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

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

FEDERAL ELECTION COMMISSION

11 CFR Parts 100 and 104

[Notice 2005–9]

Filing Documents by Priority Mail, Express Mail, and Overnight Delivery Service

AGENCY: Federal Election Commission.

ACTION: Final rules and transmittal of regulations to Congress.

SUMMARY: The Federal Election Commission is promulgating amended rules regarding the timely filing of designations, reports, and statements. Under these final rules, the Commission will consider certain documents to be filed prior to actual receipt, if such documents are sent using Priority Mail, Express Mail, or delivered by an overnight delivery service. Further information is provided in the Supplementary Information that follows.

EFFECTIVE DATE: The effective date for the amendments to 11 CFR 100.19 and 104.5 is April 18, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. Brad C. Deutsch, Assistant General Counsel, or Ms. Esa L. Sferra, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Consolidated Appropriations Act, 2004, Pub. L. 108–199, div. F, tit. VI, § 641, 188 Stat. 3 (2004) (the ''2004 Appropriations Act'') amended the Federal Election Campaign Act of 1971, as amended, 2 U.S.C. 431 *et seq.*, (''FECA'') to permit political committees and others required to file certain documents to use additional delivery options to satisfy the Commission's ''timely filing'' requirements for these documents filed with the Commission or the Secretary of the Senate. Section 434(a) of FECA previously permitted reliance on a U.S. Postal Service (''USPS'') postmark date as the date the Commission considers certain designations, reports, and statements timely filed, but only if the document was sent by either registered or certified mail.

The 2004 Appropriations Act amended section 434(a) of FECA, 2 U.S.C. 434(a)(2)(A)(i), (4)(A)(ii), and (5), by allowing filers that use priority mail and express mail to treat the date of the USPS postmark as the date of filing, so long as the mailing has a delivery confirmation. The amendments to section 434(a) of FECA also allow filers using an overnight delivery service to treat the date of deposit with the overnight delivery service as the date of filing, so long as the overnight delivery service has an on-line tracking system. Accordingly, the Commission is amending 11 CFR 100.19, which specifies when a document is ''timely filed,'' and 11 CFR 104.5, which establishes due dates for reports.

On December 22, 2004, the Commission published a Notice of Proposed Rulemaking (''NPRM'') in the **Federal Register** containing proposed rules to implement the 2004 Consolidated Appropriations Act's amendments to FECA. 69 FR 76626 (December 22, 2004). The Commission sought comments on the proposed changes and on several issues raised in the NPRM. The comment period ended January 21, 2005. The Commission received two comments, including a letter from the Internal Revenue Service indicating that it had ''no comments.'' These comments are available at *http://www.fec.gov/law/law_rulemakings.shtml#filing.htm* under ''Filing Documents by Priority Mail, Express Mail, and Overnight Delivery Service.''

Under the Administrative Procedure Act, 5 U.S.C. 553(d), and the Congressional Review of Agency Rulemaking Act, 5 U.S.C. 801(a)(1), agencies must submit final rules to the Speaker of the House of Representatives and the President of the Senate and publish them in the **Federal Register** at least 30 calendar days before they take effect. The final rules that follow were transmitted to Congress on March 11, 2005.

Explanation and Justification

I. 11 CFR 100.19. File, Filed or Filing

Section 100.19 establishes filing deadlines for certain documents and sets out criteria for when those documents will be considered timely filed. Paragraph (b) of section 100.19 specifies when a mailed document will be considered ''timely filed'' and is being revised and reorganized into three paragraphs as follows. Paragraph (b)(1) contains an amended definition of ''timely filed.'' Paragraph (b)(2) retains the requirement that documents sent by first-class mail must be received by the close of business on the prescribed filing date to be considered timely filed. Paragraph (b)(3) contains new definitions of ''overnight delivery service'' and ''postmark.''

A. 11 CFR 100.19(b)(1)

Paragraph (b)(1) now specifies that any document required to be filed under Commission regulations, other than those specified in 11 CFR 100.19(c)–(g),[1] is considered ''timely filed'' so long as the document is postmarked[2] by the due date and is deposited: (1) As registered or certified mail in an established U.S. Post Office; (2) as Priority Mail or Express Mail with a delivery confirmation in an established U.S. Post Office; or (3) with an overnight delivery service, so long as the document is scheduled to be delivered the next business day after the date of deposit and is recorded in the delivery service's on-line tracking system.

The Commission received no comments on its initial interpretation that the references to ''priority mail'' and ''express mail'' in the 2004 Appropriations Act denote USPS Priority Mail and Express Mail because the terms are registered trademarks of

[1] Certain types of documents are specifically excluded from the general definition of ''timely filed'' at 11 CFR 100.19(b) because they have their own particular filing dates and methods specified in sections 100.19 and 104.5 of the Commission's rules. These include 48-hour statements of last minute contributions, independent expenditure reports, and 24-hour statements of electioneering communications. 11 CFR 100.19(d), (e), and (f); 11 CFR 104.5(f), (g), and (j). Additionally, candidate notifications of expenditures from personal funds are considered filed only upon receipt by certain parties. 11 CFR 100.19(g).

[2] As discussed below, the new definition of ''postmark'' includes a USPS postmark and the verifiable date of deposit with an overnight delivery service.

USPS.[3] Accordingly, the final rules in paragraph (b)(1)(i)(B) reflect this interpretation.

Regarding use of an overnight delivery service, the NPRM requested comment on whether the amended rules should permit filers who use an overnight delivery service to choose any delivery option offered by such a service, so long the filing is scheduled to be delivered within three business days from the date of deposit. Alternatively, the NPRM invited comment on whether filers who use an overnight delivery service should be limited to selecting only a next day delivery option offered by such a service. No commenters addressed this issue.

The Commission concludes that it would be more consistent with the language of the 2004 Appropriations Act, which specifies use of ''an *overnight* delivery service,'' 2 U.S.C. 434(a), as amended by 2004 Appropriations Act (emphasis added), to require that filers using an overnight delivery service choose an overnight (*i.e.*, next business day) option. Accordingly, the final rules at 11 CFR 100.19(b)(1)(i)(C) require filers using an overnight delivery service to select a next business day delivery option offered by such a service.

For any filer who uses an overnight delivery service and wishes to treat the date of deposit as the date of filing, the 2004 Appropriations Act amendment to FECA requires that the filer use an overnight delivery service that has an on-line tracking system. Although the 2004 Appropriations Act requires that the overnight delivery service have an on-line tracking system, it does not specifically state that a filer must use such a system. No commenters addressed whether the rule should require the use of an on-line tracking system. Because an on-line tracking system will provide a means to settle a dispute that may arise concerning the timely filing of a document (*i.e.*, the date of deposit), the Commission interprets the statutory requirement to mean that a filer must in fact choose a delivery option that includes tracking of the document, thereby providing the filer and the Commission, or any other person, with the ability to confirm deposit and delivery dates.[4] Accordingly, under amended 11 CFR 100.19(b)(1)(i)(C) a document deposited with an overnight delivery service must be recorded in that delivery service's on-line tracking system. The Commission received no comments about whether a definition of ''on-line tracking system'' is necessary. The Commission believes that the plain meaning of ''on-line tracking system'' refers to a publicly available Internet-based tracking system and that a definition is unnecessary.

Lastly, paragraph (b)(1)(ii) retains the requirement that a document must be postmarked[5] no later than 11:59 p.m. Eastern Standard/Daylight Time on the due date, with the exception that pre-election reports must be postmarked fifteen days before the election, which is three days earlier than the report's due date.

B. 11 CFR 100.19(b)(2)

Paragraph (b)(2) continues to require that documents sent by first class mail must be received by the close of business on the prescribed filing date to be considered ''timely filed.'' However, new language in section 100.19(b)(2) clarifies that documents, other than those addressed in 11 CFR 100.19(c)–(g), sent by first class mail or by *any means* other than those specified in 11 CFR 100.19(b)(1) (*i.e.*, by any means other than registered or certified mail, Priority Mail, Express Mail, or with an overnight delivery service) must be received by the close of business on the prescribed filing date in order to be considered ''timely filed.'' The Commission received no comment on this clarification and the clarifying language is almost identical to that proposed in the NPRM.

C. 11 CFR 100.19(b)(3)

New paragraph (b)(3) contains definitions of ''overnight delivery service'' and ''postmark.'' New paragraph (b)(3)(i) defines ''overnight delivery service'' as a private delivery service of established reliability that offers an overnight (*i.e.*, next business day) delivery option. The Commission received no comments on this definition. This definition is consistent with new section 100.19(b)(1)(i)(C), discussed above, which requires filers using an overnight delivery service to select a next business day delivery option.

New paragraph (b)(3)(ii) defines ''postmark'' to include both a USPS postmark, as well as the verifiable date that a document is deposited with an overnight delivery service because filers may now also treat the date of deposit with an overnight delivery service as the date of filing.[6] One comment specifically supported this definition of ''postmark.''

II. 11 CFR 104.5. Filing Dates

Section 104.5 specifies the filing due dates for certain documents filed by political committees and other persons. The Commission is amending 11 CFR 104.5 consistent with the Commission's revised definition of ''timely filing'' in amended section 100.19(b), discussed above. These changes to 11 CFR 104.5 are almost identical to the ones proposed in the NPRM, on which the Commission received no comment.

A. 11 CFR 104.5(a)(2)(i)(A) and (c)(1)(ii)

Paragraphs 104.5(a)(2)(i)(A) and (c)(1)(ii) of this section set forth the filing due dates for pre-election reports filed by congressional candidates' principal campaign committees and non-authorized political committees. The Commission is revising these paragraphs to specify that, like pre-election reports sent by registered or certified mail, such reports sent by Priority Mail or Express Mail with a delivery confirmation, or sent with an overnight delivery service and scheduled to be delivered the next business day, must be postmarked no later than the fifteenth day before the election.

B. 11 CFR 104.5(e)

Amended paragraph 104.5(e), which specifies the date the Commission considers to be the filing date for certain designations, reports, and statements required under section 104.5, now treats documents sent by Priority Mail or Express Mail with a delivery confirmation, or sent with an overnight delivery service and scheduled to be delivered the next business day in the same manner as documents sent by registered or certified mail. Specifically, all such documents are considered filed on the date of the postmark. Pre-election reports filed by these methods must be postmarked no later than the fifteenth day before the election. Additionally, amended 11 CFR 104.5(e) contains changes to clarify to which documents the final rules apply.

The Commission is also correcting one typographical error in paragraph

[3] *See http://www.usps.com/all/welcome.htm.*

[4] Filers should retain proof of mailing or other means of transmittal of documents. See 11 CFR 104.5(i).

[5] As discussed below, the new definition of ''postmark'' includes a USPS postmark and the verifiable date of deposit with an overnight delivery service.

[6] Internal Revenue Service regulations and Department of Homeland Security regulations also define ''postmark'' to include private carrier postmarks. *See e.g.*, 26 CFR 301.7502–1(c)(1)(iii)(B) and 8 CFR 245a.12(a)(3) and (4); *see also* 50 CFR 600.10 (Wildlife and Fisheries regulations defining ''postmark'' as ''independently verifiable evidence of the date of mailing, such as a U.S. Postal Service postmark, or other private carrier postmark, certified mail receipt, overnight mail receipt, or a receipt issued upon hand delivery * * *'').

104.5(e) to clarify that designations, reports, and statements sent by first class mail or by any means other than registered or certified mail, Priority Mail, Express Mail, or an overnight delivery service must be received by the close of business *on*, rather than *of*, the prescribed filing date. This correction is technical and nonsubstantive and does not require a notice and comment period under the Administrative Procedure Act, 5 U.S.C. 553.

Certification of No Effect Pursuant to 5 U.S.C. 605(b) (Regulatory Flexibility Act)

The Commission certifies that the attached rules will not have a significant economic impact on a substantial number of small entities. The basis of this certification is that, to whatever limited extent these rules may affect small entities, expanding options for delivering statutorily required documents provides more flexibility to filers in choosing the method of fulfilling their filing requirements. In addition, these new filing methods are permissive, not required. Therefore, the rules do not increase costs of compliance and may decrease such costs.

List of Subjects

11 CFR Part 100

Elections.

11 CFR Part 104

Campaign funds, Political committees and parties, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Federal Election Commission is amending Subchapter A of Chapter I of Title 11 of the *Code of Federal Regulations* as follows:

PART 100—SCOPE AND DEFINITIONS (2 U.S.C. 431)

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

Authority: 2 U.S.C. 431, 434, and 438(a)(8).

■ 2. In section 100.19, paragraph (b) is revised to read as follows:

§ 100.19 File, filed or filing (2 U.S.C. 434(a)).

* * * * *

(b) *Timely filed.* (1) A document, other than those addressed in paragraphs (c) through (g) of this section, is timely filed if:

(i) Deposited:

(A) As registered or certified mail in an established U.S. Post Office;

(B) As Priority Mail or Express Mail, with a delivery confirmation, in an established U.S. Post Office; or

(C) With an overnight delivery service and scheduled to be delivered the next business day after the date of deposit and recorded in the overnight delivery service's on-line tracking system; and

(ii) The postmark on the document must be dated no later than 11:59 p.m. Eastern Standard/Daylight Time on the filing date, except that pre-election reports must have a postmark dated no later than 11:59 p.m. Eastern Standard/Daylight Time on the fifteenth day before the date of the election.

(2) Documents, other than those addressed in paragraphs (c) through (g) of this section, sent by first class mail or by any means other than those listed in paragraph (b)(1)(i) of this section must be received by the close of business on the prescribed filing date to be timely filed.

(3) As used in this paragraph (b) of this section and in 11 CFR 104.5,

(i) Overnight delivery service means a private delivery service business of established reliability that offers an overnight (*i.e.*, next business day) delivery option.

(ii) Postmark means a U.S. Postal Service postmark or the verifiable date of deposit with an overnight delivery service.

* * * * *

PART 104—REPORTS BY POLITICAL COMMITTEES AND OTHER PERSONS (2 U.S.C. 434)

■ 3. The authority citation for Part 104 continues to read as follows:

Authority: 2 U.S.C. 431(1), 431(8), 431(9), 432(i), 434, 438(a)(8) and (b), 439a, 441a, and 36 U.S.C. 510.

■ 4. In section 104.5, paragraphs (a)(2)(i)(A), (c)(1)(ii)(A), and (e) are revised to read as follows:

§ 104.5 Filing dates (2 U.S.C. 434(a)(2)).

(a) * * *

(2) *Additional reports in the election year.* (i) *Pre-election reports.* (A) Pre-election reports for the primary and general election must be filed no later than 12 days before any primary or general election in which the candidate seeks election. If sent by registered or certified mail, Priority Mail or Express Mail with a delivery confirmation, or with an overnight delivery service and scheduled to be delivered the next business day after the date of deposit and recorded in the overnight delivery service's on-line tracking system, the postmark on the report must be dated no later than the 15th day before any election.

* * * * *

(c) * * *

(1) * * *

(ii) *Pre-election reports.* (A) Pre-election reports for the primary and general election shall be filed by a political committee which makes contributions or expenditures in connection with any such election if such disbursements have not been previously disclosed. Pre-election reports shall be filed no later than 12 days before any primary or general election. If sent by registered or certified mail, Priority Mail or Express Mail with a delivery confirmation, or with an overnight delivery service and scheduled to be delivered the next business day after the date of deposit and recorded in the overnight delivery service's on-line tracking system, the postmark on the report shall be dated no later than the 15th day before any election.

* * * * *

(e) *Date of filing.* A designation, report or statement, other than those addressed in paragraphs (f), (g), and (j) of this section, sent by registered or certified mail, Priority Mail or Express Mail with a delivery confirmation, or with an overnight delivery service and scheduled to be delivered the next business day after the date of deposit and recorded in the overnight delivery service's on-line tracking system, shall be considered filed on the date of the postmark except that a twelve day pre-election report sent by such mail or overnight delivery service must have a postmark dated no later than the 15th day before any election. Designations, reports or statements, other than those addressed in paragraphs (f), (g), and (j) of this section, sent by first class mail, or by any means other than those listed in this paragraph (e), must be received by the close of business on the prescribed filing date to be timely filed. Designations, reports or statements electronically filed must be received and validated at or before 11:59 p.m., eastern standard/daylight time on the prescribed filing date to be timely filed.

* * * * *

Dated: March 10, 2005.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. 05–5391 Filed 3–17–05; 8:45 am]

BILLING CODE 6715–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19541; Directorate Identifier 2004–NM–129–AD; Amendment 39–14013; AD 2005–06–05]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–8 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all McDonnell Douglas Model DC–8 airplanes. This AD requires an inspection of the pushrod assemblies for the left and right elevator control tabs to determine if the pushrod assemblies are made of aluminum or steel, replacing any assembly made of aluminum with an assembly made of steel or modifying existing steel assemblies, and other specified actions. This AD also requires an inspection of the crank assemblies for the inboard and outboard geared tabs of the elevator to determine if the crank assemblies are made of aluminum or steel, replacing any assembly made of aluminum with an assembly made of steel, and other specified actions. This AD is prompted by an accident involving a DC–8 airplane. The probable cause of the accident was a loss of pitch control resulting from the disconnection of the pushrod for the right elevator control tab. The pushrod dropped down and jammed in front of the control tab crank, causing a large deflection of the control tab. We are issuing this AD to minimize the possibility of a control tab offset. A control tab offset could cause elevator deflection, an elevator airplane-nose-up condition, and reduced controllability of the airplane. This AD is also prompted by a report that the elevator on a McDonnell Douglas Model DC–8 airplane did not respond to command inputs from the flightcrew. We are also issuing this AD to minimize the possibility of crank assembly failure when the assembly is exposed to abnormal load conditions. Failure of a crank assembly could result in a jammed elevator and consequent reduced controllability of the airplane.

DATES: This AD becomes effective April 22, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of April 22, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024).

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Washington, DC. This docket number is FAA–2004–19541; the directorate identifier for this docket is 2004–NM–129–AD.

FOR FURTHER INFORMATION CONTACT: Maureen Moreland, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5238; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for all McDonnell Douglas Model DC–8 airplanes. That action, published in the **Federal Register** on November 5, 2004 (69 FR 64510), proposed to require an inspection of the pushrod assemblies for the left and right elevator control tabs to determine if the pushrod assemblies are made of aluminum or steel, replacing any assembly made of aluminum with an assembly made of steel or modifying existing steel assemblies, and other specified actions. That action also proposed to require an inspection of the crank assemblies for the inboard and outboard geared tabs of the elevator to determine if the crank assemblies are made of aluminum or steel, replacing any assembly made of aluminum with an assembly made of steel, and other specified actions.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Supportive Comment

One commenter supports the proposed AD.

Request To Revise Costs of Compliance

One commenter requests that the Costs of Compliance section of the proposed AD be revised to include detailed cost information. The commenter states that the proposed AD requires replacement or modification of certain parts, therefore, the parts costs and associated work hours should be included in the economic analysis of the final rule. The commenter provides all of the parts costs and labor figures.

We do not agree with the commenter's request. This AD requires inspections of the pushrod assemblies and inboard and outboard geared tab crank assemblies. The replacement or modification of certain parts is dependent upon the inspection results. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD, not the ''on condition'' actions. We have not changed this AD regarding this issue.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 227 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection, crank assemblies	1	$65	None	$65	170	$11,050
Inspection, pushrod assemblies	1	65	None	65	170	11,050

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–06–05 McDonnell Douglas: Amendment 39–14013. Docket No. FAA–2004–19541; Directorate Identifier 2004–NM–129–AD.

Effective Date

(a) This AD becomes effective April 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all McDonnell Douglas Model DC–8 airplanes, certificated in any category.

Unsafe Condition

(d) This AD was prompted by an accident involving a DC–8 airplane. The probable cause of the accident was a loss of pitch control resulting from the disconnection of the pushrod for the right elevator control tab. The pushrod dropped down and jammed in front of the control tab crank, causing a large deflection of the control tab. We are issuing this AD to minimize the possibility of a control tab offset. A control tab offset could cause elevator deflection, an elevator airplane-nose-up condition, and reduced controllability of the airplane. This AD was also prompted by a report that the elevator on a McDonnell Douglas Model DC–8 airplane did not respond to command inputs from the flightcrew. We are also issuing this AD to minimize the possibility of a crank assembly failure when the assembly is exposed to abnormal load conditions. Failure of a crank assembly could result in a jammed elevator and consequent reduced controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection of Pushrod Assemblies and Other Specified Actions

(f) Within 24 months after the effective date of this AD: Do an inspection of the pushrod assemblies located in the left and right elevator control tabs to determine whether the assemblies are made of aluminum or steel. Replace any pushrod assembly made of aluminum with a new, improved pushrod assembly made of steel, or modify any existing steel pushrod assembly by replacing the aft end assembly with a new, improved aft end assembly, as applicable. Do the inspection, replacement or modification, and all other applicable specified actions by accomplishing all of the actions in the Accomplishment Instructions of Boeing Alert Service Bulletin DC8–27A281, dated June 2, 2004. The replacement or modification and other applicable specified actions must be done before further flight.

Inspection of Geared Tab Crank Assemblies and Other Specified Actions

(g) Within 24 months after the effective date of this AD: Do an inspection of the inboard and outboard geared tab crank assemblies, located in the left and right elevators, to determine whether the assemblies are made of aluminum or steel. Replace any crank assembly made of aluminum with a new, improved crank assembly made of steel. Do the inspection, replacement, and other applicable specified actions by accomplishing all of the actions in the Accomplishment Instructions of Boeing Alert Service Bulletin DC8–27A280, dated June 2, 2004. The replacement and other applicable specified actions must be done before further flight.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Los Angeles Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(i) You must use Boeing Alert Service Bulletin DC8–27A280, dated June 2, 2004; and Boeing Alert Service Bulletin DC8–27A281, dated June 2, 2004; as applicable; to perform the actions that are required by this AD; unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on March 8, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–5141 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19264; Directorate Identifier 2004–NM–90–AD; Amendment 39–14014; AD 2005–06–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Model A319, A320, and A321 series airplanes. This AD requires modification of certain auxiliary power unit (APU) alternating current (AC) generators. This AD is prompted by a report of an explosion in the APU compartment, which blew open the compartment doors. We are issuing this AD to prevent oil vapor leakage from the APU AC generator, which, when combined with an electric arc at the electrical receptacle, could result in a fire or explosion in the APU compartment during flight.

DATES: This AD becomes effective April 22, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of April 22, 2005.

ADDRESSES: For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2004–19264; the directorate identifier for this docket is 2004–NM–90–AD.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Airbus Model A319, A320, and A321 series airplanes. That action, published in the **Federal Register** on October 7, 2004 (69 FR 60098), proposed to require modification of certain auxiliary power unit (APU) alternating current (AC) generators.

Explanation of New Relevant Service Information

The proposed AD refers to Airbus Service Bulletin A320–24–1106, dated May 26, 2003, as the appropriate source of service information for the modification of affected APU AC generators. Since the issuance of that service bulletin, Airbus has issued Revision 01, dated May 13, 2004. Revision 01 of the service bulletin provides additional information regarding on-airplane modification of the APU AC generators. Revision 01 also removes the concurrent action—accomplishment of Airbus Service Bulletin A320–24–1082, Revision 01, dated March 15, 1996, which was specified in the original issue of the service bulletin. We have revised paragraph (f) of this final rule to refer to Revision 01 of the service bulletin as the appropriate source of service information. We have also not included paragraph (g) of the proposed AD, which contained the requirement to accomplish Airbus Service Bulletin A320–24–1082, and we have made other editorial changes throughout the AD related to the omission of this requirement. We have added a new paragraph (g) to this final rule to specify that modification of the APU AC generators accomplished before the effective date of this AD in accordance with the original issue of the service bulletin is acceptable for compliance with this AD.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Support for the Proposed AD

One commenter supports the proposed AD.

Request To Remove Parts Installation Paragraph

One commenter requests that we do not include paragraph (h) of the proposed AD, ''Part Installation,'' in the final rule. The commenter states that prohibiting the installation of an APU AC generator having an old part number is too restrictive at the beginning of the proposed 20-month compliance time because modified generators or the parts to modify the generators may not be readily available. Also, the commenter notes that the restrictions of paragraph (h) of the proposed AD would not allow for removing and reinstalling an unmodified generator during the course of troubleshooting. The commenter states that installing an unmodified APU AC generator would not pose any additional safety risk as long as all affected units are modified within the proposed 20-month compliance time.

We agree with the commenter's request and the rationale for that request. We have determined that modifying an APU AC generator within the 20-month compliance time specified by paragraph (f) of this AD is adequate to ensure an acceptable level of safety. Accordingly, we have not included paragraph (h) of the proposed AD in this final rule, and we have re-identified subsequent paragraphs in this final rule.

Request To Refer to Alternative Parts

One commenter notes that Hamilton Sundstrand Service Bulletin 90EGS01AG–24–18, dated February 13, 2003, which is referenced in the Airbus service bulletin as a source of additional information on the modification, refers to a type of lockwire and aerospace marker that are not readily available in the U.S. The commenter recommends the use of an alternate lockwire and marker that are readily available in the U.S. The commenter states that Airbus and Hamilton Sundstrand have concurred that these are acceptable alternatives.

We acknowledge the commenter's request but do not agree to revise the AD. It would not be possible for us to consider every alternate part that might be used in accomplishing the requirements of an AD. Any operator who would like to use an alternate type of lockwire and aerospace marker may submit a request for approval of an alternative method of compliance (AMOC), as specified in paragraph (h) of this AD. The request must include data substantiating that an acceptable level of safety would be maintained by use of the alternate type of lockwire and marker. No change to the AD is needed in this regard.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes

will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

This AD will affect about 537 airplanes of U.S. registry.

The modification will take about 5 work hours per airplane, at an average labor rate of $65 per work hour. Required parts would be free of charge. Based on these figures, the estimated cost of the modification for U.S. operators is $174,525, or $325 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–06–06 Airbus: Amendment 39–14014. Docket No. FAA–2004–19264; Directorate Identifier 2004–NM–90–AD.

Effective Date

(a) This AD becomes effective April 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A319, A320, and A321 series airplanes; certificated in any category; equipped with any Hamilton Sundstrand Auxiliary Power Unit (APU) alternating current (AC) generator having part number 5906732, 5909006, or 5910047; with up to amendment 17 included; on which Airbus Modification 32614 has not been done.

Unsafe Condition

(d) This AD was prompted by a report of an explosion in the APU compartment which blew open the compartment doors. We are issuing this AD to prevent oil vapor leakage from the APU AC generator, which, when combined with an electric arc at the electrical receptacle, could result in a fire or explosion in the APU compartment during flight.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Modification

(f) Within 20 months after the effective date of this AD, modify the APU AC generator by doing all the actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–24–1106, Revision 01, dated May 13, 2004.

Note 1: Airbus Service Bulletin A320–24–1106, Revision 01, refers to Hamilton Sundstrand Service Bulletin 90EGS01AG–24–18, dated February 13, 2003, as an additional source of service information for accomplishment of the modification required by paragraph (f) of this AD.

Previously Accomplished Actions

(g) Modification of the APU AC generator accomplished before the effective date of this AD in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–24–1106, dated May 26, 2003, is acceptable for compliance with the modification required by paragraph (f) of this AD.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(i) French airworthiness directive F–2004–019, dated February 4, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(j) You must use Airbus Service Bulletin A320–24–1106, Revision 01, dated May 13, 2004, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on March 8, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–5140 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30440; Amdt. No. 3118]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are

needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective March 18, 2005. The compliance date for each SIAP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 18, 2005.

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

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The Flight Inspection Area Office which originated the SIAP; or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

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

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) telephone: (405) 954–4164.

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

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

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

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

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC on March 11, 2005.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

** * * Effective April 14, 2005*

Nantucket, MA, Nantucket Memorial, ILS OR LOC RWY 6, Orig

Nantucket, MA, Nantucket Memorial, LOC BC RWY 6, Amdt 10B, CANCELLED

** * * Effective May 12, 2005*

Deadhorse, AK, Deadhorse, LOC/DME BC RWY 22, Amdt 10

Emmonak, AK, Emmonak, RNAV (GPS) RWY 16, Amdt 1

Emmonak, AK, Emmonak, RNAV (GPS) RWY 34, Amdt 1

Emmonak, AK, Emmonak, VOR RWY 16, Amdt 1
Emmonak, AK, Emmonak, VOR RWY 34, Amdt 1
Andalusia/Opp, AL, Andalusia-Opp, NDB–A, Amdt 3
Andalusia/Opp, AL, Andalusia-Opp, GPS RWY 29, ORIG, CANCELLED
Andalusia/Opp, AL, Andalusia-Opp, RNAV (GPS) RWY 11, Orig
Andalusia/Opp, AL, Andalusia-Opp, RNAV (GPS) RWY 29, Orig
Decatur, AR, Crystal Lake, RNAV (GPS) RWY 13, Orig
Decatur, AR, Crystal Lake, VOR/DME RWY 13, Amdt 9
Crossett, AR, Z M Jack Stell Field, RNAV (GPS) RWY 23, Orig
Crossett, AR, Z M Jack Stell Field, GPS RWY 23, Orig, CANCELLED
Melbourne, AR, Melbourne Muni-John E. Miller Field, RNAV (GPS) RWY 3, Orig
Melbourne, AR, Melbourne Muni-John E. Miller Field, RNAV (GPS) RWY 21, Orig
Orlando, FL, Orlando Intl, ILS OR LOC RWY 18R, Amdt 7
Orlando, FL, Orlando Intl, ILS OR LOC RWY 36R, Amdt 8, ILS RWY 36R (CAT II), ILS RWY 36R (CAT III)
Driggs, ID, Driggs-Reed Memorial, RNAV (GPS) RWY 3, Orig
Dodge City, KS, Dodge City Regional, VOR RWY 14, Amdt 19
Dodge City, KS, Dodge City Regional, VOR/DME RWY 32, Amdt 5
Parsons, KS, Tri City, RNAV (GPS) RWY 17, Orig
Parsons, KS, Tri City RNAV (GPS) RWY 35, Orig
Parsons, KS, Tri City NDB RWY 17, Amdt 9
Parsons, KS, Tri City NDB RWY 35, Amdt 6
Parsons, KS, Tri City VOR/DME RWY 17, Orig
Parsons, KS, Tri City VOR–A, Orig-A, CANCELLED
Parsons, KS, Tri City VOR/DME RNAV RWY 17, Amdt 5B, CANCELLED
Parsons, KS, Tri City VOR/DME RNAV RWY 35, Amdt 5C, CANCELLED
Covington, KY, Cincinnati/Northern Kentucky Intl, RNAV (GPS) RWY 18C, Orig-A
Covington, KY, Cincinnati/Northern Kentucky Intl, RNAV (GPS) RWY 36C, Orig-A
Covington, KY, Cincinnati/Northern Kentucky Intl, ILS OR LOC RWY 18C, Amdt 20A
Covington, KY, Cincinnati/Northern Kentucky Intl, ILS OR LOC RWY 36C, Amdt 39A, ILS RWY 36C (CAT II), ILS RWY 36C (CAT III)
Slidell, LA, Slidell, RNAV (GPS) RWY 18, Orig
Slidell, LA, Slidell, RNAV (GPS) RWY 36, Orig
Slidell, LA, Slidell, VOR/DME RWY 18, Amdt 4
Slidell, LA, Slidell, GPS RWY 36, Orig-B, CANCELLED
Kosciusko, MS, Kosciusko-Attala County, RNAV (GPS) RWY 14, Orig
Kosciusko, MS, Kosciusko-Attala County, RNAV (GPS) RWY 32, Orig
Kosciusko, MS, Kosciusko-Attala County, NDB RWY 14, Amdt 6
Kosciusko, MS, Kosciusko-Attala County, NDB RWY 32, Amdt 5
Maple Lake, MN, Maple Lake Muni, VOR–A, Amdt 4
Washington, MO, Washington Memorial, RNAV (GPS) RWY 16, Orig, CANCELLED
Washington, MO, Washington Memorial, RNAV (GPS) RWY 34, Orig, CANCELLED
Washington, MO, Washington Memorial, VOR RWY 16, AMDT 2A, CANCELLED
Zuni Pueblo, NM, Black Rock, RNAV (GPS) RWY 6, Orig
Zuni Pueblo, NM, Black Rock, VOR/DME RWY 6, Amdt 2
Zuni Pueblo, NM, Black Rock, GPS RWY 7, Orig-A, CANCELLED
Louisburg, NC, Franklin County, ILS OR LOC RWY 4, Amdt 3
Louisburg, NC, Franklin County, VOR/DME–A, Amdt 2
Louisburg, NC, Franklin County, GPS RWY 4, Amdt 1, CANCELLED
Louisburg, NC, Franklin County, RNAV (GPS) RWY 4, Orig
Louisburg, NC, Franklin County, RNAV (GPS) RWY 22, Orig
Las Vegas, NV, Henderson Executive, RNAV (GPS)–B, Orig
Albion, NY, Pine Hill, RNAV (GPS)–B, Orig
Albion, NY, Pine Hill, VOR/DME OR GPS–A, Amdt 3, CANCELLED
Millbrook, NY, Sky Acres, VOR–A, Amdt 8
Millbrook, NY, Sky Acres, RNAV (GPS) RWY 17, Orig
Millbrook, NY, Sky Acres, GPS RWY 17, Orig, CANCELLED
Millbrook, NY, Sky Acres, RNAV (GPS) RWY 35, Orig
Millbrook, NY, Sky Acres, GPS RWY 35, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh International, ILS RWY 10R, Amdt 10B
Pittsburgh, PA, Pittsburgh International, ILS RWY 28L, Amdt 8B
Pittsburgh, PA, Pittsburgh International, RNAV (GPS) Y RWY 28C, Amdt 1A
Pittsburgh, PA, Pittsburgh International, RNAV (GPS) Y RWY 28L, Amdt 1B
Pittsburgh, PA, Pittsburgh International, RNAV (GPS) Z RWY 28C, Amdt 2A
Pittsburgh, PA, Pittsburgh International, RNAV (GPS) Z RWY 28L, Amdt 2C
Knoxville, TN, McGhee-Tyson, VOR RWY 23L, Amdt 5
Knoxville, TN, McGhee-Tyson, VOR RWY 23R, Amdt 7
Knoxville, TN, McGhee-Tyson, NDB RWY 5R, Amdt 5
Knoxville, TN, McGhee-Tyson, NDB RWY 5L, Amdt 5
Knoxville, TN, McGhee-Tyson, ILS OR LOC RWY 23R, Amdt 11, ILS RWY 23R (CAT II), Amdt 11
Knoxville, TN, McGhee-Tyson, ILS OR LOC RWY 5L, Amdt 8
Knoxville, TN, McGhee-Tyson, RADAR–1, Amdt 22
Madisonville, TN, Monroe County, NDB RWY 5, Amdt 5
Madisonville, TN, Monroe County, RNAV (GPS) RWY 23, Orig
Madisonville, TN, Monroe County, RNAV (GPS) RWY 5, Orig
Caddo Mills, TX, Caddo Mills Muni, RNAV (GPS) RWY 35L, Orig
Caddo Mills, TX, Caddo Mills Muni, NDB RWY 35L, Amdt 2B
Caddo Mills, TX, Caddo Mills Muni, GPS RWY 35L, Orig, CANCELLED
Lufkin, TX, Angelina County, RNAV (GPS) RWY 15, Orig
Lufkin, TX, Angelina County, RNAV (GPS) RWY 25, Amdt 1
Lufkin, TX, Angelina County, RNAV (GPS) RWY 33, Amdt 1
Lufkin, TX, Angelina County, ILS OR LOC RWY 7, Amdt 2
Lufkin, TX, Angelina County, GPS RWY 7, Orig-A, CANCELLED
Lufkin, TX, Angelina County, GPS RWY 15, Orig-A, CANCELLED
Lufkin, TX, Angelina County, VOR/DME RNAV RWY 7, Amdt 3A, CANCELLED
Lufkin, TX, Angelina County, VOR/DME RNAV RWY 15, Amdt 4A, CANCELLED
Rice Lake, WI, Rice Lake Regional-Carl's Field, ILS OR LOC RWY 1, Orig
Rice Lake, WI, Rice Lake Regional-Carl's Field, NDB RWY 1, Orig

** * * Effective June 9, 2005*

Louisburg, NC, Franklin County, RNAV (GPS) RWY 4, Orig-A

** * * Effective July 7, 2005*

Sparta, IL, Sparta Community-Hunter Field, NDB RWY 18, Amdt 1, CANCELLED

[FR Doc. 05–5343 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

[Docket No. 040831251–5046–03; I.D. 082504A]

RIN 0648–AS47

Fisheries of the Exclusive Economic Zone Off Alaska; Allocating Bering Sea and Aleutian Islands King and Tanner Crab Fishery Resources; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule; correcting amendment.

