations received from the NWF. The NRC's total budget authority for FY 2003 is $584.6 million, of which approximately $24.7 million has been appropriated from the NWF. Based on the 94 percent fee recovery requirement, the NRC must recover approximately $526.3 million in FY 2003 through part 170 licensing and inspection fees, part 171 annual fees, and other offsetting receipts. The total amount to be recovered through fees and other offsetting receipts for FY 2003 is $46.8 million more than the amount estimated for recovery in FY 2002.

The NRC estimates that approximately $127.5 million will be recovered in FY 2003 from part 170 fees and other offsetting receipts. For FY 2003, the NRC also estimates a net adjustment of approximately $1.9 million for FY 2003 invoices that the NRC estimates will not be paid during the fiscal year, and for payments received in FY 2003 for FY 2002 invoices. The remaining $396.8 million will be recovered through the part 171 annual fees, compared to $345.6 million for FY 2002.

A primary reason for the increase in total fees, as well as the annual fee amount, for FY 2003 compared to FY 2002 is that the amount to be recovered for FY 2003 includes $29.3 million for homeland security activities, whereas the FY 2002 funding for homeland security was excluded from fees. While the President's FY 2003 budget requested that NRC's funding for homeland security activities continue to be excluded from the fee base, the Energy and Water Development Appropriations Act, 2003, contained in the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), included NRC's budget for homeland security activities in the fee base. Therefore, the FY 2003 fees include the $29.3 million budgeted for NRC's homeland security activities. Other reasons for the fee increases include the 2003 Federal pay raise, and the increased workload for new reactor licensing activities and reactor license renewal.

Table I summarizes the budget and fee recovery amounts for FY 2003. Due to rounding, adding the individual numbers in the table may result in a total that is slightly different than the one shown.

TABLE I.—BUDGET AND FEE RECOVERY AMOUNTS FOR FY 2003

[Dollars in millions]

Total Budget Authority	$584.6
Less NWF	−24.7
Balance	$559.9
Fee Recovery Rate for FY 2003	×94.0%
Total Amount to be Recovered For FY 2003	$526.3
Less Carryover from FY 2002	−0
Amount to be Recovered Through Fees and Other Receipts	$526.3
Less Estimated Part 170 Fees and Other Receipts	−127.5
Part 171 Fee Collections Required	$398.8
Part 171 Billing Adjustments:.	
Unpaid FY 2003 Invoices (estimated)	2.4
Less Payments Received in FY 2003 for Prior Year Invoices (estimated)	−4.3
Subtotal	−1.9
Adjusted Part 171 Collections Required	$396.8

The FY 2003 final fee rule is a ''major'' final action as defined by the Small Business Regulatory Enforcement Fairness Act of 1996. Therefore, the NRC's fees for FY 2003 will become effective 60 days after publication of the final rule in the **Federal Register**. The NRC will send an invoice for the amount of the annual fee to reactors and major fuel cycle facilities upon publication of the FY 2003 final rule. For these licensees, payment will be due on the effective date of the FY 2003 final rule. Those materials licensees whose license anniversary date during FY 2003 falls before the effective date of the final FY 2003 rule will be billed for the annual fee during the anniversary month of the license at the FY 2002 annual fee rate. Those materials licensees whose license anniversary date falls on or after the effective date of the final FY 2003 rule will be billed for the annual fee at the FY 2003 annual fee rate during the anniversary month of the license, and payment will be due on the date of the invoice.

In accordance with its FY 1998 announcement, the NRC has discontinued mailing the final fee rule

to all licensees as a cost-saving measure. Accordingly, the NRC does not plan to routinely mail the FY 2003 final fee rule or future final fee rules to licensees. However, the NRC will send the final rule to any licensee or other person upon specific request. To request a copy, contact the License Fee and Accounts Receivable Branch, Division of Accounting and Finance, Office of the Chief Financial Officer, at 301–415–7554, or e-mail us at *fees@nrc.gov.* The NRC plans to publish the final fee rule in June 2003. In addition to publication in the **Federal Register**, the final rule will be available on the Internet at *http://ruleforum.llnl.gov* for at least 90 days after the effective date of the final rule.

The NRC is amending 10 CFR Parts 170 and 171 as discussed in Sections A and B below.

A. Amendments to 10 CFR Part 170: Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended

The NRC is revising the hourly rates used to calculate fees and is adjusting the part 170 fees based on the revised hourly rates and the results of the agency's biennial review of fees required by the Chief Financial Officer (CFO) Act of 1990 (Pub. L. 101–578, November 15, 1990, 104 Stat. 2838). Additionally, the NRC is revising fee category 15.A. of § 170.31 to cover all categories of radioactive waste import license applications and to revise category 15.B. to remove the radioactive waste import license applications.

The amendments are as follows:

1. Hourly Rates

The NRC is revising the professional hourly rates for NRC staff time established in § 170.20. These rates are based on the number of FY 2003 direct program FTEs and the FY 2003 NRC budget, excluding direct program support costs and NRC's appropriations from the NWF. These rates are used to determine the part 170 fees. The rate for the reactor program is $156 per hour ($276,661 per direct FTE). This rate is applicable to all activities for which fees are assessed under § 170.21 of the fee regulations. The rate for the materials program (nuclear materials and nuclear waste programs) is $158 per hour ($280,876 per direct FTE). This rate is applicable to all activities for which fees are assessed under § 170.31 of the fee regulations. In the FY 2002 final fee rule, the reactor and materials program rates were $156 and $152, respectively.

A major reason for the 4 percent increase to the materials program rate is the salary and benefits increase that results primarily from the Government-wide pay raise. While salary and benefits also increase for the reactor program, the increase is offset by a reduction in the average overhead cost per direct FTE.

The method used to determine the two professional hourly rates is as follows:

a. Direct program FTE levels are identified for the reactor program and the materials program (nuclear materials and nuclear waste programs).

b. Direct contract support, which is the use of contract or other services in support of the line organization's direct program, is excluded from the calculation of the hourly rates because the costs for direct contract support are charged directly through the various categories of fees.

c. All other program costs (*e.g.*, Salaries and Benefits, Travel) represent ''in-house'' costs and are to be collected by dividing them uniformly by the total number of direct FTEs for the program. In addition, salaries and benefits plus contracts for non-program direct management and support, and for the Office of the Inspector General, are allocated to each program based on that program's direct costs. This method results in the following costs which are included in the hourly rates. Due to rounding, adding the individual numbers in the table may result in a total that is slightly different than the one shown.

TABLE II.—FY 2003 BUDGET AUTHORITY TO BE INCLUDED IN HOURLY RATES

	Reactor program	Materials program
Direct Program Salaries & Benefits (millions)	$134.1	$34.4
Overhead Salaries & Benefits, Program Travel and Other Support (millions)	62.3	17.1
Allocated Agency Management and Support (millions)	118.5	31.1
Subtotal (millions)	$314.9	$82.6
Less offsetting receipts (million)	−0 .1	−0.00
Total Budget Included in Hourly Rate (millions)	$314.8	$82.6
Program Direct FTEs	1138.0	294.1
Rate per Direct FTE	$276,661	$280,876
Professional Hourly Rate (Rate per direct FTE divided by 1,776 hours)	$156	$158

As shown in Table II, dividing the $314.8 million budgeted amount (rounded) included in the hourly rate for the reactor program by the reactor program direct FTEs (1138.0) results in a rate for the reactor program of $276,661 per FTE for FY 2003. The Direct FTE Hourly Rate for the reactor program is $156 per hour (rounded to the nearest whole dollar). This rate is calculated by dividing the cost per direct FTE ($276,661) by the number of productive hours in one year (1,776 hours) as set forth in the revised OMB Circular A–76, ''Performance of Commercial Activities.'' Similarly, dividing the $82.6 million budgeted amount (rounded) included in the hourly rate for the materials program by the program direct FTEs (294.1) results in a rate of $280,876 per FTE for FY 2003. The Direct FTE Hourly Rate for the materials program is $158 per hour (rounded to the nearest whole dollar). This rate is calculated by dividing the cost per direct FTE ($280,876) by the number of productive hours in one year (1,776 hours).

2. Fee Adjustments

The NRC is adjusting the current part 170 fees in §§ 170.21 and 170.31 to reflect both the revised hourly rates and the results of the biennial review of part 170 fees required by the CFO Act. To comply with the requirements of the CFO Act, the NRC has evaluated historical professional staff hours used to process a new license application for those materials licensees whose fees are based on the average cost method, or ''flat'' fees. This review also included new license and amendment

applications for import and export licenses.

Evaluation of the historical data shows that fees based on the average number of professional staff hours required to complete licensing actions in the materials program should be increased in some categories and decreased in others to more accurately reflect current costs incurred in completing these licensing actions.

The data for the average number of professional staff hours needed to complete new licensing actions was last updated in FY 2001 (66 FR 32452; June 14, 2001). Thus, the revised average professional staff hours in this fee rule reflect the changes in the NRC licensing review program that have occurred since FY 2001.

As a result of the biennial review, the licensing fees that are based on the average professional staff hours reflect an increase in average time for new license applications for six of the 33 materials program fee categories, a decrease in average time for eight fee categories, and the same average time for the remaining 19 fee categories. Similarly, the average time for applications for new export and import licenses and for amendments to export and import licenses remained the same for eight fee categories in §§ 170.21 and 170.31, and decreased for two other fee categories.

The licensing fees for fee categories K.1 through K.5 of § 170.21, and fee categories 1C, 1D, 2B, 2C, 3A through 3P, 4B through 9D, 10B, 15A through 15E, and 16 of § 170.31 are based on the revised average professional staff hours needed to process the licensing actions multiplied by the revised materials program professional hourly rate for FY 2003.

The biennial review also included the ''flat'' fee for the general license registrations covered by fee Category 3.Q. As a result of this review, the fee per registration is $620, compared to $450 in FY 2002. The revised fee is based on the current estimated number of registrants, current annual resource estimates for the program, and the FY 2003 materials program FTE rate. This increase to the current fee of $450 is based on experience with the registrations to date, which indicates that the average cost per registrant is higher than originally estimated. The next biennial review of the registration fee will be included in the FY 2005 fee rule; however, the registration fee may change in the FY 2004 fee rule if there is a change to the materials program FTE rate for FY 2004.

The amounts of the materials licensing ''flat'' fees are rounded as follows: fees under $1,000 are rounded to the nearest $10, fees that are greater than$1,000 but less than $100,000 are rounded to the nearest $100, and fees that are greater than $100,000 are rounded to the nearest $1,000. Applications filed on or after the effective date of the final rule will be subject to the revised fees in this final rule.

The NRC is expanding fee Category 15.A. of § 170.31 to include all categories of radioactive waste import license applications, and modifying Category 15.B. of § 170.31 to exclude these types of import license applications. This change is being made because all applications for the import of radioactive waste must be reviewed by the Executive Branch and require the involvement of all states and compacts, as well as extensive coordination within the NRC. Therefore, the NRC efforts for the waste import license applications are more closely aligned with the efforts for the other types of export and import licenses currently covered by Category 15.A.

In addition, the Office of Nuclear Reactor Regulation revised its policy of charging the sites for administrative/overhead fees for early assignment of resident inspectors. Under this new policy, the administrative/overhead fees for the individuals selected for early assignments will not be charged to the site.

In summary, the NRC is amending 10 CFR Part 170 to —

1. Revise the materials and reactor programs FTE hourly rates;

2. Revise the licensing fees to be assessed to reflect the reactor and materials program hourly rates and to comply with the CFO Act requirement that fees be reviewed biennially and revised as necessary to reflect the cost to the agency;

3. Revise Category 15.A. of § 170.31 to include radioactive waste import licenses, and exclude these types of applications from Category 15.B.

B. Amendments to 10 CFR Part 171: Annual Fees for Reactor Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC

The NRC is revising the annual fees for FY 2003 as follows.

1. Annual Fees

The NRC is establishing rebaselined annual fees for FY 2003. The Commission's policy commitment, made in the statement of considerations accompanying the FY 1995 fee rule (60 FR 32225; June 20, 1995), and further explained in the statement of considerations accompanying the FY 1999 fee rule (64 FR 31448; June 10, 1999), determined that base annual fees will be re-established (rebaselined) at least every third year, and more frequently if there is a substantial change in the total NRC budget or in the magnitude of the budget allocated to a specific class of licenses. The fees were last rebaselined in FY 2002. Based on the change in the magnitude of the budget to be recovered through fees, the Commission has determined that it is appropriate to rebaseline the annual fees again this year. Rebaselining fees will result in increased annual fees compared to FY 2002 for four classes of licenses (power reactors, spent fuel storage/reactor decommissioning, fuel facilities, and rare earth facilities), and decreased annual fees for two classes (non-power reactors and uranium recovery). For the small materials users and transportation classes, some categories of licenses will have increased annual fees and others will have decreased annual fees.

The annual fees in §§ 171.15 and 171.16 will be revised for FY 2003 to recover approximately 94 percent of the NRC's FY 2003 budget authority, less the estimated amount to be recovered through part 170 fees and the amounts appropriated from the NWF. The total amount to be recovered through annual fees for FY 2003 is $396.8 million, compared to $345.6 million for FY 2002.

Within the fee classes, the FY 2003 annual fees will increase for many categories of licenses, decrease for other categories, and for two categories remain the same from the previous year. The two largest categories of materials licensees (which together include nearly 3,500 of NRC's approximately 4,900 materials user licenses) show annual fee decreases compared to FY 2002 of 7.4 percent and 9.8 percent. The increases in annual fees range from approximately 1.2 percent for DOE's transportation activities to approximately 62 percent for licenses issued to distribute items containing byproduct material that require device review to persons exempt from licensing requirements of part 30. The decreases in annual fees range from approximately 2.7 percent for two materials categories and for the quality assurance approvals for users to approximately 53 percent for materials licenses authorizing possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies (other than field flooding). The fees remain the same for materials licenses

authorizing possession and use of byproduct material in sealed sources for irradiation of materials where the source is not removed from its shield and licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material.

Factors affecting the changes to the annual fee amounts include adjustments in budgeted costs for the different classes of licenses (including the addition of budgeted costs for NRC's homeland security activities), the reduction in the fee recovery rate from 96 percent for FY 2002 to 94 percent for FY 2003, the estimated part 170 collections for the various classes of licenses, the increased hourly rate for the materials and waste program, and decreases in the numbers of licensees for certain categories of licenses. In addition, there is no carryover from FY 2002 to reduce the FY 2003 fees. The FY 2002 fees were reduced by a $1.7 million carryover from FY 2001.

Table IV below shows the rebaselined annual fees for FY 2003 for representative categories of licenses.

TABLE IV.—REBASELINED ANNUAL FEES FOR FY 2003

Class/category of licenses	FY 2003 annual fee
Operating Power Reactors (including Spent Fuel Storage/Reactor Decommissioning annual fee)	$3,251,000
Spent Fuel Storage/Reactor Decommissioning	319,000
Nonpower Reactors	63,300
High Enriched Uranium Fuel Facility	5,836,000
Low Enriched Uranium Fuel Facility	1,957,000
UF_6 Conversion Facility	839,000
Uranium Mills	63,700
Transportation:	
Users/Fabricators	76,200
Users Only	7,100
Typical Materials Users:	
Radiographers	12,200
Well Loggers	4,700
Gauge Users	1,900
Broad Scope Medical	24,700

The annual fees assessed to each class of licenses include a surcharge to recover those NRC budgeted costs that are not directly or solely attributable to the classes of licenses, but must be recovered from licensees to comply with the requirements of OBRA–90, as amended. Based on the FY 2001 Energy and Water Appropriations Act which amended OBRA–90 to decrease the NRC's fee recovery amount by 2 percent per year beginning in FY 2001, until the fee recovery amount is 90 percent in FY 2005, the total surcharge costs for FY 2003 will be reduced by about $33.6 million. The total FY 2003 budgeted costs for these activities and the reduction to the total surcharge amount for fee recovery purposes are shown in Table V. Due to rounding, adding the individual numbers in the table may result in a total that is slightly different than the one shown.

TABLE V.—SURCHARGE COSTS

[Dollars in millions]

Category of costs	FY 2003 budgeted costs
1. Activities not attributable to an existing NRC licensee or class of licensee:	
a. International activities	$10.3
b. Agreement State oversight	8.8
c. Low-level waste disposal generic activities	2.7
d. Site decommissioning management plan activities not recovered under part 170	3.6
2. Activities not assessed part 170 licensing and inspection fees or part 171 annual fees based on existing law or Commission policy:	
a. Fee exemption for nonprofit educational institutions	6.7
b. Licensing and inspection activities associated with other Federal agencies	2.9
c. Costs not recovered from small entities under 10 CFR 171.16(c)	4.5
3. Activities supporting NRC operating licensees and others:	
a. Regulatory support to Agreement States	13.4
b. Generic decommissioning/reclamation (except those related to power reactors)	4.9
Total surcharge costs	57.8
Less 6 percent of NRC's FY 2003 total budget (less NWF)	−33.6
Total Surcharge Costs to be Recovered	$24.2

As shown in Table V, $24.2 million is the total surcharge cost allocated to the various classes of licenses for FY 2003. The NRC will continue to allocate the surcharge costs, except Low-Level Waste (LLW) surcharge costs, to each

class of licenses based on the percent of the budget for that class. The NRC will continue to allocate the LLW surcharge costs based on the volume of LLW disposed of by certain classes of licenses. The surcharge costs allocated to each class will be included in the annual fee assessed to each licensee. The FY 2003 surcharge costs allocated to each class of licenses are shown in Table VI. Due to rounding, adding the individual numbers in the table may result in a total that is slightly different than the one shown.

TABLE VI.—ALLOCATION OF SURCHARGE

	LLW surcharge		Non-LLW surcharge		Total surcharge $,M
	Percent	$,M	Percent	$,M	
Operating Power Reactors	74	2.0	79.3	17.1	19.1
Spent Fuel Storage/Reactor Decomm.	.....	.....	8.2	1.8	1.8
Nonpower Reactors	.....	.....	0.1	0.0	0.0
Fuel Facilities	8	0.2	6.7	1.4	1.6
Materials Users	18	0.5	3.8	0.8	1.3
Transportation	.....	.....	1.2	0.3	0.3
Rare Earth Facilities	.....	.....	0.2	0.0	0.0
Uranium Recovery	.....	.....	0.7	0.1	0.1
Total Surcharge	100	2.7	100.0	21.5	24.2

The budgeted costs allocated to each class of licenses and the calculations of the rebaselined fees are described in a. through h. below. The workpapers which support this final rule show in detail the allocation of NRC's budgeted resources for each class of licenses and how the fees are calculated. The workpapers are available electronically at the NRC's Electronic Reading Room on the Internet at Web site address *http://www.gov/reading-rm/adams.html.* For a period of 90 days after the effective date of this final rule, the workpapers may also be examined at the NRC Public Document Room located at One White Flint North, Room O–1F22, 11555 Rockville Pike, Rockville, MD 20852–2738.

a. *Fuel Facilities.* The revised annual fees for the fuel facility class reflect increased budgeted costs for activities that are not subject to cost recovery under part 170, primarily homeland security activities related to fuel facilities. Such activities include the issuance and follow-up of orders directing the fuel facility licensees to take interim compensatory measures to increase security, and a series of risk-informed vulnerability assessments the NRC is conducting on fuel facilities.

The FY 2003 budgeted costs of approximately $27.0 million to be recovered in annual fees assessed to the fuel facility class is allocated to the individual fuel facility licensees based on the effort/fee determination matrix established in the FY 1999 final fee rule (64 FR 31448; June 10, 1999). In the matrix (which is included in the NRC workpapers that are publicly available), licensees are grouped into five categories according to their licensed activities (*i.e.*, nuclear material enrichment, processing operations, and material form) and according to the level, scope, depth of coverage, and rigor of generic regulatory programmatic effort applicable to each category from a safety and safeguards perspective. This methodology can be applied to determine fees for new licensees, current licensees, licensees in unique license situations, and certificate holders.

The methodology is adaptable to changes in the number of licensees or certificate holders, licensed-certified material/activities, and total programmatic resources to be recovered through annual fees. When a license or certificate is modified, it may result in a change of category for a particular fuel facility licensee as a result of the methodology used in the fuel facility effort/fee matrix. Consequently, this change may also have an effect on the fees assessed to other fuel facility licensees and certificate holders. For example, if a fuel facility licensee amends its license/certificate in such a way (*e.g.*, decommissioning or license termination) that results in them not being subject to part 171 costs applicable to the fee class, then the budgeted costs for the safety and/or safeguards components will be spread among the remaining fuel facility licensees/certificate holders, resulting in higher fees for those affected licensees.