SUMMARY: NMFS issues this final rule, correcting amendment to the regulations governing the Bering Sea and Aleutian Islands crab fisheries. This action is necessary to correct Office of Management and Budget (OMB) control numbers for information collections previously approved under the Paperwork Reduction Act provided under an earlier rulemaking. This final rule in no way alters or amends those previously approved information collections. The sole purpose of this final rule is to display the appropriate control numbers for the approved information collections.

DATES: Effective on April 1, 2005.

FOR FURTHER INFORMATION CONTACT: Patsy A. Bearden, 907–586–7008 or *patsy.bearden@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Background

In January 2004, the U.S. Congress amended section 313(j) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) through the Consolidated Appropriations Act of 2004 (Pub. L. 108–199, section 801). As amended, section 313(j)(1) requires the Secretary to approve and implement by regulation the so-called Crab Rationalization Program (Program), as it was approved by the North Pacific Fishery Management Council (Council) between June 2002 and April 2003, and all trailing amendments, including those reported to Congress on May 6, 2003. In June 2004, the Council consolidated its actions on the Program into the Council motion, which is contained in its entirety in Amendment 18 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (FMP). Additionally, in June 2004, the Council developed Amendment 19 to the FMP, which represents minor changes necessary to implement the Program. The Notice of Availability for these amendments was published in the **Federal Register** on September 1, 2004 (69 FR 53397). NMFS approved Amendments 18 and 19 on November 19, 2004. NMFS published a proposed rule to implement Amendments 18 and 19 in the **Federal Register** on October 29, 2004 (69 FR 63200). NMFS published a final rule to implement Amendments 18 and 19 on March 2, 2005 (70 FR 10174).

Need for Corrections

In the final rule, published on March 2, 2005 (70 FR 10174), five of the eight OMB control numbers listed in the crab final rule classification section were incorrect. This final rule replaces the incorrect numbers with correct OMB control numbers in the classification section of the final rule and in the regulatory text at 15 CFR part 902.1.

On page 10231, column 2, third heading, replace OMB No. 0648–0272 with OMB No. 0648–0517.

On page 10231, column 3, first heading, replace OMB No. 0648–0503 with OMB No. 0648–0516.

On page 10231, column 3, second heading, replace OMB No. 0648–0504 with OMB No. 0648–0514.

On page 10231, column 3, third heading, replace OMB No. 0648–0503 with OMB No. 0648–0515.

On page 10231, column 3, fourth heading, replace OMB No. 0648 0506 with OMB No. 0648–0518.

Classification

The Administrator, Alaska Region, NMFS (Regional Administrator), has determined that this final rule is necessary for the conservation and management of the BSAI crab fisheries. The Regional Administrator also has determined that this final rule is consistent with the Magnuson-Stevens Act and other applicable laws.

This final rule has been determined to be not significant for the purposes of Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator of Fisheries, NOAA (AA) finds good cause to waive prior notice and opportunity for public comment otherwise required by the section. NOAA finds that prior notice and comment are unnecessary as this rule is purely technical in nature, having no substantive impact whatsoever. This action merely corrects OMB control numbers for approved collections-of-information, in no way altering those approved collections. NOAA finds that because of the non-substantive nature of the correction, no particular public interest exists in this final rule for which there is justification or need for prior notice and opportunity for comment.

Because this correcting amendment does not institute any substantive obligations for the public, the requirement for a 30-day delay in the effective date to this action pursuant to 5 U.S.C. 553(d) does not apply.

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C., or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

List of Subjects in 15 CFR Part 902

Reporting and recordkeeping requirements.

Dated: March 11, 2005.

William T. Hogarth

Assistant Administrator for Fisheries, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 15 CFR part 902 is amended as follows:

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT; OMB CONTROL NUMBERS

■ 1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

■ 2. In § 902.1, the table in paragraph (b) under 50 CFR is amended by revising in numerical order entries for § 679.5(l)(3)(i), § 679.5(l)(4), § 680.4, § 680.5, § 680.6, § 680.20, § 680.21, § 680.40(f), (g), (h), (i), (j), (k), (l), and (m), § 680.41, § 680.43, and § 680.44 (a) through (f) to read as follows:

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

* * * * *

(b) * * *

CFR part or section where the information collection requirement is located	Current OMB control number (All numbers begin with 0648-)
* * * * *	
50 CFR	
* * * * *	
679.5(l)(3)(i), (l)(4)	-0272, -0517
* * * * *	
680.4	-0514
680.5	-0515
680.6	-0518
680.20	-0516
680.21	-0514
* * * * *	
680.40(f), (g), (h), (i), (j), (k), (l), and (m)	-0514
680.41	-0514
680.43	-0514
680.44(a), (b), (c), (d), (e)	-0515
680.44(f)	-0514
* * * * *	

[FR Doc. 05–5349 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Tiamulin Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of tiamulin soluble powder to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia.

DATES: This rule is effective March 18, 2005.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–344 that provides for use of Tiamulin Soluble Antibiotic to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia. Phoenix Scientific, Inc.'s Tiamulin Soluble Antibiotic is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s DENAGARD (tiamulin) Soluble Antibiotic approved under NADA 134–644. The ANADA is approved as of February 16, 2005, and the regulations are amended in 21 CFR 520.2455 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

FDA is also amending the regulations in 21 CFR 520.2455 to reflect a more recent genus name for the causative pathogen for swine dysentery and in the tables in 21 CFR 510.600(c) to reflect accepted style for the sponsor's street address. These actions are being taken to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) in the entry for ''Phoenix Scientific, Inc.'' and in the table in paragraph (c)(2) in the entry for ''059130'' by removing ''St. Terrace'' and by adding in its place ''Street Ter.''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2455 [Amended]

■ 4. Section 520.2455 is amended in paragraph (b) by removing ''*Sponsor*. See No. 000010'' and by adding in its place ''*Sponsors*. See Nos. 000010 and 059130''; and in paragraph (d)(1)(i) by removing ''*Treponema*'' and by adding in its place ''*Brachyspira*''.

Dated: March 9, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–5380 Filed 3–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

Food Additives Permitted in Feed and Drinking Water of Animals; Poly(2–vinylpyridine-co-styrene); Salts of Volatile Fatty Acids

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal food additive regulations to correct the specifications for two food additives used in cattle feed. Incorrect symbols describing permitted levels of heavy metals such as lead and arsenic are being corrected with text to reflect the maximum permitted levels of these two impurities in these food additives. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective March 18, 2005.

FOR FURTHER INFORMATION CONTACT: Sharon Benz, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6864, e-mail: *sbenz@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: FDA has found that part 573 (21 CFR part 573) of the Code of Federal Regulations does not accurately reflect the approved specifications for two food additives used in cattle feed, poly(2–vinylpyridine-co-styrene) and salts of volatile fatty acids. The greater than symbols in the tables describing the permitted levels of heavy metals such as lead and arsenic were incorrect. FDA is amending the regulations in §§ 573.870 and 573.914 to correctly reflect the maximum permitted levels of these two impurities in these food additives. This action is being taken to improve the accuracy of the agency's regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

List of Subjects in 21 CFR 573

Animal feeds, Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the

Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 573.870 is amended in paragraph (a) in the table by revising the entries for ''Heavy metals such as lead'' and ''Arsenic'' to read as follows:

§ 573.870 Poly(2–vinylpyridine-co-styrene).

* * * * *

(a) * * *

Component/property	Limitation
* * *	* *
Heavy metals such as lead	10 parts per million maximum.
Arsenic	3 parts per million maximum.

* * * * *

■ 3. Section 573.914 is amended in the tables in paragraphs (b)(1) and (b)(2) by revising the entries for ''Arsenic'' and ''Heavy metals as lead'' to read as follows:

§ 573.914 Salts of volatile fatty acids.

* * * * *

(b) * * *

(1) * * *

Components	Amount
* * *	* *
Arsenic	3 parts per million maximum.
Heavy metals such as lead	10 parts per million maximum.

(2) * * *

Components	Amount
* * *	* *
Arsenic	3 parts per million maximum.
Heavy metals such as lead	10 parts per million maximum.

* * * * *

Dated: March 8, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–5344 Filed 3–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9191]

RIN 1545–BD16

Time and Manner of Making Section 163(d)(4)(B) Election To Treat Qualified Dividend Income as Investment Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations relating to an election that may be made by noncorporate taxpayers to treat qualified dividend income as investment income for purposes of calculating the deduction for investment interest. The regulations reflect changes to the law made by the Jobs and Growth Tax Relief Reconciliation Act of 2003. The regulations affect taxpayers making the election under section 163(d)(4)(B) to treat qualified dividend income as investment income.

DATES: *Effective Date:* These regulations are effective March 18, 2005.

Applicability Dates: For dates of applicability, *see* § 1.163(d)–1(d).

FOR FURTHER INFORMATION CONTACT: Amy Pfalzgraf, (202) 622–4950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 1 under section 163(d) of the Internal Revenue Code (Code). On August 5, 2004, temporary regulations (TD 9147) were published in the **Federal Register** (69 FR 47364) relating to an election that may be made by noncorporate taxpayers to treat qualified dividend income as investment income for purposes of calculating the deduction for investment interest. A notice of proposed rulemaking (REG–171386–03) cross-referencing the temporary regulations also was published in the **Federal Register** (69 FR 47395) on August 5, 2004. No comments in response to the notice of proposed rulemaking or requests to speak at a public hearing were received, and no hearing was held. This Treasury decision adopts the proposed regulations and removes the temporary regulations.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the proposed regulations preceding these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Amy Pfalzgraf of the Office of Associate Chief Counsel (Income Tax & Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.163(d)–1 is revised to read as follows:

§ 1.163(d)–1 Time and manner for making elections under the Omnibus Budget Reconciliation Act of 1993 and the Jobs and Growth Tax Relief Reconciliation Act of 2003.

(a) *Description.* Section 163(d)(4)(B)(iii), as added by section 13206(d) of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66, 107 Stat. 467), allows an electing taxpayer to take all or a portion of certain net capital gain attributable to dispositions of property held for investment into account as investment income. Section 163(d)(4)(B), as amended by section 302(b) of the Jobs and Growth Tax Relief Reconciliation Act of 2003 (Pub. L. 108–27, 117 Stat. 762), allows an electing taxpayer to take all or a portion of qualified dividend income, as defined in section 1(h)(11)(B), into account as investment income. As a consequence, the net capital gain and qualified dividend

income taken into account as investment income under these elections are not eligible to be taxed at the capital gains rates. An election may be made for net capital gain recognized by noncorporate taxpayers during any taxable year beginning after December 31, 1992. An election may be made for qualified dividend income received by noncorporate taxpayers during any taxable year beginning after December 31, 2002, but before January 1, 2009.

(b) *Time and manner for making the elections*. The elections for net capital gain and qualified dividend income must be made on or before the due date (including extensions) of the income tax return for the taxable year in which the net capital gain is recognized or the qualified dividend income is received. The elections are to be made on Form 4952, ''Investment Interest Expense Deduction,'' in accordance with the form and its instructions.

(c) *Revocability of elections*. The elections described in this section are revocable with the consent of the Commissioner.

(d) *Effective date*. The rules set forth in this section regarding the net capital gain election apply beginning December 12, 1996. The rules set forth in this section regarding the qualified dividend income election apply to any taxable year beginning after December 31, 2002, but before January 1, 2009.

■ **Par. 3.** Section 1.163–1T is removed.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Approved: March 10, 2005.

Eric Solomon,

Acting Assistant Secretary of the Treasury.

[FR Doc. 05–5433 Filed 3–17–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–127]

RIN 1625–AA09

Drawbridge Operation Regulations: Shrewsbury River, NJ

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard has changed the drawbridge operation regulations that govern the operation of the Route 36 Bridge, mile 1.8, across the Shrewsbury River at Highlands, New Jersey. This change to the drawbridge operation regulations will allow the bridge owner to require an advance notice for bridge openings during periods the bridge has received few requests to open from 11 p.m. to 7 a.m., each day, and during the winter months from December 1 through March 31. This action is expected to help relieve the bridge owner from the burden of crewing the bridge at all times while continuing to meet the present needs of navigation.

DATES: This rule is effective April 18, 2005.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–04–127) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Gary Kassof, Bridge Administrator, First Coast Guard District, (212) 668–7165.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On December 13, 2004, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Shrewsbury River, New Jersey, in the **Federal Register** (69 FR 72138). We received no comments in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

Background and Purpose

The Route 36 Bridge, mile 1.8, across the Shrewsbury River at Highlands, New Jersey, has a vertical clearance of 35 feet at mean high water and 39 feet at mean low water.

The existing regulations listed at 33 CFR 117.755, require the Route 36 Bridge to open on signal; except that, from May 15 through October 15, 7 a.m. to 8 p.m., the draw need open only on the hour and half hour.

The bridge owner, New Jersey Department of Transportation (NJDOT), requested a change to the drawbridge operation regulations that govern the Route 36 Bridge to allow the bridge owner to require a 4-hour advance notice for bridge openings from 11 p.m. to 7 a.m., each day, and all day from December 1 through March 31. The bridge rarely opens after 11 p.m. and during the winter months. A summary of the regulations and the advance notice contact number shall be posted at the bridge.

This final rule relieves the bridge owner from the burden of crewing the bridge during time periods when the bridge has had few requests to open.

Discussion of Comments and Changes

The Coast Guard received no comments in response to the notice of proposed rulemaking and as a result, no changes have been made to this final rule.

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).

This conclusion is based on the fact that the bridge will continue to open for vessel traffic at all times after the advance notice to open is given.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we 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 less than 50,000.

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

This conclusion is based on the fact that the bridge will continue to open for vessel traffic at all times after the advance notice to open is given.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

No small entities requested Coast Guard assistance and none was given.

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 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 an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect 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 concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this final rule under Commandant Instruction M16475.1D, 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 (32)(e), of the Instruction, from further environmental documentation. It has been determined that this final rule does not significantly impact the environment.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

■ 2. Section 117.755 is amended by revising paragraph (a) to read as follows:

§ 117.755 Shrewsbury River.

(a) The Route 36 Bridge, mile 1.8, at Highlands, New Jersey, shall open on signal; except that:

(1) From 11 p.m. to 7 a.m. the draw shall open on signal after at least a 4-hour advance notice is given by calling the number posted at the bridge.

(2) From May 15 through October 15, 7 a.m. to 8 p.m., the draw need only open on the hour and half hour.

(3) From December 1 through March 31, the draw shall open on signal at all times after at least a 4-hour advance notice is given by calling the number posted at the bridge.

(4) The owners of the bridge shall provide and keep in good legible condition, two clearance gauges, with figures not less than eight inches high, designed, installed, and maintained according to the provisions of § 118.160 of this chapter.

* * * * *

Dated: March 9, 2005.

John L. Grenier,

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

[FR Doc. 05–5338 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 174

[USCG–2003–15708]

RIN 1625–AA75

Terms Imposed by States on Numbering of Vessels

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This rule expands the number of conditions that a State may require in order for owners to obtain vessel numbering certificates in that State. Current Federal statutes and regulations limit these conditions to proof of ownership or payment of State or local taxes. The rule allows any State to impose proof of liability insurance as a condition for obtaining vessel numbering certificates in that State. Currently, States are not prohibited from requiring proof of liability insurance to operate a recreational vessel. However, States are prohibited from using an efficient mechanism, such as vessel registration, to manage and enforce such a requirement.

DATES: This final rule is effective April 18, 2005.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2003–15708 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC, 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*.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Audrey Pickup, Office of Boating Safety, at Coast Guard Headquarters, telephone 202–267–0872. If you have questions on viewing the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, Department of Transportation, telephone 202–366–0271.

SUPPLEMENTARY INFORMATION:

Regulatory History

On January 14, 2004, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled Terms Imposed by States on Numbering of Vessels, in the **Federal Register** (69 FR 2098). We received ten letters commenting on the proposed rule. No public hearing was requested and none was held.

Background and Purpose

Title 46 of the United States Code contains provisions, in chapter 123, for the numbering of undocumented vessels equipped with propulsion machinery of any kind, which primarily include recreational boats and some types of commercial vessels. Vessels must carry an identification number issued in compliance with the Standard Numbering System (SNS) maintained by the Coast Guard. States can administer their own numbering programs if those programs comply with SNS requirements and receive Coast Guard approval. SNS requirements include a limitation on the conditions that States can impose on applicants for vessel numbering. A State cannot impose any condition unless it relates to proof of tax payment, or has been sanctioned by Coast Guard regulations. The relevant Coast Guard regulation is 33 CFR 174.31. It permits States to impose only two conditions: proof of tax payment, and proof of ownership.

In recent years, States have expressed an interest in imposing an additional condition—proof of liability insurance—which many people think will promote public safety. Currently, however, a State cannot impose such a requirement as a condition for vessel numbering without going beyond what 33 CFR 174.31 authorizes. As a result, a State imposing a liability insurance requirement as a condition for vessel numbering would not be in compliance with the SNS requirements of Federal law. This could threaten continued Coast Guard approval of the State's numbering system. Loss of that approval could result in decreased Federal funding for the State's recreational boating safety program. The Coast Guard views these as undesirable results in light of the possible public safety benefit that could result from a State's decision to add an insurance condition. This rule avoids those results by amending 33 CFR 174.31.

Discussion of Comments and Changes

We received 10 sets of comments on this rule. The comments came from 2 State agencies, 2 national associations, 1 group of students, and 5 individuals.

Three comments explicitly expressed support for the rule, which we appreciate.

A State agency commented that most boat dealers who were polled showed strong opposition to the rule, with mild support from others. The State agency's position is that it can support the rule as long as proof of liability insurance is not a mandatory requirement.

Response: This rule does not require liability insurance. It simply allows a State to decide whether or not to impose a liability insurance requirement, without risking the loss of Coast Guard approval of its vessel numbering system.

One commenter noted that the rule would give States more flexibility in managing undocumented vessels. The commenter said it would allow States to provide an important assurance that the damage caused by a boater would be compensated by the boater's insurer, and that this in turn would promote boating safety by deterring unsafe boaters.

Response: We agree with this commenter that the rule should provide States with greater flexibility in managing undocumented vessels that operate in their waters. However, we express no opinion on the policy issues raised by the commenter.

Many other commenters took sides on whether or not proof of insurance should be required. Most of them expressed the opinion that such a requirement would not increase public safety. Others felt such a requirement would be worthwhile if one life could benefit from it, and one association reported that its members strongly support an insurance requirement. One commenter asked if any statistics could be presented to demonstrate the impact of insurance on public safety.

Response: We express no opinion on the policy issues raised by these commenters. In some states, many people think boaters should carry liability insurance and that it could promote boating safety. However, under current regulations, if a State requires boaters to carry insurance as a condition for vessel numbering, the State could lose Coast Guard approval for its vessel numbering system. A State without a Coast Guard-approved vessel numbering system could lose valuable Federal funding. The only difference this rule makes is that, now, a State will be able to require insurance without losing Coast Guard approval of its numbering system.

One commenter argued that the State-imposed requirements currently permitted by our regulation—proof of ownership and proof of tax payment—are both relevant to the process of numbering a vessel, whereas the vessel's insurance status is not. This commenter stated that States that impose an insurance requirement would be treating vessel ownership and, indirectly, the use of recreational vessels as a privilege and not as a right. Another commenter with a similar position stated that the rule would be forcing another cost on the marine industry.

Response: Because this rule does not impose any liability insurance requirement and leaves that decision to States, we take no position on whether or not such a requirement could turn rights into privileges, whether some data might be more directly related to vessel numbering than others, or whether it could force a cost on the marine industry. This rule simply gives

States the ability to make these determinations for themselves, without jeopardizing the approved status of their vessel numbering systems.

One group of students challenged various aspects of our regulatory analysis. They said our environmental checklist wrongly denies that the rule will have an impact on public health or safety; they felt the impact would be positive. Likewise, they challenged our small entities analysis and said the rule would affect local businesses and recreational boat owners, and should be changed to cover foreign boat manufacturers and operators as well. Finally, this group felt we were overlooking the rule's positive impact on protecting children.

Response: We acknowledge that some persons believe requiring, or not requiring, boaters to carry liability insurance will have a bearing on the issues raised by this group. However, the Coast Guard takes no position on such a requirement, and the rule itself neither imposes nor prohibits such a requirement. Our only purpose is to allow each State to decide whether or not to impose such a requirement, without risking the loss of Coast Guard approval of its vessel numbering system.

One commenter suggested that the Coast Guard should consider ways to ensure that a liability policy is maintained in force by the boater even after the vessel's certificate is issued.

Response: Because this rule does not impose any liability insurance requirement and leaves that decision to States, the details of any such requirement are beyond the scope of this rule.

Regulatory Evaluation

This final 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 (OMB) has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

Cost of Rule

This rule would allow States to require proof of liability insurance as a condition for vessel registration. Because this rule simply allows a State to decide whether or not to impose a liability insurance requirement as a condition for vessel numbering, it would not impose any direct costs on vessel owners in any State.

Benefits of Rule

This rule expands the number of conditions States can consider in administering vessel numbering programs.

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.

This rule allows any State to impose proof of liability insurance as a condition for obtaining vessel numbering certificates in that State. It imposes no costs on the public. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

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 final rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This final rule will not effect 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 final 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 final 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 final 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with

applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

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)(d), of the Instruction, from further environmental documentation. This rule simply allows a State to decide whether or not to impose a liability insurance requirement as a condition for vessel numbering. An ''Environmental Analysis Checklist'' and a ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 174

Marine safety, Reporting and recordkeeping requirements.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 174 as follows:

PART 174—STATE NUMBERING AND CASUALTY REPORTING SYSTEMS

■ 1. The authority citation for part 174 is revised to read as follows:

Authority: 46 U.S.C. 6101 and 12302; Department of Homeland Security Delegation No. 0170.1 (92).

■ 2. Amend § 174.31 by revising the section title, redesignating paragraph (b) as paragraph (c), and adding a new paragraph (b) to read as follows:

§ 174.31 Terms imposed by States for numbering of vessels.

* * * * *

(b) Proof of liability insurance for a vessel except a recreational-type public vessel of the United States; or

* * * * *

Dated: December 20, 2004.

R. D. Sirois,

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

[FR Doc. 05–5337 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52

[R05–OAR–2005–OH–0001; FRL–7886–7]

Approval and Promulgation of Maintenance Plan Revisions; Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving Ohio's March 1, 2005, submittal of a revision to the Clinton County 1-hour ozone maintenance plan. Ohio held a public hearing on the submittal on February 8, 2005. This maintenance plan revision establishes a new transportation conformity motor vehicle emissions budget (MVEB) for the year 2006. EPA is approving the allocation of a portion of the safety margin for oxides of nitrogen (NO_X) to the area's 2006 MVEB for transportation conformity purposes. This allocation will still maintain the total emissions for the area at or below the attainment level required by the transportation conformity regulations. The transportation conformity budget for volatile organic compounds will remain the same as previously approved in the maintenance plan. In this action, EPA is also correcting the codification for a previous approval action for Cincinnati, Ohio.

DATES: This rule is effective on May 2, 2005, unless EPA receives adverse written comments by April 18, 2005. If EPA receives adverse comments, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2005–OH–0001, by one of the following methods: Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments. Agency Web site: *http://docket.epa.gov/rmepub/*. Regional RME, EPA's electronic public docket and comments system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

E-mail: *mooney.john@epa.gov*.

Fax: (312) 886–5824.

Mail: You may send written comments to: John M. Mooney, Chief, Criteria Pollutant Section, (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: John M. Mooney, Chief, Criteria Pollutant Section, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604.

Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to RME ID No. R05–OAR–2005–OH–0001. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov, or e-mail. The EPA RME Web site and the Federal regulations.gov Web site are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I of the **SUPPLEMENTARY INFORMATION** section of the related proposed rule which is published in the Proposed Rules section of this **Federal Register**.

Docket: All documents in the electronic docket are listed in the RME index at *http://docket.epa.gov/rmepub/*.

Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. We recommend that you telephone Patricia Morris, Environmental Scientist, at (312) 353–8656 before visiting the Region 5 office. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Patricia Morris, Environmental Scientist, Criteria Pollutant Section, Air Programs Branch (AR–18J), EPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8656, *morris.patricia@epa.gov*.

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I. General Information

A. Does This Action Apply to Me?

This action is rulemaking on a non-regulatory planning document intended to ensure the maintenance of air quality in Clinton County, Ohio. This action changes the MVEB used for transportation conformity.

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

1. The Regional Office has established an electronic public rulemaking file available for inspection at RME under ID No. R05–OAR–2005–OH–0001, and a hard copy file which is available for inspection at the Regional Office. The official public file 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 rulemaking file does not include CBI or other information whose disclosure is restricted by statute. The official public rulemaking file is the collection of materials that is available for public viewing at the Air Programs Branch, Air and Radiation Division, EPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. EPA requests that, if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the regulations.gov Web site located at *http://www.regulations.gov* where you can find, review, and submit comments on Federal rules that have been published in the **Federal Register**, the Government's legal newspaper, and that are open for comment.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at the EPA Regional Office, as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose 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 the official public rulemaking file. The entire printed comment, including the copyrighted material, will be available at the Regional Office for public inspection.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate rulemaking identification number by including the text ''Public comment on proposed rulemaking Region 5 Air Docket R05–OAR–2005–OH–0001'' in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

For detailed instructions on submitting public comments and on what to consider as you prepare your comments see the **ADDRESSES** section and the section I of the **SUPPLEMENTARY INFORMATION** section of the related proposed rule which is published in the proposed rules section of this **Federal Register**.

II. Background

A. When Did Ohio Hold a Public Hearing and Officially Submit the Revision Request?

Ohio held a public hearing on the State Implementation Plan (SIP) revision request on February 8, 2005, in Clinton County, Ohio. The formal comment period extended from December 30, 2004, until February 11, 2005. No adverse comments were received. Ohio submitted transcripts of the public hearing and copies of the announcement of the 30 day public comment period to EPA. Ohio sent a letter dated December 22, 2004, which requested that EPA initiate review of the draft SIP revision and proceed to parallel process the request. The official submittal with all documentation including transcripts of the hearing were submitted in a letter dated March 1, 2005.

B. What Change Is Ohio Requesting?

Ohio is requesting a change to the transportation conformity budget in the approved 1-hour ozone maintenance plan for Clinton County, Ohio. Clinton County is an ozone maintenance area under the 1-hour ozone standard. Clinton County is part of the Cincinnati 8-hour ozone nonattainment area, however this change only addresses the 1-hour ozone maintenance plan. The maintenance plan was approved by EPA on March 21, 1996, (61 FR 11560).

In this submittal, Ohio is requesting a change to the transportation conformity budget. The approved maintenance plan has a ''safety margin'' of emissions which can be allocated to the MVEB. The requested change only changes the NO_X budget for transportation conformity.

III. Transportation Conformity Budgets

A. What Are Transportation Conformity Budgets?

A transportation conformity budget is the projected level of controlled emissions from the transportation sector (mobile sources) that is estimated in the SIP. The SIP controls emissions through regulations, for example, on fuels and exhaust levels for cars. The emissions budget concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes

how to establish the MVEB in the SIP and how to revise the emissions budget. The transportation conformity rule allows the MVEB to be changed as long as the total level of emissions from all sources remains below the attainment level.

B. What Is a Safety Margin?

A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The attainment level of emissions is the level of emissions during one of the years in which the area met the air quality health standard. For example: Clinton County first attained the one hour ozone standard during the 1993–1996 time period. The State uses 1996 as the attainment level of emissions for Clinton County. The emissions from point, area and mobile sources in 1996 equaled 5.82 tons per day of NO_X. The Ohio Environmental Protection Agency projected emissions out to the year 2006 and projected a total of 4.91 tons per day of NO_X from all sources. The safety margin for the Ohio portion of the Cincinnati area is calculated to be the difference between these amounts or 0.91 tons per day of NO_X. Detailed information on the estimated emissions from each source category is summarized in the proposed approval of the maintenance plan at 61 FR 11560 published on March 21, 1996. Ohio has requested to allocate 0.2 tons per day of the NO_X safety margin to the mobile source emission budgets for NO_X. With the added safety margin in the motor vehicle emission estimate for 2006, the total NO_X emissions for the area continue to be below the 1996 attainment year. Ohio is not asking to use the entire safety margin in the maintenance plan. Even with the allocation of 0.2 tons per day of NO_X to mobile sources, it leaves the area with 0.71 tons per day NO_X safety margin.

The emissions are projected to maintain the area's air quality consistent with the air quality health standard. The safety margin credit can be allocated to the transportation sector. The total emission level, even with this allocation will be below the attainment level or safety level and thus is acceptable. The safety margin is the extra safety points that can be allocated as long as the total level is maintained.

C. How Does This Action Change the Maintenance Plan?

This action changes the budget for mobile sources. The maintenance plan is designed to provide for future growth while still maintaining the ozone air quality standard. Growth in industries, population, and traffic is offset with reductions from cleaner cars and other emission reduction programs. Through the maintenance plan, the State and local agencies can manage and maintain air quality while providing for growth.

In the submittal, Ohio requested to allocate a portion of the NO_X safely margin to the 2006 MVEB. The VOC MVEB will remain the same as approved and only the NO_X budget is requested to change. The NO_X MVEB will change from 3.25 tons of NO_X to 3.45 tons per day of NO_X. This budget would be the constraining number for mobile sources and transportation conformity. The Transportation Plan and Transportation Improvement Program for Cincinnati will need to be below the MVEB to demonstrate conformity. These requirements are detailed in the transportation conformity regulations which were approved as part of the Ohio SIP on May 16, 1996 (61 FR 24702) and approved as amended in a **Federal Register** notice dated May 30, 2000 (65 FR 34395).

D. Why Is the Request Approvable?

The emissions from point, area and mobile sources in 1996 equaled 5.82 tons per day of NO_X. This is the level of emissions which allow attainment of the one hour ozone standard. The Ohio Environmental Protection Agency projected emissions out to the year 2006 and projected a total of 4.91 tons per day of NO_X from all sources in Clinton County, Ohio. The allocation of the safety margin will keep the total emissions below the attainment level. Thus, the emissions are projected to maintain the area's air quality consistent with the air quality health standard. After review of the SIP revision request, EPA finds that the allocation of the 0.2 tons per day from the safety margin to the 2006 NO_X MVEB for the Clinton County, Ohio area is approvable because the new MVEB for NO_X will maintain the total emissions at or below the attainment year inventory level as required by the transportation conformity regulations.

IV. What Action Is EPA Taking Today?

EPA is approving Ohio's March 1, 2005, submittal of a revision to the Clinton County 1-Hour ozone maintenance plan establishing a new transportation conformity MVEB for the year 2006. EPA is approving the allocation of a portion of the NO_X safety margin to the area's 2006 MVEB for transportation conformity purposes. This allocation will still maintain the total emissions for the area at or below the attainment level required by the transportation conformity regulations. The transportation conformity budget for volatile organic compounds will remain the same as previously approved in the maintenance plan.

For convenience, EPA is also using this rulemaking to correct the codification of its prior approval of the revision to the ozone maintenance plan for the Cincinnati, Ohio area. In our July 20, 2004, approval at 69 FR 43322, the revision was incorrectly added into 40 CFR 52 as paragraph 52.1885(b)(12). EPA is amending the codification of 40 CFR 52 by moving the approved Ohio revision to paragraph 52.1885(a)(16).

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective May 2, 2005, without further notice unless we receive relevant adverse written comments by April 18, 2005. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective May 2, 2005.

V. Statutory and Executive Order Reviews

Executive Order 12866; Regulatory Planning and Review

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.

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

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant energy action,'' 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).

Regulatory Flexibility Act

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.*).

Unfunded Mandates Reform Act

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 (Pub. L. 104–4).

Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

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 (59 FR 22951, November 9, 2000).

Executive Order 13132 Federalism

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 Clean Air Act.