The methodology is applied as follows. First, a fee category is assigned based on the nuclear material and activity authorized by license or certificate. Although a licensee/certificate holder may elect not to fully utilize a license/certificate, the license/certificate is still used as the source for determining authorized nuclear material possession and use/activity. Next, the category and license/certificate information are used to determine where the licensee/certificate holder fits into the matrix. The matrix depicts the categorization of licensees/certificate holders by authorized material types and use/activities, and the relative generic regulatory programmatic effort associated with each category. The programmatic effort (expressed as a value in the matrix) reflects the safety and safeguards risk significance associated with the nuclear material and use/activity, and the commensurate generic regulatory program (*i.e.*, scope, depth and rigor) level of effort.

The effort factors for the various subclasses of fuel facility licenses are summarized in Table VII.

TABLE VII.—EFFORT FACTORS FOR FUEL FACILITIES

Facility type	Number of facilities	Effort factors (In percent)	
		Safety	Safeguards
High Enriched Uranium Fuel	2	91 (36.0)	76 (57.1)
Enrichment	2	70 (27.7)	34 (25.6)

TABLE VII.—EFFORT FACTORS FOR FUEL FACILITIES—Continued

Facility type	Number of facilities	Effort factors (In percent)	
		Safety	Safeguards
Low Enriched Uranium Fuel	3	66 (26.1)	18 (13.5)
UF_6 Conversion	1	12 (4.7)	0 (0)
Limited Operations Facility	1	8 (3.2)	3 (2.3)
Others	1	6 (2.4)	2 (1.5)

Applying these factors to the safety, safeguards, and surcharge components of the $27.0 million total annual fee amount for the fuel facility class results in annual fees for each licensee within the subcategories of this class summarized in Table VIII.

TABLE VIII.—ANNUAL FEES FOR FUEL FACILITIES

Facility type	FY 2003 annual fee
High Enriched Uranium Fuel	$5,836,000
Uranium Enrichment	3,634,000
Low Enriched Uranium	1,957,000
UF_6 Conversion	839,000
Limited Operations Facility	769,000
Others	559,000

b. *Uranium Recovery Facilities.* The FY 2003 budgeted costs, including surcharge costs, to be recovered through annual fees assessed to the uranium recovery class is approximately $1.5 million. Approximately $1.0 million of this amount will be assessed to DOE. The remaining $0.5 million will be recovered through annual fees assessed to conventional mills, in-situ leach solution mining facilities, and 11e.(2) mill tailings disposal facilities.

Consistent with the change in methodology adopted in the FY 2002 final fee rule (67 FR 42612; June 24, 2002), the total annual fee amount, less the amounts specifically budgeted for Title I activities, is allocated equally between Title I and Title II licensees. This results in an annual fee being assessed to DOE to recover the costs specifically budgeted for NRC's Title I activities plus 50 percent of the remaining annual fee amount, including the surcharge, for the uranium recovery class. The remaining surcharge, generic, and other costs are assessed to the NRC Title II program licensees that are subject to annual fees. The costs to be recovered through annual fees assessed to the uranium recovery class are shown below. Due to rounding, adding the individual numbers in the table may result in a total that is slightly different than the one shown.

DOE Annual Fee Amount (UMTRCA Title I and Title II general licenses):	
UMTRCA Title I budgeted costs	$393,227
50% of generic/other uranium recovery budgeted costs	485,513
50% of uranium recovery surcharge	70,829
Total Annual Fee Amount for DOE	949,569
Annual Fee Amount for UMTRCA Title II Specific Licenses:	
50% of generic/other uranium recovery budgeted costs	485,513
50% of uranium recovery surcharge	70,829
Total Annual Fee Amount for Title II Specific Licenses	556,342

The costs allocated to the various categories of Title II specific licensees are based on the uranium recovery matrix established in the FY 1999 final fee rule (64 FR 31448; June 10, 1999). The methodology for establishing part 171 annual fees for Title II uranium recovery licensees has not changed and is as follows:

(1) The methodology identifies three categories of licenses: conventional uranium mills (Class I facilities), uranium solution mining facilities (Class II facilities), and mill tailings disposal facilities (11e.(2) disposal facilities). Each of these categories benefits from the generic uranium recovery program efforts (*e.g.*, rulemakings, staff guidance documents);

(2) The matrix relates the category and the level of benefit by program element and subelement;

(3) The two major program elements of the generic uranium recovery program are activities related to facility operations and those related to facility closure;

(4) Each of the major program elements was further divided into three subelements;

(5) The three major subelements of generic activities associated with uranium facility operations are regulatory efforts related to the operation of mills, handling and disposal of waste, and prevention of groundwater contamination. The three major subelements of generic activities associated with uranium facility closure are regulatory efforts related to decommissioning of facilities and land clean-up, reclamation and closure of tailings impoundments, and groundwater clean-up. Weighted values were assigned to each program element and subelement considering health and safety implications and the associated effort to regulate these activities. The applicability of the generic program in each subelement to each uranium recovery category was qualitatively estimated as either significant, some, minor, or none.

The relative weighted factors per facility type for the various subclasses of specifically licensed Title II uranium recovery licensees are as follows:

TABLE IX.—WEIGHTED FACTORS FOR URANIUM RECOVERY LICENSES

Facility type	Number of facilities	Category weight	Level of benefit total weight	
			Value	Percent
Class I (conventional mills)	3	770	2,310	34
Class II (solution mining)	6	645	3,870	58
11e.(2) disposal	1	475	475	7
11e.(2) disposal incident to existing tailings sites	1	75	75	1

Applying these factors to the $0.5 million in budgeted costs to be recovered from Title II specific licensees results in the following revised annual fees:

TABLE X.—ANNUAL FEES FOR TITLE II SPECIFIC LICENSES

Facility type	FY 2003 annual fee
Class I (conventional mills)	$ 63,700
Class II (solution mining)	53,300
11e.(2) disposal	39,300
11e.(2) disposal incidental to existing tailings sites	6,200

In the FY 2001 final rule (66 FR 32478; June 14, 2001), the NRC revised § 171.19 to establish a quarterly billing schedule for the Class I and Class II licensees, regardless of the annual fee amount. Therefore, as provided in § 171.19(b), if the amounts collected in the first three quarters of FY 2003 exceed the amount of the revised annual fee, the overpayment will be refunded; if the amounts collected in the first three quarters are less than the final revised annual fee, the remainder will be billed after the FY 2003 final fee rule is published. The remaining categories of Title II facilities are subject to billing based on the anniversary date of the license as provided in § 171.19(c).

c. *Power Reactors.* The approximately $305.0 million in budgeted costs to be recovered through FY 2003 annual fees assessed to the power reactor class, which includes NRC's budgeted costs for homeland security activities related to power reactors, is divided equally among the 104 power reactors licensed to operate. This results in a FY 2003 annual fee of $2,932,000 per reactor. Additionally, each power reactor licensed to operate will be assessed the FY 2003 spent fuel storage/reactor decommissioning annual fee of $319,000. This results in a total FY 2003 annual fee of $3,251,000 for each power reactor licensed to operate.

d. *Spent Fuel Storage/Reactor Decommissioning.* For FY 2003, budgeted costs of approximately $38.6 million for spent fuel storage/reactor decommissioning are to be recovered through annual fees assessed to part 50 power reactors, and to part 72 licensees who do not hold a part 50 license. Those reactor licensees that have ceased operations and have no fuel onsite are not subject to these annual fees. The costs are divided equally among the 121 licensees, resulting in a FY 2003 annual fee of $319,000 per licensee.

e. *Non-power Reactors.* Approximately $253,000 in budgeted costs is to be recovered through annual fees assessed to the non-power reactor class of licenses for FY 2003. This amount is divided equally among the four non-power reactors subject to annual fees. This results in a FY 2003 annual fee of $63,300 for each licensee.

f. *Rare Earth Facilities.* The FY 2003 budgeted costs of approximately $187,000 for rare earth facilities to be recovered through annual fees will be divided equally among the two licensees who have a specific license for receipt and processing of source material. Prior to the beginning of FY 2003, one rare earth facility permanently ceased operations and requested that its license be amended to authorize decommissioning activities only. Consequently, this license is no longer subject to annual fees. The result is a FY 2003 annual fee of $93,600 for each of the two remaining rare earth facilities.

g. *Materials Users.* To equitably and fairly allocate the $23.7 million in FY 2003 budgeted costs to be recovered in annual fees assessed to the approximately 5,000 diverse materials users and registrants, the NRC has continued to use the FY 1999 methodology to establish baseline annual fees for this class. The annual fees are based on the part 170 application fees and an estimated cost for inspections. Because the application fees and inspection costs are indicative of the complexity of the license, this approach continues to provide a proxy for allocating the generic and other regulatory costs to the diverse categories of licenses based on how much it costs the NRC to regulate each category. The fee calculation also continues to consider the inspection frequency (priority), which is indicative of the safety risk and resulting regulatory costs associated with the categories of licenses. The annual fee for these categories of licenses is developed as follows:

Annual fee = Constant × [Application Fee + (Average Inspection Cost divided by Inspection Priority)] + Inspection Multiplier × (Average Inspection Cost divided by Inspection Priority) + Unique Category Costs.

The constant is the multiple necessary to recover approximately $18.0 million in general costs and is 1.18 for FY 2003. The inspection multiplier is the multiple necessary to recover approximately $4.5 million in inspection costs for FY 2003, and is 0.92 for FY 2003. The unique category costs are any special costs that the NRC has budgeted for a specific category of licenses. For FY 2003, approximately $65,300 in budgeted costs for the implementation of revised part 35, Medical Use of Byproduct Material (unique costs), has been allocated to holders of NRC human use licenses.

The annual fee assessed to each licensee also includes a share of the $800,000 in surcharge costs allocated to the materials user class of licenses and, for certain categories of these licenses, a share of the approximately $500,000 in LLW surcharge costs allocated to the class. The annual fee for each fee category is shown in § 171.16(d).

h. *Transportation.* Of the approximately $5.0 million in FY 2003 budgeted costs to be recovered through annual fees assessed to the transportation class of licenses (including homeland security costs), approximately $1.4 million will be recovered from annual fees assessed to DOE based on the number of part 71 Certificates of Compliance that it holds. Of the remaining $3.6 million, approximately 25 percent is allocated to the 89 quality assurance plans authorizing use only and the 40 quality assurance plans authorizing use and design/fabrication. The remaining 75 percent is allocated only to the 40 quality assurance plans authorizing use and design/fabrication. This results in an annual fee of $7,100 for each of the holders of quality assurance plans that authorize use only, and an annual fee of $76,200 for each of the holders of quality assurance plans that authorize use and design/fabrication.