Executive Order 13045 Protection of Children From Environmental Health and Safety Risks

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.

National Technology Transfer Advancement Act

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. 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 Clean Air Act. 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.

Paperwork Reduction Act

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.*).

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).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 17, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Volatile organic compounds, Ozone.

Dated: March 7, 2005.

Norman Niedergang,

Acting Regional Administrator, Region 5.

■ Part 52, 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 KK—Ohio

■ 2. Section 52.1885 is amended by removing paragraph (b)(12) and by adding paragraphs (a)(16) and (17) to read as follows:

§ 52.1885 Control Strategy: Ozone.

(a) * * *

(16) Approval—On April 19, 2004, Ohio submitted a revision to the ozone maintenance plan for the Cincinnati, Ohio area. The revision consists of allocating a portion of the area's NO_X safety margin to the transportation conformity motor vehicle emissions budget. The motor vehicle emissions budget for NO_X for the Cincinnati, Ohio area is now 62.3 tons per day for the year 2010. This approval only changes the NO_X transportation conformity emission budget for Cincinnati, Ohio.

(17) Approval—On March 1, 2005, Ohio submitted a revision to the 1-hour ozone maintenance plan for Clinton County, Ohio. The revision consists of allocating a portion of the area's oxides of nitrogen (NO_X) safety margin to the transportation conformity motor vehicle emissions budget. The motor vehicle emissions budget for NO_X for the Clinton County, Ohio area is now 3.45 tons per day for the year 2006. This approval only changes the NO_X transportation conformity emission budget for Clinton County, Ohio.

* * * * *

[FR Doc. 05–5409 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[R06–OAR–2004–TX–0004; FRL–7886–4]

National Emission Standards for Hazardous Air Pollutants; Delegation of Authority to Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; delegation of authority.

SUMMARY: The Texas Commission on Environmental Quality (TCEQ) has submitted updated regulations for receiving delegation of EPA authority for National Emission Standards for Hazardous Air Pollutants (NESHAPs) for all sources. These regulations apply to certain NESHAPs promulgated by EPA, as adopted by the TCEQ. The delegation of authority under this notice does not apply to sources located in Indian Country. EPA is taking direct final action to approve the delegation of certain NESHAPs to TCEQ.

DATES: This rule is effective on May 17, 2005 without further notice, unless EPA receives relevant adverse comment by April 18, 2005. If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Regional Materials in EDocket (RME) ID No. R06–OAR–2004–TX–0004, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Agency Web site: http://docket.epa.gov/rmepub/,* Regional Materials in EDocket (RME), EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.
- U.S. EPA Region 6 ''Contact Us'' Web site: *http://epa.gov/region6/r6coment.htm.* Please click on ''6PD'' (Multimedia) and select ''Air'' before submitting comments.
- *E-mail:* Jeff Robinson at *robinson.jeffrey@epa.gov.*
- *Fax:* Mr. Jeff Robinson, Air Permits Section (6PD–R), at fax number 214–665–7263.
- *Mail:* Mr. Jeff Robinson, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.
- *Hand or Courier Delivery:* Mr. Jeff Robinson, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Regional Materials in EDocket (RME) ID No. R06–OAR–2004–TX–0004. EPA's policy is that all comments received will be included in the public file without change, and may be made available online at *http://docket.epa.gov/rmepub/,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through Regional Material in EDocket (RME), regulations.gov, or e-mail if you believe that it is CBI or otherwise protected from disclosure. The EPA RME Web site and the federal regulations.gov are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public file and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the Regional Materials in EDocket (RME) index at *http://docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in the official file which is available at the Air Permitting Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittal is also available for public inspection at the State Air Agency listed below during official business hours by appointment:

Texas Commission on Environmental Quality, Office of Air Quality, 12100 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Robinson, U.S. EPA, Region 6, Multimedia Planning and Permitting Division (6PD), 1445 Ross Avenue, Dallas, TX 75202–2733, telephone (214) 665–6435; fax number 214–665–7263; or electronic mail at *robinson.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

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I. General Information

A. Tips for Preparing Your Comments

When submitting comments, remember to:

1. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

2. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

4. Describe any assumptions and provide any technical information and/or data that you used.

5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

6. Provide specific examples to illustrate your concerns, and suggest alternatives.

7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

8. Make sure to submit your comments by the comment period deadline identified.

B. Submitting Confidential Business Information (CBI)

Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

II. What Does This Action Do?

EPA is taking direct final action to approve the delegation of certain NESHAPs to TCEQ. With this delegation, TCEQ has the primary responsibility to implement and enforce the delegated standards.

III. What Is the Authority for Delegation?

Section 112(l) of the CAA and 40 CFR part 63, Subpart E, authorizes EPA to delegate authority to any state or local agency which submits adequate regulatory procedures for implementation and enforcement of emission standards for hazardous air pollutants. The hazardous air pollutant standards are codified at 40 CFR part 63.

IV. What Criteria Must Texas' Program Meet To Be Approved?

Section 112(l) of the CAA enables EPA to approve State air toxics programs or rules to operate in place of the Federal air toxics program or rules. 40 CFR part 63, subpart E (subpart E) governs EPA's approval of State rules or programs under section 112(l).

EPA will approve an air toxics program if we find that:

(1) The State program is ''no less stringent'' than the corresponding Federal program or rule;

(2) the State has adequate authority and resources to implement the program;

(3) the schedule for implementation and compliance is sufficiently expeditious; and

(4) the program otherwise complies with Federal guidance.

In order to obtain approval of its program to implement and enforce Federal section 112 rules as promulgated without changes (straight delegation), only the criteria of 40 CFR 63.91(d) must be met. 40 CFR 63.91(d)(3) provides that interim or final Title V program approval will satisfy the criteria of 40 CFR 63.91(d) for part 70 sources.

V. How Did TCEQ Meet the Subpart E Approval Criteria?

As part of its Title V submission, TCEQ stated that it intended to use the mechanism of incorporation by reference to adopt unchanged Federal section 112 into its regulations. This applied to both existing and future standards as they applied to part 70 sources ((60 FR 30444 (June 7, 1995) and 61 FR 32699 (June 25, 1996)). On December 6, 2001, EPA promulgated final full approval of the State's operating permits program effective November 30, 2001 (66 FR 63318). Under 40 CFR 63.91(d)(2), once a state has satisfied up-front approval criteria, it needs only to reference the previous demonstration and reaffirm that it still meets the criteria for any subsequent submittals. TCEQ has affirmed that it still meets the up-front approval criteria.

In addition, Texas has requested delegation of a State requirement to adjust a section 112 rule. The approval of this adjustment is regulated at 40 CFR 63.92. The TCEQ has modified the General Provisions at 40 CFR part 63, subpart A, by promulgating different timing requirements at Texas Administrative Code (TAC), Title 30, Part 1, Chapter 113, Subchapter C, section 113.100. Public notice was given pursuant to the requirements of the Texas Health and Safety Code Annotated, section 382.017 (Vernon's 1992) and Texas Government Code Annotated, Subchapter B, Chapter 2001 (Vernon's 2000). The TCEQ (formally the Texas Natural Resource Conservation Commission) conducted a public hearing on April 11, 1997, to receive testimony regarding the revision to 30 TAC Chapter 113 which included the General Provisions at section 113.100. EPA believes the timing requirement adjustments do not result in a reduction of stringency of the part 63 emission standards. The TCEQ has met the criteria of 40 CFR 63.91, and the State is requesting EPA approval of the exceptions to the General Provisions (40 CFR part 63, subpart A) pursuant to 40 CFR 63.92.

VI. What Is Being Delegated?

EPA received requests from TCEQ to delegate certain NESHAP subparts on August 20, 1997; October 15, 1997; July 9, 1998; October 14, 1998; January 13, 2000, July 13, 2000, and December 2, 2004. The TCEQ requests delegation of certain NESHAP for all sources (both part 70 and non-part 70 sources). For the part 63 NESHAPs, Texas's requests included the NESHAPs set forth in Table 1 below.

TABLE 1.—40 CFR PART 63 NESHAP FOR SOURCE CATEGORIES

Subpart	Emission standard
A	General Provisions.
F	Hazardous Organic NESHAP (HON)—Synthetic Organic Chemical Manufacturing Industry (SOCMI).
G	HON—SOCMI Process Vents, Storage Vessels, Transfer Operations and Wastewater.
H	HON—Equipment Leaks.
I	HON—Certain Processes Negotiated Equipment Leak Regulation.
J	Polyvinyl Chloride and Copolymers Production.
L	Coke Oven Batteries.
M	Perchloroethylene Dry Cleaning.
N	Chromium Electroplating.
O	Ethylene Oxide Sterilizers.
Q	Industrial Process Cooling Towers.
R	Gasoline Distribution.

TABLE 1.—40 CFR PART 63 NESHAP FOR SOURCE CATEGORIES—Continued

Subpart	Emission standard
S	Pulp and Paper Industry.
T	Halogenated Solvent Cleaning.
U	Polymers and Resins I.
W	Polymers and Resins II—Epoxy Resins and Non-Nylon Polyamides.
X	Secondary Lead Smelting.
Y	Marine Tank Vessel Loading.
AA	Phosphoric Acid.
BB	Phosphate Fertilizers.
CC	Petroleum Refineries.
DD	Off-Site Waste and Recovery.
EE	Magnetic Tape Manufacturing.
GG	Aerospace Manufacturing and Rework Facilities.
HH	Oil and Natural Gas Production.
II	Shipbuilding and Ship Repair.
JJ	Wood Furniture Manufacturing.
KK	Printing and Publishing Industry.
LL	Primary Aluminum Reduction Plants.
MM	Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills.
OO	Tanks—Level 1.
PP	Containers.
QQ	Surface Impoundments.
RR	Individual Drain Systems.
SS	Closed Vent Systems, Control Devices, Recovery Devices and Routing to a Fuel Gas System or a Process.
TT	Equipment Leaks—Level 1.
UU	Equipment Leaks—Level 2 Standards.
VV	Oil-Water Separators and Organic-Water Separators.
WW	Storage Vessels (Tanks)—Control Level 2.
XX	Ethylene Manufacturing Process Units.
YY	Generic Maximum Achievable Control Technology Standards.
CCC	Steel Pickling—HCl Process Facilities and Hydrochloric Acid Regeneration.
DDD	Mineral Wool Production.
EEE	Hazardous Waste Combustors.
GGG	Pharmaceuticals Production.
HHH	Natural Gas Transmission and Storage.
III	Flexible Polyurethane Foam Production.
JJJ	Polymers and Resins, Group IV.
LLL	Portland Cement Manufacturing.
MMM	Pesticide Active Ingredient Production.
NNN	Wool Fiberglass Manufacturing.
OOO	Polymer and Resins III—Amino Resins and Phenolic Resins.
PPP	Polyether Polyols Production.
QQQ	Primary Copper Smelting.
RRR	Secondary Aluminum.
TTT	Primary Lead Smelting.
UUU	Petroleum Refineries—Catalytic Cracking, Catalytic Reforming and Sulfer Plants.
VVV	Publicly Owned Treatment Works (POTW).
XXX	Ferroalloys Production.
AAAA	Municipal Solid Waste Landfills.
CCCC	Nutritional Yeast Mfg.
GGGG	Vegetable Oil Production—Solvent Extraction.
HHHH	Wet Formed Fiberglass Mat Production.
JJJJ	Paper and Other Web Coating.
NNNN	Surface Coating of Large Appliances.
SSSS	Surface Coating for Metal Coil.
TTTT	Leather Finishing Operations.
UUUU	Cellulose Production Manufacture.
VVVV	Boat Manufacturing.
XXXX	Rubber Tire Manufacturing.
QQQQQ	Friction Materials Manufacturing.

VII. What Is Not Being Delegated?

EPA cannot delegate to a State any of the Category II subpart A authorities set forth in 40 CFR 63.91(g)(2). These include the following provisions: § 63.6(g), Approval of Alternative Non-Opacity Standards; § 63.6(h)(9), Approval of Alternative Opacity Standards; § 63.7(e)(2)(ii) and (f), Approval of Major Alternatives to Test Methods; § 63.8(f), Approval of Major Alternatives to Monitoring; and § 63.10(f), Approval of Major Alternatives to Recordkeeping and Reporting. In addition, some MACT standards have certain provisions that cannot be delegated to the States. Therefore, any MACT standard that EPA is delegating to TCEQ that provides that certain authorities cannot be delegated are retained by EPA and not delegated. Furthermore, no authorities are delegated that require rulemaking in the **Federal Register** to implement, or where Federal overview is the only way to ensure national consistency in the

application of the standards or requirements of CAA section 112. Finally, section 112(r), the accidental release program authority, is not being delegated by this approval.

All of the inquiries and requests concerning implementation and enforcement of the excluded standards in the State of Texas should be directed to the EPA Region 6 Office.

In addition, this delegation to TCEQ to implement and enforce certain NESHAPs does not extend to sources or activities located in Indian country, as defined in 18 U.S.C. 1151. Under this definition, EPA treats as reservations, trust lands validly set aside for the use of a Tribe even if the trust lands have not been formally designated as a reservation. Consistent with previous federal program approvals or delegations, EPA will continue to implement the NESHAPs in Indian country because TCEQ has not submitted information to demonstrate authority over sources and activities located within the exterior boundaries of Indian reservations and other areas in Indian country.

VIII. How Will Applicability Determinations Under Section 112 Be Made?

In approving this delegation, TCEQ will obtain concurrence from EPA on any matter involving the interpretation of section 112 of the CAA or 40 CFR part 63 to the extent that implementation, administration, or enforcement of these sections have not been covered by EPA determinations or guidance.

IX. What Authority Does EPA Have?

We retain the right, as provided by CAA section 112(l)(7), to enforce any applicable emission standard or requirement under section 112. EPA also has the authority to make certain decisions under the General Provisions (subpart A) of part 63. We are granting TCEQ some of these authorities, and retaining others, as explained in sections VI and VII above. In addition, EPA may review and disapprove of State determinations and subsequently require corrections. (*See* 40 CFR 63.91(g) and 65 FR 55810, 55823, September 14, 2000.)

Furthermore, we retain any authority in an individual emission standard that may not be delegated according to provisions of the standard.[1] Also, listed in the footnotes of the part 63 delegation table at the end of this rule are the authorities that cannot be delegated to any State or local agency which we therefore retain.

X. What Information Must TCEQ Provide to EPA?

In delegating the authority to implement and enforce these rules and in granting a waiver of EPA notification requirements, we require TCEQ to input all source information into the Aerometric Information Retrieval System (AIRS) for both point and area sources. TCEQ must enter this information into the AIRS system and update the information by September 30 of every year. TCEQ must provide any additional compliance related information to EPA, Region 6, Office of Enforcement and Compliance Assurance within 45 days of a request under 40 CFR 63.96(a).

In receiving delegation for specific General Provisions authorities, TCEQ must submit to EPA Region 6 on a semi-annual basis, copies of determinations issued under these authorities. For part 63 standards, these determinations include: applicability determinations (§ 63.1); approval/disapprovals of construction and reconstruction (§ 63.5(e) and (f)); notifications regarding the use of a continuous opacity monitoring system (§ 63.6(h)(7)(ii)); finding of compliance (§ 63.6(h)(8)); approval/disapprovals of compliance extensions (§ 63.6(i)); approvals/disapprovals of minor (§ 63.7(e)(2)(i)) or intermediate (§ 63.7(e)(2)(ii) and (f)) alternative test methods; approval of shorter sampling times and volumes (§ 63.7(e)(2)(iii)); waiver of performance testing (§ 63.7(e)(2)(iv) and (h)(2), (3)); approvals/disapprovals of minor or intermediate alternative monitoring methods (§ 63.8(f)); approval of adjustments to time periods for submitting reports (§ 63.9 and 63.10); and approvals/disapprovals of minor alternatives to recordkeeping and reporting (§ 63.10(f)).

Additionally, EPA's Emissions, Monitoring, and Analysis Division must receive copies of any approved intermediate changes to test methods or monitoring. (Please note that intermediate changes to test methods must be demonstrated as equivalent through the procedures set out in EPA method 301.) This information on approved intermediate changes to test methods and monitoring will be used to compile a database of decisions that will be accessible to State and local agencies and EPA Regions for reference in making future decisions. (For definitions of major, intermediate and minor alternative test methods or monitoring methods, see 40 CFR 63.90). The TCEQ should forward these intermediate test methods or monitoring changes via mail or facsimile to: Chief, Air Measurements and Quality Group, Emissions Monitoring and Analysis Division, Office of Air Quality Planning and Standards, Mailcode D205–02, Research Triangle Park, NC 27711, Facsimile telephone number: (919) 541–0516.

XI. What Is EPA's Oversight of This Delegation to TCEQ?

EPA must oversee TCEQ's decisions to ensure the delegated authorities are being adequately implemented and enforced. We will integrate oversight of the delegated authorities into the existing mechanisms and resources for oversight currently in place. If, during oversight, we determine that TCEQ made decisions that decreased the stringency of the delegated standards, then TCEQ shall be required to take corrective actions and the source(s) affected by the decisions will be notified, as required by 40 CFR 63.91(g)(1)(ii). We will initiate withdrawal of the program or rule if the corrective actions taken are insufficient.

XII. Should Sources Submit Notices to EPA or TCEQ?

For the NESHAPS being delegated and included in the table above, all of the information required pursuant to the general provisions and the relevant subpart of the Federal NESHAP (40 CFR part 63) should be submitted by sources located outside of Indian country, directly to the TCEQ at the following address: Texas Commission on Environmental Quality, Office of Permitting, Remediation and Registration, Air Permits Division (MC 163), P.O. Box 13087, Austin, Texas 78711–3087. The TCEQ is the primary point of contact with respect to delegated NESHAPs. Sources do not need to send a copy to EPA. EPA Region 6 waives the requirement that notifications and reports for delegated standards be submitted to EPA in addition to TCEQ in accordance with 40 CFR 63.9(a)(4)(ii) and 63.10(a)(4)(ii). For those standards which are not delegated, sources must continue to submit all appropriate information to EPA.

[1] EPA amended several NESHAPs to clarify the implementation and enforcement authorities within the standards that we may delegate to each State, local or tribal agency such as TCEQ. 68 FR 37334 (June 23, 2003). A complete list of the standards is contained in the official file available for review at the Dallas Regional Office. An electronic copy of the rule may be obtained from EPA's Internet site, *http://www.epa.gov/fedrgstr/EPA–AIR/2003/June/Day-23/a14190.pdf*. EPA believes the changes make all of the standards consistent in defining what may not be delegated in actions such as the one we are taking today.

XIII. How Will Unchanged Authorities Be Delegated to TCEQ in the Future?

In the future, TCEQ will only need to send a letter of request to EPA, Region 6, for NESHAP regulations that TCEQ has adopted by reference. The letter must reference the previous up-front approval demonstration and reaffirm that it still meets the up-front approval criteria. We will respond in writing to the request stating that the request for delegation is either granted or denied. If a request is approved, the effective date of the delegation will be the date of our response letter. A **Federal Register** will be published to inform the public and affected sources of the delegation, indicate where source notifications and reports should be sent, and to amend the relevant portions of the Code of Federal Regulations showing which NESHAP standards have been delegated to TCEQ.

XIV. What Is The Relationship Between RCRA And The Hazardous Waste Combustor MACT?

As part of today's rule, we are delegating, under the CAA, implementation and enforcement authority for the Hazardous Waste Combustor (HWC) MACT (subpart EEE) to TCEQ. Many of the sources subject to the HWC MACT are also subject to the RCRA permitting requirements. We expect air emissions and related operating requirements found in the HWC MACT will be included in part 70 permits issued by TCEQ. However, RCRA permits will still be required for all other aspects of the combustion unit and the facility that are governed by RCRA (*e.g.*, corrective action, general facility standards, other combustor-specific concerns such as materials handling, risk-based emissions limits and operating requirements, as appropriate and other hazardous waste management units).[2] See the HWC MACT rule preamble discussion (64 FR 52828, 52839–52843 (September 30, 1999)), and the RCRA Site-Specific Risk Assessment Policy for HWC Facilities dated June 2000 for more information on the interrelationship of the MACT rule with the RCRA Omnibus provision and site specific risk assessments.

XV. Final Action

The public was provided the opportunity to comment on the proposed approval of the program and mechanism for delegation of section 112 standards, as they apply to part 70 sources, on June 7, 1995, for the proposed interim approval of TCEQ's title V operating permits program; and on October 11, 2001, for the proposed final approval of TCEQ's title V operating permits program. In EPA's final full approval of Texas' Operating Permits Program on December 6, 2001, (66 FR 63318), the EPA discussed the public comments on the proposed final delegation of the title V operating permits program. In today's action, the public is given the opportunity to comment on the approval of TCEQ's request for delegation of authority to implement and enforce certain section 112 standards for all sources (both part 70 and non-part 70 sources) which have been adopted by reference into Texas' state regulations. However, the Agency views the approval of these requests as a noncontroversial action and anticipates no adverse comments. Therefore, EPA is publishing this rule without prior proposal. However, in the ''Proposed Rules'' section of today's **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the program and delegation of authority described in this action if adverse comments are received. This action will be effective May 17, 2005 without further notice unless the Agency receives relevant adverse comments by April 18, 2005.

If EPA receives relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if we receive relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a relevant adverse comment.

XVI. 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 (Pub. L. 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 request to receive delegation of certain Federal standards, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. 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.

[2] EPA promulgated the HWC MACT (40 CFR part 63, subpart EEE) under the joint authority of the CAA and RCRA. Before this rule went into effect, the air emissions from these sources were primarily regulated under the authority of RCRA. *See* 40 CFR parts 264, 265, 266, and 270. With the release of HWC MACT, the air emissions are now regulated under both CAA and RCRA. Even though both statutes give EPA the authority to regulate air emissions, we determined that having the emissions standards and permitting requirements in both sets of implementing regulations would be duplicative. For this reason, using the authority provided by section 1006(b) of RCRA, EPA deferred the RCRA requirements for the HWC emission controls to the CAA requirements of 40 CFR part 63, subpart EEE. After a facility has demonstrated compliance with the HWC MACT, the RCRA standards for air emissions from these units will no longer apply, with the exception of section 3005(c)(3) of RCRA, which requires that each RCRA permit contain the terms and conditions necessary to protect human health and the environment. Under this provision of RCRA, if a regulatory authority determines that more stringent conditions than the HWC MACT are necessary to protect human health and the environment for a particular facility, then that regulatory authority may impose those conditions in the facility's RCRA permit.

In reviewing delegation submissions, EPA's role is to approve submissions provided that they meet the criteria of the Clean Air Act. 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 delegation submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA to use VCS in place of a delegation submission that otherwise satisfies the provisions of the Clean Air Act. 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 Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 17, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 63

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

Authority: This action is issued under the authority of section 112 of the Clean Air Act, as amended, 42 U.S.C. 7412.

Dated: March 9, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

■ 40 CFR part 63 is amended as follows:

PART 63—[AMENDED]

■ 1. The authority citation for part 63 continues to read as follows:

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

■ 2. Section 63.99 is amended by adding paragraph (a)(43) to read as follows:

§ 63.99 Delegated Federal authorties.

(a) * * *

(43) *Texas.* (i) The following table lists the specific part 63 standards that have been delegated unchanged to the Texas Commission on Environmental Quality for all sources. The ''X'' symbol is used to indicate each subpart that has been delegated. The delegations are subject to all of the conditions and limitations set forth in Federal law, regulations, policy, guidance, and determinations. Some authorities cannot be delegated and are retained by EPA. These include certain General Provisions authorities and specific parts of some standards. Any amendments made to these rules after this effective date are not delegated.

DELEGATION STATUS FOR PART 63 STANDARDS—STATE OF TEXAS [1]

Subpart	Source Category	TCEQ [2]
F	Hazardous Organic NESHAP (HON)—Synthetic Organic Chemical Manufacturing Industry (SOCMI)	X
G	HON—SOCMI Process Vents, Storage Vessels, Transfer Operations and Wastewater	X
H	HON—Equipment Leaks	X
I	HON—Certain Processes Negotiated Equipment Leak Regulation	X
J	Polyvinyl Chloride and Copolymers Production	X
K	(Reserved).	
L	Coke Oven Batteries	X
M	Perchloroethylene Dry Cleaning	X
N	Chromium Electroplating and Chromium Anodizing Tanks	X
O	Ethylene Oxide Sterilizers	X
P	(Reserved).	
Q	Industrial Process Cooling Towers	X
R	Gasoline Distribution	X
S	Pulp and Paper Industry	X
T	Halogenated Solvent Cleaning	X
U	Group I Polymers and Resins	X
V	(Reserved).	
W	Epoxy Resins Production and Non-Nylon Polyamides Production	X
X	Secondary Lead Smelting	X
Y	Marine Tank Vessel Loading	X
Z	(Reserved).	
AA	Phosphoric Acid Manufacturing Plants	X
BB	Phosphate Fertilizers Production Plants	X
CC	Petroleum Refineries	X
DD	Off-Site Waste and Recovery Operations	X
EE	Magnetic Tape Manufacturing	X
FF	(Reserved).	
GG	Aerospace Manufacturing and Rework Facilities	X
HH	Oil and Natural Gas Production Facilities	X
II	Shipbuilding and Ship Repair Facilities	X
JJ	Wood Furniture Manufacturing Operations	X
KK	Printing and Publishing Industry	X
LL	Primary Aluminum Reduction Plants	X

DELEGATION STATUS FOR PART 63 STANDARDS—STATE OF TEXAS [1]—Continued

Subpart	Source Category	TCEQ [2]
MM	Chemical Recovery Combustion Sources at Kraft, Soda, Sulfide, and Stand-Alone Semichemical Pulp Mills.	X
NN	(Reserved).	
OO	Tanks–Level 1	X
PP	Containers	X
QQ	Surface Impoundments	X
RR	Individual Drain Systems	X
SS	Closed Vent Systems, Control Devices, Recovery Devices and Routing to a Fuel Gas System or a Process.	X
TT	Equipment Leaks—Control Level 1	X
UU	Equipment Leaks—Control Level 2 Standards	X
VV	Oil-Water Separators and Organic-Water Separators	X
WW	Storage Vessels (Tanks)—Control Level 2	X
XX	(Reserved).	
YY	Generic Maximum Achievable Control Technology Standards	X
ZZ–BBB	(Reserved).	
CCC	Steel Pickling—HCl Process Facilities and Hydrochloric Acid Regeneration	X
DDD	Mineral Wool Production	X
EEE	Hazardous Waste Combustors	X
FFF	(Reserved).	
GGG	Pharmaceuticals Production	X
HHH	Natural Gas Transmission and Storage Facilities	X
III	Flexible Polyurethane Foam Production	X
JJJ	Group IV Polymers and Resins	X
KKK	(Reserved).	
LLL	Portland Cement Manufacturing	X
MMM	Pesticide Active Ingredient Production	X
NNN	Wool Fiberglass Manufacturing	X
OOO	Amino/Phenolic Resins	X
PPP	Polyether Polyols Production	X
QQQ	Primary Copper Smelting	X
RRR	Secondary Aluminum Production	X
SSS	(Reserved).	
TTT	Primary Lead Smelting	X
UUU	Petroleum Refineries—Catalytic Cracking Units, Catalytic Reforming Units and Sulfur Recovery Plants.	X
VVV	Publicly Owned Treatment Works (POTW)	X
WWW	(Reserved).	
XXX	Ferroalloys Production: Ferromanganese and Silicomanganese	X
AAAA	Municipal Solid Waste Landfills	X
CCCC	Nutritional Yeast Manufacturing	X
DDDD	Plywood and Composite Wood Products.	
EEEE	Organic Liquids Distribution.	
FFFF	Miscellaneous Organic Chemical Manufacturing (MON).	
GGGG	Solvent Extraction for Vegetable Oil Production	X
HHHH	Wet Formed Fiberglass Mat Production	X
IIII	Auto & Light Duty Truck.	
JJJJ	Paper and other Web (Surface Coating)	X
KKKK	Surface Coating of Metal Cans.	
MMMM	Miscellaneous Metal Parts and Products Surface Coating.	
NNNN	Surface Coating of Large Appliances	X
OOOO	Fabric Printing Coating and Dyeing.	
PPPP	Surface Coating of Plastic Parts and Products.	
QQQQ	Surface Coating of Wood Building Products.	
RRRR	Surface Coating of Metal Furniture.	
SSSS	Surface Coating for Metal Coil	X
TTTT	Leather Finishing Operations	X
UUUU	Cellulose Production Manufacture	X
VVVV	Boat Manufacturing	X
WWWW	Reinforced Plastic Composites Production.	
XXXX	Tire Manufacturing	X
YYYY	Stationary Combustion Turbines.	
ZZZZ	Reciprocating Internal Combustion Engines.	
AAAAA	Lime Manufacturing.	
BBBBB	Semiconductor Manufacturing.	
CCCCC	Coke Ovens: Pushing, Quenching and Battery Stacks.	
DDDDD	Industrial, Commercial, and Institutional Boilers and Process Heaters.	
EEEEE	Iron and Steel Foundries.	
FFFFF	Integrated Iron and Steel.	
GGGGG	Site Remediation.	
HHHHH	Miscellaneous Coating Manufacturing.	
IIIII	Mercury Cell Chlor-Alkali Plants.	

DELEGATION STATUS FOR PART 63 STANDARDS—STATE OF TEXAS [1]—Continued

Subpart	Source Category	TCEQ [2]
JJJJJ	Brick and Structural Clay Products Manufacturing.	
KKKKK	Clay Ceramics Manufacturing.	
LLLLL	Asphalt Roofing and Processing.	
MMMMM	Flexible Polyurethane Foam Fabrication Operation.	
NNNNN	Hydrochloric Acid Production, Fumed Silica Production.	
PPPPP	Engine Test Facilities.	
QQQQQ	Friction Materials Manufacturing	X
RRRRR	Taconite Iron Ore Processing.	
SSSSS	Refractory Products Manufacture.	
TTTTT	Primary Magnesium Refining.	

[1] Program delegated to Texas Commission on Environmental Quality (TCEQ).
[2] Authorities which may not be delegated include: § 63.6(g), Approval of Alternative Non-Opacity Emission Standards; § 63.6(h)(9), Approval of Alternative Opacity Standards; § 63.7(e)(2)(ii) and (f), Approval of Major Alternatives to Test Methods; § 63.8(f), Approval of Major Alternatives to Monitoring; § 63.10(f), Approval of Major Alternatives to Recordkeeping and Reporting; and all authorities identified in the subparts (*e.g.*, under "Delegation of Authority") that cannot be delegated.

(ii) Affected sources within Texas shall comply with the Federal requirements of 40 CFR part 63—subpart A—General Provisions, adopted by reference by the Texas Commission on Environmental Quality (TCEQ), with the exception of § 63.5(e)(2)(i), § 63.6(i)(12)(i), § 63.6(i)(13)(i) and (ii), § 63.8(e)(5)(ii), § 63.9(i)(3), and § 63.10(e)(2)(ii). The TCEQ has adopted alternative provisions for the cited exceptions above and affected sources in Texas that are subject to the requirements of Subpart A shall comply with the requirements established at Texas Administrative Code, Title 30, Part 1, Chapter 113, Subchapter C, section 113.100.

* * * * *

[FR Doc. 05–5411 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–632, MM Docket No. 00–119, RM–9879]

Digital Television Broadcast Service; Hazleton, PA

AGENCY: Federal Communications Commission.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to the final regulation (47 CFR Part 73), which the Federal Communications Commission published in the **Federal Register** on February 6, 2001 (66 FR 9038). The rule change related to a change to the DTV Table of Allotments reflecting the substitution of DTV channel 45c for DTV channel 9 at Hazleton. However, DTV channel 45 was inadvertently published without the "c" designation. This document corrects that amendment contained in § 73.622(b) of the Commission's Rules.

DATES: Effective on March 25, 2005.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION:

Background

The FCC published a document in the **Federal Register** on February 6, 2001 (66 FR 9038) removing DTV channel 9 and adding DTV channel 45 at Hazleton, Pennsylvania. This correction removes DTV channel 45 at Hazleton, Pennsylvania, and adds DTV channel 45c at Hazleton, Pennsylvania.

Need for Correction

As published, the final regulations contain an error, which may prove to be misleading, and needs to be clarified.

This document does not contain (new or modified) information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

The Commission will send a copy of this Erratum in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television, Digital television broadcasting.

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

PART 73—[AMENDED]

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

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

§ 73.622 [Amended]

■ 2. Section 73.622(b), the Table of Digital Television Allotments under Pennsylvania, is amended by removing DTV channel 45 and adding DTV channel 45c at Hazleton.

Federal Communications Commission.

Barbara Kreisman,

Chief, Video Division, Media Bureau.

[FR Doc. 05–5401 Filed 3–17–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–561; MB Docket No. 04–401; RM–11095]

Radio Broadcasting Services; Durant, OK and Tom Bean, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In response to a *Notice of Proposed Rule Making*, 69 FR 65118 (November 10, 2004), this document reallots Channel 248C2 from Durant, Oklahoma to Tom Bean, Texas, and modifies the license of Station KLAK (FM) accordingly. The coordinates for Channel 248C2 at Tom Bean are 33–28–52 North Latitude and 96–32–03 West Longitude, with a site restriction of 6.4 kilometers (4 miles) southwest of the community.

DATES: Effective April 18, 2005.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau, (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 04–401, adopted March 2, 2005, and released March 4, 2005. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

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

PART 73—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by removing Channel 248C2 at Durant.

■ 3. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Tom Bean, Channel 248C2.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–5400 Filed 3–17–05; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 222 and 229

[Docket No. FRA–1999–6439, Notice No. 14]

RIN 2130–AA71

Use of Locomotive Horns at Highway-Rail Grade Crossings

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Interim final rule; change of effective date.

SUMMARY: On December 18, 2003, FRA published an Interim Final Rule in the **Federal Register** addressing the use of locomotive horns at highway-rail grade crossings. As FRA was interested in receiving public comments on all aspects of the Interim Final Rule, FRA held a public hearing in Washington, DC on February 4, 2004, and extended the comment period from the originally scheduled deadline of February 17, 2004, to April 19, 2004. However, by the close of the extended comment period, FRA had received more than 1,400 comments on the Interim Final Rule and Environmental Impact Statement. Given the extensive amount of time needed to review and analyze the comments received, on November 22, 2004, FRA extended the effective date of the Interim Final Rule until April 1, 2005. However, as a result of delays related to the publication of the final rule, which FRA intends to issue before the Interim Final Rule takes effect, FRA is issuing this document to announce the change of the Interim Final Rule effective date to June 24, 2005.