2. Small Entity Annual Fees

The NRC stated in the FY 2001 fee rule (66 FR 32452; June 14, 2001), that it would re-examine the small entity fees every two years, in the same years in which it conducts the biennial review of fees as required by the CFO Act. Accordingly, the NRC has re-examined the small entity fees, and does not believe that a change to the small entity fees is warranted for FY 2003. The revision to the small entity fees in FY 2000 (65 FR 36946; June 12, 2000) was based on the 25 percent increase in average total fees assessed to other materials licensees in selected categories since the small entity fees were first established and changes that had occurred in the fee structure for materials licensees over time.

Unlike the annual fees assessed to other licensees, the small entity fees are not designed to recover the agency costs associated with particular licensees. Instead, the reduced fees for small entities are designed to provide some fee relief for qualifying small entity licensees while at the same time recovering from them some of the agency's costs for activities that benefit

them. The costs not recovered from small entities for activities that benefit them must be recovered from other licensees. Given the reduction in annual fees and the relative low inflation rates, the NRC has determined that the current small entity fees of $500 and $2,300 continue to meet the objective of providing relief to many small entities while recovering from them some of the costs that benefit them.

Therefore, the NRC is retaining the $2,300 small entity annual fee and the $500 lower tier small entity annual fee for FY 2003. The NRC plans to re-examine the small entity fees again in FY 2005.

In summary, the NRC has—

1. Established rebaselined annual fees for FY 2003;

2. Retained the current reduced fees for small entities.

IV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this final rule, the NRC is amending the licensing, inspection, and annual fees charged to its licensees and applicants as necessary to recover approximately 94 percent of its budget authority in FY 2003 as is required by the Omnibus Budget Reconciliation Act of 1990, as amended. This action does not constitute the establishment of a standard that contains generally applicable requirements.

V. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental assessment nor an environmental impact statement has been prepared for the final regulation. By its very nature, this regulatory action does not affect the environment and, therefore, no environmental justice issues are raised.

VI. Paperwork Reduction Act Statement

This final rule does not contain information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Analysis

With respect to 10 CFR Part 170, this final rule was developed pursuant to Title V of the Independent Offices Appropriation Act of 1952 (IOAA) (31 U.S.C. 9701) and the Commission's fee guidelines. When developing these guidelines the Commission took into account guidance provided by the U.S. Supreme Court on March 4, 1974, in *National Cable Television Association, Inc.* v. *United States,* 415 U.S. 36 (1974) and *Federal Power Commission* v. *New England Power Company,* 415 U.S. 345 (1974). In these decisions, the Court held that the IOAA authorizes an agency to charge fees for special benefits rendered to identifiable persons measured by the ''value to the recipient'' of the agency service. The meaning of the IOAA was further clarified on December 16, 1976, by four decisions of the U.S. Court of Appeals for the District of Columbia: *National Cable Television Association* v. *Federal Communications Commission,* 554 F.2d 1094 (D.C. Cir. 1976); *National Association of Broadcasters* v. *Federal Communications Commission,* 554 F.2d 1118 (D.C. Cir. 1976); *Electronic Industries Association* v. *Federal Communications Commission,* 554 F.2d 1109 (D.C. Cir. 1976); and *Capital Cities Communication, Inc.* v. *Federal Communications Commission,* 554 F.2d 1135 (D.C. Cir. 1976). The Commission's fee guidelines were developed based on these legal decisions.

The Commission's fee guidelines were upheld on August 24, 1979, by the U.S. Court of Appeals for the Fifth Circuit in *Mississippi Power and Light Co.* v. *U.S. Nuclear Regulatory Commission,* 601 F.2d 223 (5th Cir. 1979), *cert. denied,* 444 U.S. 1102 (1980). This court held that—

(1) The NRC had the authority to recover the full cost of providing services to identifiable beneficiaries;

(2) The NRC could properly assess a fee for the costs of providing routine inspections necessary to ensure a licensee's compliance with the Atomic Energy Act and with applicable regulations;

(3) The NRC could charge for costs incurred in conducting environmental reviews required by NEPA;

(4) The NRC properly included the costs of uncontested hearings and of administrative and technical support services in the fee schedule;

(5) The NRC could assess a fee for renewing a license to operate a low-level radioactive waste burial site; and

(6) The NRC's fees were not arbitrary or capricious.

With respect to 10 CFR Part 171, on November 5, 1990, the Congress passed Pub. L. 101–508, the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), which required that, for FYs 1991 through 1995, approximately 100 percent of the NRC budget authority be recovered through the assessment of fees. OBRA–90 was subsequently amended to extend the 100 percent fee recovery requirement through FY 2000. The FY 2001 Energy and Water Development Appropriations Act amended OBRA–90 to decrease the NRC's fee recovery amount by 2 percent per year beginning in FY 2001, until the fee recovery amount is 90 percent in FY 2005. The NRC's fee recovery amount for FY 2003 is 94 percent. To comply with this statutory requirement and in accordance with § 171.13, the NRC is publishing the amount of the FY 2003 annual fees for reactor licensees, fuel cycle licensees, materials licensees, and holders of Certificates of Compliance, registrations of sealed source and devices and QA program approvals, and Government agencies. OBRA–90, consistent with the accompanying Conference Committee Report, and the amendments to OBRA–90, provides that—

(1) The annual fees be based on approximately 94 percent of the Commission's FY 2003 budget of $584.6 million less the amounts collected from part 170 fees and funds directly appropriated from the NWF to cover the NRC's high level waste program;

(2) The annual fees shall, to the maximum extent practicable, have a reasonable relationship to the cost of regulatory services provided by the Commission; and

(3) The annual fees be assessed to those licensees the Commission, in its discretion, determines can fairly, equitably, and practicably contribute to their payment.

10 CFR Part 171, which established annual fees for operating power reactors effective October 20, 1986 (51 FR 33224; September 18, 1986), was challenged and upheld in its entirety in *Florida Power and Light Company* v. *United States,* 846 F.2d 765 (D.C. Cir. 1988), *cert. denied,* 490 U.S. 1045 (1989). Further, the NRC's FY 1991 annual fee rule methodology was upheld by the D.C. Circuit Court of Appeals in *Allied Signal* v. *NRC,* 988 F.2d 146 (D.C. Cir. 1993).

VIII. Regulatory Flexibility Analysis

The NRC is required by the Omnibus Budget Reconciliation Act of 1990, as amended, to recover approximately 94 percent of its FY 2003 budget authority through the assessment of user fees. This act further requires that the NRC establish a schedule of charges that

fairly and equitably allocates the aggregate amount of these charges among licensees.

This final rule establishes the schedules of fees that are necessary to implement the Congressional mandate for FY 2003. The final rule will result in increases in the annual fees charged to certain licensees and holders of certificates, registrations, and approvals, and decreases in annual fees for others. Licensees affected by the annual fee increases and decreases include those that qualify as a small entity under NRC's size standards in 10 CR 2.810. The Regulatory Flexibility Analysis, prepared in accordance with 5 U.S.C. 604, is included as Appendix A to this final rule.

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) was signed into law on March 29, 1996. The SBREFA requires all Federal agencies to prepare a written compliance guide for each rule for which the agency is required by 5 U.S.C. 604 to prepare a regulatory flexibility analysis. Therefore, in compliance with the law, Attachment 1 to the Regulatory Flexibility Analysis is the small entity compliance guide for FY 2003.

IX. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and that a backfit analysis is not required for this final rule. The backfit analysis is not required because these amendments do not require the modification of or additions to systems, structures, components, or the design of a facility or the design approval or manufacturing license for a facility or the procedures or organization required to design, construct, or operate a facility.

X. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104–121, the NRC has determined that this action is a major rule and has verified the determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

List of Subjects

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, Registrations, Approvals, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Parts 170 and 171.

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

■ 1. The authority citation for part 170 continues to read as follows:

Authority: Sec. 9701, Pub. L. 97–258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92–314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, Pub. L. 101–576, 104 Stat. 2842, as amended (31 U.S.C. 901, 902).

■ 2. Section 170.20 is revised to read as follows:

§ 170.20 Average cost per professional staff-hour.

Fees for permits, licenses, amendments, renewals, special projects, part 55 re-qualification and replacement examinations and tests, other required reviews, approvals, and inspections under §§ 170.21 and 170.31 will be calculated using the following applicable professional staff-hour rates:

(a) Reactor Program (§ 170.21 Activities): $156 per hour

(b) Nuclear Materials and Nuclear Waste Program (§ 170.31 Activities): $158 per hour

■ 3. In § 170.21, Category K in the table is revised to read as follows:

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses.

* * * * *

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

Facility categories and type of fees	Fees [1,2]
* * * * * * *	
K. Import and export licenses:	
Licenses for the import and export only of production and utilization facilities or the export only of components for production and utilization facilities issued under 10 CFR Part 110:	
1. Application for import or export of reactors and other facilities and exports of components which must be reviewed by the Commissioners and the Executive Branch, for example, actions under 10 CFR 110.40(b). This category includes application for import of radioactive waste.	
Application-new license	$10,300
Amendment	$10,300
2. Application for export of reactor and other components requiring Executive Branch review only, for example, those actions under 10 CFR 110.41(a)(1)–(8). This category includes application for the export of radioactive waste.	
Application-new license	$6,000
Amendment	$6,000
3. Application for export of components requiring foreign government assurances only.	
Application-new license	$1,900
Amendment	$1,900
4. Application for export of facility components and equipment not requiring Commissioner review, Executive Branch review, or foreign government assurances.	
Application-new license	$1,300
Amendment	$1,300

SCHEDULE OF FACILITY FEES—Continued

[See footnotes at end of table]

Facility categories and type of fees	Fees [1,2]
5. Minor amendment of any export or import license to extend the expiration date, change domestic information, or make other revisions which do not require in-depth analysis or review.	
Amendment	$240

[1] Fees will not be charged for orders issued by the Commission under § 2.202 of this chapter or for amendments resulting specifically from the requirements of these types of Commission orders. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (*e.g.*, 10 CFR 50.12, 73.5) and any other sections in effect now or in the future, regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. Fees for licenses in this schedule that are initially issued for less than full power are based on review through the issuance of a full power license (generally full power is considered 100 percent of the facility's full rated power). Thus, if a licensee received a low power license or a temporary license for less than full power and subsequently receives full power authority (by way of license amendment or otherwise), the total costs for the license will be determined through that period when authority is granted for full power operation. If a situation arises in which the Commission determines that full operating power for a particular facility should be less than 100 percent of full rated power, the total costs for the license will be at that determined lower operating power level and not at the 100 percent capacity.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect at the time the service was provided. For those applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for any topical report, amendment, revision or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20.

* * * * *

■ 4. Section 170.31 is revised to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

Applicants for materials licenses, import and export licenses, and other regulatory services, and holders of materials licenses or import and export licenses shall pay fees for the following categories of services. The following schedule includes fees for health and safety and safeguards inspections where applicable:

SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees[1]	Fee [2,3]
1. Special nuclear material:	
A. Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U–235 in unsealed form or 200 grams or more of U–233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only:	
Licensing and Inspection	Full Cost.
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI):	
Licensing and inspection	Full Cost.
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers:[4]	
Application	$730.
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1A:[4]	
Application	$1,500.
E. Licenses or certificates for construction and operation of a uranium enrichment facility:	
Licensing and inspection	Full Cost.
2. Source material:	
A. (1) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, ore buying stations, and ion exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode:	
Licensing and inspection	Full Cost.
(2) Licenses that authorize the receipt of byproduct material, as defined in Section 11e(2) of the Atomic Energy Act, from other persons for possession and disposal except those licenses subject to fees in Category 2A(1):	
Licensing and inspection	Full Cost
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2A(1):	
Licensing and inspection	Full Cost.
B. Licenses which authorize the possession, use, and/or installation of source material for shielding:	
Application	$170.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees[1]	Fee [2,3]
C. All other source material licenses:	
Application	$6,200
3. Byproduct material:	
A. Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application	$7,400.
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application	$2,900.
C. Licenses issued under §§ 32.72, 32.73, and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). These licenses are covered by fee Category 3D.	
Application	$6,100.
D. Licenses and approvals issued under §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources or devices not involving processing of byproduct material. This category includes licenses issued under §§ 32.72, 32.73, and/or 32.74 of this chapter to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4).	
Application	$2,700.
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units):	
Application	$1,800.
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application	$3,700.
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application	$8,800.
H. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter. The category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter:	
Application	$4,300.
I. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter:	
Application	$4,300.
J. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter:	
Application	$1,100.
K. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter:	
Application	$650.
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution:	
Application	$6,200
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution:	
Application	$3,000.
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C:	
Application	$3,300.
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations:	
Application	$3,300.
P. All other specific byproduct material licenses, except those in Categories 4A through 9D:	
Registration	$1,200.
Q. Registration of a device(s) generally licensed under part 31 of this chapter:	
Application	$620.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees[1]	Fee [2,3]
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material:	
Licensing and inspection	Full Cost.
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application	$1,900.
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application	$2,800.
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies:	
Application	$2,000.
B. Licenses for possession and use of byproduct material for field flooding tracer studies:	
Licensing	Full Cost.
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material:	
Application	$12,600.
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application	$6,900.
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application	$4,900.
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application	$1,900.
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities:	
Application	$360.
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution:	
Application—each device	$5,700.
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices:	
Application—each device	$5,700.
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution:	
Application—each source	$1,800.
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel:	
Application—each source	$600.
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers:	
Licensing and inspections	Full Cost.
B. Evaluation of 10 CFR Part 71 quality assurance programs:	
Application	$2,100.
Inspections	Full Cost.
11. Review of standardized spent fuel facilities:	
Licensing and inspection	Full Cost.
12. Special projects:	
Approvals and preapplication/Licensing activities	Full Cost.
Inspections	Full Cost.
13. A. Spent fuel storage cask Certificate of Compliance:	
Licensing	Full Cost.
B. Inspections related to spent fuel storage cask Certificate of Compliance	Full Cost.
C. Inspections related to storage of spent fuel under § 72.210 of this chapter	Full Cost.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees[1]	Fee[2,3]
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter:	
Licensing and inspection	Full Cost.
15. Import and Export licenses:	
Licenses issued under part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, heavy water, or nuclear grade graphite.	
A. Application for export or import of high enriched uranium and other materials, including radioactive waste, which must be reviewed by the Commissioners and the Executive Branch, for example, those actions under 10 CFR 110.40(b). This category includes application for import of radioactive waste.	
Application—new license	$10,300.
Amendment	$10,300.
B. Application for export or import of special nuclear material, source material, tritium and other byproduct material, heavy water, or nuclear grade graphite, including radioactive waste, requiring Executive Branch review but not Commissioner review. This category includes application for the export of radioactive waste.	
Application—new license	$6,000.
Amendment	$6,000.
C. Application for export of routine reloads of low enriched uranium reactor fuel and exports of source material requiring only foreign government assurances under the Atomic Energy Act.	
Application—new license	$1,900.
Amendment	$1,900.
D. Application for export or import of other materials, including radioactive waste, not requiring Commissioner review, Executive Branch review, or foreign government assurances under the Atomic Energy Act. This category includes application for export or import of radioactive waste where the NRC has previously authorized the export or import of the same form of waste to or from the same or similar parties, requiring only confirmation from the receiving facility and licensing authorities that the shipments may proceed according to previously agreed understandings and procedures.	
Application—new license	$1,300.
Amendment	$1,300.
E. Minor amendment of any export or import license to extend the expiration date, change domestic information, or make other revisions which do not require in-depth analysis, review, or consultations with other agencies or foreign governments.	
Amendment	$240.
16. Reciprocity:	
Agreement State licensees who conduct activities under the reciprocity provisions of 10 CFR 150.20.	
Application	$1,500.

[1] *Types of fees*—Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews and applications for new licenses and approvals, issuance of new licenses and approvals, certain amendments and renewals to existing licenses and approvals, safety evaluations of sealed sources and devices, generally licensed device registrations, and certain inspections. The following guidelines apply to these charges:

(a) *Application and registration fees.* Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee Category 1C only.

(b) *Licensing fees.* Fees for reviews of applications for new licenses and for renewals and amendments to existing licenses, for pre-application consultations and for reviews of other documents submitted to NRC for review, and for project manager time for fee categories subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 12, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(b).

(c) *Amendment fees.* Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to a license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category would apply.

(d) *Inspection fees.* Inspections resulting from investigations conducted by the Office of Investigations and non-routine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) *Generally licensed device registrations under 10 CFR 31.5.* Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will not be charged for orders issued by the Commission under 10 CFR 2.202 or for amendments resulting specifically from the requirements of these types of Commission orders. However, fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (*e.g.,* 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect at the time the service is provided, and the appropriate contractual support services expended. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20.

[4] Licensees paying fees under Categories 1A, 1B, and 1E are not subject to fees under Categories 1C and 1D for sealed sources authorized in the same license except for an application that deals only with the sealed sources authorized by the license.

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIAL LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 5. The authority citation for part 171 continues to read as follows:

Authority: Sec. 7601, Pub. L. 99–272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100–203, 101 Stat. 1330, as amended by sec. 3201, Pub. L. 101–239, 103 Stat. 2132, as amended by sec. 6101, Pub. L. 101–508, 104 Stat. 1388, as amended by sec. 2903a, Pub. L. 102–486, 106 Stat. 3125 (42 U.S.C. 2213, 2214); sec. 301, Pub. L. 92–314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

■ 6. In § 171.15 paragraphs (b), (c), (d), and (e) are revised to read as follows:

§ 171.15 Annual Fees: Reactor licenses and independent spent fuel storage licenses.

* * * * *

(b)(1) The FY 2003 annual fee for each operating power reactor which must be collected by September 30, 2003, is $3,251,000.

(2) The FY 2003 annual fee is comprised of a base annual fee for power reactors licensed to operate, a base spent fuel storage/reactor decommissioning annual fee, and associated additional charges (surcharges). The activities comprising the FY 2003 spent storage/reactor decommissioning base annual fee are shown in paragraph (c)(2)(i) and (ii) of this section. The activities comprising the FY 2003 surcharge are shown in paragraph (d)(1) of this section. The activities comprising the FY 2003 base annual fee for operating power reactors are as follows:

(i) Power reactor safety and safeguards regulation except licensing and inspection activities recovered under part 170 of this chapter and generic reactor decommissioning activities.

(ii) Research activities directly related to the regulation of power reactors, except those activities specifically related to reactor decommissioning.

(iii) Generic activities required largely for NRC to regulate power reactors, *e.g.*, updating part 50 of this chapter, or operating the Incident Response Center. The base annual fee for operating power reactors does not include generic activities specifically related to reactor decommissioning.

(c)(1) The FY 2003 annual fee for each power reactor holding a part 50 license that is in a decommissioning or possession only status and has spent fuel on-site and each independent spent fuel storage part 72 licensee who does not hold a part 50 license is $319,000.

(2) The FY 2003 annual fee is comprised of a base spent fuel storage/reactor decommissioning annual fee (which is also included in the operating power reactor annual fee shown in paragraph (b) of this section), and an additional charge (surcharge). The activities comprising the FY 2003 surcharge are shown in paragraph (d)(1) of this section. The activities comprising the FY 2003 spent fuel storage/reactor decommissioning rebaselined annual fee are:

(i) Generic and other research activities directly related to reactor decommissioning and spent fuel storage; and

(ii) Other safety, environmental, and safeguards activities related to reactor decommissioning and spent fuel storage, except costs for licensing and inspection activities that are recovered under part 170 of this chapter.

(d)(1) The activities comprising the FY 2003 surcharge are as follows:

(i) Low level waste disposal generic activities;

(ii) Activities not attributable to an existing NRC licensee or class of licenses (*e.g.*, international cooperative safety program and international safeguards activities, support for the Agreement State program, and site decommissioning management plan (SDMP) activities); and

(iii) Activities not currently subject to 10 CFR part 170 licensing and inspection fees based on existing law or Commission policy, *e.g.*, reviews and inspections conducted of nonprofit educational institutions, licensing actions for Federal agencies, and costs that would not be collected from small entities based on Commission policy in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

(2) The total FY 2003 surcharge allocated to the operating power reactor class of licenses is $19.1 million, not including the amount allocated to the spent fuel storage/reactor decommissioning class. The FY 2003 operating power reactor surcharge to be assessed to each operating power reactor is approximately $183,300. This amount is calculated by dividing the total operating power reactor surcharge ($19.1 million) by the number of operating power reactors (104).