DATES: The effective date of the Interim Final Rule published at 68 FR 70586 and delayed at 69 FR 67858 is changed from April 1, 2005, to June 24, 2005.

FOR FURTHER INFORMATION CONTACT: Ron Ries, Office of Safety, FRA, 1120 Vermont Avenue, NW., Washington, DC 20590 (telephone 202–493–6299); or Kathryn Shelton, Office of Chief Counsel, FRA, 1120 Vermont Avenue, NW., Washington, DC 20590 (telephone 202–493–6038).

SUPPLEMENTARY INFORMATION: This document changes the Interim Final Rule effective date to June 24, 2005. Therefore, any requirements imposed by the Interim Final Rule that pertain to 49 CFR parts 222 and 229 and would have taken effect before June 24, 2005, need not be complied with before that date. This change of the Interim Final Rule effective date will give public authorities additional time within which to establish the necessary conditions that will permit them to continue or establish quiet zones within their respective jurisdictions.

As the provisions of the Interim Final Rule remain subject to further modification under the terms of the final rule, FRA intends to issue the final rule prior to the Interim Final Rule effective date stated above. However, in order to address the concerns of communities that have been anxiously awaiting the issuance of the final rule, the provisions of the final rule for quiet zone-related administrative matters will become effective 30 days after publication of the final rule. Therefore, public authorities will be permitted to provide quiet zone-related documentation 30 days after the final rule is published.

Issued in Washington, DC, on March 14, 2005.

Robert D. Jamison,

Acting Administrator.

[FR Doc. 05–5362 Filed 3–15–05; 1:19 pm]

BILLING CODE 4910–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 001005281–0369–02; I.D. 031105G]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Trip Limit Reduction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason action; trip limit reduction.

SUMMARY: NMFS reduces the commercial trip limit of Atlantic group Spanish mackerel in or from the exclusive economic zone (EEZ) in the southern zone to 500 lb (227 kg) per day. This trip limit reduction is necessary to maximize the socioeconomic benefits of the quota.

DATES: Effective 6 a.m., local time, March 16, 2005, through March 31, 2005.

FOR FURTHER INFORMATION CONTACT: Steve Branstetter, telephone: 727–570–5305, fax: 727–570–5583, e-mail: *Steve.Branstetter@noaa.gov*.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, and, in the Gulf of Mexico only, dolphin and bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, on August 2, 2000, (65 FR 41015, July 3, 2000) NMFS implemented a commercial quota of 3.87 million lb (1.76 million kg) for the Atlantic migratory group of Spanish mackerel. For the southern zone, NMFS specified an adjusted quota of 3.62 million lb (1.64 million kg) calculated to allow continued harvest at a set rate for the remainder of the fishing year in accordance with 50 CFR 622.44(b)(2). In accordance with 50 CFR 622.44(b)(1)(ii)(D), after 100 percent of the adjusted quota of Atlantic group Spanish mackerel is taken, Spanish mackerel in or from the EEZ in the southern zone may be possessed on board or landed from a permitted vessel in amounts not exceeding 500 lb (227 kg) per day. The southern zone for Atlantic migratory group Spanish mackerel extends from 30°42′45.6″ N. lat., which is a line directly east from the Georgia/Florida boundary, to 25°20.4′ N. lat., which is a line directly east from the Miami-Dade/Monroe County, FL boundary.

NMFS has determined that 100 percent of the adjusted quota for Atlantic group Spanish mackerel has been taken. Accordingly, the 500–lb (227–kg) per day commercial trip limit applies to Spanish mackerel in or from the EEZ in the southern zone effective 6:00 a.m., local time, March 16, 2005, through March 31, 2005.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B), as such prior notice and opportunity for public comment is unnecessary and contrary to the public interest. Such procedures would be unnecessary because the rule itself already has been subject to notice and comment, and all that remains is to notify the public of the trip limit reduction. Allowing prior notice and opportunity for public comment is contrary to the public interest because of the need to immediately implement this action in order to protect the fishery since the capacity of the fishing fleet allows for rapid harvest of the quota. Prior notice and opportunity for public comment will require time and would potentially result in a harvest well in excess of the established quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30–day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

This action is taken under 50 CFR 622.43(a) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 14, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–5347 Filed 3–14–05; 4:33 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 040830250–5062–03; I.D. 081304C]

RIN 0648–AS27

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Biennial Specifications and Management Measures; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Correcting amendment

SUMMARY: This document contains corrections to the final regulations that were published in the **Federal Register** on Thursday, December 23, 2004. These regulations implemented the 2005–2006 fishery specifications and management measures for groundfish taken in the U.S. exclusive economic zone off the coasts of Washington, Oregon, and California.

DATES: Effective on March 18, 2005.

FOR FURTHER INFORMATION CONTACT: Yvonne deReynier (Northwest Region, NMFS), phone: 206–526–6129; fax: 206–526–6736 and; e-mail: *yvonne.dereynier@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Electronic Access

This correcting notice also is accessible via the Internet at the Office of the **Federal Register**'s website at *http://www.gpoaccess.gov/fr/index.html*. Background information and documents are available at the NMFS Northwest Region website *http://www.nwr.noaa.govlsustfsh/gdfsh01.htm* and at the Council's website at *http://www.pcouncil.org*.

Background

The final regulations that are the subject of these corrections revised portions of 50 CFR 660.302 through 660.373 and added §§ 660.380 through 660.394. These regulations affect persons operating fisheries for groundfish species off the U.S. West Coast.

Need for Correction

As published, the final regulations contain errors that may prove to be misleading to the public and which need to be corrected. This action provides six corrections to the final regulations, all of which are either corrections of spelling mistakes, grammar mistakes, or to mis-numbered paragraphs.

Classification

The Assistant Administrator for Fisheries, NOAA, finds good cause to waive the requirement to provide prior notice and opportunity for public comment on this action pursuant to 5 U.S.C. 553(b)(3)(B), because providing prior notice and opportunity for comment would be unnecessary and because all of the changes are non-substantive. Two of the corrections provided in this document correctly re-number misdesignated paragraphs within the Code of Federal Regulations. Re-numbering these misdesignated paragraphs has no effect on the public except to eliminate any confusion that may have resulted from the mis-designated paragraphs. One correction is to remove the word ''and'' from within a long list of latitude/longitude coordinates and to then place that word ''and'' after the penultimate coordinate in that same list. This correction has no effect on the public except to eliminate any confusion that may have occurred over the mis-placement of that word. Two corrections are to correct mis-spellings of the words ''*Hexagrammos*,'' ''management,'' and ''fishery'' in Federal regulations, which also has no effect on the public except to eliminate any confusion that may have resulted from the incorrect spellings of these words. Therefore, it is unnecessary to provide prior notice and opportunity for public comment on these corrections.

Pursuant to 5 U.S.C. 553(d), this non-substantive rule is not subject to a 30 day delay in effectiveness.

List of Subjects in 50 CFR Part 660

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaiian Natives, Indians, Northern Mariana Islands, Reporting and recordkeeping requirements.

Dated: March 14, 2005.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

■ Accordingly, 50 CFR part 660 is corrected by making the following correcting amendments:

PART 660—FISHERIES OFF WEST COAST STATES AND IN THE WESTERN PACIFIC

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 660.302, in the definition for ''North-South management area,'' the second paragraph (1)(i) and paragraphs (1)(ii) through (iv) are correctly redesignated as paragraphs (1)(ii) through (v) and republished to read as follows:

§ 660.302 Definitions.

* * * * *

North-South management area * * *

(1) * * *

(ii) *Columbia.* (A) The northern limit is 47°30′ N. lat.

(B) The southern limit is 43°00′ N. lat.

(iii) *Eureka.* (A) The northern limit is 43°00′ N. lat.

(B) The southern limit is 40°30′ N. lat.

(iv) *Monterey.* (A) The northern limit is 40°30′ N. lat.

(B) The southern limit is 36°00′ N. lat.

(v) *Conception.* (A) The northern limit is 36°00′ N. lat.

(B) The southern limit is the U.S.-Mexico International Boundary, which is a line connecting the following coordinates in the order listed:

Point	N. Lat.	W. Long.
1	32°35.37′	117°27.82′
2	32°37.62′	117°49.52′
3	31°07.97′	118°36.30′
4	30°32.52′	121°51.97′

* * * * *

§ 660.373 [Corrected]

■ 3. In § 660.373, amend paragraph (b)(4) so that the words ''managmenet'' and ''fishey'' are correctly spelled as ''management and ''fishery,'' respectively.

§ 660.384 [Corrected]

■ 4. In § 660.384, amend paragraph (c)(3) so that the references to ''*Hexogrammos*'' or ''*Hexogrammas*'' in the introductory text and in (c)(3)(i)(B) are correctly spelled as ''*Hexagrammos.*''

§ 660.393 [Corrected]

■ 5. In § 660.393, redesignate paragraphs (i) and (j) as (j) and (k), respectively, and redesignate the second occurrence of paragraph (h) as paragragh (i).

■ 6. In § 660.394, revise paragraph (m)(149) through (164) to read as follows:

§ 660.394 Latitude/longitude coordinates defining the 180–fm (329–m) through 250–fm (457–m) depth contours.

* * * * *

(m) * * *

(149) 38°46.81′ N. lat., 123°51.49′ W. long.;

(150) 38°45.28′ N. lat., 123°51.55′ W. long.;

(151) 38°42.76′ N. lat., 123°49.73′ W. long.;

(152) 38°41.53′ N. lat., 123°47.80′ W. long.;

(153) 38°41.41′ N. lat., 123°46.74′ W. long.;

(154) 38°38.01′ N. lat., 123°45.74′ W. long.;

(155) 38°37.19′ N. lat., 123°43.98′ W. long.;

(156) 38°35.26′ N. lat., 123°41.99′ W. long.;

(157) 38°33.38′ N. lat., 123°41.76′ W. long.;

(158) 38°19.95′ N. lat., 123°32.90′ W. long.;

(159) 38°14.38′ N. lat., 123°25.51′ W. long.;

(160) 38°09.39′ N. lat., 123°24.39′ W. long.;

(161) 38°10.09′ N. lat., 123°27.21′ W. long.;

(162) 38°03.76′ N. lat., 123°31.90′ W. long.;

(163) 38°02.06′ N. lat., 123°31.26′ W. long.; and

(164) 38°00.00′ N. lat., 123°29.56′ W. long.

* * * * *

[FR Doc. 05–5350 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041126333–5040–02; I.D. 030805C]

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 630 of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason adjustment; request for comments.

SUMMARY: NMFS issues an inseason adjustment opening directed fishing for pollock in Statistical Area 630 of the Gulf of Alaska (GOA) for 12 hours effective 1200 hrs, Alaska local time (A.l.t.), March 10, 2005, until 2400 hrs, A.l.t., March 10, 2005. This adjustment is necessary to allow the fishing industry opportunity to harvest pollock without exceeding the B season allowance of the 2005 total allowable catch (TAC) of pollock specified for Statistical Area 630 of the GOA.

DATES: Effective 1200 hrs, A.l.t., March 10, 2005, until 2400 hrs, A.l.t., March 10, 2005. Comments must be received at the following address no later than 4:30 p.m., A.l.t., March 29, 2005.

ADDRESSES: Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Lori Durall. Comments may be submitted by:

- Mail to: P.O. Box 21668, Juneau, AK 99802;
- Hand delivery to the Federal Building, 709 West 9th Street, Room 420A, Juneau, Alaska;
- FAX to 907–586–7557;
- E-mail to *G63plk2s12@noaa.gov* and include in the subject line of the e-mail comment the document identifier: g63plk2s12 (E-mail comments, with or without attachments, are limited to 5 megabytes); or
- Webform at the Federal eRulemaking Portal: *www.regulations.gov*. Follow the instructions at that site for submitting comments.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season allowance of the 2005 TAC of pollock in Statistical Area 630 of the GOA is 2,021 metric tons (mt) as established by the 2005 and 2006 harvest specifications for groundfish of the GOA (70 FR 8958, February 24, 2005). In accordance with § 679.20(a)(5)(iii)(B) the Administrator, Alaska Region, NMFS (Regional Administrator), hereby decreases the B season pollock TAC by 283 mt, the amount the A season allowance of the pollock TAC in Statistical Area 630 was exceeded. The revised B season allowance of the pollock TAC in Statistical Area 630 is therefore 1,738 mt (2,021 mt minus 283 mt).

In accordance with § 679.20(d)(1)(i), the Regional Administrator, has determined that the B season allowance

of the 2005 TAC of pollock in Statistical Area 630 of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,538 mt, and is setting aside the remaining 200 mt as bycatch to support other anticipated groundfish fisheries.

Regulations at § 679.23(b) specify that the time of all openings and closures of fishing seasons other than the beginning and end of the calendar fishing year is 1200 hrs, A.l.t. Current information shows the catching capacity of vessels catching pollock for processing by the inshore component in Statistical Area 630 of the GOA is about 4,000 mt per day. The Regioanl Administrator has determined that the B season allowance of the 2005 TAC of pollock in Statistical Area 630 would be exceeded if a 24-hour fishery were allowed to occur. NMFS intends that the seasonal allowance not be exceeded and, therefore, will not allow a 24-hour directed fishery. NMFS, in accordance with §§ 679.25(a)(1)(i), (a)(2)(i)(A), and (a)(2)(i)(C), is adjusting the directed fishery for pollock in Statistical Area 630 of the GOA by opening the fishery at 1200 hrs, A.l.t., March 10, 2005, and closing the fishery at 2400 hrs, A.l.t., March 10, 2005, at which time directed fishing for pollock will be prohibited. This action has the effect of opening the fishery for 12 hours.

NMFS is taking this action to allow a controlled fishery to occur, thereby preventing the overharvest of the B season allowance of the 2005 TAC of pollock in Statistical Area 630 designated in accordance with the 2005 and 2006 harvest specifications for groundfish of the GOA (70 FR 8958, February 24, 2005) and § 679.20(a)(5)(iii). In accordance with § 679.25(a)(2)(iii)(C), NMFS has determined that prohibiting directed fishing at 2400 hrs, A.l.t., March 10, 2005, after a 12 hour opening is the least restrictive management adjustment to achieve the B season allowance of the 2005 TAC of pollock in Statistical Area 630 of the GOA. Pursuant to § 679.25(b)(2), NMFS has considered data regarding catch per unit of effort and rate of harvest in making this adjustment.

After the effective date of this closure the maximum retainable amounts at §§ 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would prevent the full utilization of the B season allowance of the 2005 TAC of pollock in Statistical Area 630 of the GOA.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Without this inseason adjustment, NMFS could not allow the B season allowance of the 2005 TAC of pollock in Statistical Area 630 of the GOA to be harvested in an expedient manner and in accordance with the regulatory schedule. Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until March 29, 2005.

This action is required by §§ 679.20 and 679.25 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 11, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–5345 Filed 3–14–05; 4:33 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041126332–5039–02; I.D. 031505B]

Fisheries of the Exclusive Economic Zone Off Alaska; Yellowfin Sole by Vessels Using Trawl Gear in Bycatch Limitation Zone 1 of the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is closing directed fishing for yellowfin sole by vessels using trawl gear in Bycatch Limitation Zone 1 (Zone 1) of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2005 bycatch allowance of red king crab specified for the trawl yellowfin sole fishery in Zone 1.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 16, 2005, until 2400 hrs, A.l.t., December 31, 2005.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

In accordance with § 679.21(e)(3)(iv)(B)(*1*), the 2005 red king crab bycatch allowance specified for Zone 1 of the BSAI trawl yellowfin sole fishery is 33,843 animals as established by the 2005 and 2006 final harvest specifications for groundfish of the BSAI (70 FR 8979, February 24, 2005).

In accordance with § 679.21(e)(7)(ii), the Administrator, Alaska Region, NMFS, has determined that the 2005 bycatch allowance of red king crab specified for the trawl yellowfin sole fishery in Zone 1 of the BSAI has been reached. Consequently, the Regional Administrator is closing directed fishing for yellowfin sole by vessels using trawl gear in Zone 1 of the BSAI.

After the effective date of this closure the maximum retainable amounts at §§ 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of the trawl yellowfin sole fishery in Zone 1 of the BSAI.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 15, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–5422 Filed 3–15–05; 4:02 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 70, No. 52
Friday, March 18, 2005

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 HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD07–05–015]

RIN 1625–AA08

Special Local Regulations; Dania Beach/Hollywood Super Boat Race, Dania Beach/Hollywood, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary special local regulation for the Dania Beach/Hollywood Super Boat Race offshore in Dania Beach/Hollywood, Florida. These special local regulations restrict the movement of non-participating vessels and persons in the regulated race area and provide a viewing area for spectator craft. This rule is needed to provide for the safety of life on navigable waters during the event.

DATES: Comments and related material must reach the Coast Guard on or before May 17, 2005.

ADDRESSES: You may mail comments and related material to: Commander, Coast Guard Sector Miami, 100 MacArthur Causeway, Miami Beach, Fl 33139 Attn: BMC R. Terrell or BMC D. Vaughn. Sector Miami Deck/ATON maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Coast Guard Sector Miami, 100 MacArthur Causeway, Miami Beach, Florida between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Boatswain's Mate Chief Richard Terrell or Boatswain's Mate Chief Daniel Vaughn, at (305) 535–4317.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking CGD07–05–015, indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Commander, U.S. Coast Guard Sector Miami at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Super Boat International Productions Inc. is sponsoring a high-speed power boat race event on July 17, 2005, from 10 a.m. until 5 p.m. in the Atlantic Ocean offshore from Dania Beach/Hollywood, Florida. The race organizers anticipate 35 race participants and 100 spectator craft. The event will take place outside of the marked channel and will not interfere with commercial shipping. Recreational and fishing vessels normally operate in the area that will be affected by the establishment of a special local regulation. This rule is required to provide for the safety of life on navigable waters, due to the dangers associated with power boat races. The proposed rule prohibits non-participating vessels and persons from entering the regulated race areas during the event. A Coast Guard Patrol Commander will be present during the event to monitor compliance with this regulation.

Discussion of Proposed Rule

This rule creates two regulated areas, a regulated race area and a regulated viewing area (regulated areas). These regulated areas provide for the safety of life on navigable waters and minimize the dangers associated with powerboat races. These dangers include race craft traveling at high speeds in close proximity to race participants, spectator craft. This regulation keeps event participants, spectator craft and recreational vessels at a safe distance from one another.

Regulatory Evaluation

This proposed 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).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

The proposed rule affects a limited area offshore of Dania Beach/Hollywood, Florida and will be effective for only 7 hours on July 17, 2005, specifically from 10 a.m. until 5 p.m.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed 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.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the Atlantic

Ocean near Dania Beach/Hollywood, Florida from 10 a.m. until 5 p.m. on July 17, 2005. The Coast Guard certifies under U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities, because this rule would be in effect for only 7 hours. The rule also regulates a small area, and commercial and recreational vessels may be allowed to transit through the zone between races with permission of the Coast Guard Patrol Commander. Moreover, all vessel traffic can pass safely around the regulated areas. Before the effective period, we will issue maritime advisories over VHF–FM radio to allow the maritime community to plan accordingly.

If you think your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect 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 proposed 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 proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 proposed 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed 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 should be categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction, from further environmental documentation because this regulation is a special local regulation issued in conjunction with an organized water event of limited duration. Under Figure 2–1, Paragraph 34(h), an ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are not required for this rule. Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.1.

2. Add temporary § 100.35T–07–021 to read as follows:

§ 100.35T–07–021 Dania Beach/Hollywood Super Boat Race; Dania Beach/Hollywood, Florida.

(a) *Definitions*. (1) *Regulated race area*. The regulated race area encompasses all waters located inside of a line connecting the following positions offshore of Dania Beach/Hollywood, Florida:

Point 1: 26°03′41″ N, 080°05′01″ W

Point 2: 26°03′41″ N, 080°06′23″ W

Point 3: 26°00′07″ N, 080°05′36″ W

Point 4: 26°00′10″ N, 080°06′50″ W

All coordinates referenced use Datum: NAD 1983.

(2) *Regulated viewing area*. The regulated viewing area for spectator craft encompasses all waters located within a line connecting the following positions offshore Dania Beach/Hollywood, Florida;

Point 1: 26°03′41″ N, 080°05′30″ W

Point 2: 26°03′41″ N, 080°05′01″ W

Point 3: 26°00′07″ N, 080°05′56″ W

Point 4: 26°00′07″ N, 080°05′36″ W

All coordinates referenced use Datum NAD: 1983.

(3) *Coast Guard Patrol Commander*. The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commanding Officer, Coast Guard Sector Miami, Florida.

(b) *Special Local Regulations*. Vessels and persons are prohibited from entering the regulated race area, unless they are race participants or authorized by the Coast Guard Patrol Commander. Spectator craft may enter the regulated viewing area upon authorization of the Coast Guard Patrol Commander. If entry is authorized, all persons must follow the instructions of the Coast Guard Patrol Commander.

(c) *Effective Period*: This rule is effective from 10 a.m. until 5 p.m. on July 17, 2005.

Dated: March 3, 2005.

W.E. Justice,

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

[FR Doc. 05–5336 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2005–OH–0001; FRL–7886–8]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve Ohio's March 1, 2005, submittal of a revision to the Clinton County 1-Hour ozone maintenance plan under the Clean Air Act. This maintenance plan revision establishes a new transportation conformity motor vehicle emissions budget (MVEB) for the area for the year 2006. EPA is proposing to approve the allocation of a portion of the safety margin for oxides of nitrogen (NO_X) to the area's 2006 MVEB for transportation conformity purposes. This allocation will still maintain the total emissions for the area at or below the attainment level required by the transportation conformity regulations. The transportation conformity budget for volatile organic compounds will remain the same as previously approved in the maintenance plan. In this action, EPA is also correcting the codification for a previous approval action for Cincinnati, Ohio.

In the final rules section of this **Federal Register**, EPA is approving the SIP revision as a direct final rule without prior proposal, because EPA views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we do not receive any adverse comments in response to these direct final and proposed rules, we do not contemplate taking any further action in relation to this proposed rule. If EPA receives adverse comments, we will withdraw the direct final rule and will respond to all public comments in a subsequent final rule based on this proposed rule. 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.

DATES: Written comments must be received on or before April 18, 2005.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2005–OH–0001 by one of the following methods: Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

Agency Web site: *http://docket.epa.gov/rmepub/.* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the online instructions for submitting comments.

E-mail: *mooney.john@epa.gov.*

Fax: (312) 886–5824.

Mail: You may send written comments to: John Mooney, Chief, Criteria Pollutant Section, (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: John Mooney, Chief, Criteria Pollutant Section (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604.

Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to RME ID No. R05–OAR–2005–OH–0001. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov, or e-mail. The EPA RME Web site and the Federal regulations.gov Web site are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on

submitting comments, go to Section I(B) of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Patricia Morris, Environmental Scientist, at (312) 353–8656 before visiting the Region 5 office.)

FOR FURTHER INFORMATION CONTACT: Patricia Morris, Environmental Scientist, Criteria Pollutant Section, Air Programs Branch (AR–18J), EPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8656. *morris.patricia@epa.gov*

SUPPLEMENTARY INFORMATION:

I. General Information
A. Does This Action Apply to Me?
B. What Should I Consider as I Prepare My Comments for EPA?
II. What Action Is EPA Taking Today?
III. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

I. General Information

A. Does This Action Apply to Me?

This action is rulemaking on a non-regulatory planning document intended to ensure the maintenance of air quality in Clinton County, Ohio. This action changes the motor vehicle emissions budget used for transportation conformity.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through RME, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. What Action Is EPA Taking Today?

EPA is proposing to approve a March 1, 2005, SIP revision to the Clinton County 1-Hour ozone maintenance plan establishing a new transportation conformity MVEB for the year 2006. EPA is proposing to approve the allocation of a portion of the NO_X safety margin to the area's 2006 MVEB for transportation conformity purposes. This allocation will still maintain the total emissions for the area at or below the attainment level required by the transportation conformity regulations. The transportation conformity budget for volatile organic compounds will remain the same as previously approved in the maintenance plan.

III. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

For additional information, see the Direct Final Rule which is located in the Rules section of this **Federal Register**. Copies of the request and the EPA's analysis are available electronically at RME or in hard copy at the above address. (Please telephone Patricia Morris at (312) 353–8656 before visiting the Region 5 Office.)

Dated: March 7, 2005.

Norman Niedergang,

Acting Regional Administrator, Region 5.

[FR Doc. 05–5408 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ 137–087a; FRL–7886–1]

Revisions to the Arizona State Implementation Plan, Maricopa County Environmental Services Department

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Maricopa County Environmental Services Department (MCESD) portion of the Arizona State Implementation Plan (SIP). This revision concerns volatile organic compound (VOC) emissions from the fiberboard saturation process at W.R. Meadows, Inc., Goodyear, AZ. We are proposing to approve a local permit condition that regulates these source-specific emissions under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: Any comments must arrive by April 18, 2005.

ADDRESSES: Send comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, or e-mail to *steckel.andrew@epa.gov,* or submit comments at *http://www.regulations.gov.*

You can inspect a copy of the submitted SIP revision, EPA's technical support document (TSD), and public comments at our Region IX office during normal business hours by appointment. You may also see copies of the submitted SIP revisions by appointment at the following locations:

Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, Room B–102, (Mail Code 6102T), 1301 Constitution Avenue, NW., Washington, DC 20460.

Arizona Department of Environmental Quality, 1110 West Washington Street, Phoenix, AZ 85007.

Maricopa County Environmental Services Department, 1001 North Central Avenue, Suite 695, Phoenix, AZ 85004.

A copy of the rule may also be available via the Internet at *http://www.maricopa.gov/envsvc/air/ruledesc.asp.* Please be advised that this is not an EPA Web site and may not contain the same version of the rule that was submitted to EPA.

FOR FURTHER INFORMATION CONTACT: Al Petersen, EPA Region IX, (415) 947–4118, *petersen.alfred@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

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I. The State's Submittal

A. What Rule Did the State Submit?

Table 1 lists the source-specific permit condition which we are proposing for full approval.

TABLE 1.—SUBMITTED RULE

Local agency	Rule #	Rule title	Adopted	Submitted
MCESD	Permit V98–004, condition 23.	W.R. Meadows of Arizona, Inc., Goodyear, AZ, *RACT Requirements for the Fiberboard Saturation Process.*		

On February 28, 2005, we received a request from ADEQ to parallel process our review of MCESD Permit V98–004, condition 23, concurrently with the MCESD rule adoption process. We have agreed to parallel process this permit condition using our authority under 40 CFR part 51, appendix V, paragraph 2.3.1. Arizona's proposed SIP revision and parallel processing request consists of the SIP Completeness Checklist with the following documents as appendix 1, Resolution to Redact Title V Permit conditions from the W.R. Meadows Plant in Goodyear, Arizona; appendix 2, Permit Conditions, W.R. Meadows of Arizona, Inc., V98–004, April 19, 2004; appendix 3, Reasonably Available Control Technology (RACT) for W.R. Meadows Goodyear, Arizona Production Facility; and appendix 4, Schedule for Final Adoption, W.R. Meadows Permit Resolution.

After receiving the state supplemental submittal once Permit V98–004, condition 23 has been adopted by the MCESD Board of Supervisors, we will determine whether or not the submittal is complete according to the criteria in 40 CFR part 51, appendix V. Our completeness finding will be part of our subsequent final action on this proposal.

B. Are There Other Versions of This Rule?

There are no previous versions of the source-specific permit condition cited in Table 1.

C. What Is the Purpose of the Submitted Rule?

VOCs help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions.

The fiberboard saturation process consists of a saturator and a curing area. Recovery of VOC emissions from the saturator by thermal oxidation was determined to fulfill RACT requirements. We believe that regenerative thermal oxidation would also fulfill RACT requirements. Recovery of VOC emissions from the curing area was determined to be not required to fulfill RACT requirements. The TSD has more information about the RACT determination.

II. EPA's Evaluation and Action

A. How Is EPA Evaluating the Rule?

Generally, SIP rules must be enforceable (see section 110(a) of the CAA), must require RACT for major sources of VOC in nonattainment areas (see section 182(a)(2)(A)), and must not relax existing requirements (see sections 110(l) and 193). The MCESD regulates a 1-hour serious ozone nonattainment area (*see* 40 CFR part 81), so major VOC emission sources must fulfill the requirements of RACT. Such sources that are not in a pre-established VOC source category covered by an existing state or county rule or addressed by a federal control techniques guideline are required to conduct a case-by-case RACT analysis using established EPA guidance. The W.R. Meadows, Goodyear, AZ facility is a major source of VOC that does not fall into a pre-established category. Therefore, a case-by-case RACT analysis is required. The Title V Permit V98–004, condition 23, *RACT Requirements for the Fiberboard Saturation Process,* describes the RACT requirements determined for the W.R. Meadows, Goodyear, AZ fiberboard saturation process. The source-specific RACT determination described in permit condition 23 must be submitted to the EPA Administrator for approval into the SIP.

Guidance and policy documents that we use to help evaluate specific enforceability and RACT requirements consistently include the following:

- *Requirements for Preparation, Adoption, and Submittal of Implementation Plans,* EPA, 40 CFR part 51.
- Portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987).
- *Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,* EPA, (May 25, 1988). (the Bluebook)
- *Guidance Document for Correcting Common VOC & Other Rule Deficiencies,* EPA Region IX (August 21, 2001). (the Little Bluebook)

B. Does the Rule Meet the Evaluation Criteria?

We believe the source-specific RACT determination in the permit condition 23 cited in Table 1 is consistent with the relevant policy and guidance regarding enforceability and RACT requirements. The TSD has more information on our evaluation.

C. Public Comment and Final Action

Because EPA believes the submitted permit condition fulfills all relevant requirements, we are proposing to fully approve it as described in section 110(k)(3) of the CAA. We will accept comments from the public on this proposal for the next 30 days. Unless we receive convincing new information during the comment period, and assuming the final submitted permit condition is substantially identical to the proposed permit condition, we intend to publish a final approval action that will incorporate the rule into the federally enforceable SIP.

III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed 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 proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed 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 proposes to approve 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 (Pub. L. 104–4).

This proposed 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 proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed 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 Clean Air Act. 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 Clean Air Act. 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 proposed 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 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: March 3, 2005.

Wayne Nastri,

Regional Administrator, Region IX.

[FR Doc. 05–5407 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[R06–OAR–2004–TX–0004; FRL–7886–3]

Approval of the Clean Air Act Section 112(l) Program for Hazardous Air Pollutants and Delegation of Authority to the State of Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Texas Commission on Environmental Quality (TCEQ) has submitted requests for receiving delegation of EPA authority for implementation and enforcement of National Emission Standards for Hazardous Air Pollutants (NESHAPs) for all sources. The requests apply to certain NESHAPs promulgated by EPA, as adopted on various dates by TCEQ. The delegation of authority under this notice does not apply to sources located in Indian Country. EPA is providing notice that proposes to approve the delegation of certain NESHAPs to TDEQ.

DATES: Written comments must be received on or before April 18, 2005.

ADDRESSES: Comments may be mailed to Mr. Jeff Robinson, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the Addresses section of the direct final rule located in the final rules section of the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Robinson, Air Permits Section, Multimedia Planning and Permitting Division (6PD–R), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, at (214) 665–6435, or at *robinson.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving TCEQ's request for delegation of authority to implement and enforce certain NESHAPs for all sources (both Part 70 and non-Part 70 sources). TCEQ has adopted certain NESHAPs into Texas' state regulations. In addition, EPA is waiving its notification requirements so sources will only need to send notifications and reports to TCEQ.

The EPA is taking direct final action without prior proposal because EPA views this as a noncontroversial action and anticipates no adverse comments. A detailed rationale for this approval is set forth in the preamble to the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives 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 rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is published in the Rules section of this **Federal Register**.

Authority: 42 U.S.C. 7412.

Dated: March 9, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. 05–5412 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7886–2]

Texas: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The State of Texas has applied for final authorization of certain revisions, identified in Section F in the Supplementary Information, to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The EPA has determined that these revisions satisfy all the requirements needed to qualify for final authorization, and is proposing to authorize the State's revisions through this action.

DATES: This proposed revision is available for public comment for April 18, 2005.

ADDRESSES: Submit your comments by one of the following methods:

1. Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
2. E-mail: Comments may be sent by electronic mail to *patterson.alima@epa.gov.*
3. Mail: Send comments to: Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas Texas 75202–2733.
4. Hand Delivery or Courier. Deliver your comments to Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas Texas 75202–2733.

Instructions: Please refer to Docket Number TX–01–05. Do not submit information that you consider to be confidential business information (CBI) or otherwise protected through e-mail. The Federal regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

You can view and copy Texas's application and associated publicly available materials from 8:30 a.m. to 4 p.m. Monday through Friday at the following locations: Texas Commission on Environmental Quality (TCEQ), 12100 Park 35, Circle, Austin TX 78753–3087, (512) 239–1121 and EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8533. Interested persons wanting to examine these documents should make an appointment with the office at least two weeks in advance.

FOR FURTHER INFORMATION CONTACT: Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, *patterson.alima@epa.gov,* (214) 665–8533, Bruce Jones, Senior Assistant Regional Counsel, Office of Regional Counsel (214) 665–3184 and Darrin Swartz-Larson, RCRA Combustion Team Contact, (214) 665–7115 or submit your questions electronically to *jones.bruced@epa.gov* and *swartz-larson.darrin@epa.gov* for more information on the proposed rule to delegate MACT authority to Texas.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from the EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask the EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to the EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273, and 279.

This is not the first time EPA has taken action on these revisions to Texas' program. On April 15, 2003, EPA published an immediate final rule which covered the same revisions as this Proposal. On June 16, 2003, the revisions of that immediate final rule became effective. EPA discovered that adverse comments were properly filed challenging approval of the immediate final revisions for Texas. Since EPA had not responded to the comments or properly investigated them prior to finalization of the immediate final rule, EPA was required to withdraw final approval of the immediate final revisions. On July 22, 2003, EPA formally removed the immediate final rule published on April 15, 2003. Significant time has elapsed since EPA removal of the rule, therefore, the Agency is once again publishing these revisions to the Texas program. However, this action is a proposal to take comment on authorizing Texas for the revisions that were removed on July 22, 2003. This will allow the original commenter to resubmit his comments or submit new comments as well as allow other members of the public an opportunity to comment.