(3) The FY 2003 surcharge allocated to the spent fuel storage/reactor decommissioning class of licenses is $1.8 million. The FY 2003 spent fuel storage/reactor decommissioning surcharge to be assessed to each operating power reactor, each power reactor in decommissioning or possession only status that has spent fuel onsite, and to each independent spent fuel storage part 72 licensee who does not hold a part 50 license is approximately $14,900. This amount is calculated by dividing the total surcharge costs allocated to this class by the total number of power reactor licenses, except those that permanently ceased operations and have no fuel on site, and part 72 licensees who do not hold a part 50 license.

(e) The FY 2003 annual fees for licensees authorized to operate a non-power (test and research) reactor licensed under part 50 of this chapter, unless the reactor is exempted from fees under § 171.11(a), are as follows:

Research reactor	$63,300
Test reactor	$63,300

■ 7. In § 171.16, paragraphs (c), (d), and (e) are revised to read as follows:

§ 171.16 Annual Fees: Materials Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

* * * * *

(c) A licensee who is required to pay an annual fee under this section may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification along with its annual fee payment, the licensee may pay reduced annual fees as shown in the following table. Failure to file a small entity certification in a timely manner could result in the denial of any refund that might otherwise be due. The small entity fees are as follows:

	Miximum annual fee per licensed category
Small Businesses Not Engaged in Manufacturing and Small Not-For-Profit Organizations (Gross Annual Receipts):	
$350,000 to $5 million	$2,300

	Miximum annual fee per licensed category
Less than $350,000	500
Manufacturing entities that have an average of 500 employees or less:	
35 to 500 employees	2,300
Less than 35 employees	500
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 50,000	2,300
Less than 20,000	500
Educational Institutions that are not State or Publicly Supported, and have 500 Employees or Less:	
35 to 500 employees	$2,300
Less than 35 employees	$500

(1) A licensee qualifies as a small entity if it meets the size standards established by the NRC (*See* 10 CFR 2.810).

(2) A licensee who seeks to establish status as a small entity for the purpose of paying the annual fees required under this section must file a certification statement with the NRC. The licensee must file the required certification on NRC Form 526 for each license under which it is billed. NRC Form 526 can be accessed through the NRC's Web site at *http://www.nrc.gov.* For licensees who cannot access the NRC's Web site, NRC Form 526 may be obtained through the local point of contact listed in the NRC's ''Materials Annual Fee Billing Handbook,'' NUREG/BR–0238, which is enclosed with each annual fee billing. The form can also be obtained by calling the fee staff at 301–415–7554, or by e-mailing the fee staff at *fees@nrc.gov.*

(3) For purposes of this section, the licensee must submit a new certification with its annual fee payment each year.

(4) The maximum annual fee a small entity is required to pay is $2,300 for each category applicable to the license(s).

(d) The FY 2003 annual fees are comprised of a base annual fee and an additional charge (surcharge). The activities comprising the FY 2003 surcharge are shown for convenience in paragraph (e) of this section. The FY 2003 annual fees for materials licensees and holders of certificates, registrations or approvals subject to fees under this section are shown in the following table:

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees[1,2,3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material:	
BWX Technologies SNM–42	$5,836,000
Nuclear Fuel Services SNM–124	5,836,000
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel:	
Global Nuclear Fuel SNM–1097	1,957,000
Framatome ANP Richland SNM–1227	1,957,000
Westinghouse Electric Company SNM–1107	1,957,000
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations:	
Framatome ANP SNM–1168	769,000
(b) All Others:	
General Electric SNM–960.	559,000
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI)	[11]N/A
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers	1,900
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1.A.(2)	4,500
E. Licenses or certificates for the operation of a uranium enrichment facility	3,634,000
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride	839,000
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
Class I facilities[4]	63,700
Class II facilities[4]	53,300
Other facilities[4]	93,600
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2A(2) or Category 2A(4)	39,300

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees[1,2,3]
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2A(2)	6,200
B. Licenses that authorize only the possession, use and/or installation of source material for shielding	730
C. All other source material licenses	11,400
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution	21,800
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution	6,600
C. Licenses issued under §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when included on the same license. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 171.11(a)(1). These licenses are covered by fee Category 3D	10,900
D. Licenses and approvals issued under §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material. This category includes licenses issued under §§ 32.72, 32.73 and 32.74 of this chapter to nonprofit educational institutions whose processing or manufacturing is exempt under § 171.11(a)(1). This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when included on the same license	4,700
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units)	3,600
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes	6,600
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes	24,100
H. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter	6,000
I. Licenses issued under Subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter	6,100
J. Licenses issued under Subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter	2,200
K. Licenses issued under Subpart B of part 31 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter	1,400
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution	11,800
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution	5,600
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P; and.	
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C	6,100
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license	12,200
P. All other specific byproduct material licenses, except those in Categories 4A through 9D	2,500
Q. Registration of devices generally licensed pursuant to part 31 of this chapter	[13] N/A
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material	[5] N/A
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material	10,300

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees[1,2,3]
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material	7,400
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies	4,700
B. Licenses for possession and use of byproduct material for field flooding tracer studies	[5] N/A
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material	23,100
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license	11,000
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9]	24,700
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9]	4,600
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities	1,300
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	7,000
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	7,000
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	2,200
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	730
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers.	
Spent Fuel, High-Level Waste, and plutonium air packages	[6] N/A
Other Casks	[6] N/A
B. Quality assurance program approvals issued under part 71 of this chapter.	
Users and Fabricators	76,200
Users	7,100
11. Standardized spent fuel facilities	[6] N/A
12. Special Projects	[6] N/A
13. A. Spent fuel storage cask Certificate of Compliance	[6] N/A
B. General licenses for storage of spent fuel under 10 CFR 72.210	[12] N/A
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter	[7] N/A
15. Import and Export licenses	[8] N/A
16. Reciprocity	[8] N/A
17. Master materials licenses of broad scope issued to Government agencies	228,000
18. Department of Energy:	
A. Certificates of Compliance	[10] 1,386,000
B. Uranium Mill Tailing Radiation Control Act (UMTRCA) Activities	950,000

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current fiscal year. However, the annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses prior to October 1, 2002, and permanently ceased licensed activities entirely by September 30, 2002. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession only license during the fiscal year and for new licenses issued during the fiscal year will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (*e.g.*, human use and irradiator activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1A(1) are not subject to the annual fees for Category 1C and 1D for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each fiscal year, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the **Federal Register** for notice and comment.

[4] A Class I license includes mill licenses issued for the extraction of uranium from uranium ore. A Class II license includes solution mining licenses(in-situ and heap leach) issued for the extraction of uranium from uranium ores including research and development licenses. An ''other'' license includes licenses for extraction of metals, heavy metals, and rare earths.

[5] There are no existing NRC licenses in these fee categories. If NRC issues a license for these categories, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, 10 CFR Parts 71 and 72 Certificates of Compliance, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Categories 7B or 7C.

[10] This includes Certificates of Compliance issued to DOE that are not under the Nuclear Waste Fund.

[11] *See* § 171.15(c).

[12] *See* § 171.15(c).

[13] No annual fee is charged for this category because the cost of the general license registration program applicable to licenses in this category will be recovered through 10 CFR part 170 fees.

(e) The activities comprising the surcharge are as follows:

(1) LLW disposal generic activities;

(2) Activities not directly attributable to an existing NRC licensee or class(es) of licenses; e.g., international cooperative safety program and international safeguards activities; support for the Agreement State program; Site Decommissioning Management Plan (SDMP) activities; and

(3) Activities not currently assessed licensing and inspection fees under 10 CFR part 170 based on existing law or Commission policy (e.g., reviews and inspections of nonprofit educational institutions and reviews for Federal agencies; activities related to decommissioning and reclamation; and costs that would not be collected from small entities based on Commission policy in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*)

Dated at Rockville, Maryland, this 30th day of May, 2003.

For the Nuclear Regulatory Commission.

Jesse L. Funches,

Chief Financial Officer.

Note: This appendix will not appear in the Code of Federal Regulations.

Appendix A to This Final Rule—Final Regulatory Flexibility Analysis for the Amendments to 10 CFR Part 170 (License Fees) and 10 CFR Part 171 (Annual Fees)

I. Background

The Regulatory Flexibility Act (RFA), as amended, (5 U.S.C. 601 *et seq.*) requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

The NRC has established standards for determining which NRC licensees qualify as small entities (10 CFR 2.810). These size standards were established on the basis of the Small Business Administration's most common receipts-based size standards and include a size standard for business concerns that are manufacturing entities. The NRC uses the size standards to reduce the impact of annual fees on small entities by establishing a licensee's eligibility to qualify for a maximum small entity fee. The small entity fee categories in § 171.16(c) of this final rule are based on the NRC's size standards.

From FY 1991 through FY 2000, the Omnibus Budget Reconciliation Act (OBRA–90), as amended, required that the NRC recover approximately 100 percent of its budget authority, less appropriations from the Nuclear Waste Fund, by assessing license and annual fees. The FY 2001 Energy and Water Development Appropriations Act amended OBRA–90 to decrease the NRC's fee recovery amount by 2 percent per year beginning in FY 2001, until the fee recovery amount is 90 percent in FY 2005. The amount to be recovered for FY 2003 is approximately $526.3 million.

OBRA–90 requires that the schedule of charges established by rule should fairly and equitably allocate the total amount to be recovered from the NRC's licensees and be assessed under the principle that licensees who require the greatest expenditure of agency resources pay the greatest annual charges. Since FY 1991, the NRC has complied with OBRA–90 by issuing a final rule that amends its fee regulations. These final rules have established the methodology used by NRC in identifying and determining the fees to be assessed and collected in any given fiscal year.

In FY 1995, the NRC announced that, in order to stabilize fees, annual fees would be adjusted only by the percentage change (plus or minus) in NRC's total budget authority, adjusted for changes in estimated collections for 10 CFR Part 170 fees, the number of licensees paying annual fees, and as otherwise needed to assure the billed amounts resulted in the required collections. The NRC indicated that if there were a substantial change in the total NRC budget authority or the magnitude of the budget allocated to a specific class of licenses, the annual fee base would be recalculated.