In addition, EPA expects to receive adverse comments on these revisions, therefore, publishing as a proposed rule rather than as an immediate final rule conforms with EPA guidance. After the close of the public comment period for today's proposal, EPA will timely publish a document in the **Federal Register** which responds to any comments received and either (a) finalize the proposed decision based on comments, (b) modify the decision and finalize this action, or (c) based on comments, EPA may decide not to finalize this proposal.

The original specific comments raised concerns about public participation in Texas' enforcement program, limits on Federal agencies' ability to comment on certain State actions, whether Texas' regulation of hazardous waste combustors was protective, and whether risk assessments are necessary to ensure protectiveness. EPA specifically requests that any additional comments or information that the public may have on these or other similar related issues be submitted for our consideration on this proposal. In addition, the commenter raised some issues about the interplay between the RCRA rules on emissions from hazardous waste combustors and the Clean Air Act (CAA) rules covering the same emissions. EPA directs the public to the discussion about the interplay between the two rules in Section F of this document. In addition and in a completely separate rulemaking, EPA is also currently proposing to delegate to Texas the authority implementing the CAA rules covering hazardous waste combustors known as the Maximum Achievable Control Technology (MACT) rules. Any specific comments or concerns regarding the delegation to Texas of the MACT rules for combustors in the State of Texas should be

submitted during the public comment period for that proposal.

B. What Decisions Have We Made in This Rule?

EPA concludes that Texas' application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, EPA is proposing to authorize the State's revisions to the Texas hazardous waste program as described in this document. Texas has the responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in Texas, including issuing permits, until the State is granted authorization to do so.

C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in the State of Texas subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. The State of Texas has enforcement responsibilities under its State hazardous waste program for violations of such program, but the EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

- Do inspections, require monitoring, tests, analyses, or reports; and
- Enforce RCRA requirements and suspend or revoke permits.

This action does not impose additional requirements on the regulated community because the regulations for which the State of Texas is being authorized by today's action are already effective under State law, and are not changed by today's action.

D. What Happens if EPA Receives Comments That Oppose This Action?

EPA believes that, because of the adverse comments received on the original notice in 2003, there will be comments on this proposal as well. If EPA receives comments which oppose this authorization, it will respond to those comments and take the appropriate final action on the proposal in light of the comments received.

E. For What Has the State of Texas Previously Been Authorized?

Texas received final authorization to implement its Hazardous Waste Management Program on December 12, 1984, effective December 26, 1984 (49 FR 48300). This authorization was clarified in a notice published in the **Federal Register** on March 26, 1985 (50 FR 11858). Texas received final authorization for revisions to its program in notices published in the **Federal Register** on January 31, 1986, effective October 4, 1985 (51 FR 3952); and on December 18, 1986, effective February 17, 1987 (51 FR 45320). EPA authorized the following revisions: March 1, 1990, effective March 15, 1990 (55 FR 7318); on May 24, 1990, effective July 23, 1990 (55 FR 21383); on August 22, 1991, effective October 21, 1991 (56 FR 41626); on October 5, 1992, effective December 4, 1992 (57 FR 45719); on April 11, 1994, effective June 27, 1994, (59 FR 16987); on April 12, 1994, effective June 27, 1994 (59 FR 17273); On September 12, 1997, effective November 26, 1997 (62 FR 47947); and on August 18, 1999 effective October 18, 1999 (64 FR 44836) and July 13, 2000; effective September 11, 2000 (65 FR 43246). EPA incorporated by reference the State of Texas Base Program and additional program revisions in RCRA Clusters III and IV into the CFR on September 14, 1999 (64 FR 49673); effective November 15, 1999. On March 28, 2002, Texas submitted a final complete program revision application, seeking authorization of its program revision in accordance with 40 CFR 271.21.

In 1991, Texas Senate Bill 2 created the Texas Natural Resource Conservation Commission (TNRCC), which combined the functions of the former Texas Water Commission and the former Texas Air Control Board. The transfer of functions to the TNRCC from the two agencies became effective on September 1, 1993. House Bill 2912, Article 18, of the 77th Texas Legislature, 2001, changed the name of the TNRCC to the Texas Commission on Environmental Quality (TCEQ) and directed the TNRCC to adopt a timetable for phasing in the change of the agency's name. The TNRCC decided to make the change of the agency's name to TCEQ effective September 1, 2002. The change of name became effective September 1, 2002, and the legislative history of the name change is documented in the Attorney General Statement. The TCEQ may perform any act for which it was authorized as either TNRCC or TWC. Therefore, references to TCEQ are references to TWC and to its successor, TNRCC. For further legislative history on the name-change (*See,* Act of June 15, 2001, 77th Leg. R. S., Ch 965, Section 18.01, 2001 Tex. Gen. Laws 1985).

The TCEQ has primary responsibility for administration of laws and regulations concerning hazardous waste, under the Texas Solid Waste Disposal Act (codified in Chapter 361 of the Texas Health & Safety Code). The TCEQ is authorized to administer the RCRA program. However, the Railroad Commission (RRC) has jurisdiction over the discharge, storage, handling, transportation, reclamation, or disposal of waste materials (both hazardous and non hazardous) that result from the activities associated with the exploration, development, or production of oil or gas or geothermal resources and other activities regulated by the RRC. *See* Tex. Water Code Ann. Section 26.131 and Ch. 27 (Vernon 2000). A list of activities that generate wastes that are subject to the jurisdiction of the RRC is found at 16 Tex. Admin. Code Section 3.8(a)(30) and at 30 Tex. Admin. Code § 335.1. Such wastes are termed ''oil and gas wastes.'' The TCEQ has responsibility to administer the RCRA program; however, hazardous wastes generated at natural gas or natural gas liquids processing plants or reservoir pressure maintenance or repressurizing plants are subject to the jurisdiction of the TCEQ until the RRC is authorized by EPA to administer those wastes under RCRA. When the RRC is authorized by EPA to administer the RCRA program for these wastes, jurisdiction over such hazardous wastes will transfer from the TCEQ to the RRC. The EPA has designated the TCEQ as the lead agency to coordinate RCRA activities between the two agencies. The EPA is responsible for the regulation of any hazardous waste for which TCEQ has not been previously authorized.

Further clarification of the jurisdiction between the TCEQ and the RRC can be found in a separate document. This document, a Memorandum of Understanding (MOU), became effective on May 31, 1998. The MOU clarified the jurisdictional boundaries between the agencies for the management and regulation of waste associated with exploration, development, production and refining of oil and gas. The MOU has been adopted by rule, which is an adoption by reference of the RRC's rule, and describes the division of responsibilities as well as the procedures for coordination between the two agencies.

See TCEQ's rule 30 Tex. Admin. Code Section 7.117 and RRC's rule at 16 Tex. Admin. Code Section 3.30.

The TCEQ has the rules necessary to implement RCRA Clusters VII through X revisions to the Federal Hazardous Waste Program promulgated from July 1, 1995, to June 30, 2000. The TCEQ authority to incorporate Federal rules by reference can be found at Texas Government Code Annotated Section 311.027 (Vernon 1998), and adoption of the hazardous waste rules in general are pursuant to the following statutory provisions: (1) Tex. Water Code Ann. Section 5.103 (Vernon 2000), effective September 1995, as amended (TCEQ's authority to adopt any rules necessary to carry out its powers and duties); (2) Tex. Health & Safety Code Ann. Section 361.024 (Vernon 2001), effective September 1, 1995, as amended (authority to adopt rules necessary to ''establish minimum standards of operation for the management and control of solid waste''); and (3) Tex. Health & Safety Code Ann.Section 361.078 (Vernon 2001), effective September 1, 1989 (specifically recognizing TCEQ's authority to adopt hazardous waste rules and to issue and enforce permits to the extent necessary to receive and maintain RCRA authorization). The TCEQ partially adopted the Hazardous Remediation Waste Management Requirements (HWIR-Media). The following are the Federal rules: 40 CFR 260.10, 261.4(g) through 261.4(g)(2)(ii), 264.1(j)(3)(i) through 264.1(j)(3), 264.554 through 264.554(m), 265.1(b), 268.2(c), 268.50(g) and 270.42 Appendix I. The HWIR-Media rule is an optional rule; States can partially adopt the rule if it has in place another mechanism to address those hazardous wastes. The TCEQ did not adopt 40 CFR 270.11(d)(1)–(3), 270.68, 270.73(a), 270.79, 270.80(a)–(f), 270.85(a)–(c), 270.95, 270.100, 270.105, 270.110 introduction through 270.110(i), 270.115, 270.120, 270.125, 270.130(a)–(b), 270.135 introduction through 270.135(c), 270.140 introduction through 270.140(c), 270.145(a) introduction through 270.145(d)(3), 270.150(a)–(g), 270.155(a) introduction through 270.155(b), 270.160 introduction through 270.160(c), 270.165, 270.170, 270.175(a) introduction through 270.175(c), 270.180(a)–(b), 270.185, 270.190(a)–(d), 270.195, 270.200, 270.205, 270.210 introduction through 270.210(b), 270.215(a), 270.215(a)–(d), 270.220(a)–(b), 270.225, and 270.230(a) through 270.230(e)(2). Therefore, the Federal rules listed in this document that the State did not adopt are not part of the authorized program. However, the TCEQ has an Office of Remediation which is responsible for the cleanup of releases of hazardous waste and pollutants so that threats to human health and the environment are controlled or eliminated. The TCEQ rules which address the Remedial Action Plan requirement of the HWIR-media rule are covered in the Texas Risk Reduction Program rules at 30 Tex. Admin. Code Ch. 350 and 30 Tex. Admin. Code Section 350.75. The Texas Risk Reduction Rules are not part of Texas' authorized Federal RCRA program.

F. What Changes Are We Authorizing With Today's Action?

On March 28, 2002, the State of Texas submitted a final complete program revision application, seeking authorization of their changes in accordance with 40 CAR 271.21. Texas' revisions consist of regulations which specifically govern Federal Hazardous Waste promulgated from July 1, 1995, to June 30, 2000 (RCRA Clusters VII through X). Texas' requirements are included in a chart with this document. The EPA is now proposing certain revisions to the Texas Hazardous Waste Program. The proposed revisions are:

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
1. Criteria for Classification of Solid Waste Disposal Facilities and Practices; Identification and Listing of Hazardous Waste; Requirements for Authorization of State Hazardous Waste Programs. (Checklist 153).	61 FR 34252 July 01, 1996	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1989, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.78(f)(3)(A)–G and (g)(3)(A)–(G), effective October 19, 1998.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
2. Hazardous Waste Treatment; Storage and Disposal Facilities and Hazardous Waste Generators; Organic Air Emission Standards for Tanks, Surface Impoundments and Containers. (Checklists 154, 154.1, 154.2, 154.3, 154.4, 154.5, and 154.6).	61 FR 59931 November 25, 1996; 59 FR 62896 December 6, 1994; 60 FR 26828 May 19, 1995; 60 FR 50426 September 29, 1995; 60 FR 56952 November 13, 1995; 61 FR 4903; 61 FR 28508 June 5, 1996.	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.061 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.31, effective November 15, 2001, as amended; Section 335.24(e), and, effective April 4, 1999, as amended, Sections 335.69(f)(2), 335.69(a)(1)(A)–(B), effective November 15, 2001, as amended; and 305.50(4)(A), effective November 18, 2001. Sections 335.152(a)(1), 335.152(a)(4), 335.152(a)(7)–(9), 335.152(a)(16)–(19), effective November 18, 2001; 335.111(a), effective November 15, 2001; 335.112(a)(1), 335.112(a)(4), 335.112(a)(8)–(10), 335.112(a)(19)–(21), 335.112(a)(24), effective November 18, 2001; 305.122(a), effective November 15, 2001, as amended.
3. Land Disposal Restrictions Phase III-Emergency Extension of the K088 Capacity Variance. (Checklist 155).	62 FR 1992 January 14,1997	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.341(c), effective April 30, 2000.
4. Military Munitions Rule; Hazardous Waste Identification and Management Explosives Emergencies; Manifest Exemptions for Transport of Hazardous Waste on Right-of-Ways on Contiguous Properties. (Checklist 156).	62 FR 6622 February 12, 1997	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1989, as amended; Texas Health & Safety Code Annotated Section 361.061 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; Texas Health & Safety Code Annotated Section 361.061 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Sections 335.1, and 335.61, effective April 12, 2001, as amended; Sections 335.10 (h), effective May 20, 1999, 335.91 (f), and (g), 335.41(d)(2), effective April 12, 2001, as amended, 335.271, 335.272, effective April 12, 2001, as amended; 335.152(a)(4), 335.152(a)(20), 335.112(a)(4), 335.112(a)(22), effective November 18, 2001, as amended and 305.69(j) effective April 12, 2001, as amended.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
5. Land Disposal Restrictions—Phase IV: Treatment Standards for Wood Preserving Wastes, Paperwork Reduction and Streamlining, Exemptions From RCRA for Certain Processed Materials; and Miscellaneous Hazardous Waste Provisions. (Checklist 157).	62 FR 25998 May 12, 1997	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431, effective April 30, 2000, as amended; 30 Texas Administrative Code Section 335.1 (definition of solid waste), effective May 30, 2001, as amended; 335.17(a)(9)–(12), and 335.24(c)(2), effective April 4, 1999 as amended. The State law is more stringent than the Federal rule because the State does not have provisions equivalent to 40 CFR 268.(a)(10) regarding tolling agreements. State law has no provision equivalent to 40 CFR 268.44(a), under which EPA may assure a variance from an applicable treatment standard.
6. Hazardous Waste Management System; Testing and Monitoring Activities. (Checklist 158).	62 FR 32452 June 13, 1997	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.31, effective October 19, 1998; Sections 335.152(a)(17)–(18), 335.152(a)(22)(E), 335.112(a)(19)–(20), effective April 12, 2001; 335.221(a)(15), 335.221(17)–(18), effective April 4, 1999 and 335.221(a), effective April 4, 1999.
7. Hazardous Waste Management System; Carbamate Production, Identification and Listing of Hazardous Waste; Land Disposal Restrictions. (Checklist 159).	62 FR 32974 June 17, 1997	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.003 (Vernon 2001), effective September 1, 1991, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, 30 Texas Administrative Code Section 335.1 (def of Hazardous waste), effective January 26, 1994, as amended and Section 335.29, effective April 4, 1999.
8. Land Disposal Restrictions Phase III—Emergency Extension of the K088 National Capacity Variance. (Checklist 160).	62 FR 37694 July 14, 1997	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431(c), effective April 30, 2000.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
9. Second Emergency Revision of the Land Disposal Restrictions (LDR) Treatment Standards for Listed Hazardous Wastes From Carbamate Production. (Checklist 161).	62 FR 45568 August 28, 1997	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1989, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431(c), effective April 30, 2000.
10. Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers; Clarification and Technical Amendments. (Checklist 163).	62 FR 64636 December 8, 1997 ..	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Sections 335.152(a)(1), 335.152(a)(4), 335.152(a)(17)–(19); 335.112(a)(1), 335.112(a)(4), 335.112(a)(19)–(21), 335.112(a)(24), effective November 18, 2001, as amended; 305.50(4)(A), effective March 21, 2000.
11. Kraft Mill Steam Stripper Condensate Exclusion. (Checklist 164).	63 FR 18504 April 15, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of solid waste) (A)(iv), effective November 15, 2001.
12. Recycled Used Oil Management Standards; Technical Correction and Clarification. (Checklist 166).	63 FR 24963 May 6, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; Texas Health & Safety Code Annotated Chapter 371, effective September 1, 1991, as amended; 30 Texas Administrative Code Section 355.78(j), effective October 19, 1998; Section 335.24(c)(4)(A)–(C), effective April 14, 1999; Sections 324.1, 324.3, 324.6, 324.11–14, effective August 8, 1999.
13. Land Disposal Restrictions Phase IV–Treatment Standards for Metal Wastes and Mineral Processing Wastes. (Checklist 167 A).	63 FR 28556 May 26, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of a hazardous waste), effective January 26, 1994, as amended; Section 335.1 (A)(iv) (definition of solid waste), effective May 30, 2001, as amended; Section 335.431(c), effective November 15, 2001.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
14. Land Disposal Phase IV—Hazardous Soils Treatment Standards and Exclusions. (Checklist 167 B).	63 FR 28556 May 26, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.69(f)(4)(C), effective March 18, 2001; Section 335.431(c), effective November 15, 2001. State law has no provision equivalent to 40 CFR 268.44(a), under which EPA may assure a variance from an applicable treatment standard.
15. Land Disposal Restrictions Phase IV—Corrections. (Checklist 167 C).	63 FR 28556 May 26, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431(c), effective November 15, 2001 and Section 335.431, effective April 30, 2000, as amended. State law has no provision equivalent to 40 CFR 268.44(a), under which EPA may assure a variance from an applicable treatment standard.
16. Mineral Processing Secondary Material Exclusion. (Checklist 167 D).	63 FR 28556 May 26, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1989, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of solid waste), effective May 30, 2001.
17. Bevil Exclusion Revision and Clarification. (Checklist 167 E).	63 FR 28556 May 26, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of solid waste) (A)(iv), effective May 30, 2001 as amended; 335.1 (definition of a hazardous waste, effective January 26, 1994, as amended.
18. Exclusion of Recycled Wood Preserving Wastewater. (Checklist 167 F).	63 FR 28556 May 26, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1989, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of solid waste) (A)(iv), effective May 30, 2001 as amended; 335.1 (definition of a hazardous waste, effective January 26, 1994, as amended.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
19. Hazardous Waste Combustors Revised Standards. (Checklist 168).	63 FR 33782 June 19, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Sections 335.1 (definition of solid waste)(A)(iv), effective May 30, 2001; Sections 305.69(i), 305.69(k), effective April 12, 2001; 305.51(a)(8), effective December 5, 1999.
20. Petroleum Refining Process (Checklist 169 &169.1).	63 FR 42110 August 6, 1998; 63 FR 54356 October 9, 1998.	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.003; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of hazardous waste) effective January 26, 1994, as amended, 335.1(129)(A)(iv) (def. of a solid waste), effective May 30, 2001, as amended; 335.431, effective April 30, 2000, as amended.
21. Land Disposal Restrictions Phase IV—Zinc Micronutrient Fertilizers, Administrative Stay. (Checklist 170).	63 FR 46332 August 31, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431, effective November 15, 2001.
22. Emergency Revision of Land Disposal Restrictions (LDR) Treatment Standards for Listed Hazardous Waste from Carbamate Production. (Checklist 171).	63 FR 47409 September 4, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431(c) effective November 15, 2001.
23. Land Disposal Restrictions Phase IV—Extension of Compliance Date for Characteristic Slags. (Checklist 172).	63 FR 48124 September 9, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431, effective November 15, 2001, as amended.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
24. Land Disposal Restrictions—Treatment Standards for Spent Potliners from Primary Aluminum Reduction (K088). (Checklist 173).	63 FR 51254 September 24, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.431(c), effective November 15, 2001.
25. Hazardous Remediation Waste Management Requirements (HWIR-Media). (Checklist 175).	63 FR 65874 November 30, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.003 (Vernon 2001), effective September 1, 1991, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of a hazardous waste), effective January 26, 1994, as amended; Sections 335.1 (definition of staging pile), and 335.111(a), effective November 15, 2001; 335.431, effective November 15, 2001; and 335.152(a)(14), effective November 18, 2001.
26. Universal Waste Rule—Technical Amendments. (Checklist 176).	63 FR 71225 December 24, 1998	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.261(b)(16)(D), effective April 30, 2000; Section 335.251, effective October 19, 1998.
27. Organic Air Emission Standards: Clarification and Technical Amendments. (Checklist 177).	64 FR 3382 January 21, 1999	Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Sections 335.69(a)(1)(A)–(B) effective March 18, 2001; 335.152(a)(17), (19), and (21), effective November 18, 2001.
28. Petroleum Refining Process Wastes—Leachate Exemption. (Checklist 178).	64 FR 6806 February 11, 1999	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.003 (Vernon 2001), September 1, 1991, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of a hazardous waste), effective January 26, 1994 as amended.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
29. Land Disposal Restrictions Phase IV—Technical Corrections and Clarifications to Treatment Standards. (Checklist 179).	64 FR 25408 May 11, 1999	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.003 (Vernon 2001), effective September 1, 1991, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of a hazardous waste), effective January 26, 1994, as amended; Section 335.1 (definition of solid waste), effective May 30, 2001; Section 335.431(c), effective November 15, 2001; and Section 335.69(f)(4)(C), effective March 18, 2001.
30. Guideline for Establishing Test Procedures for the Analysis of Oil and Grease and Non-Polar Material Under the Clean Water Act and Resource Conservation and Recovery Act. (Checklist 180).	64 FR 26315 June 14, 1999	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.31, effective November 15, 2001.
31. Universal Waste Rule: Specific Provisions for Hazardous Waste Lamps. (Checklist 181).	64 FR 36466 July 6, 1999	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of universal waste), effective May 30, 2001; Section 335.2(1), effective April 30, 2000; Section 335.41(j), effective April 12, 2001; Section 335.151(b), effective February 22, 1994; Sections 335.261(a)–(b), effective April 30, 2000; and Section 335.431(b)(3), effective November 15, 2001.
32. NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors, Miscellaneous Units, and Secondary Lead Smelters; Clarification of BIF Requirements Technical Correction to Fast-track Rule (MACT Rule). (Checklists 182 & 182.1).	64 FR 52827 September 30,1999; 64 FR 63209 November 19, 1999.	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended. 30 Texas Administrative Code Sections 335.1 (129)(A)(iv) (def. of solid waste), effective November 15, 2001, 335.12001(a)(13), 335.112(a)(14), effective November 18, 2001; Section 305.50(4)(A), effective March 21, 2000; Section 305.175, effective November 15, 2001; Section 335.152(a)(14), effective November 18, 2001; Sections 305.69(i), effective November 15, 2001; Sections 335.1 (definitions), 335.221(a), 335.221(a)(1), 305.50(4)(A), 305.571(b), and 335.222(a)(c), effective November 15, 2001.

Description of Federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
33. Land Disposal Restrictions Phase IV—Technical Corrections. (Checklist 183).	64 FR 56469 October 20, 1999	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of a hazardous waste), effective January 26, 1994, as amended; Section 335.431(c) effective November 15, 2001.
34. Waste Water Treatment Sludges from Metal Finishing Industry; 180-day Accumulation time. (Checklist 184).	65 FR 12378 March 8, 2000	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.69(j)–(l) effective March 18, 2001.
35. Organobromine Production Waste. (Checklist 185).	65 FR 14472 March 17, 2000	Texas Water Code Annotated Section 5.103 (Vernon 2000), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.017 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.024 (Vernon 2001), effective September 1, 1995, as amended; Texas Health & Safety Code Annotated Section 361.078 (Vernon 2001), effective September 1, 1989, as amended; 30 Texas Administrative Code Section 335.1 (definition of a hazardous waste), effective January 26, 1994, as amended; Section 335.431(c) effective November 15, 2001.

G. What Is the Relationship Between the Resource Conservation and Recovery Act and the Hazardous Waste Combustor MACT?

In this authorization document, the State of Texas is also seeking authorization for the Hazardous Waste Combustors Revised Standards (Checklist 168). On September 30, 1999, EPA finalized the National Emission Standards for Hazardous Air Pollutants (NESHAP) for three categories of hazardous waste combustors (HWCs): incinerators, cement kilns, and lightweight aggregate kilns (64 FR 52828). The EPA promulgated this rule under joint authority of the Clean Air Act (CAA) and RCRA. Before this rule went into effect, the air emissions from these three types of HWCs were primarily regulated under the authority of RCRA (*see* 40 CFR parts 264, 265, 266, and 270). However, with the release of the final HWC NESHAP (*see* 40 CFR part 63, subpart EEE), the air emissions from these sources are now regulated under RCRA and CAA. Even though both statutes give EPA the authority to regulate these emissions, EPA has determined that having emissions standards and permitting requirements in both sets of implementing regulations would be duplicative. For this reason, using the authority provided by section 1006(b) of RCRA, EPA deferred the RCRA requirements for HWC emission controls to the CAA requirements of 40 CFR part 63, subpart EEE.

Therefore, with today's authorization of the State of Texas for the RCRA provisions of the September 30, 1999, HWC NESHAP rule, the RCRA waste management standards for air emissions from these units will no longer apply after the facility has demonstrated compliance with 40 CFR part 63, subpart EEE. One notable exception concerns the RCRA Omnibus provision in section 3005(c)(3) of RCRA, which requires each RCRA permit to contain terms and conditions necessary to protect human health and the environment. Under this provision of RCRA, if a regulatory authority determines that more stringent conditions than the HWC NESHAP are necessary to protect human health and the environment for a particular facility, then the regulatory authority may impose those conditions in the facility's RCRA permit. (*See* the HWC MACT rule preamble discussion on the interrelationship of the MACT rule with the RCRA Omnibus provision and site specific risk assessment at 64 FR 52828, pages 52839–52843, September 30, 1999, and the RCRA Site-Specific Risk Assessment Policy for Hazardous Waste Combustion Facilities, dated June, 2000, for more information).

H. Where Are the Revised State Rules Different From the Federal Rules?

The State law is more stringent than the Federal rule because the State does not have provisions equivalent to 40 CFR 268.44(a)(10) regarding tolling agreements. Also, the State law has no provision equivalent to 40 CFR 268.44(a), under which EPA may approve a variance from an applicable

treatment standard. In this authorization, there are no broader in scope provisions. Broader-in-scope requirements are not part of the authorized program and EPA cannot enforce them.

I. Who Handles Permits After the Authorization Takes Effect?

The State of Texas will issue and administer permits for all the provisions for which it is authorized. The EPA will continue to administer any RCRA hazardous waste permits or portions of permits which we issued prior to the effective date of this authorization. Upon authorization of the State program, EPA will suspend issuance of Federal permits for hazardous waste treatment, storage, and disposal facilities for which the State is receiving authorization. EPA will not issue any more new permits or new portions of permits for the provisions listed in the Table above after the effective date of this authorization. The EPA will continue to implement and issue permits for HSWA requirements for which State of Texas is not yet authorized.

J. When Will This Approval Take Effect?

EPA, after the close of the public comment period, will review and respond to comments it receives and then will subsequently publish a final action that responds to the comments and may either finalize the proposal without change, modify the proposal based on comments, or announce a decision not to finalize the proposal.

K. How Does Today's Action Affect Indian Country in Texas?

Texas is not authorized to carry out its Hazardous Waste Program in Indian Country within the State. This authority remains with EPA. Therefore, this action has no effect in Indian Country.

L. What Is Codification and Is EPA Codifying Texas' Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized State rules in 40 CFR part 272. We reserve the amendment of 40 CFR part 272, subpart SS for this authorization of Texas' program changes until a later date. EPA is not codifying the State of Texas' statutes or regulations in this program revision.

M. Statutory and Executive Order Reviews

The Office of Management and Budget has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, I certify that this action 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 action authorizes 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 (Pub. L. 104–4). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action 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), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. 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)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. 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. 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. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This proposed 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 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous material transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This proposed rule is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: March 10, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. 05–5410 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 15 and 73

[ET Docket No. 05–24; FCC 05–17]

DTV Tuner Requirements

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to adjust the schedule by which new broadcast television receivers are required to include the capability to tune digital television (DTV) signals. The Commission request comment on whether there is need to revise the implementation schedule of the DTV tuner requirement for receivers with screen sizes 25 to 36 inches and, if so, how that schedule should be revised to achieve our goal that all new television

receivers include DTV tuning capability by July 1, 2007.

DATES: Comments must be filed on or before April 18, 2005, and reply comments must be filed on or before May 2, 2005.

ADDRESSES: You may submit comments, identified by (ET Docket No. 05–24) by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Federal Communications Commission's Web site: *http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Alan Stillwell, Office of Engineering and Technology, (202) 418–2925, e-mail: *Alan.Stillwell@fcc.gov,* TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making* (NPRM), ET Docket No. 05–24, FCC 05–17, adopted January 19, 2005, and released February 14, 2005. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI), 445 12th Street, SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternate formats are available to persons with disabilities at TTY (202) 418–7365.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on or before April 18, 2005, and reply comments on or before May 2, 2005. 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.

All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. 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, Natek, 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.

Summary of Notice of Proposed Rulemaking

1. The Commission commences this proceeding to consider adjusting the schedule by which new broadcast television receivers with screen sizes 25 to 36 inches are required to include the capability to tune digital television (DTV) signals. This provision of the rules is an element of the Commission's phase-in plan for requiring that all new broadcast television receivers include DTV reception capability by July 1, 2007. The DTV reception requirement was adopted by the Commission in the *Second Report and Order and Second Memorandum Opinion and Order* (DTV Tuner Order), 67 FR 63290, October 11, 2002, in the DTV review proceeding and is also often termed the ''DTV tuner requirement.'' This requirement is being phased-in over a four-year period to avoid imposing undue costs on manufacturers and consumers and to avoid disruption of the TV receiver market. On November 5, 2004, the Consumer Electronics Association and the Consumer Electronics Retailers Coalition (CEA–CERC) submitted a Petition for Rulemaking requesting that we eliminate the scheduled July 1, 2005, date for 50 percent of new TV receivers with screen sizes 25 to 36 inches to include DTV reception capability and advance the date on which 100 percent of such receivers must include that capability by three months, from July 1, 2006, to March 1, 2006. CEA–CERC submit that this change is needed to resolve certain adverse consequences of the 50 percent aspects of the phase-in plan for the DTV tuner requirement that have become apparent recently through experience in retailing and manufacturing. In response to the CEA–CERC petition, we request comment on whether there is need to revise the implementation schedule of the DTV tuner requirement for receivers with screen sizes 25 to 36 inches and, if so, how that schedule should be revised to achieve our goal that all new television receivers include DTV tuning capability by July 1, 2007.

2. In the *DTV Tuner Order,* the Commission adopted rules requiring that all TV receivers shipped in interstate commerce or imported into the United States, for sale or resale to the public, with screen sizes 13 inches or larger and TV interface devices be capable of receiving the signals of DTV broadcast stations over-the-air no later than July 1, 2007. Under these rules, TV broadcast receivers are required only to provide useable picture and sound commensurate with their video and audio capabilities when receiving DTV signals. The DTV tuner requirement was intended to facilitate the transition to digital television by promoting the availability of DTV reception equipment and to protect consumers by ensuring that their TV receivers will provide off-the-air TV reception in the digital world just as they do today. In order to minimize the impact of the DTV tuner requirement on both manufacturers and consumers, the Commission adopted a phase-in schedule that applies the

requirement first to receivers with the largest screens and then to progressively smaller screen receivers and TV interface devices. This phase-in plan is intended to allow increasing economies of scale with production volume to be realized so that tuner costs will be lower when they are required to be included in smaller sets and TV interface devices. The phase-in plan is currently as follows:

Receivers with screen sizes 36″ and above—50% of a responsible party's units must include DTV tuners effective July 1, 2004; 100% of such units must include DTV tuners effective July 1, 2005;

Receivers with screen sizes 25″ to 36″—50% of a responsible party's units must include DTV tuners effective July 1, 2005; 100% of such units must include DTV tuners effective July 1, 2006;

Receivers with screen sizes 13″ to 24″—100% of all such units must include DTV tuners effective July 1, 2007;

TV Interface Devices (videocassette recorders (VCRs), digital versatile disk (DVD) players/recorders, etc.) that receive broadcast television signals—100% of all such units must include DTV tuners effective July 1, 2007.

3. In their petition for rulemaking, CEA–CERC request that we eliminate the July 1, 2005, requirement for 50 percent of TV receivers with screen sizes 25 to 36 inches to include DTV reception capability and instead advance from July 1, 2006, to March 1, 2006, date for all such receivers to include a DTV tuner. They submit that manufacturers and retailers experience with the 50 percent provision for 36 inch and larger receivers is that the 50 percent aspect of the phase-in plan is antithetical to the purpose of the requirement. CEA–CERC state that, in practice, the 50 percent requirement has proven to be unduly disruptive in the marketplace in ways unforeseen and, in fact, threatens to slow, rather than speed, consumer migration to TV receivers with DTV tuners. They indicate that this is because consumers typically choose a lower-priced product with otherwise similar features except for the DTV tuner.

4. The DTV tuner requirement is intended to provide this capability to the general population on a schedule that will promote a rapid completion of the transition while minimizing the potential for the incremental costs of DTV tuning capability to disrupt the television receiver market. At the time we adopted the 50 percent of production elements of the phase-in provisions of the DTV tuner requirement, our intent was that these intermediate increases in the proportions of new receivers with DTV tuners would gradually apply the tuner requirement to progressively greater proportions of receivers as manufacturers develop efficiencies in production and thereby minimize the impact of the tuner requirement on both manufacturers/importers and consumers. As described in the CEA–CERC petition, it now appears that the partial production elements of this plan may be impeding rather than promoting the introduction of TV receivers that include DTV tuners. We are initiating this rulemaking proceeding to consider whether there is a need to modify the implementation schedule of the DTV tuner requirement for receivers with screen sizes 25 to 36 inches to address the disruptive effects on the TV receiver market indicated in the CEA–CERC petition and, if so, to develop revisions to that plan that will achieve our goal that all new television receivers include DTV tuning capability by July 1, 2007, in a phased in approach that will help develop economies of scale, and our goal of furthering the DTV transition.

5. In considering this matter, it is our intent that any revisions we may make to the tuner requirement should not serve to delay the completion of the DTV transition. We believe it is important that the implementation schedule under any such revisions should foster a more rapid introduction of DTV reception capability and in no event should extend the current July 1, 2007, date for full implementation. We also continue to believe that it is desirable and important to provide for the gradual introduction of the DTV tuner requirement in order to allow manufacturers and importers to develop the economies of scale that are necessary to reduce the costs of DTV tuners when they are included in smaller screen sets and other devices such as videocassette and DVD recorders that do not include a viewing screen.