In FY 1999, the NRC concluded that there had been significant changes in the allocation of agency resources among the various classes of licenses and established rebaselined annual fees for FY 1999. The NRC stated in the final FY 1999 rule that to stabilize fees it would continue to adjust the annual fees by the percent change method established in FY 1995, unless there is a substantial change in the total NRC budget or the magnitude of the budget allocated to a specific class of licenses, in which case the annual fee base would be reestablished.

Based on the change in the magnitude of the budget to be recovered through fees, the Commission has determined that it is appropriate to rebaseline its part 171 annual fees again in FY 2003. Rebaselining fees will result in increased annual fees for a majority of the categories of licenses, decreased annual fees for other categories (including many materials licensees), and no change for one category.

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) is intended to reduce regulatory burdens imposed by Federal agencies on small businesses, nonprofit organizations, and governmental jurisdictions. SBREFA also provides Congress with the opportunity to review agency rules before they go into effect. Under this legislation, the NRC annual fee rule is considered a ''major'' rule and must be reviewed by Congress and the Comptroller General before the rule becomes effective. SBREFA also requires that an agency prepare a guide to assist small entities in complying with each rule for which a final regulatory flexibility analysis is prepared. This Regulatory Flexibility Analysis (RFA) and the small entity compliance guide (Attachment 1) have been prepared for the FY 2003 fee rule as required by law.

II. Impact on Small Entities

The fee rule results in substantial fees being charged to those individuals, organizations, and companies that are licensed by the NRC, including those licensed under the NRC materials program. The comments received on previous proposed fee rules and the small entity certifications received in response to previous final fee rules indicate that NRC licensees qualifying as small entities under the NRC's size standards are primarily materials licensees. Therefore, this analysis will focus on the economic impact of the annual fees on materials licensees. About 24 percent of these licensees (approximately 1,200 licensees for FY 2002) have requested small entity certification in the past. A 1993 NRC survey of its materials licensees indicated that about 25 percent of these licensees could qualify as small entities under the NRC's size standards.

The commenters on previous fee rulemakings consistently indicated that the following results would occur if the proposed annual fees were not modified:

1. Large firms would gain an unfair competitive advantage over small entities.

Commenters noted that small and very small companies (''Mom and Pop'' operations) would find it more difficult to absorb the annual fee than a large corporation or a high-volume type of operation. In competitive markets, such as soils testing, annual fees would put small licensees at an extreme competitive disadvantage with their much larger competitors because the proposed fees would be the same for a two-person licensee as for a large firm with thousands of employees.

2. Some firms would be forced to cancel their licenses. A licensee with receipts of less than $500,000 per year stated that the proposed rule would, in effect, force it to relinquish its soil density gauge and license, thereby reducing its ability to do its work effectively. Other licensees, especially well-loggers, noted that the increased fees would force small businesses to get rid of the materials license altogether. Commenters stated that the proposed rule would result in about 10 percent of the well-logging licensees terminating their licenses immediately and approximately 25 percent terminating their licenses before the next annual assessment.

3. Some companies would go out of business.

4. Some companies would have budget problems. Many medical licensees noted that, along with reduced reimbursements, the proposed increase of the existing fees and the introduction of additional fees would significantly affect their budgets. Others noted that, in view of the cuts by Medicare and other third party carriers, the fees would produce a hardship and some facilities would experience a great deal of difficulty in meeting this additional burden.

Approximately 3,000 license, approval, and registration terminations have been requested since the NRC first established annual fees for materials licenses. Although some of these terminations were requested because the license was no longer needed or licenses or registrations could be combined, indications are that other termination requests were due to the economic impact of the fees.

To alleviate the significant impact of the annual fees on a substantial number of small entities, the NRC considered the following alternatives in accordance with the RFA, in developing each of its fee rules since FY 1991.

1. Base fees on some measure of the amount of radioactivity possessed by the licensee (e.g., number of sources).

2. Base fees on the frequency of use of the licensed radioactive material (e.g., volume of patients).

3. Base fees on the NRC size standards for small entities.

The NRC has reexamined its previous evaluations of these alternatives and continues to believe that establishment of a maximum fee for small entities is the most appropriate and effective option for reducing the impact of its fees on small entities.

III. Maximum Fee

The RFA and its implementing guidance do not provide specific guidelines on what constitutes a significant economic impact on a small entity; therefore, the NRC has no benchmark to assist it in determining the amount or the percent of gross receipts that should be charged to a small entity. In developing the maximum small entity annual fee in FY 1991, the NRC examined its 10 CFR Part 170 licensing and inspection fees and Agreement State fees for those fee categories which were expected to have a substantial number of small entities. Six Agreement States, Washington, Texas, Illinois, Nebraska, New York, and Utah, were used as benchmarks in the establishment of the maximum small entity annual fee in FY 1991. Because small entities in those Agreement States were paying the fees, the NRC concluded that these fees did not have a significant impact on a substantial number of small entities. Therefore, those fees were considered a useful benchmark in establishing the NRC maximum small entity annual fee.

The NRC maximum small entity fee was established as an annual fee only. In addition to the annual fee, NRC small entity licensees were required to pay amendment, renewal and inspection fees. In setting the small entity annual fee, NRC ensured that the total amount small entities paid annually would not exceed the maximum paid in the six benchmark Agreement States.

Of the six benchmark states, the maximum Agreement State fee of $3,800 in Washington was used as the ceiling for the total fees. Thus the NRC's small entity fee was developed to ensure that the total fees paid by NRC small entities would not exceed $3,800. Given the NRC's FY 1991 fee structure for inspections, amendments, and renewals, a small entity annual fee established at $1,800 allowed the total fee (small entity annual fee plus yearly average for inspections, amendments and renewal fees) for all categories to fall under the $3,800 ceiling.

In FY 1992, the NRC introduced a second, lower tier to the small entity fee in response to concerns that the $1,800 fee, when added to the license and inspection fees, still imposed a significant impact on small entities with relatively low gross annual receipts. For purposes of the annual fee, each small entity size standard was divided into an upper and lower tier. Small entity licensees in the upper tier continued to pay an annual fee of $1,800 while those in the lower tier paid an annual fee of $400.

Based on the changes that had occurred since FY 1991, the NRC re-analyzed its maximum small entity annual fees in FY 2000, and determined that the small entity fees should be increased by 25 percent to reflect the increase in the average fees paid by other materials licensees since FY 1991 as well as changes in the fee structure for materials licensees. The structure of the fees that NRC charged to its materials licensees changed during the period between 1991 and 1999. Costs for materials license inspections, renewals, and amendments, which were previously recovered through part 170 fees for services, are now included in the part 171 annual fees assessed to materials licensees. As a result, the maximum small entity annual fee increased from $1,800 to $2,300 in FY 2000. By increasing the maximum annual fee for small entities from $1,800 to $2,300, the annual fee for many small entities was reduced while at the same time materials licensees, including small entities, would pay for most of the costs attributable to them. The costs not recovered from small entities are allocated to other materials licensees and to power reactors.

While reducing the impact on many small entities, the NRC determined that the maximum annual fee of $2,300 for small entities may continue to have a significant impact on materials licensees with annual gross receipts in the thousands of dollars range. Therefore, the NRC continued to provide a lower-tier small entity annual fee for small entities with relatively low gross annual receipts, and for manufacturing concerns and educational institutions not State or publicly supported, with less than 35 employees. The NRC also increased the lower tier small entity fee by the same percentage increase to the maximum small entity annual fee. This 25 percent increase resulted in the lower tier small entity fee increasing from $400 to $500 in FY 2000.

The NRC examined the small entity fees again in FY 2001 (66 FR 32452; June 14, 2001), and determined that a change was not warranted to the small entity fees established in FY 2000. The NRC stated in the Regulatory Flexibility Analysis for the FY 2001 final fee rule that it would re-examine the small entity fees every two years, in the same years in which it conducts the biennial review of fees as required by the CFO Act.

Accordingly, the NRC has re-examined the small entity fees for FY 2003, and does not believe that a change to the small entity fees is warranted this year. Unlike the annual fees assessed to other licensees, the small entity fees are not designed to recover the agency costs associated with particular licensees. Instead, the reduced fees for small entities are designed to provide some fee relief for qualifying small entity licensees while at the same time recovering from them some of the agency's costs for activities that benefit them. The costs not recovered from small entities for activities that benefit them must be recovered from other licensees. Given the reduction in annual fees and the relative low inflation rates, the NRC has determined that the current small entity fees of $500 and $2,300 continue to meet the objective of providing relief to many small entities while recovering from them some of the costs that benefit them.

Therefore, the NRC is retaining the $2,300 small entity annual fee and the $500 lower tier small entity annual fee for FY 2003. The NRC plans to re-examine the small entity fees again in FY 2005.

IV. Summary

The NRC has determined that the 10 CFR Part 171 annual fees significantly impact a substantial number of small entities. A maximum fee for small entities strikes a balance between the requirement to recover 94 percent of the NRC budget and the requirement to consider means of reducing the impact of the fee on small entities. On the basis of its regulatory flexibility analysis, the NRC concludes that a maximum annual fee of $2,300 for small entities and a lower-tier small entity annual fee of $500 for small

businesses and not-for-profit organizations with gross annual receipts of less than $350,000, small governmental jurisdictions with a population of less than 20,000, small manufacturing entities that have less than 35 employees, and educational institutions that are not State or publicly supported and have less than 35 employees reduces the impact on small entities. At the same time, these reduced annual fees are consistent with the objectives of OBRA–90. Thus, the fees for small entities maintain a balance between the objectives of OBRA–90 and the RFA. Therefore, the analysis and conclusions previously established remain valid for FY 2003.

Attachment 1 to Appendix A—U.S. Nuclear Regulatory Commission Small Entity Compliance Guide; Fiscal Year 2003

Contents

Introduction

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires all Federal agencies to prepare a written guide for each ''major'' final rule as defined by the Act. The NRC's fee rule, published annually to comply with the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), as amended, is considered a ''major'' rule under SBREFA. Therefore, in compliance with the law, this guide has been prepared to assist NRC material licensees in complying with the FY 2003 fee rule.

Licensees may use this guide to determine whether they qualify as a small entity under NRC regulations and are eligible to pay reduced FY 2003 annual fees assessed under 10 CFR Part 171. The NRC has established two tiers of separate annual fees for those materials licensees who qualify as small entities under NRC's size standards.