6. In this context, we request comment on whether there is need to revise the TV tuner requirement implementation schedule for receivers with screen sizes 25 to 36 inches and suggestions for specific revisions to the schedule for such devices to address that need. We specifically request comment on the approach suggested by CEA–CERC whereby the requirement that 50 percent of receivers with screen sizes 25 inches to 36 inches incorporate a DTV tuner in the period from July 1, 2005, to July 1, 2006, would be eliminated and replaced with a new provision requiring that all receivers with screen sizes 25 inches to 36 inches be required to include a DTV tuner effective March 1, 2006. We also invite alternative approaches for addressing the market situation described in the CEA–CERC petition and intend to consider the full range of options that are consistent with our stated goals. However, commenting parties are advised that we do not intend to extend the July 1, 2007, date by which all broadcast television receivers include DTV reception capability.

Initial Regulatory Flexibility Analysis

7. As required by the Regulatory Flexibility Act of 1980, as amended (''RFA''),[1] the Commission has prepared this Initial Regulatory Flexibility Analysis (''IRFA'') of the possible significant economic impact on small entities by the policies and rules proposed in this Notice of Proposed Rulemaking (''NPRM''). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the NPRM provided in paragraph 11. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.[2] In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.[3]

A. *Need for and Objectives of the Proposed Rules.* As described in the NPRM, the changes to the rules being considered in this proceeding are intended to ensure a smooth transition of the nation's television system to digital television. Beginning in 1987, the Commission undertook to bring the most up-to-date technology to broadcast television. That resulted in several Commission decisions, including those adopting a digital television (DTV) standard, DTV service rules, and a Table of DTV Allotments. The Table of DTV Allotments provides each existing television broadcaster with a second channel on which to operate a DTV station for the transition period, after which one of its channels will revert to the government for use in other services. The transition deadline established by Congress is December 31, 2006. Consistent with its efforts to promote the expeditious completion of the DTV transition, the Commission has adopted a requirement that all new television

[1] *See* 5 U.S.C. 603. The RFA, *See* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, Title II, 110 Stat. 857 (1996).

[2] *See* 5 U.S.C. 603(a).

[3] *See id.*

receivers imported or shipped in interstate commerce after July 1, 2007, include the capability to receive DTV signals off-the-air. In order to minimize the impact of the DTV tuner requirement on both manufacturers and consumers, the Commission adopted a phase-in schedule that applies the DTV tuner requirement first to receivers with the screens and then to progressively smaller screen receivers and TV interface devices. The Consumer Electronics Association and the Consumer Electronics Retailers Coalition (CEA–CERC) submitted a petition for rule making requesting that the Commission eliminate the portion of the phase-in schedule requiring that 50 percent of TV receivers with screen sizes 25″ to 36″ include DTV reception capability from July 1, 2005, to July 1, 2006, and instead advance the date for requiring all such receivers to include a DTV tuner to March 1, 2006, from July 1, 2006. CEA–CERC indicates that the 50 percent requirement has proven to be disruptive to the market in the case of larger screen receivers. We issued the NPRM to consider whether there is a need to modify the portion of the DTV tuner requirement phase-in plan that applies to receivers with screen sizes 24″ to 36″, and if so, to develop revisions to that plan that will achieve our goal that all new television receivers include DTV tuning capability by July 1, 2007.

B. *Legal Basis.* The authority for the action proposed in this rulemaking is contained in sections 4(i) & (j), 303, 307, 309 and 336 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) & (j), 303, 307, 309 and 336.

C. *Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply.* The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules.[4] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental entity.''[5] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[6] A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (''SBA'').[7]

Electronics Equipment Manufacturers. Rules adopted in this proceeding would apply to manufacturers of DTV receiving equipment and other types of consumer electronics equipment. The SBA has developed definitions of small entity for manufacturers of audio and video equipment[8] as well as radio and television broadcasting and wireless communications equipment.[9] These categories both include all such companies employing 750 or fewer employees. The Commission has not developed a definition of small entities applicable to manufacturers of electronic equipment used by consumers, as compared to industrial use by television licensees and related businesses. Therefore, we will utilize the SBA definitions applicable to manufacturers of audio and visual equipment and radio and television broadcasting and wireless communications equipment, since these are the two closest NAICS Codes applicable to the consumer electronics equipment manufacturing industry. However, these NAICS categories are broad and specific figures are not available as to how many of these establishments manufacture consumer equipment. According to the SBA's regulations, an audio and visual equipment manufacturer must have 750 or fewer employees in order to qualify as a small business concern.[10] Census Bureau data indicates that there are 554 U.S. establishments that manufacture audio and visual equipment, and that 542 of these establishments have fewer than 500 employees and would be classified as small entities.[11] The remaining 12 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. Under the SBA's regulations, a radio and television broadcasting and wireless communications equipment manufacturer must also have 750 or fewer employees in order to qualify as a small business concern.[12] Census Bureau data indicates that there 1,215 U.S. establishments that manufacture radio and television broadcasting and wireless communications equipment, and that 1,150 of these establishments have fewer than 500 employees and would be classified as small entities.[13] The remaining 65 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. We therefore conclude that there are no more than 542 small manufacturers of audio and visual electronics equipment and no more than 1,150 small manufacturers of radio and television broadcasting and wireless communications equipment for consumer/household use.

Computer Manufacturers. The Commission has not developed a definition of small entities applicable to computer manufacturers. Therefore, we will utilize the SBA definition of electronic computers manufacturing. According to SBA regulations, a computer manufacturer must have 1,000 or fewer employees in order to qualify as a small entity.[14] Census Bureau data indicates that there are 563 firms that manufacture electronic computers and of those, 544 have fewer than 1,000 employees and qualify as small entities.[15] The remaining 19 firms have 1,000 or more employees. We conclude that there are approximately 544 small computer manufacturers.

D. *Description of Projected Reporting, Recordkeeping and other Compliance Requirements.* At this time, we do not expect that the rule changes being considered in this proceeding would impose any significant additional

[4] 5 U.S.C. 603(b)(3).

[5] 5 U.S.C. 601(6).

[6] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[7] 15 U.S.C. 632.

[8] 13 CFR 121.201 (NAICS Code 334310).

[9] 13 CFR 121.201 (NAICS Code 334220).

[10] 13 CFR 121.201 (NAICS Code 334310).

[11] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Audio and Video Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information.

[12] 13 CFR 121.201 (NAICS Code 513220).

[13] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information.

[14] 13 CFR 121.201 (NAICS Code 334111).

[15] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Electronic Computer Manufacturing, Table 4 at 9 (1999).

recordkeeping or recordkeeping requirements. While the modifications being considered in the Notice could have an impact on consumer electronics manufacturers and broadcasters, such impact would be similarly costly for both large and small entities. We seek comment on whether others perceive a need for more extensive recordkeeping under specific options for addressing the issues in the NPRM and, if so, whether the burden would fall on large and small entities differently.

E. *Steps Taken to Minimize Significant Impact on Small Entities, and Significant Alternatives Considered.* The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[16]

The rule changes under consideration in this proceeding would revise the schedule for implementation of the requirement that new television receivers include the capability for reception of broadcast DTV signals. We requested comment on a suggestion for revising the schedule submitted by CEA–CERC in their petition for rulemaking. We also invited interested parties to submit alternative suggestions for revising the implementation schedule.[17]

F. *Federal Rules Which Duplicate, Overlap, or Conflict with the Commission's Proposals.* None.

8. *Ordering Clauses.* Pursuant to the authority contained in sections 2(a), 4(i) & (j), 7, and 303 of the Communications Act of 1934 as amended, 47 U.S.C. 152(a), 154(i) & (j), 157, and 303, this Notice of Proposed Rule Making *is adopted.*

9. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of this NPRM, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration, in accordance with the Regulatory Flexibility Act.

[16] 5 U.S.C. 603.

[17] *See NPRM,* paragraph 8.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–5402 Filed 3–17–05; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[WT Docket No. 05–62; FCC 05–31]

Amendment of the Commission's Rules to Provide for Flexible Use of the 896–901 MHz and 935–940 MHz Bands Allotted to the Business and Industrial Land Transportation Pool, and Oppositions

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes amendments of its rules to facilitate more flexible use of the 199 channels allocated to the Business and Industrial Land Transportation (B/ILT) Pools in the 896–901/935–940 MHz (900 MHz) bands, by permitting any use of the B/ILT channels in the 900 MHz band that is consistent with the band's fixed and mobile allocations. In addition, the Commission proposes to license the remaining spectrum using a geographic area licensing scheme, and to adopt service rules, including licensing, technical and operational rules for the new geographic licensees. Further, the Commission seeks comment on competitive bidding rules and procedures to be used in the event that mutually exclusive applications are filed for the 900 MHz proposed geographic licenses.

DATES: Comments are due on or before April 18, 2005. Reply comments are due May 2, 2005.

ADDRESSES: You may submit comments, identified by WT Docket No. 05–62, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Federal Communications Commission's Web Site: *http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- Email: To receive 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. Include the docket number(s) in the subject line of the message.
- Mail: Appropriate addresses for submitting comments and reply comments may be found in the **SUPPLEMENTARY INFORMATION** section of this document.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

In addition to filing comments with the Secretary, a copy of any comments on the Paperwork Reduction Act information collection requirements contained herein should be submitted to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Judith-B.Herman@fcc.gov,* and to Kristy L. LaLonde, OMB Desk Officer, Room 10234 NEOB, 725 17th Street, NW., Washington, DC 20503, via the Internet to *Kristy_L. LaLonde@omb.eop.gov*, or via fax at 202–395–5167.

FOR FURTHER INFORMATION CONTACT: Michael Connelly, Wireless Telecommunications Bureau, at (202) 418–0620.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's *Notice and Proposed Rulemaking* (*NPRM*), FCC 05–31, in WT Docket No. 05–62, adopted February 10, 2005, and released February 16, 2005. The full text of this document is available for public inspection during regular business hours at the FCC Reference Information Center, 445 12th St., SW., Room CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission's duplicating contractor: Best Copy & Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 800–378–3160, facsimile 202–488–5563, or via e-mail at *www.fcc@bcpiweb.com.*

Paperwork Reduction Act

This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002,

Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

• Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the Federal eRulemaking Portal: *http://www.regulations.gov.* Filers should follow the instructions provided on the website for submitting comments.

• For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers 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, filers should send an e-mail to *ecfs@fcc.gov,* and include the following words in the body of the message, ''get form.'' A sample form and directions will be sent in response.

• Paper Filers: 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, filers 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). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• The Commission's contractor 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, Express, and Priority mail should be addressed to 445 12th Street, SW., Washington DC 20554.

People with Disabilities: Contact the FCC to request materials in accessible formats (braille, large print, electronic files, audio format, etc.) by e-mail at *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0531 (voice), 202–418–7365 (TTY).

Synopsis of Notice of Proposed Rulemaking

I. Background

1. In 1986, the Commission established a pool structure for the 900 MHz PLMR spectrum and allocated 2.5 MHz for the Industrial/Land Transportation Pool (99 channels) and 2.5 MHz for the Business Pool (100 channels) (collectively, the B/ILT Pools). The B/ILT Pools were established for use by site-by-site licensees engaged in commercial activities, the operation of educational, philanthropic, or ecclesiastical institutions, clergy activities, or the operation of hospitals, clinics, or medical associations. In addition, eligibility was also provided for any corporations furnishing nonprofit radio communication service to its parent corporation or subsidiary. Currently, applications for use of the B/ILT frequencies are limited to private, internal use systems.

2. On July 8, 2004, in its *800 MHz Report and Order*, 69 FR 67,823, the Commission adopted significant technical and procedural measures designed to address the problem of interference to public safety communications in the 800 MHz band. As part of its reconfiguration plan at 800 MHz, the Commission consolidated the B/ILT Pools in the 800 MHz and 900 MHz bands, allowing any eligible B/ILT licensee to be licensed on the consolidated channels. The Commission also provided for additional flexibility in the 900 MHz band by allowing 900 MHz PLMR licensees to initiate CMRS operations on their currently authorized spectrum or to assign their authorizations to others for CMRS use. The Commission reasoned that since it permitted CMRS use of PLMR frequencies in the 800 MHz land mobile band, similar rules should apply in the 900 MHz land mobile spectrum, in the interest of regulatory symmetry. The Commission also noted that in order to provide the ''green space'' necessary to effect reconfiguration of the 800 MHz band, some operations may need to shift from the 800 MHz to 900 MHz band.

II. Discussion

A. Flexible Use, Regulatory Framework, and Assignment of Licenses

3. The Commission proposes service rules for the new 900 MHz channels that would provide licensees flexible use. The Commission expects the economic efficiencies of flexibility to foster, not deter, technology development and investment in communications services and systems. The Commission seeks comment on its tentative conclusion to continue to license these bands under the framework of part 90 of our rules.

B. Band Plan and Size of Geographic Service Areas

4. The Commission tentatively concludes that it should license this 900 MHz spectrum using a geographic area licensing scheme, believing that geographic area licensing will maximize flexibility, permit new and innovative technologies to rapidly develop in these bands, and allow a licensee substantial flexibility to respond to market demand, resulting in significant improvements in spectrum utilization. Should the Commission adopt a geographic area approach for licensing the flexible-use spectrum, it seeks comment on the appropriate size of that geographic area. In particular, the Commission asks whether it should adopt Major Economic Areas (MEAs) or Basic Economic Areas (EAs). The Commission notes that MEAs may have the effect of creating opportunities for both existing licensees and new entrants to meet customer demands for wide-area service, increasing spectrum efficiency, providing better quality service to end users, and allowing service to reach potential end users that may otherwise be without adequate communication options, while Basic Economic Areas (EAs) may provide greater opportunities for small and medium-sized businesses to successfully compete against larger, well-financed bidders, and that EAs may facilitate the ability of incumbents and other small and medium-sized operators of smaller systems to participate in geographic area licensing.

C. Channel Block Size

5. The Commission seeks comment on its proposal to license the 900 MHz flexible-use channels in nineteen blocks of ten contiguous channels each, and one block of nine contiguous channels.

The Commission believes the proposed configuration can provide operational flexibility and efficiency by allowing providers to use new technologies and compete effectively with other commercial providers, and avoids the transaction costs associated with reaggregation of spectrum, while promoting the flexibility necessary to facilitate secondary market uses. The Commission also asks whether a more viable option under an EA-based licensing approach might include nine blocks of twenty non-contiguous channels each and one block of nineteen non-contiguous channels, which would allow potential bidders to acquire a larger number of channels, albeit in smaller geographic areas. Commenters might also consider the option of dedicating the upper four channel blocks (*i.e.*, QQ, RR, SS, TT) to traditional B/ILT services. The Commission also asks commenters to consider whether to permit potential bidders to bid on licenses comprising multiple band plans according to the band plan configuration they prefer and use the bidders' collective valuation of licenses consistent with each band plan in determining which band plan to implement. The Commission seeks comment on its proposal to permit licensees to aggregate blocks and to allow both incumbents and new entrants to bid on the spectrum.

D. Operational Flexibility

6. The Commission seeks comment on its tentative conclusion that geographic area licensees in the 900 MHz band should be permitted to construct stations at any authorized site and on any available channel within their licensing area, and that geographic area licensees may expand or modify facilities throughout their service areas without prior Commission approval, so long as the systems continue to be in compliance with the Commission's technical and operational rules, protect incumbents, and are consistent with international requirements and approvals.

E. Treatment of Incumbent Systems

7. The Commission proposes that geographic area licensees afford the same protection to incumbent B/ILT systems as is provided to incumbents by existing 900 MHz SMR MTA licensees, and tentatively concludes that the geographic area licensee's co-channel obligations cease upon the deletion of a revoked or terminated co-channel station authorization from the Commission's licensing records. Although the Commission believes this interference protection proposal will adequately protect incumbent operations, it asks commenters to consider whether additional interference protection requirements are needed. The Commission notes that licensees may be faced with the same interference problems that necessitated the remedies adopted in the *800 MHz R&O* unless equivalent interference abatement requirements are established at 900 MHz. Also, the Commission proposes to define the existing service area of an incumbent B/ILT system by its originally-licensed 40 dBμV/m field strength contour, and to permit incumbent licensees to add or modify transmit sites in their existing service area, without prior approval or without post construction notification to the Commission, so long as their original 40 dBμV/m signal is not expanded.

8.The Commission also seeks comment on whether to provide an option for incumbent licensees to return their licensees through an auction that includes the new geographic area overlay licenses for white space as well as any site-based licenses currently held by incumbent licensees who may be willing to exchange or sell their licenses. In versions of this general form of auction discussed by the Commission, existing licensees would not be required to relinquish their rights, but they would be likely to do so if compensation for their license exceeded the value to them of continuing with their current use. Such a mechanism to promote the efficient transition of incumbent users may be most useful in situations in which the anticipated use of the spectrum under new service rules is incompatible with the continued existence of incumbents operating legacy systems in the band. While the Commission expects that the overlay licenses it makes available in this proceeding will be useful for providing new services regardless of the existence of site-based B/ILT users, the availability of incumbent providers' licenses may encourage a quicker and smoother transition of the 900 MHz spectrum to uses consistent with the more flexible service rules proposed here.

F. Emission and Field Strength Limits

9. Regarding emissions, the Commission seeks comment on its proposal that, on any frequency in a geographic area licensee's spectrum block that is adjacent to a non-geographic area frequency, the power of any emission shall be attenuated below the transmitter power (P) by at least 43 plus 10 $\log_{10}$ (P) decibels or 80 decibels, whichever is the lesser attenuation; the Commission tentatively concludes that this emission mask would adequately protect licensees in neighboring spectrum. Regarding field strength limits, the Commission requests comment on whether 40 dBμV/m is an appropriate field strength level for a geographic area licensee's operations at its service area border, and asks commenters to address whether this limit furthers the Commission's goal of avoiding harmful interference or whether stricter requirements are necessary.

G. Performance Requirements and Other Operating and Technical Rules

10. The Commission proposes to require new 900 MHz licensees to submit to the Commission a showing of substantial service (as opposed to a population benchmark) in their licensed area within either five or ten years of being licensed, believing that this performance requirement could provide greater flexibility for parties interested in entering into spectrum leasing arrangements involving this spectrum, as well as for providing service to rural or sparsely populated areas. The Commission also seeks comment on whether it should modify existing coverage requirements for 900 MHz SMR services to mirror the proposed substantial service showing for those 900 MHz licensees permitted flexible spectrum use; whether to retain or eliminate loading requirements as they apply to existing B/ILT authorizations; and whether the general provisions of part 90 to the 900 MHz B/ILT ''white space'' spectrum is appropriate.

H. Competitive Bidding Procedures

11. The Commission proposes to conduct the auction for these 900 MHz channel licenses under the general competitive bidding rules established in part 1, subpart Q of the Commission's Rules, and substantially consistent with the bidding procedures that have been employed in previous Commission auctions, including rules governing designated entities, application and payment procedures, reporting requirements, collusion issues, and unjust enrichment. The Commission also proposes small business bidding credits to further the statutory goals of ensuring that small businesses, rural telephone companies, and businesses owned by members of minority groups and women are given the opportunity to participate in the provision of spectrum-based services. The Commission seeks comment on its proposal to define a small business as an entity with average annual gross revenues for the three preceding years not to exceed $15 million, and to define a very small

business as an entity with average annual gross revenues for the three preceding years not to exceed $3 million. The Commission seeks comment on these proposals.

III. Procedural Matters

A. Initial Regulatory Flexibility Act Analysis

12. As required by the Regulatory Flexibility Act of 1980 (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and rules proposed in the Notice. The analysis is found in Appendix B of the *NPRM*. The Commission requests written public comment on the analysis. Comments must be filed by the same dates as listed in paragraph 70 of the *NPRM*, and must have a separate and distinct heading designating them as responses to the IRFA. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of the *NPRM*, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

B. Need for, and Objectives of, the Notice of Proposed Rulemaking and Memorandum Opinion and Order

13. In the *NPRM*, the Commission proposes amendments to part 90 of its rules to facilitate more flexible use of the 199 channels allocated to the Business and Industrial Land Transportation (B/ILT) Pool in the 896–901/935–940 MHz (900 MHz) bands. The Commission proposes to permit any use of the B/ILT channels in the 900 MHz band that is consistent with the band's fixed and mobile allocations, and to license the remaining spectrum or ''white space'' using a geographic area licensing scheme and propose competitive bidding rules to select from among mutually exclusive applicants. The Commission also sets forth proposals for auction procedures for the remaining 900 MHz spectrum in the B/ILT category channels. The Commission believes these proposed rules will serve its twin goals of providing service to the public consistently and expeditiously, and allowing the marketplace to respond to consumer demands, and notes that allowing for flexible use of this spectrum will greatly aid in facilitating band reconfiguration occurring at 800 MHz. The Commission believes that the rules and policies proposed in the *NPRM* strike a fair and equitable balance between the interests of incumbent B/ILT licensees, and those seeking to provide geographic area service, and further believes that these rules and policies will promote competition, while providing opportunities for incumbents to continue to pursue their business plans.

C. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

14. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules and policies, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

15. *Small Businesses*. Nationwide, there are a total of 22.4 million small businesses, according to SBA data.

16. *Small Organizations*. Nationwide, there are approximately 1.6 million small organizations.

17. *Small Governmental Jurisdictions*. The term ''small governmental jurisdiction'' is defined as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' As of 1997, there were approximately 87,453 governmental jurisdictions in the United States. This number includes 39,044 county governments, municipalities, and townships, of which 37,546 (approximately 96.2%) have populations of fewer than 50,000, and of which 1,498 have populations of 50,000 or more. Thus, we estimate the number of small governmental jurisdictions overall to be 84,098 or fewer.

18. The Commission has determined that 1,040, or more, licenses will be awarded in the 896–901 MHz and 935–940 MHz B/ILT MHz bands; the Commission does not yet know how many applicants or licensees in these bands will be small entities. Thus, the Commission assumes, for purposes of this IRFA, that all prospective licensees are small entities as that term is defined by the SBA or by our proposed small business definitions for these bands. The Commission invites comment on this analysis.

19. *Wireless Service Providers*. The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of ''Paging'' and ''Cellular and Other Wireless Telecommunications.'' Under both SBA categories, a wireless business is small if it has 1,500 or fewer employees. For the census category of Paging, Census Bureau data for 1997 show that there were 1,320 firms in this category, total, that operated for the entire year. Of this total, 1,303 firms had employment of 999 or fewer employees, and an additional 17 firms had employment of 1,000 employees or more. Thus, under this category and associated small business size standard, the great majority of firms can be considered small. For the census category Cellular and Other Wireless Telecommunications, Census Bureau data for 1997 show that there were 977 firms in this category, total, that operated for the entire year. Of this total, 965 firms had employment of 999 or fewer employees, and an additional 12 firms had employment of 1,000 employees or more. Thus, under this second category and size standard, the great majority of firms can, again, be considered small.

20. *Wireless Telephony*. Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. The SBA has developed a small business size standard for ''Cellular and Other Wireless Telecommunications'' services. Under that SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to Commission data, 447 carriers reported that they were engaged in the provision of wireless telephony. We have estimated that 245 of these are small under the SBA small business size standard.

21. *Broadband Personal Communications Service*. The broadband personal communications services (PCS) spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission has created a small business size standard for Blocks C and F as an entity that has average gross revenues of less than $40 million in the three previous calendar years. For Block F, an additional small business size standard for ''very small business'' was added and is defined as an entity that, together with its affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. These small business size standards, in the context of broadband PCS auctions, have been approved by the SBA. No small businesses within the SBA-approved small business size standards bid successfully for licenses

in Blocks A and B. There were 90 winning bidders that qualified as small entities in the Block C auctions. A total of 93 ''small'' and ''very small'' business bidders won approximately 40 percent of the 1,479 licenses for Blocks D, E, and F. On March 23, 1999, the Commission reauctioned 155 C, D, E, and F Block licenses; there were 113 small business winning bidders.

22. On January 26, 2001, the Commission completed the auction of 422 C and F Broadband PCS licenses in Auction No. 35. Of the 35 winning bidders in this auction, 29 qualified as ''small'' or ''very small'' businesses. Subsequent events concerning Auction 35, including judicial and agency determinations, resulted in a total of 163 C and F Block licenses being available for grant.

23. *Cellular Licensees*. The SBA has developed a small business size standard for wireless firms within the broad economic census category ''Cellular and Other Wireless Telecommunications.'' Under this SBA category, a wireless business is small if it has 1,500 or fewer employees. For the census category Cellular and Other Wireless Telecommunications firms, Census Bureau data for 1997 show that there were 977 firms in this category, total, that operated for the entire year. Of this total, 965 firms had employment of 999 or fewer employees, and an additional 12 firms had employment of 1,000 employees or more. Thus, under this category and size standard, the great majority of firms can be considered small. According to Commission data, 447 carriers reported that they were engaged in the provision of cellular service, personal communications service, or specialized mobile radio telephony services, which are placed together in the data. We have estimated that 245 of these are small, under the SBA small business size standard.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

24. The *NPRM* proposes to amend part 90 of the Commission's rules to facilitate more flexible use of the 199 channels allocated to the Business and Industrial Land Transportation (B/ILT) Pools in the 896–901/935–940 MHz (900 MHz) bands, to permit any use of the B/ILT channels in the 900 MHz band that is consistent with the band's fixed and mobile allocations. It also proposes to license the unencumbered spectrum through geographic area licensing. Accordingly, the Commission proposes service rules, including licensing, technical and operational rules for the new geographic licensees, and seeks comment on defining the rights of B/ILT licensees already operating in the 900 MHz band. The Commission also seeks comment on competitive bidding rules and procedures to be used in the event that mutually exclusive applications are filed for the 900 MHz proposed geographic licenses.

25. In paragraphs 12–14 of the *NPRM*, the Commission proposes service rules for the new 900 MHz channels that would provide licensees with the flexibility to employ this spectrum for any use permitted by the United States Table of Frequency Allocations contained in part 2 of our rules (*i.e.*, fixed or mobile services), believing that such flexibility fully meets criteria set forth in section 303(y) of the Communications Act of 1934, as amended. The *NPRM* tentatively concludes that such use would be consistent with applicable international agreements, and that the public interest benefits of flexibility are numerous, and notes that the Commission has identified the establishment of maximum feasible flexibility in both spectrum designations and allocations and service rules as a critical means of ensuring that spectrum is put to its most beneficial use.

The Commission believes that the economic efficiencies of flexibility foster, rather than deter, technology development and investment in communications services and systems.

26. In paragraphs 17–19 of the *NPRM*, the Commission seeks comment on its proposal to license this 900 MHz spectrum using geographic area licensing, believing that such a licensing scheme is well-suited for the types of fixed and mobile services that will likely develop in this overlay band. The Commission invites commenters to explain any opposition and the costs and benefits associated with any preferable licensing proposal. In paragraphs 21–25, the Commission seeks comment on its proposal to adopt Major Economic Areas (''MEAs''), or, in the alternative, Economic Areas (''EAs'') as the appropriate geographic size. On the one hand, allowing the new 900 MHz licensees the use of frequencies for systems providing coverage across wide areas will increase spectrum efficiency, provide better quality service to end users, and allow service to reach potential end users that may otherwise be without adequate communication options, and that the MEA-based licensees will be in a better position to address the needs of system users, customers, or lessees that have wide-area requirements; on the other hand, EAs, which are more than three times the number of delineated economic areas than MEAs, may facilitate the ability of incumbents and other small and medium-sized operators of smaller systems to participate in geographic area licensing. Adopting an EA-based licensing scheme may permit small bidders and rural companies wishing smaller license areas to obtain them directly at auction rather than facing the uncertainty and transaction costs of working out post-auction partitioning agreements.

27. In paragraphs 26–30 of the *NPRM*, the Commission proposes to license the 900 MHz flexible-use channels in nineteen blocks of ten contiguous channels each, and one block of nine contiguous channels, with each ten-channel block separately licensed. Under the Commission's proposal, applicants would be permitted to aggregate blocks if they wish, without eligibility restriction for any channel block. The Commission seeks comment on whether the proposed 900 MHz channel block plan strikes a balance in affording small, medium and large operators the opportunity to obtain sufficient spectrum to establish viable and competitive wide-area systems, and whether the plan offers a middle ground between larger channel blocks that may block entry to new, smaller operators, and smaller block sizes that may hinder wide-area operations.

28. In paragraphs 45–51 of the *NPRM*, the Commission proposes that the new 900 MHz licensees submit to the Commission a showing of substantial service in their licensed area within five or ten years of being licensed. In making this proposal, the Commission notes that a population-based benchmark may be a considerable obstacle for the provision of services in rural or sparsely populated areas, and that population-based coverage requirements may be difficult to achieve due to existing band encumbrances. The Commission also believes that the ten-year substantial service requirement provides greater flexibility for parties interested in entering into spectrum leasing arrangements involving this spectrum.

29. In paragraphs 58–63 of the *NPRM*, the Commission proposes small business bidding credits to further the goals of ensuring that small businesses, rural telephone companies, and businesses owned by members of minority groups and women are given the opportunity to participate in the provision of spectrum-based services, and promoting economic opportunity and competition by avoiding excessive concentration of licenses and by disseminating licenses among a wide variety of applicants, including small businesses, rural telephone companies,

and businesses owned by members of minority groups and women. To that end, the Commission proposes a 10 percent bidding credit for small business and a 15 percent bidding credit for very small businesses.

30. The Commission requests comment on how these proposed rules may be modified to reduce the burden on small entities and still meet the objectives of the proceeding.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

31. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof for small entities.

32. The *NPRM* proposes to establish small business bidding credits to further the goals of ensuring that small businesses, rural telephone companies, and businesses owned by members of minority groups and women are given the opportunity to participate in the provision of spectrum-based services, with a 10 percent bidding credit for small business and a 15 percent bidding credit for very small businesses. In addition, the *NPRM* solicits comment on a number of proposals and alternatives regarding the service rules for the 900 MHz band, and seeks to adopt rules that will reduce regulatory burdens, promote innovate services and encourage flexible use of this spectrum. The Commission believes the proposed rules will open up economic opportunities to a variety of spectrum users, which could include small businesses. Because the Commission seeks to minimize, to the extent possible, the economic impact on small businesses, the *NPRM* sets forth various proposals and alternatives for parties to consider.

33. The *NPRM* invites comment on various alternative licensing and service rules and on a number of issues relating to how the Commission should craft service rules for this spectrum that could have an impact on small entities. The *NPRM* proposes a geographic area approach to service areas, as opposed to a station-defined licensing approach, and seeks comment on the appropriate size of service areas. Specifically, the *NPRM* asks for comment on whether smaller geographic areas would better serve the needs of small entities.

34. The regulatory burdens proposed in the *NPRM* appear necessary in order to ensure that the public receives the benefits of innovative new services, or enhanced existing services, in a prompt and efficient manner. The Commission will continue to examine alternatives in the future with the objectives of eliminating unnecessary regulations and minimizing any significant economic impact on small entities. The Commission invites comment on any additional significant alternatives parties believe should be considered and on how the approach outlined in the *NPRM* will impact small entities, including small businesses and small government entities.

IV. Ordering Clauses

35. Pursuant to the authority of sections 1, 2, 4(i), 7, 10, 201, 214, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332 and 333 of the Communications Act of 1934, 47 U.S.C. 151, 152, 154(i), 157, 160, 201, 214, 301, 302, 303, 307, 308, 309, 310, 319, 324, 332, 333, this *Notice of Proposed Rulemaking* is adopted.

List of Subjects of 47 CFR part 90

Communications common carriers.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Proposed Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 90 as follows:

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

1. The authority citation of part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7).

2. Amend § 90.7 by adding the definitions ''Major Economic Area (MEA)'' and ''MEA-based license or MEA license'' in alphabetical order to read as follows:

§ 90.7 Definitions.

* * * * *

Major Economic Area (MEA). An aggregation of Basic Economic Areas (BEAs) into 52 regions, including the Gulf of Mexico.

* * * * *

MEA-based license or MEA license. A license authorizing the right to use a specified block of SMR spectrum with one of the 52 Major Economic Areas (''MEAs'').

* * * * *

§ 90.210 [Amended]

3. Amend § 90.210 as follows:

(a) In the entry for 5850–5925 of the table ''APPLICABLE EMISSIONS MASKS'' redesignate footnote 4 as footnote 5; and

(b) In the same table amend the entry for 896–901/935–940 Frequency band MHz by adding a new footnote 4.

§ 90.210 Emission masks.

* * * * *

APPLICABLE EMISSION MASKS

Frequency band (MHz)	Mask for equipment with audio low pass filter	Mask for equipment without audio low pass filter
* * * * *	*	*
896–901/935–940 [4]	I	J
* * * * *	*	*

[4] Equipment used in this band licensed to MTA, EA or MEA or non geographic based systems shall comply with the emission mask provisions of § 90.669 of this chapter.

* * * * *

4. Amend § 90.617 by revising the section heading, revising paragraph (c) preceding Table 3, by removing the undesignated paragraph also preceding Table 3 (Table 3 remains unchanged), by revising paragraph (f) preceding Table 6 (Table 6 remains unchanged), and by adding Table 7 and a Note to Table 7 to paragraph (f) to read as follows:

§ 90.617 Frequencies in the 809.750–824/854.750–869 MHz, and 896–901/935–940 MHz bands available for trunked, conventional, or cellular system use in non-border areas.

* * * * *

(c) The channels listed in Table 3 are available to applicants eligible in the Industrial/Business Pool of subpart C of this part but exclude Special Mobilized Radio Systems as defined in § 90.603(c). These frequencies are available in non-border areas. Specialized Mobile Radio (SMR) systems may be authorized on these frequencies after [*Effective date of Report and Order*]. For multi-channel systems, channels may be grouped vertically or horizontally as they appear in the following table.

* * * * *

(f) The channels listed in Table 6 are available for operations only to eligibles in the SMR category—which consists of Specialized Mobile Radio (SMR) stations and eligible end users. These frequencies are available in non-border areas.

* * * * *

Note to Table 7: The channels listed in Table 7 are available to Business/Industrial/Land Transportation of SMR eligibles for EA-based or MEA-based licensing.

TABLE 7.—896–901/935–940 MHZ BAND CHANNELS (199 CHANNELS) AVAILABLE AFTER [EFFECTIVE DATE OF REPORT AND ORDER] FOR BUSINESS/INDUSTRIAL/LAND TRANSPORTATION OR SMR ELIGIBLES FOR EA-BASED OR MEA-BASED LICENSING

Block	Channel Nos.
AA	11–12–13–14–15–16–17–18–19–20
BB	31–32–33–34–35–36–37–38–39–40
CC	51–52–53–54–55–56–57–58–59–60
DD	71–72–73–74–75–76–77–78–79–80
EE	91–92–93–94–95–96–97–98–99–100
FF	111–112–113–114–115–116–117–118–119–120
GG	131–132–133–134–135–136–137–138–139–140
HH	151–152–153–154–155–156–157–158–159–160
II	171–172–173–174–175–176–177–178–179–180
JJ	191–192–193–194–195–196–197–198–199–200
KK	211–212–213–214–215–216–217–218–219–220
LL	231–232–233–234–235–236–237–238–239–240
MM	251–252–253–254–255–256–257–258–259–260
NN	271–272–273–274–275–276–277–278–279–280
OO	291–292–293–294–295–296–297–298–299–300
PP	311–312–313–314–315–316–317–318–319–320
QQ	331–332–333–334–335–336–337–338–339–340
RR	351–352–353–354–355–356–357–358–359–360
SS	371–372–373–374–375–376–377–378–379–380
TT	391–392–393–394–395–396–397–398–399

* * * * *

5. Amend § 90.619 by revising paragraph (b)(1) and removing the undesignated text following paragraph (b)(1) (Table 1 remains unchanged); revise paragraph (b)(2) and redesignate Table 2 in paragraph (b)(2) as Table 2A, and by adding Table 2B, and a Note to Table 2B in paragraph (b)(2) to read as follows:

§ 90.619 Frequencies available for use in the U.S./Mexico and U.S./Canada border areas.

* * * * *

(b) * * *

(1) The channels listed in Table 1 are available to applicants eligible in the Industrial/Business Pool of subpart C of this part but exclude Special Mobilized Radio Systems as defined in § 90.603(c). These frequencies are available within the Mexico border region. Specialized Mobile Radio (SMR) systems may be authorized on these frequencies after [*Effective date of Report and Order*]. For multi-channel systems, channels may be grouped vertically or horizontally as they appear in the following table. Channels numbered above 200 may be used only subject to the power flux density limits stated in paragraph (a)(2) of this section.

* * * * *

(2) The channels listed in Table 2A below are available for operations only to eligibles in the SMR category—which consists of Specialized Mobile Radio (SMR) stations and eligible end users. These frequencies are available in the Mexico border region.

* * * * *

Note to Table 2B: The channels listed in Table 2B are available to Business/Industrial/Land Transportation or SMR eligibles for EA or MEA based licensing in the Mexico border region after [*Effective date of Report and Order*].

TABLE 2B.—896–901/935–940 MHZ BAND CHANNELS (199 CHANNELS) AVAILABLE AFTER [EFFECTIVE DATE OF REPORT AND ORDER] FOR BUSINESS/INDUSTRIAL/LAND TRANSPORTATION OR SMR ELIGIBLES FOR EA-BASED OR MEA-BASED LICENSING IN UNITED STATES-MEXICO BORDER AREA

Block	Channel Nos.
AA	11–12–13–14–15–16–17–18–19–20

TABLE 2B.—896–901/935–940 MHZ BAND CHANNELS (199 CHANNELS) AVAILABLE AFTER [EFFECTIVE DATE OF REPORT AND ORDER] FOR BUSINESS/INDUSTRIAL/LAND TRANSPORTATION OR SMR ELIGIBLES FOR EA-BASED OR MEA-BASED LICENSING IN UNITED STATES-MEXICO BORDER AREA—Continued

Block	Channel Nos.
BB	31–32–33–34–35–36–37–38–39–40
CC	51–52–53–54–55–56–57–58–59–60
DD	71–72–73–74–75–76–77–78–79–80
EE	91–92–93–94–95–96–97–98–99–100
FF	111–112–113–114–115–116–117–118–119–120
GG	131–132–133–134–135–136–137–138–139–140
HH	151–152–153–154–155–156–157–158–159–160
II	171–172–173–174–175–176–177–178–179–180
JJ	191–192–193–194–195–196–197–198–199–200
KK	211–212–213–214–215–216–217–218–219–220
LL	231–232–233–234–235–236–237–238–239–240
MM	251–252–253–254–255–256–257–258–259–260
NN	271–272–273–274–275–276–277–278–279–280
OO	291–292–293–294–295–296–297–298–299–300
PP	311–312–313–314–315–316–317–318–319–320
QQ	331–332–333–334–335–336–337–338–339–340
RR	351–352–353–354–355–356–357–358–359–360
SS	371–372–373–374–375–376–377–378–379–380
TT	391–392–393–394–395–396–397–398–399

Channels numbered above 200 may only be used subject to the power flux density limits at or beyond the Mexico border as stated in paragraph (4) of this section.

* * * * *

6. Amend § 90.621 by revising paragraph (b) introductory text to read as follows:

§ 90.621 Selection and assignment of frequencies.

* * * * *

(b) Stations authorized on frequencies listed in this subpart, except for those stations authorized pursuant to paragraph (g) of this section and geographic-area-based systems, will be assigned frequencies solely on the basis of fixed distance separation criteria. The separation between co-channel systems will be a minimum of 113 km (70 mi) with one exception. For incumbent licensees in Channel Blocks G through V, that have received the consent of all affected parties or a certified frequency coordinator to utilize an 18 dBμV/m signal strength interference contour (see § 90.693), the separation between co-channel systems will be a minimum of 173 km (107 mi). The following exceptions to these separations shall apply:

* * * * *

7. Amend § 90.669 by revising paragraph (a) to read as follows. The note following paragraph (a) remains unchanged.

§ 90.669 Emission limits.

(a) Out-of-band emission requirements shall apply only to the ''outer'' channels included in an MTA, EA, or MEA licensee and to spectrum adjacent to interior channels used by incumbent licensees. On any frequency in a MTA, EA, or MEA geographic-area-based licensee's spectrum block that is adjacent to another licensee's frequency, the power of any emission shall be attenuated below the transmitter power (P) by at least 43 plus 10 $\log_{10}$(P) decibels or 80 decibels, whichever is the lesser attenuation.

* * * * *

8. Revise § 90.671 to read as follows:

§ 90.671 Field strength limits.

The predicted or measured field strength at any location on the border of the service area for 896–901/935–940 MHz geographic-area-based licensees shall not exceed 40 dBμV/m unless all co-channel bordering geographic-area-based licensees agree to a higher field strength. Geographic-area-based licensees are also required to coordinate their frequency usage with co-channel adjacent geographic-area-based licensees and all other affected parties. To the extent that a single entity obtains licenses for adjacent MTAs, EAs or MEAs on the same channel block, it will not be required to coordinate its operations in this manner. In the event that this standard conflicts with the geographic-area-based licensee's obligation to provide co-channel protection to incumbent licensees under § 90.621(b), the requirements of § 90.621(b) shall prevail.

9. Amend subpart S by adding the undesignated center heading and §§ 90.678, 90.679, and 90.680 to read as follows:

Policies Governing Licensing and Use of EA-Based or MEA-Based Business/Industrial/Land Transportation or SMR Systems in the 896–901/935–940 MHz Band

§ 90.678 EA-Based or MEA-Based Business/Industrial/Land Transportation or SMR service areas.

EA or MEA licenses for spectrum blocks AA, BB, through TT, in the 896–940 MHz band listed in table 7 of § 90.617(f) are available in 175 Economic Areas (EAs) or 52 Major Economic Areas (MEAs) as defined in § 90.7. Within these EAs or MEAs, licenses will be authorized in ten channel blocks as specified in table 7 of § 90.617(f) through the competitive bidding procedures described in subpart U of this part.

§ 90.679 EA or MEA-based Business/Industrial/Land Transportation or SMR system operations.

(a) EA or MEA-based licensees authorized in the 896–901/935–940 MHz band pursuant to § 90.678 may construct and operate base stations using any frequency identified in their spectrum block anywhere within their authorized licensed area, provided that:

(1) The EA or MEA licensee complies with any rules and international agreements that restrict use of frequencies identified in their spectrum block, including the provisions of § 90.619 relating to U.S./Canadian and U.S./Mexican border areas.

(2) The EA or MEA licensee limits its field strength at any location on the border of the service area in accordance

with § 90.671 and masks its emissions in accordance with § 90.669.

(b) In the event that the authorization for a previously authorized co-channel station within the geographic-area-based licensee's authorized spectrum block is terminated or revoked, the licensee's co-channel obligations to such station will cease upon deletion of the facility from the Commission's licensing record. The EA or MEA licensee then will be able to construct and operate base stations using such frequency.

§ 90.680 Authorization, construction and implementation of EA or MEA-based licenses and Grandfathering provisions for incumbent licensees.

(a) Geographic-area-based licenses in the 896–901/935–940 MHz band will be issued for a term not to exceed ten years.

(b) Each geographic-area-based licensee in the 896–901/935–940 MHz band must demonstrate, through a showing to the Commission ten years from the date of license grant, that it is providing substantial service within its service area.

(c) Geographic-area-based licensees who fail to make a convincing showing of substantial service by the end of the tenth year after grant of authorization will forfeit the portion of the geographic-area-based license that exceeds licensed facilities constructed and operating on the date of the license grant.

(d) *Grandfathering provisions for incumbent licensees.* An incumbent licensee's service area shall be defined by its originally-licensed 40 dBμV/m field strength contour. Incumbent licensees are permitted to add new or modify transmit sites in this existing service area so long as the original 40 dBμV/m field strength contour is not expanded.

[FR Doc. 05–5406 Filed 3–17–05; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 050304058–5058–01; I.D. No. 060204C]

RIN 0648–XB29

Endangered and Threatened Wildlife and Plants; 12–Month Finding on a Petition To List Elkhorn Coral, Staghorn coral, and Fused-staghorn coral as Threatened or Endangered

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of petition finding and availability of a status review document.

SUMMARY: NMFS announces a 12–month finding on a petition to add the elkhorn coral (*Acropora palmata*), staghorn coral (*A. cervicornis*), and fused-staghorn coral (*A. prolifera*), throughout their known range, to the list of threatened and endangered wildlife and to designate critical habitat under the Endangered Species Act (ESA). Based on a review of the best available scientific and commercial information on the status of the species, NMFS finds that the petitioned action is warranted with respect to elkhorn and staghorn corals and will promptly publish a proposed rule to list these two species as threatened. Furthermore, NMFS concludes that listing fused-staghorn coral is not warranted as it is a hybrid and does not constitute a species.

DATES: The finding announced in this document was made on March 3, 2005.

ADDRESSES: Copies of the Atlantic *Acropora* status review document are available upon request from the Protected Resources Division, NMFS, 9721 Executive Center Drive North, St. Petersburg, FL 33702. After March 17, 2005, please direct requests to our new address: 263 13th Ave. South, St. Peterburg, FL 33701. The status review is also available on the NMFS website at *http://sero.nmfs.noaa.gov/pr/protres.htm*.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Moore or Dr. Stephania Bolden, NMFS Southeast Region, 727–570–5312, or Ms. Marta Nammack, HQ Office of Protected Resources, 301–713–1401, ext. 180. Please note the NMFS Southeast Regional Office is moving March 17, 2005 and after March 21, 2005, the new telephone exchange will be 727–824–5312.

SUPPLEMENTARY INFORMATION: Pursuant to section 4(b)(3)(B) of the ESA (16 U.S.C. 1531 *et seq.*), for any petition to revise the List of Endangered or Threatened Wildlife and Plants which presents substantial scientific and commercial information, NMFS is required to make a finding within 12 months of the date of receipt of the petition on whether the petitioned action is (a) not warranted, (b) warranted, or (c) warranted but precluded from immediate proposal by other pending proposals of higher priority.

On March 4, 2004, the Center for Biological Diversity (CBD) petitioned NMFS to list elkhorn (*Acropora palmata*), staghorn (*A. cervicornis*), and fused-staghorn (*A. prolifera*) coral as either threatened or endangered under the Endangered Species Act (ESA) and to designate critical habitat. On June 23, 2004, NMFS made a positive 90–day finding (69 FR 34995) that the CBD presented substantial information indicating that the petitioned actions may be warranted and announced the initiation of a formal status review as required by section 4(b)(3)(A) of the ESA.

In order to conduct a comprehensive review, NMFS convened an Atlantic *Acropora* Biological Review Team (BRT) to conduct the status review, which incorporates and summarizes the best available scientific and commercial data to date. It addresses the status of the species, the five ESA listing factors, and current regulatory, conservation and research efforts that may yield protection. The BRT also reviewed and considered materials received by NMFS as a result of a **Federal Register** notice and public meetings; substantive materials were incorporated into the status review. Copies of the status review are available upon request from the Protected Resources Division, NMFS (see **ADDRESSES**). NMFS finds that with respect to elkhorn and staghorn corals, the petitioned action is warranted at this time. NMFS will promptly publish a proposed rule to list these two species as threatened. Furthermore, NMFS concludes that listing fused-staghorn coral is not warranted as it is a hybrid and does not constitute a species.

According to section 4(b)(3(B) of the ESA, 16 U.S.C. 4(b)(3)(B), when a petitioned action is warranted, a proposed regulation to implement the action shall be promptly published in the **Federal Register**. NMFS will immediately begin developing a proposed rule to list the two species as threatened to comply with the ESA's requirement to publish the proposed listing rule promptly. NMFS will also

begin contacting and coordinating with State/Territory and NOAA resource managers to identify activities that may adversely affect the species and potential take exemptions that should be identified in a 4(d) rule, as necessary to provide for the conservation of these threatened species.

After publication of a proposed rule to list the species and establish protective regulations, regulations at 50 CFR 424.16 specify that NMFS allow for public comments regarding the proposed rule and hold public hearings if requested. Within 1 year of publishing the proposed listing regulation, a final rule to list the species, a notice extending the 1–year period, or a notice withdrawing the proposed listing must be published in the **Federal Register**.

The ESA requires that a final rule designating critical habitat of an endangered or threatened species shall be, to the maximum extent prudent, published concurrently with the final rule listing the species (ESA 4(a)(3)(A)). If at that time critical habitat is undeterminable, the period may be extended by not more than 1 additional year.

Authority

The authority for this section is the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 11, 2005.

William T. Hogarth,

Assistant Administrator for Fisheries,National Marine Fisheries Service.

[FR Doc. 05–5346 Filed 3–14–05; 4:33 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 050309066–5066–01; I.D. 030105D]

RIN 0648–AS53

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Amendment 15

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule to implement Amendment 15 to the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). This proposed rule would establish a limited access system for the commercial fishery for Gulf and Atlantic migratory group king mackerel by capping participation at the current level. The proposed rule also would change the fishing year for Atlantic migratory group king and Spanish mackerel to be March through February. The intended effects of this proposed rule are to provide economic and social stability in the fishery by preventing speculative entry into the fishery and to mitigate adverse impacts associated with potential quota closures.

DATES: Comments must be received no later than 5 p.m., eastern time, on May 2, 2005.

ADDRESSES: You may submit comments on the proposed rule by any of the following methods:

- E-mail: *0648–AS53.Proposed@noaa.gov*. Include in the subject line the following document identifier: 0648–AS53.
- Federal e-Rulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Steve Branstetter, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.
- Fax: From March 22, 2005, through May 2, 2005, 727–824–5308. Comments cannot be received via fax from March 18 through March 21, 2005.

Copies of Amendment 15, which includes an environmental assessment, a regulatory impact review (RIR), and an initial regulatory flexibility analysis (IRFA), may be obtained from the Gulf of Mexico Fishery Management Council, The Commons at Rivergate, Suite 1000, 3018 U.S. Highway 301 North, Tampa, FL 33619; telephone: 813–228–2815; fax: 813–225–7015; e-mail: *gulfcouncil@gulfcouncil.org*; or from the South Atlantic Fishery Management Council, One Southpark Circle, Suite 306, Charleston, SC 29407–4699; telephone: 843–571–4366; fax: 843–769–4520; e-mail: *safmc@safmc.net*.

FOR FURTHER INFORMATION CONTACT: Steve Branstetter; telephone: 727–570–5305; fax: 727–570–5583 (through March 18, 2005), 727–824–5308 (on and after March 22, 2005); e-mail: *Steve.Branstetter@noaa.gov*.

SUPPLEMENTARY INFORMATION: The fisheries for coastal migratory pelagic resources are managed under the FMP. The FMP was prepared jointly by the Gulf of Mexico Fishery Management Council and the South Atlantic Fishery Management Council (Councils), approved by NMFS, and implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Background

Prior to 1998, the commercial king mackerel fishery in the exclusive economic zone of the Gulf of Mexico and Atlantic operated under open access. Due to concerns about increasing levels of participation in these fisheries, the Councils established a commercial king mackerel vessel permit moratorium in Amendment 8 to the FMP in March 1998. Amendment 12 extended the expiration date of the moratorium through October 15, 2005, or until the moratorium could be replaced with a license limitation, limited access, and/or individual fishing quota or individual transferable quota system, whichever occurred earlier. The effects of the existing permit moratorium have been to prevent increases in effort, reduce the number of permittees in the king mackerel fishery, and help stabilize the economic performance of current participants. Under the moratoria, the number of commercial king mackerel permits has declined from a peak of 2,172 in July 1998 to 1,683 in August 2004.

Current commercial king mackerel fishery participants, especially in the Gulf of Mexico, have demonstrated the capability of harvesting the applicable quotas well in advance of the end of the various fishing seasons, resulting in early closures of the fishery. Allowing the fishery to revert to open access would result in an increased number of participants in these mackerel fisheries, most likely negating any reductions in effort that have been achieved as a result of the current moratorium. Any increase in participants would: exacerbate the current derby fisheries that occur in the western Gulf zone and in the Florida west coast gillnet fishery, lead to even earlier closures, possibly result in closures of the Atlantic group king mackerel fishery, and have an adverse impact on the economic performance of current participants. Increased participation would also compound the complexity of any future consideration by the Councils to develop a more comprehensive controlled access system for this fishery. For these reasons, the Councils have concluded that a limited access system to continue restrictions on participation levels in these fisheries is appropriate.

Provisions of Amendment 15

Limited Access System

Amendment 15 would establish a limited access system for the commercial fishery for Gulf and Atlantic group king mackerel by capping participation at the current level. Under the proposed limited access system, an owner of a vessel with a valid commercial vessel permit for king mackerel and/or a valid king mackerel gillnet endorsement on the date that Amendment 15 is approved (assuming approval) would be issued the applicable permits under the limited access system. Commercial vessel permits for king mackerel would become limited access permits and king mackerel gillnet endorsements would become king mackerel gillnet permits, upon their renewal. Other than the changes in the terminology, i.e., limited access versus moratorium, there would be no changes to the current procedures for application, qualification, issuance, renewal, or transferability of these permits.

Change the Fishing Year

Amendment 15 would also change the fishing year for Atlantic migratory groups of king and Spanish mackerel to March 1 through February 28–29. The current fishing year for Atlantic migratory groups of both king and Spanish mackerel extends from April 1 through March 31. The commercial quota for Atlantic group king mackerel has only been met three times to date. However, should quotas need to be reduced in the future, there is a potential for the commercial quota to be met and the fishery to be closed prior to and through the end of the season (i.e., in March). A March closure could adversely affect the social and economic stability of South Atlantic mackerel fisheries due to the compounding effect of established seasonal commercial closures for alternative target species during that same month. For example, the red porgy fishery is closed January through April, and the gag and black grouper fishery is closed in March and April. By changing the opening date of the season to March 1, the Councils reduce the possibility of multiple overlapping or simultaneous commercial fishery closures.

Classification

At this time, NMFS has not determined whether Amendment 15, which this rule would implement, is consistent with the national standards of the Magnuson-Stevens Act and other applicable laws. NMFS, in making that determination, will take into account the data, views, and comments received during the comment periods on Amendment 15 and on this proposed rule.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

NMFS prepared an IRFA, as required by section 603 of the Regulatory Flexibility Act. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the SUMMARY section of the preamble. A copy of the full analysis is available from the Council office (see **ADDRESSES**). A summary of the analysis follows.

This proposed rule would establish a limited access system for the commercial fishery for Gulf and Atlantic group king mackerel and change the Atlantic migratory group king and Spanish mackerel fishing year to begin March 1 rather than the current April 1. The purpose of the proposed rule is to provide stability in the Southeast commercial king mackerel fishery as part of the overall strategy to achieve optimum yield and maximize the overall benefits to the Nation provided by the fishery and insure that the Atlantic group king mackerel fishery is open in March. The Magnuson-Stevens Act provides the statutory basis for the proposed rule.

No duplicative, overlapping, or conflicting Federal rules have been identified.

An estimated 1,740 vessels were permitted to fish for commercial king mackerel in 2003, down from 2,172 in 1998. Approximately half of the vessels with permits had logbook-reported landings, 1,066 in 1998 and 951 in 2003. The median annual gross revenue from all logbook-reported sales of finfish by these vessels ranged from approximately $11,000 to $12,000 during this period. The median percentage of gross revenues attributable to king mackerel ranged from 22 percent to 33 percent. Although participation in the fishery has declined since 1998, this decline has been voluntary and presumed attributable to economic conditions in this fishery and fishing in general and not due to regulatory restrictions. Although a permit moratorium has been in place in this fishery since 1998, permit transfer is not restricted, and those seeking to enter the fishery can purchase a permit from permit holders. Such transfers in fact occur, and 309 of the 1,740 permits in 2003 were permits that had been transferred since 1998. Thus, entry into the fishery occurs; however, total participation, in terms of both the number of permits and the number of permitted vessels that land fish, has consistently declined since 1998, indicating that entry is not limited by a lack of available permits.

The proposed rule would affect all current participants in the fishery. The rule would similarly affect all entities interested in entering the fishery. No estimate of this number can be provided, though it is not expected to be substantial due to the decline in total participation in the fishery despite available entry opportunities.

The proposed rule would not change current reporting, recordkeeping, and other compliance requirements under the FMP. These requirements include qualification criteria for the commercial vessel permit and logbook landing reports. All of the information elements required for these processes are standard elements essential to the successful operation of a fishing business and should, therefore, already be collected and maintained as standard operating practice by the business. The requirements do not require professional skills; therefore, they are not deemed to be onerous.

One general class of small business entities would be directly affected by the final rule--commercial fishing vessels. The Small Business Administration defines a small business that engages in commercial fishing as a firm that is independently owned and operated, is not dominant in its field of operation, and has annual receipts up to $3.5 million per year. Based on the revenue profiles provided above, all commercial entities operating in the king mackerel fisheries are considered small entities.

The proposed rule would apply to all entities that operate in the commercial king mackerel fishery and those entities interested in or seeking to enter the fishery. The proposed rule would, therefore, affect a substantial number of small entities.

Whether a rule has a ''significant economic impact'' can be ascertained by examining two issues: disproportionality and profitability. The disproportionality question is: Do the regulations place a substantial number of small entities at a significant competitive disadvantage to large entities? All the vessel operations affected by the proposed rule are considered small entities, so the issue of disproportionality does not arise in the present case.

The profitability question is: Do the regulations significantly reduce profit for a substantial number of small

entities? The proposed rule would continue the limited access system in the fishery. Continuation of this system would be expected to increase profitability for the entities remaining in the fishery if participation continues to decline, as has occurred since 1998. Should the decline in participation cease, profits would be expected to continue at current levels. Should the fishery revert to open access, participation would be expected to increase, and average profit per participant would be expected to decline, possibly to the point of elimination of all profits from this fishery. The specification of the fishing year is essentially an administrative action, because no closures of either the Atlantic migratory group king or Spanish mackerel fisheries are expected. Thus, change of the start of the fishing year is not expected to have any effect on profits of fishery participants.

The proposed rule would continue the requirement to have a vessel permit in order to participate in the commercial king mackerel fishery. The cost of the permit is $50, and renewal is required every other year (the permit is automatically renewed the second year). Because this is a current requirement, there would be no additional impacts on participant profits as a result of this requirement.

Three alternatives were considered to establishment of the proposed limited access system. The no action alternative would allow the fishery to revert to open access. Open access conditions would be expected to lead to an increase in the number of permitted vessels (1,740 vessels in 2003), or, at least, slow the rate of decline in participation that has occurred. Any increase in the number of vessels landing king mackerel would lead to an expected decrease in producer surplus from that in 2003, estimated at $142,650 to $380,400.

Two alternatives would continue the current moratorium on issuing new king mackerel commercial permits for 5 years or 10 years, respectively, compared to the proposed rule which would establish an indefinite limited access program. Thus, the fishery would continue as a limited access fishery under each of these alternatives. It is not possible to distinguish these alternatives from the proposed rule empirically in terms of fishery behavior using available data. However, it is not unreasonable to assume that fishermen believe that regardless of the duration of the program specified, a precedent for indefinite use of private market mechanisms to allow entry into the fishery has been established, given the history of successfully functioning private markets for vessel permits. Thus, the outcomes of these three alternatives are expected to be functionally equivalent. As stated previously, under the current permit moratorium program, the fishery is estimated to have generated $142,650 to $380,400 in producer surplus. Assuming the increase in producer surplus mirrors the rate of fleet contraction exhibited from 1998 through 2003 (2.2 percent), the resultant estimates of producer surplus are approximately $166,000 to $443,000 by 2010, and $185,000 to $494,000 by 2015. Each alternative would also continue to provide for market-based compensation for vessels that exit the fishery, and the permit market would continue to provide an economically rational basis for regulating the entry of vessels into the commercial king mackerel fishery and allocating access to fishery resources among competing users in the commercial fisheries.

Although the preferred alternative would imply a more permanent system than the alternatives, the system established under any alternative could be suspended at any time through appropriate regulatory action. Establishing an indefinite duration, however, eliminates the need for action to continue the system at specific time intervals, thereby eliminating the costs associated with the regulatory process. The administrative and development cost of the current action is estimated to be $200,000. Further, the preferred alternative may better address the Councils' purpose of providing stability in the commercial and recreational fisheries for king mackerel, preventing speculative entry into the commercial fisheries, and achieving optimum yield. The status quo alternative would not achieve the Councils' objectives.

Two alternatives are considered relative to the proposed change in the fishing year for Atlantic migratory group king and Spanish mackerel. The status quo alternative would maintain the current fishing year, April 1 through March 31, while a second alternative would establish a January 1 through December 31 fishing year. The Councils' objective is to insure that the Atlantic group mackerel fisheries are open in March, because other fishing opportunities are limited during this month. Both the preferred alternative and a January 1 opening would reduce the potential of a March closure, however, only the preferred alternative would guarantee such, absent a 0–lb (0–kg) quota. Thus, the preferred alternative best meets the Councils' objectives.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: March 14, 2005.

Rebecca Lent

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 622.4, paragraphs (a)(2)(ii), (a)(2)(iii), (g)(1), (o), and (q) are revised to read as follows:

§ 622.4 Permits and fees.

(a) * * *

(2) * * *

(ii) *Gillnets for king mackerel in the southern Florida west coast subzone.* For a person aboard a vessel to use a run-around gillnet for king mackerel in the southern Florida west coast subzone (see § 622.42(c)(1)(i)(A)(3)), a commercial vessel permit for king mackerel and a king mackerel gillnet permit must have been issued to the vessel and must be on board. See paragraph (o) of this section regarding a limited access system applicable to king mackerel gillnet permits and restrictions on transferability of king mackerel gillnet permits.

(iii) *King mackerel.* For a person aboard a vessel to be eligible for exemption from the bag limits and to fish under a quota for king mackerel in or from the Gulf, Mid-Atlantic, or South Atlantic EEZ, a commercial vessel permit for king mackerel must have been issued to the vessel and must be on board. To obtain or renew a commercial vessel permit for king mackerel, at least 25 percent of the applicant's earned income, or at least $10,000, must have been derived from commercial fishing (i.e., harvest and first sale of fish) or from charter fishing during one of the three calendar years preceding the application. See paragraph (q) of this section regarding a limited access system applicable to commercial vessel permits for king mackerel, transfers of permits under the limited access system, and limited exceptions to the earned income or gross sales requirement for a permit.

* * * * *

(g) * * *

(1) *Vessel permits, licenses, and endorsements and dealer permits.* A vessel permit, license, or endorsement or a dealer permit issued under this section is not transferable or assignable, except as provided in paragraph (m) of this section for a commercial vessel permit for Gulf reef fish, in paragraph (n) of this section for a fish trap endorsement, in paragraph (o) of this section for a king mackerel gillnet permit, in paragraph (p) of this section for a red snapper license, in paragraph (q) of this section for a commercial vessel permit for king mackerel, in paragraph (r) of this section for a charter vessel/headboat permit for Gulf coastal migratory pelagic fish or Gulf reef fish, in § 622.17(c) for a commercial vessel permit for golden crab, in § 622.18(e) for a commercial vessel permit for South Atlantic snapper-grouper, or in § 622.19(e) for a commercial vessel permit for South Atlantic rock shrimp. A person who acquires a vessel or dealership who desires to conduct activities for which a permit, license, or endorsement is required must apply for a permit, license, or endorsement in accordance with the provisions of this section. If the acquired vessel or dealership is currently permitted, the application must be accompanied by the original permit and a copy of a signed bill of sale or equivalent acquisition papers.

* * * * *

(o) *Limited access system for king mackerel gillnet permits applicable in the southern Florida west coast subzone.* Except for applications for renewals of king mackerel gillnet permits, no applications for king mackerel gillnet endorsements will be accepted. Application forms for permit renewal are available from the RA.

(1) An owner of a vessel with a king mackerel gillnet permit issued under this limited access system may transfer that permit upon a change of ownership of a permitted vessel with such permit from one to another of the following: Husband, wife, son, daughter, brother, sister, mother, or father. Such permit also may be transferred to another vessel owned by the same entity.

(2) A king mackerel gillnet permit that is not renewed or that is revoked will not be reissued. A permit is considered to be not renewed when an application for renewal is not received by the RA within one year after the expiration date of the permit.

* * * * *

(q) *Limited access system for commercial vessel permits for king mackerel.* (1) No applications for additional commercial vessel permits for king mackerel will be accepted. Existing vessel permits may be renewed, are subject to the restrictions on transfer or change in paragraphs (q)(2) through (q)(5) of this section, and are subject to the requirement for timely renewal in paragraph (q)(6) of this section.

(2) An owner of a permitted vessel may transfer the commercial vessel permit for king mackerel issued under this limited access system to another vessel owned by the same entity.

(3) An owner whose percentage of earned income or gross sales qualified him/her for the commercial vessel permit for king mackerel issued under this limited access system may request that NMFS transfer that permit to the owner of another vessel, or to the new owner when he or she transfers ownership of the permitted vessel. Such owner of another vessel, or new owner, may receive a commercial vessel permit for king mackerel for his or her vessel, and renew it through April 15 following the first full calendar year after obtaining it, without meeting the percentage of earned income or gross sales requirement of paragraph (a)(2)(iii) of this section. However, to further renew the commercial vessel permit, the owner of the other vessel, or new owner, must meet the earned income or gross sales requirement not later than the first full calendar year after the permit transfer takes place.

(4) An owner of a permitted vessel, the permit for which is based on an operator's earned income and, thus, is valid only when that person is the operator of the vessel, may request that NMFS transfer the permit to the income-qualifying operator when such operator becomes an owner of a vessel.

(5) An owner of a permitted vessel, the permit for which is based on an operator's earned income and, thus, is valid only when that person is the operator of the vessel, may have the operator qualification on the permit removed, and renew it without such qualification through April 15 following the first full calendar year after removing it, without meeting the earned income or gross sales requirement of paragraph (a)(2)(iii) of this section. However, to further renew the commercial vessel permit, the owner must meet the earned income or gross sales requirement not later than the first full calendar year after the operator qualification is removed. To have an operator qualification removed from a permit, the owner must return the original permit to the RA with an application for the changed permit.

(6) NMFS will not reissue a commercial vessel permit for king mackerel if the permit is revoked or if the RA does not receive an application for renewal within one year of the permit's expiration date.

* * * * *

3. In § 622.30, paragraph (b)(2) is revised, and paragraph (b)(3) is added to read as follows:

§ 622.30 Fishing years.

* * * * *

(b) * * *

(2) *Gulf migratory group Spanish mackerel* - April through March.

(3) *South Atlantic migratory group king and Spanish mackerel* - March through February.

* * * * *

4. In § 622.44, paragraph (a)(2)(ii)(A) is revised to read as follows:

§ 622.44 Commercial trip limits.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(A) *Gillnet gear.* (*1*) In the southern Florida west coast subzone, king mackerel in or from the EEZ may be possessed on board or landed from a vessel for which a commercial vessel permit for king mackerel and a king mackerel gillnet permit have been issued, as required under § 622.4(a)(2)(ii), in amounts not exceeding 25,000 lb (11,340 kg) per day, provided the gillnet fishery for Gulf group king mackerel is not closed under § 622.34(p) or § 622.43(a).

(*2*) In the southern Florida west coast subzone:

(*i*) King mackerel in or from the EEZ may be possessed on board or landed from a vessel that uses or has on board a run-around gillnet on a trip only when such vessel has on board a commercial vessel permit for king mackerel and a king mackerel gillnet permit.

(*ii*) King mackerel from the southern west coast subzone landed by a vessel for which a commercial vessel permit for king mackerel and a king mackerel gillnet permit have been issued will be counted against the run-around gillnet quota of § 622.42(c)(1)(i)(A)(*2*)(*i*).

(*iii*) King mackerel in or from the EEZ harvested with gear other than run-around gillnet may not be retained on board a vessel for which a commercial vessel permit for king mackerel and a king mackerel gillnet permit have been issued.

* * * * *

[FR Doc. 05–5351 Filed 3–17–05; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 050304060–5060–01; I.D. 030105A]

RIN 0648–AS72

Fisheries of the Northeastern United States; Monkfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to establish target total allowable catch (TAC) levels for the monkfish fishery for the 2005 fishing year (FY), and adjust trip limits for limited access monkfish vessels fishing in the Southern Fishery Management Area (SFMA) based upon the annual target TAC setting and trip limit adjustment methods established in Framework Adjustment 2 (Framework 2) to the Monkfish Fishery Management Plan (FMP). The proposed action is necessary to comply with the rebuilding plan established in the FMP and modified in Framework 2. The target TACs for FY 2005, based upon the target TAC setting method, would be 13,160 mt for the Northern Fishery Management Area (NFMA), and 9,673 mt for the SFMA. This action would also adjust the trip limits for vessels fishing in the SFMA, in accordance with the trip limit analysis method established in Framework 2, to be 700 lb (318 kg) tail weight per day-at-sea (DAS) for limited access Category A and C vessels, and 600 lb (272 kg) tail weight per DAS for limited access Category B and D vessels. The intent of this action is to eliminate overfishing and rebuild the monkfish resource in accordance with Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requirements.