Licensees who meet NRC's size standards for a small entity must submit a completed NRC Form 526 ''Certification of Small Entity Status for the Purposes of Annual Fees Imposed Under 10 CFR Part 171'' to qualify for the reduced annual fee. This form can be accessed on the NRC's Web site at *http://www.nrc.gov.* The form can then be accessed by selecting ''License Fees'' and under ''Forms'' selecting NRC Form 526. For licensees who cannot access the NRC's Web site, NRC Form 526 may be obtained through the local point of contact listed in the NRC's ''Materials Annual Fee Billing Handbook,'' NUREG/BR–0238, which is enclosed with each annual fee billing. Alternatively, the form may be obtained by calling the fee staff at 301–415–7554, or by e-mailing the fee staff at *fees@nrc.gov.* The completed form, the appropriate small entity fee, and the payment copy of the invoice should be mailed to the U.S. Nuclear Regulatory Commission, License Fee and Accounts Receivable Branch, to the address indicated on the invoice. Failure to file the NRC small entity certification Form 526 in a timely manner may result in the denial of any refund that might otherwise be due.

NRC Definition of Small Entity

The NRC has defined a small entity for purposes of compliance with its regulations (10 CFR 2.810) as follows:

1. *Small business*—a for-profit concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $5 million or less over its last 3 completed fiscal years;

2. *Manufacturing industry*—a manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months;

3. *Small organizations*—a not-for-profit organization which is independently owned and operated and has annual gross receipts of $5 million or less;

4. *Small governmental jurisdiction*—a government of a city, county, town, township, village, school district or special district with a population of less than 50,000;

5. *Small educational institution*—an educational institution supported by a qualifying small governmental jurisdiction, or one that is not state or publicly supported and has 500 or fewer employees.[1]

To further assist licensees in determining if they qualify as a small entity, we are providing the following guidelines, which are based on the Small Business Administration's regulations (13 CFR Part 121).

1. A small business concern is an independently owned and operated entity which is not considered dominant in its field of operations.

2. The number of employees means the total number of employees in the parent company, any subsidiaries and/or affiliates, including both foreign and domestic locations (i.e., not solely the number of employees working for the licensee or conducting NRC licensed activities for the company).

3. Gross annual receipts includes all revenue received or accrued from any source, including receipts of the parent company, any subsidiaries and/or affiliates, and account for both foreign and domestic locations. Receipts include all revenues from sales of products and services, interest, rent, fees, and commissions, from whatever sources derived (i.e., not solely receipts from NRC licensed activities).

4. A licensee who is a subsidiary of a large entity does not qualify as a small entity.

NRC Small Entity Fees

In 10 CFR 171.16 (c), the NRC has established two tiers of small entity fees for licensees that qualify under the NRC's size standards. The fees are as follows:

	Maximum annual fee per licensed category
Small Business Not Engaged in Manufacturing and Small Not-For-Profit Organizations (Gross Annual Receipts):	
$350,000 to $5 million	$2,300
Less than $350,000	500
Manufacturing entities that have an average of 500 employees or less:	
35 to 500 employees	2,300
Less than 35 employees	500
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 50,000	2,300
Less than 20,000	500
Educational Institutions that are not State or Publicly Supported, and have 500 Employees or Less:	
35 to 500 employees	2,300
Less than 35 employees	500

To pay a reduced annual fee, a licensee must use NRC Form 526. Licensees can access this form on the NRC's Web site at *http://www.nrc.gov.* The form can then be accessed by selecting ''License Fees'' and under ''Forms'' selecting NRC Form 526. Those licensees that qualify as a ''small entity'' under the NRC size standards at 10 CFR Part 2.810 can complete the form in accordance with the instructions provided, and submit the completed form and the appropriate payment to the address provided on the invoice. For licensees who cannot access the NRC's Web site, NRC Form 526 may be obtained through the local point of

[1] An educational institution referred to in the size standards is an entity whose primary function is education, whose programs are accredited by a nationally recognized accrediting agency or association, who is legally authorized to provide a program of organized instruction or study, who provides an educational program for which it awards academic degrees, and whose educational programs are available to the public.

contact listed in the NRC's ''Materials Annual Fee Billing Handbook,'' NUREG/BR–0238, which is enclosed with each annual fee invoice. Alternatively, licensees may obtain the form by calling the fee staff at 301–415–7544, or by e-mailing us at *fees@nrc.gov.*

Instructions for Completing NRC Small Entity Form 526

1. File a separate NRC Form 526 for each annual fee invoice received.

2. Complete all items on NRC Form 526 as follows:

a. The license number and invoice number must be entered exactly as they appear on the annual fee invoice.

b. The Standard Industrial Classification (SIC) or North American Industry Classification System (NAICS) Code must be entered if known.

c. The licensee's name and address must be entered as they appear on the invoice. Name and/or address changes for billing purposes must be annotated on the invoice. Correcting the name and/or address on NRC Form 526, or on the invoice does not constitute a request to amend the license. Any request to amend a license is to be submitted to the respective licensing staffs in the NRC Regional or Headquarters Offices.

d. Check the appropriate size standard for which the licensee qualifies as a small entity. Check only one box. Note the following:

(1) A licensee who is a subsidiary of a large entity does not qualify as a small entity.

(2) The size standards apply to the licensee, including all parent companies and affiliates— not the individual authorized users listed in the license or the particular segment of the organization that uses licensed material.

(3) Gross annual receipts means all revenue in whatever form received or accrued from whatever sources —not solely receipts from licensed activities. There are limited exceptions as set forth at 13 CFR 121.104. These are: the term receipts excludes net capital gains or losses; taxes collected for and remitted to a taxing authority if included in gross or total income; proceeds from the transactions between a concern and its domestic or foreign affiliates (if also excluded from gross or total income on a consolidated return filed with the IRS); and amounts collected for another entity by a travel agent, real estate agent, advertising agent, or conference management service provider.

(4) The owner of the entity, or an official empowered to act on behalf of the entity, must sign and date the small entity certification.

The NRC sends invoices to its licensees for the full annual fee, even though some entities qualify for reduced fees as a small entity. Licensees who qualify as a small entity and file NRC Form 526, which certifies eligibility for small entity fees, may pay the reduced fee, which for a full year is either $2,300 or $500 depending on the size of the entity, for each fee category shown on the invoice. Licensees granted a license during the first six months of the fiscal year, and licensees who file for termination or for a possession only license and permanently cease licensed activities during the first six months of the fiscal year, pay only 50 percent of the annual fee for that year. Such an invoice states the ''Amount Billed Represents 50% Proration.'' This means the amount due from a small entity is not the prorated amount shown on the invoice, but rather one-half of the maximum annual fee shown on NRC Form 526 for the size standard under which the licensee qualifies, resulting in a fee of either $1150 or $250 for each fee category billed, instead of the full small entity annual fee of $2,300 or $500.

A new small entity form (NRC Form 526) must be filed with the NRC each fiscal year to qualify for reduced fees in that year. Because a licensee's ''size,'' or the size standards, may change from year to year, the invoice reflects the full fee and a new Form 526 must be completed and returned in order for the fee to be reduced to the small entity fee amount. *Licensees will not be issued a new invoice for the reduced amount.* The completed NRC Form 526, the payment of the appropriate small entity fee, and the ''Payment Copy'' of the invoice should be mailed to the U.S. Nuclear Regulatory Commission, License Fee and Accounts Receivable Branch at the address indicated on the invoice.

If you have questions regarding the NRC's annual fees, please call the license fee staff at 301–415–7554, e-mail the fee staff at *fees@nrc.gov,* or write to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of the Chief Financial Officer.

False certification of small entity status could result in civil sanctions being imposed by the NRC under the Program Fraud Civil Remedies Act, 31 U.S.C. 3801 *et. seq.* NRC's implementing regulations are found at 10 CFR part 13.

[FR Doc. 03–14960 Filed 6–17–03; 8:45 am]

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CFR PARTS AFFECTED DURING JUNE

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT JUNE 18, 2003

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- Azoxystrobin; published 6-18-03; comments due by 12-30-99; published 6-18-03 [FR 03-15261]
- Bacillus pumilus (strain QST2808); published 6-18-03; comments due by 12-30-99; published 6-18-03 [FR 03-15129]
- Glyphosate; published 6-18-03; comments due by 12-30-99; published 6-18-03 [FR 03-15128]

Solid wastes:
- Residential lead-based paint waste disposal; solid waste disposal facilities and municipal solid waste landfills; classification and practices criteria; published 6-18-03; comments due by 12-30-99; published 6-18-03 [FR 03-15363]

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- Child support enforcement program; revision or elimination of obsolete or inconsistent provisions; published 5-12-03; comments due by 12-30-99; published 5-12-03 [FR 03-11223]

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Organization, functions, and authority delegations:
- Maritime Administrator; published 6-18-03; comments due by 12-30-99; published 6-18-03 [FR 03-15400]

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- Eurocopter France; published 6-3-03; comments due by 8-4-03; published 6-3-03 [FR 03-13654]

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- California; comments due by 6-23-03; published 4-22-03 [FR 03-09843]

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

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- Tuberculosis in cattle and bison—
  - State and area classifications; comments due by 6-24-03; published 4-25-03 [FR 03-10242]

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- Federal Prison Industries, Inc.; increased waiver threshold; comments due by 6-23-03; published 5-22-03 [FR 03-12305]

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- Vermont; comments due by 6-23-03; published 5-22-03 [FR 03-12863]

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- Vermont; comments due by 6-23-03; published 5-22-03 [FR 03-12864]

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- West Virginia; comments due by 6-26-03; published 5-27-03 [FR 03-13176]

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  - National priorities list update; comments due by 6-23-03; published 5-22-03 [FR 03-12612]

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  - National priorities list update; comments due by 6-23-03; published 5-22-03 [FR 03-12613]

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  - National priorities list update; comments due by 6-23-03; published 5-22-03 [FR 03-12614]

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.nara.gov/fedreg/plawcurr.html*.

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S. 243/P.L. 108–28

Concerning participation of Taiwan in the World Health Organization. (May 29, 2003; 117 Stat. 769)

S. 330/P.L. 108–29

Veterans' Memorial Preservation and Recognition Act of 2003 (May 29, 2003; 117 Stat. 772)

S. 870/P.L. 108–30

To amend the Richard B. Russell National School Lunch Act to extend the availability of funds to carry out the fruit and vegetable pilot program. (May 29, 2003; 117 Stat. 774)

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