DATES: Comments must be received by 5 p.m. on April 4, 2005.

ADDRESSES: Written comments on the proposed rule may be submitted by any of the following methods:

- E-mail: E-mail comments may be submitted to *2005monkfish@noaa.gov*. Include in the subject line the following ''Comments on the Proposed Rule for the 2005 Monkfish Annual Adjustment.''
- Federal e-Rulemaking Portal: *http://www.regulations.gov*.
- Mail: Comments submitted by mail should be sent to Patricia A. Kurkul, Regional Administrator, Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298. Mark the outside of the envelope ''Comments on the Proposed Rule for the 2005 Monkfish Annual Adjustment.''
- Facsimile (fax): Comments submitted by fax should be faxed to (978) 281–9135.

Copies of the Environmental Assessment (EA), including the Regulatory Impact Review (RIR) and Initial Regulatory Flexibility Analysis (IRFA), prepared for this action are available upon request from Paul Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA, 01950. The document is also available online at www.nefmc.org.

FOR FURTHER INFORMATION CONTACT: Allison Ferreira, Fishery Policy Analyst, e-mail *Allison.Ferreira@noaa.gov*, phone (978) 281–9103, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Background

The monkfish fishery is jointly managed by the New England Fishery Management Council (NEFMC) and the Mid-Atlantic Fishery Management Council (MAFMC), with the NEFMC having the administrative lead. Framework 2 to the FMP, which became effective on May 1, 2003 (68 FR 22325; April 28, 2003), implemented a method to set the annual target TAC. This method is based upon the relationship between the 3–year running average of NMFS's fall trawl survey biomass index (3–year average biomass index) and established annual biomass index targets (annual index target). The annual index targets are based on 10 equal increments between the 1999 biomass index (the start of the rebuilding program) and the biomass target (B_{target}), which is to be achieved by 2009 according the rebuilding plan established in the FMP. According to this target TAC setting method, annual target TACs are set based on the ratio of the current 3–year average biomass index to the annual index target applied to the monkfish landings for the previous fishing year. Since the stock rebuilding program established in Framework 2 is based on established formulas for calculating TACs, trip limits, and DAS allocations, the Councils had no discretion to evaluate alternatives relative to this program for FY 2005.

The Monkfish Monitoring Committee reviewed the fall trawl survey biomass indices and monkfish landings for FY 2003, and calculated the target TACs for FY 2005 in accordance with the procedures established in Framework 2. According to these procedures, if the current 3–year average biomass index is below the annual index target, then the target TAC for the upcoming fishing year is set equivalent to the monkfish landings for the previous fishing year, minus the percentage difference between the 3–year average biomass index and the annual index target. Based on the information presented in Table 1, the current 3–year average biomass indices are less than the current targets for both management areas. Therefore, the proposed FY 2005 target TAC for the NFMA is 13,160 mt (6.02 percent less than FY 2003 landings), and the proposed FY 2005 target TAC for the SFMA is 9,673 mt (18.26 percent less than FY 2003 landings).

TABLE 1. CALCULATION OF 2005 TARGET TACS.

Management Area	FY 2003 Landings (mt)	2004 3–year Average (kg/tow)	2004 Biomass Target (kg/tow)	% Below Biomass Target	2005 Target TAC (mt)
NFMA	14,004	1.56	1.66	6.02 %	13,160
SFMA	11,834	0.94	1.15	18.26 %	9,673

This action does not propose any changes to the management measures for limited access monkfish vessels fishing in the NFMA, since such changes are unnecessary in order to achieve the proposed target TAC for FY 2005. Currently, limited access monkfish vessels fishing exclusively in the NFMA are not subject to a monkfish trip limit when fishing under either a monkfish or a Northeast (NE) multispecies DAS. However, it is

unlikely that vessels fishing in the NFMA would exceed the proposed target TAC of 13,160 mt, since this target TAC is less than 900 mt below the 2003 landings, and the reduction in NE multispecies DAS allocations under Amendment 13 to the NE Multispecies FMP, implemented in FY 2004, is expected to further constrain monkfish landings. In fact, current FY 2004 monkfish landings (preliminary) for May through September are 3,913 mt for the NFMA, which is 70 percent of the May through September landings for the NFMA for FY 2003 (5,551 mt). If current FY 2004 and future FY 2005 landings continue to follow the same trajectory, expected landings of approximately 10,000 mt would be well below the FY 2004 and proposed FY 2005 target TACs. However, if changes to the management measures for the NFMA were required to prevent the target TAC from being exceeded, a separate regulatory action would be required, since changes to management measures in the NFMA are currently not authorized under the annual adjustment procedures specified under 50 CFR 648.96(b).

For the SFMA, this action proposes to restore the DAS available to limited access monkfish vessels fishing in the SFMA, but adjust the trip limits to correspond to the proposed target TAC. Framework 2 established a procedure for the SFMA that requires either the DAS or the trip limits to be adjusted as follows: (1) For years in which the target TAC is less than 8,000 mt, the trip limits will be held constant at 550 lb (250 kg) (for Category A and C vessels) and 450 lb (204 kg) (for Category B and D vessels), and the available DAS will be reduced from 40 DAS to provide the necessary reduction in landings; and (2) for years in which the target TAC is greater than 8,000 mt, the available DAS will be held constant at 40 DAS, but the trip limits will be adjusted to a level appropriate to ensure that the target TAC is not exceeded. Currently, limited access monkfish vessels are allowed to fish only 28 of their annual allocation of 40 monkfish DAS (plus carryover DAS) in the SFMA. This DAS usage restriction was implemented for FY 2004 because the target TAC of 6,772 mt was less than 8,000 mt. Because the proposed 2005 target TAC for the SFMA is above the 8,000–mt threshold, limited access monkfish vessels would be authorized to use all 40 monkfish DAS allocated annually (plus carryover DAS) in either management area under the proposed action.

To account for the proposed FY 2005 target TAC being 18 percent less than FY 2003 landings, this action proposes to establish trip limits of 700 lb (318 kg) tail weight per DAS for limited access Category A and C vessels, and 600 lb (272 kg) tail weight per DAS for limited access Category B and D vessels. The proposed trip limits represent a 27–percent increase for Category A and C vessels, and a 25–percent increase for Category B and D vessels when compared to current FY 2004 trip limits (550 lb (250 kg) and 450 lb (204 kg)) tail weight for Category A and C, and Category B and D vessels, respectively). These trip limits were calculated using the trip limit analysis procedures established in Framework 2, and outlined in the regulations at § 648.96(b)(2).

Classification

NMFS has determined that the proposed rule is consistent with the FMP and preliminarily determined that the rule is consistent with the Magnuson-Stevens Act and other applicable laws.

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

The NEFMC prepared an IRFA as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this preamble and in the SUMMARY. A summary of the analysis follows:

The FMP requires that the status of the monkfish resource be reviewed on an annual basis. In addition, the measures contained in Framework 2 established an annual target TAC setting method that is based on the most recent 3–year running average of the NMFS fall trawl survey biomass index as compared to an established annual index target. Framework 2 also established a method for adjusting trip limits and DAS, as necessary, for vessels fishing in the SFMA in order to achieve the target TAC for that area. This action utilizes the target TAC setting method and the trip limit adjustment implemented in Framework 2 to establish target TACs and trip limits for FY 2005.

The regulations implementing the FMP, found at 50 CFR part 648, subpart F, authorize the Council to adjust the management measures as needed in order to achieve the goals of the FMP. Framework 2 adjusted FMP management measures by establishing a streamlined process for setting annual target TACs, and for adjusting trip limits and DAS allocations, as needed, to achieve those target TACs. The objective of this action is to achieve the goals of the FMP through the application of the target TAC setting method established in Framework 2 for FY 2005.

All of the entities (fishing vessels) affected by this action are considered small entities under the Small Business Administration size standards for small fishing businesses ($3.5 million in gross sales). There are approximately 737 limited access monkfish permit holders, including permits held in confirmation of permit history. This action would affect only limited access monkfish vessels while fishing for monkfish in the SFMA, since no changes to the management measures for the NFMA are proposed. Based on activity reports for FY 2003 (the most recent fishing year for which complete information is available), there were 534 limited access permit holders participating in the monkfish fishery. Of these, 158 vessels fished for monkfish exclusively in the SFMA, while 235 vessels fished for monkfish in both management areas. Thus, the proposed measures would likely affect at least the 393 vessels that fished for monkfish for at least part of the fishing year in the SFMA, but would likely have the greatest effect on the 158 vessels that fished for monkfish exclusively in the SFMA.

The combined target TAC for both monkfish management areas would be decreased by approximately 3 percent compared to fishing year 2004. While the target TAC for the NFMA would be decreased by approximately 22 percent, the target TAC for the SFMA would be increased by nearly 43 percent. As a result of the increased target TAC for the SFMA, monkfish trip limits in the SFMA would be increased by approximately 30 percent. Furthermore, since the target TAC for the SFMA has been set at a level greater than the 8,000–mt threshold, below which DAS reductions are triggered, allowable DAS that may be fished in the SFMA would be increased back to the full 40–day allotment. Thus, the proposed measures would have differential impacts on participating vessels depending on the management area in which they fish.

A trip limit model was used to estimate the impact of the proposed SFMA trip limits on the average per trip return for vessels on monkfish trips. Based on this analysis, on average, a trip taken in the SFMA would produce 21.2 percent more income towards fixed costs, debt, and owner profit under the proposed trip limits for FY 2005 as compared to FY 2004 trip limits. In addition, net pay per crew member would be increased by an average of 20.8 percent per trip.

As previously stated, vessels fishing in the NFMA would not be affected by the proposed measures for the SFMA. The average impact on vessels fishing in both management areas was estimated to be approximately a 2–percent increase in both net pay to crew and net return to the vessel. However, the average impact on vessels fishing exclusively in the SFMA was estimated to be a 14–percent increase in net pay to the crew, and a 12–percent increase in returns to the vessel owner. These effects vary greatly between states, with vessels from NC and NY experiencing small increases relative to vessels from MA and NJ.

The annual target TAC setting method established in Framework 2 is based on a formula that integrates an annual biomass index target with the 3–year running average of the NMFS fall trawl survey and the monkfish landings for the previous fishing year. Therefore, the target TACs resulting from the application of this method are non-discretionary. As a result, there are no alternatives to the proposed action to establish target TACs of 14,004 mt for the NFMA and 11,834 mt for the SFMA, other than no action. Furthermore, Framework 2 also established an formulaic method for adjusting trip limits for the SFMA that is based on the distribution of monkfish landings used by limited access monkfish vessels. Thus, there are no alternatives to the proposed trip limits of 700 lb (318 kg) per DAS for limited access Category A and C vessels, and 600 lb (272 kg) per DAS for limited access Category B and D vessels, other than no action.

This proposed rule does not duplicate, overlap or conflict with other Federal rules, and does not contain new reporting or recordkeeping requirements.

A copy of this analysis is available from the NEFMC (see **ADDRESSES**).

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: March 11, 2005.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

§ 648.92 [Amended]

2. In § 648.92, paragraph (b)(1)(ii) is removed and reserved.

3. In § 648.94, paragraphs (b)(2)(i) and (ii) are revised to read as follows:

§ 648.94 Monkfish possession and landing restrictions.

* * * * *

(b) * * *

(2) * * *

(i) *Category A and C vessels.* Category A and C vessels fishing under the monkfish DAS program in the SFMA may land up to 700 lb (318 kg) tail weight or 2,324 lb (1,054 kg) whole weight of monkfish per monkfish DAS (or any prorated combination of tail-weight and whole weight based on the conversion factor for tail weight to whole weight of 3.32), unless modified pursuant to § 648.96(b)(2)(ii).

(ii) *Category B and D vessels.* Category B and D vessels fishing under the monkfish DAS program in the SFMA may land up to 600 lb (272 kg) tail weight or 1,992 lb (904 kg) whole weight of monkfish per monkfish DAS (or any prorated combination of tail-weight and whole weight based on the conversion factor for tail weight to whole weight of 3.32), unless modified pursuant to § 648.96(b)(2)(ii).

* * * * *

[FR Doc. 05–5348 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 70, No. 52

Friday, March 18, 2005

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

Office of the Secretary

Notice of the USDA Technology and eGovernment Advisory Council Meeting

AGENCY: Office of the Chief Information Officer, USDA.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, the United States Department of Agriculture announces a meeting of the USDA Technology and eGovernment Advisory Council. The Council will advise the Secretary and the Chief Information Officer in planning and developing strategies for technology and eGovernment Initiatives.

DATES: The USDA Technology and eGovernment Advisory Council will meet on March 29, 2005 from 8:30 a.m. to 4:30 p.m.; and March 30, 2004 from 8:30 a.m. to 4 p.m.

Written comments for the public record will be welcomed before or up to two weeks after the meeting and should be submitted to the Contact Person in this notice. All comments will become part of the official record of the Advisory Council.

ADDRESSES: The meeting will take place at the South Building, Room s107; and the Jamie L. Whitten Building, Room 104A, 1400 Independence Ave., SW., Washington, DC 20250. Please send written comments to the Contact Person identified herein at: Office of the Chief Information Officer, 1400 Independence Ave., SW., Room 405W, Jamie L. Whitten Building, United States Department of Agriculture, Washington, DC 20250; and electronic comments to the Contact Person at *sandy.facinoli2@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Sandy Facinoli, Designated Federal Official, USDA Technology and eGovernment Advisory Council; telephone: (202) 720–2786; fax: (202) 205–2831.

SUPPLEMENTARY INFORMATION: On Tuesday and Wednesday, March 29, 2005 from 8:30 a.m. to 4:30 p.m.; and March 30, 2005 from 8:30 a.m. to 4 p.m., the USDA Technology and eGovernment Advisory Council will hold a meeting at the South and Jamie L. Whitten Building, United States Department of Agriculture, 1400 Independence Ave., SW., Washington, DC 20250.

Pursuant to 41 CFR 102–3.160, the meeting will be closed to the public so that the Council can conduct administrative matters. The Council is editing and revising their draft report due to the Secretary by May 31, 2005. The report will be presented at a subsequent public meeting and be available for public comment as well as published on the USDA public Web site, *http://www.usda.gov.*

Scott Charbo,

Chief Information Officer.

[FR Doc. 05–5405 Filed 3–17–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 02–088–5]

Notice of Request for Emergency Approval of an Information Collection

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Emergency approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request emergency approval of an information collection in support of a final rule published in today's issue of the **Federal Register** regarding the possession, use, and transfer of select agents and toxins.

DATES: We will consider all comments that we receive on or before March 25, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- *EDOCKET:* Go to *http://www.epa.gov/feddocket* 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. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. 02–088–5, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–088–5.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: For information concerning the regulations in 7 CFR part 331, contact Dr. Charles L. Divan, Senior Agricultural Microbiologist, Pest Permit Evaluations, Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–8758.

For information concerning the regulations in 9 CFR part 121, contact Dr. Lee Ann Thomas, Director, Animals, Organisms and Vectors, and Select Agents, VS, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231; (301) 734–5960.

For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

SUPPLEMENTARY INFORMATION: In an interim rule published in the **Federal Register** on December 13, 2002 (67 FR 76908–76938, Docket No. 02–088–1) and effective on February 11, 2003, the Animal and Plant Health Inspection

Service (APHIS) established regulations in 7 CFR part 331 and 9 CFR part 121 governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal health, to plant health, or to animal or plant products. In a final rule published in today's issue of the **Federal Register**, APHIS is adopting, with changes, the December 2002 interim rule.

The final rule includes certain regulatory provisions that differ from those included in the December 2002 interim rule. Some of those provisions involve changes from the information collection requirements set out in the December 2002 interim rule, which were approved by the Office of Management and Budget (OMB) under OMB control number 0579–0213 (expires May 31, 2005). These changes include the following:

- As a condition of exemption, an entity must report any theft, loss, or release of a select agent or toxin during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin. This is a new requirement in the final rule.
- As a condition of exemption, an entity must immediately report the identification of specified select agents and toxins; identification of the other select agents and toxins must be reported within 7 calendar days after identification. This is a change from the requirement in the December 2002 interim rule that identifications of any select agent or toxin be immediately reported.
- The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification. This is a change from the requirement in the December 2002 interim rule that the responsible official immediately report the identification of a select agent or toxin contained in a specimen presented for diagnosis.
- The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. This is a new requirement in the final rule.
- A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from APHIS or the Centers for Disease Control and Prevention (CDC) provided that, at least 7 calendar days prior to the transfer, the sender reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient. This is a change from the requirement in the December 2002 interim rule that the transfer of a select agent or toxin be authorized by APHIS or CDC prior to the transfer.
- An individual or entity must report the theft, loss, or release of a select agent or toxin. This is a change from the December 2002 interim rule that required such reporting for registered entities only.
- The responsible official is no longer required to notify APHIS 5 business days prior to the planned inactivation of a select agent or toxin if he/she wishes to discontinue possessing, using, or transferring a particular agent or toxin. In addition, the responsible official is no longer required to submit information about an individual's training and skills. These requirements have been deleted in the final rule.

In addition, there are a number of nonsubstantive changes, including changes in terminology and changes to form numbers.

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in the final rule have been submitted for emergency approval to the Office of Management and Budget (OMB). The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 2.8495857 hours per response.

Respondents: Researchers, universities, research and development organizations, diagnostic laboratories and other interested parties who possess, use, or transfers select agents or toxins.

Estimated annual number of respondents: 915.

Estimated annual number of responses per respondent: 5.1442622.

Estimated annual number of responses: 4,707.

Estimated total annual burden on respondents: 13,413. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

APHIS will provide OMB with a copy of all comments received on this notice. All comments will also become a matter of public record.

When OMB notifies us of its decision, we will publish a document in the **Federal Register** providing notice of the assigned OMB control number or, if approval is denied, providing notice of what action we plan to take.

Done in Washington, DC, this 10th day of March 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–5065 Filed 3–17–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Child Nutrition Programs—Income Eligibility Guidelines

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This Notice announces the Department's annual adjustments to the Income Eligibility Guidelines to be used in determining eligibility for free and reduced price meals or free milk for the period from July 1, 2005 through June 30, 2006. These guidelines are used by schools, institutions, and facilities participating in the National School Lunch Program (and Commodity School Program), School Breakfast Program, Special Milk Program for Children, Child and Adult Care Food Program and Summer Food Service Program. The annual adjustments are required by section 9 of the Richard B. Russell National School Lunch Act. The guidelines are intended to direct benefits to those children most in need and are revised annually to account for changes in the Consumer Price Index.

EFFECTIVE DATE: July 1, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. Robert M. Eadie, Chief, Policy and Program Development Branch, Child Nutrition Division, FNS, USDA, Alexandria, Virginia 22302, or by phone at (703) 305–2590.

SUPPLEMENTARY INFORMATION: This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This action is exempted from review by the Office of Management and Budget under Executive Order 12866.

These programs are listed in the Catalog of Federal Domestic Assistance under No. 10.553, No. 10.555, No. 10.556, No. 10.558 and No. 10.559 and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (*See* 7 CFR part 3015, subpart V, and the final rule related notice published at 48 FR 29114, June 24, 1983.)

Background

Pursuant to sections 9(b)(1) and 17(c)(4) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1758(b)(1) and 42 U.S.C. 1766(c)(4)), and sections 3(a)(6) and 4(e)(1)(A) of the Child Nutrition Act of 1966 (42 U.S.C. 1772(a)(6) and 1773(e)(1)(A)), the Department annually issues the Income Eligibility Guidelines for free and reduced price meals for the National School Lunch Program (7 CFR part 210), the Commodity School Program (7 CFR part 210), School Breakfast Program (7 CFR part 220), Summer Food Service Program (7 CFR part 225) and Child and Adult Care Food Program (7 CFR part 226) and the guidelines for free milk in the Special Milk Program for Children (7 CFR part 215). These eligibility guidelines are based on the Federal income poverty guidelines and are stated by household size. The guidelines are used to determine eligibility for free and reduced price meals and free milk in accordance with applicable program rules.

Definition of Income

In accordance with the Department's policy as provided in the Food and Nutrition Service publication *Eligibility Guidance for School Meals Manual,* ''income,'' as the term is used in this Notice, means income before any deductions such as income taxes, Social Security taxes, insurance premiums, charitable contributions and bonds. It includes the following: (1) Monetary compensation for services, including wages, salary, commissions or fees; (2) net income from nonfarm self-employment; (3) net income from farm self-employment; (4) Social Security; (5) dividends or interest on savings or bonds or income from estates or trusts; (6) net rental income; (7) public assistance or welfare payments; (8) unemployment compensation; (9) government civilian employee or military retirement, or pensions or veterans payments; (10) private pensions or annuities; (11) alimony or child support payments; (12) regular contributions from persons not living in the household; (13) net royalties; and (14) other cash income. Other cash income would include cash amounts received or withdrawn from any source including savings, investments, trust accounts and other resources that would be available to pay the price of a child's meal.

''Income,'' as the term is used in this Notice, does *not* include any income or benefits received under any Federal programs that are excluded from consideration as income by any legislative prohibition. Furthermore, the value of meals or milk to children shall not be considered as income to their households for other benefit programs in accordance with the prohibitions in section 12(e) of the Richard B. Russell National School Lunch Act and section 11(b) of the Child Nutrition Act of 1966 (42 U.S.C. 1760(e) and 1780(b)).

The Income Eligibility Guidelines

The following are the Income Eligibility Guidelines to be effective from July 1, 2005 through June 30, 2006. The Department's guidelines for free meals and milk and reduced price meals were obtained by multiplying the year 2005 Federal income poverty guidelines by 1.30 and 1.85, respectively, and by rounding the result upward to the next whole dollar.

The income eligibility chart for School Year 2005–2006 contains a few minor changes that were implemented for School Year 2004–2005. Prior to School Year 2004–2005, the Department displayed the monthly and weekly amounts for the Federal poverty guidelines in addition to the annual figures as issued by the Department of Health and Human Services. This Notice, however, only displays the annual figures because the monthly and weekly Federal poverty guidelines were not used to determine the Income Eligibility Guidelines. As detailed below, all calculations are based on the annual figures.

In addition, the chart which details the free and reduced price eligibility criteria includes columns for income received twice monthly as well as income received every two weeks. To differentiate: a person paid every two weeks is paid 26 times per year, whereas a person paid twice monthly is paid 24 times per year. Furthermore, the inclusion of information about income received twice per month as well as income received every two weeks conforms to the format used by the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) (42 U.S.C. 1786; 7 CFR part 246).

Income calculations are made based on the following formulas: Monthly income is calculated by dividing the annual income by 12; twice monthly income is computed by dividing annual income by 24; income received every two weeks is calculated by dividing annual income by 26; and weekly income is computed by dividing annual income by 52. All numbers are rounded upward to the next whole dollar. The numbers reflected in this notice for a family of four in the 48 contiguous states, the District of Columbia, Guam and the territories represent an increase of 2.65 % over the July 2004 numbers for a family of the same size.

BILLING CODE 3410–30–P

INCOME ELIGIBILITY GUIDELINES

Effective from July 1, 2005 to June 30, 2006

HOUSEHOLD SIZE	FEDERAL POVERTY GUIDELINES	REDUCED PRICE MEALS - 185 %					FREE MEALS - 130 %				
	ANNUAL	ANNUAL	MONTHLY	TWICE PER MONTH	EVERY TWO WEEKS	WEEKLY	ANNUAL	MONTHLY	TWICE PER MONTH	EVERY TWO WEEKS	WEEKLY
48 CONTIGUOUS STATES, DISTRICT OF COLUMBIA, GUAM, AND TERRITORIES											
1	9,570	17,705	1,476	738	681	341	12,441	1,037	519	479	240
2	12,830	23,736	1,978	989	913	457	16,679	1,390	695	642	321
3	16,090	29,767	2,481	1,241	1,145	573	20,917	1,744	872	805	403
4	19,350	35,798	2,984	1,492	1,377	689	25,155	2,097	1,049	968	484
5	22,610	41,829	3,486	1,743	1,609	805	29,393	2,450	1,225	1,131	566
6	25,870	47,860	3,989	1,995	1,841	921	33,631	2,803	1,402	1,294	647
7	29,130	53,891	4,491	2,246	2,073	1,037	37,869	3,156	1,578	1,457	729
8	32,390	59,922	4,994	2,497	2,305	1,153	42,107	3,509	1,755	1,620	810
For each add'l family member, add	3,260	6,031	503	252	232	116	4,238	354	177	163	82
ALASKA											
1	11,950	22,108	1,843	922	851	426	15,535	1,295	648	598	299
2	16,030	29,656	2,472	1,236	1,141	571	20,839	1,737	869	802	401
3	20,110	37,204	3,101	1,551	1,431	716	26,143	2,179	1,090	1,006	503
4	24,190	44,752	3,730	1,865	1,722	861	31,447	2,621	1,311	1,210	605
5	28,270	52,300	4,359	2,180	2,012	1,006	36,751	3,063	1,532	1,414	707
6	32,350	59,848	4,988	2,494	2,302	1,151	42,055	3,505	1,753	1,618	809
7	36,430	67,396	5,617	2,809	2,593	1,297	47,359	3,947	1,974	1,822	911
8	40,510	74,944	6,246	3,123	2,883	1,442	52,663	4,389	2,195	2,026	1,013
For each add'l family member, add	4,080	7,548	629	315	291	146	5,304	442	221	204	102
HAWAII											
1	11,010	20,369	1,698	849	784	392	14,313	1,193	597	551	276
2	14,760	27,306	2,276	1,138	1,051	526	19,188	1,599	800	738	369
3	18,510	34,244	2,854	1,427	1,318	659	24,063	2,006	1,003	926	463
4	22,260	41,181	3,432	1,716	1,584	792	28,938	2,412	1,206	1,113	557
5	26,010	48,119	4,010	2,005	1,851	926	33,813	2,818	1,409	1,301	651
6	29,760	55,056	4,588	2,294	2,118	1,059	38,688	3,224	1,612	1,488	744
7	33,510	61,994	5,167	2,584	2,385	1,193	43,563	3,631	1,816	1,676	838
8	37,260	68,931	5,745	2,873	2,652	1,326	48,438	4,037	2,019	1,863	932
For each add'l family member, add	3,750	6,938	579	290	267	134	4,875	407	204	188	94

Authority: (42 U.S.C. 1758(b)(1)).

Dated: March 11, 2005.

Roberto Salazar,

Administrator.

[FR Doc. 05–5393 Filed 3–17–05; 8:45 am]

BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers; Correction

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice; correction.

SUMMARY: The Foreign Agricultural Service (FAS) published a document in the **Federal Register** of March 4, 2005, concerning the approval of a petition for trade adjustment assistance (TAA) that was filed on February 1, 2005, by Gollott's Oil Dock and Icehouse, Inc., Biloxi, Mississippi. The document contained incorrect state information.

FOR FURTHER INFORMATION CONTACT: Jean-Louis Pajot, 202–720–2916.

Correction

In the **Federal Register** of March 4, 2005, in FR Doc. 05–4164, on page 10591, in the third column, correct the notice to read:

The Administrator, Foreign Agricultural Service (FAS), approved a petition for trade adjustment assistance (TAA) that was filed on February 1, 2005, by Gollott's Oil Dock and Icehouse, Inc., Biloxi, Mississippi. The certification date is March 14, 2005. Beginning on this date, shrimpers who land their catch in Mississippi will be eligible to apply for fiscal year 2005 benefits during an application period ending June 13, 2005.

SUPPLEMENTARY INFORMATION: Upon investigation, the Administrator determined that increased imports of farmed shrimp contributed importantly to a decline in the landed prices of shrimp in Mississippi by 30.4 percent during January 2003 through December 2003, when compared with the previous 5-year average.

Eligible producers must apply to the Farm Service Agency for benefits. After submitting completed applications, producers shall receive technical assistance provided by the Extension Service at no cost and may receive an adjustment assistance payment, if certain program criteria are satisfied. Applicants must obtain the technical assistance from the Extension Service by September 12, 2005, in order to be eligible for financial payments.

Producers of raw agricultural commodities wishing to learn more about TAA and how they may apply should contact the Department of Agriculture at the addresses provided below for General Information.

Producers Certified as Eligible for TAA, Contact: Farm Service Agency service centers in Mississippi.

Dated: March 10, 2005.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 05–5359 Filed 3–17–05; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Kelsey Vegetation Management Project, Deschutes National Forest, Deschutes County, OR

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA, Forest Service, will prepare an environmental impact statement (EIS) on a proposed action to improve forest health conditions within the 46,175-acre Kelsey planning area. An analysis was initiated to assess tree density and hazardous fuels and associated forest related concerns of wildfire, insect infestations, and disease pathogens. Methods that would be used to reduce tree density and hazardous fuels are: Non-commercial and commercial thinning, mechanical shrub treatment, and prescribed burning. The planning area is located adjacent to the southern urban growth boundary of Bend, Oregon, east and adjacent to the Deschutes River and the community of Sunriver, north of Forest Road 9720, and west of Forest Road 1810. The planning area is a combination of public lands (99%), managed by the Deschutes National Forest, and private lands (1%). The alternatives will include the proposed action, no action, and additional alternatives that respond to issues generated through the scoping process. The agency will give notice of the full environmental analysis and decision-making process so interested and affected public may participate and contribute to the final decision.

DATES: Comments concerning the scope of the analysis must be received by 30 days following the date that this notice appears in the **Federal Register**.

ADDRESSES: Send written comments to Kristin M. Bail, Acting District Ranger, Bend-Fort Rock Ranger District, Red Oaks Square, 1230 NE Third Street Suite A–262, Bend, Oregon 97701.

FOR FURTHER INFORMATION CONTACT: David Frantz, Writer/Editor, Bend-Fort Rock Ranger District, Red Oaks Square, 1230 NE Third Street Suite A–262, Bend, Oregon 97701, phone (541) 383–4721. E-mail *dfrantz@fs.fed.us.*

Responsible Official: The responsible official will be Leslie Weldon, Forest Supervisor, Deschutes National Forest, P.O. Box 1645 Hwy 20 East, Bend, OR 97701.

SUPPLEMENTARY INFORMATION: *Background.* The analysis of the 46,175-acre Kelsey planning area was initiated in 1999. The planning area includes wildland urban interface, winter deer habitat, key elk habitat, the Upper Deschutes Wild and Scenic River, and the Newberry National Volcanic Monument. In July 2003, the 18 Fire burned approximately 3,520 acres within the planning area along the northeast boundary. The area within the fire perimeter was analyzed separately in the 18 Fire Salvage Recovery Project EIS.

The Kelsey planning area is located within the dry eastside forests of central Oregon. Large ponderosa pine (greater than 21″ in diameter) once dominated the landscape. During the 1930s and 1940s, this area was owned and clearcut by private commercial enterprises, leaving few residual individual large trees and very few small stands of larger, older ponderosa pine. The Forest Service acquired these private lands during the ensuing years. The area now consists primarily of an even-aged, single story, black bark ponderosa pine forest with encroaching lodgepole pine. The average size of the ponderosa pine is approximately 12 inches in diameter at breast height (dbh), with much of the tree size within the 9 to 14 inch dbh range. Less than one (1) percent of the planning area is classified as large, old growth ponderosa pine. Highly flammable shrubs are the primary understory vegetation throughout the planning area and beyond. As a result of suppression of wildlife for approximately 90 years, large contiguous areas of dense shrubs can spread fire into the tree canopy.

Desired Condition. To provide a sustainable forest, one where disturbances such as wildfire, insects, and disease occurrences are more typical of a properly functioning eastside forest.

Purpose and Need. Low intensity wildfire frequently burned the eastside ponderosa forest ecosystem with a fire interval of generally less than 30 years, reducing stand density and natural fuels. The combination of fire suppression since the early 1900s and clear cutting has created a scenario with uncharacteristically high stand density

and fuels when compared to an historical eastside forest.

Because of high tree density across much of the analysis area, a more destructive crown fire could be sustained, including areas adjacent to the wildland urban interface. Also, due to the lack of a historical frequent and low intensity fire regime, large, contiguous areas of bitterbrush provide potential high hazard fuels. Remnant, large ponderosa pine that would ordinarily be fire resistant are placed at risk because of increased competition with lodgepole pine and increased ground to crown ladder fuels. In addition to the potential for large, uncharacteristic wildfire, tree mortality from insects and disease is becoming evident and stands are becoming susceptible due to high stand density and periods of low precipitation.

The purpose and need of the project is to address opportunities for protecting and enhancing the forest ecosystem within the Kelsey planning area, including:

- Provide this fire-dependent ecosystem with a landscape that is capable for sustaining a characteristic low intensity wildfire.
- Reduce tree density to assist in a transition toward a forest ecosystem that is more resilient and resistant to disturbance.
- Protect and accelerate development of late and old structure trees.
- Provide stand structural diversity in even-aged stands to provide future big game habitat.
- Utilize opportunities that result from vegetation management activities to offset costs and provide products to stimulate the economy.

Proposed Action. The proposed action includes non-commercial and commercial thinning of conifers less than 21 inches diameter at breast height to reduce tree stand density (5,495 acres); Reducing the shrub component to fragment high hazard fuels, including preparing stands for careful application of prescribed fire (8,955 acres); Creating small openings and replanting to provide areas for future deer forage and vertical stand diversity (260 acres).

Issues. Preliminary issues include the potential effect of the proposed action on cultural resources, developed and dispersed recreation, noxious weeds, air quality, water quality, and wildlife habitat.

Comment. Public comments regarding this proposal are requested in order to assist in identifying issues, determine how to best manage the resources, and to focus the analysis. Comments received to this notice, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision in accordance with 36 CFR parts 215 and 217. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

A draft EIS will be filed with the Environmental Protection Agency (EPA) and available for public review by July 15, 2005. The EPA will publish a Notice of Availability (NOA) of the draft EIS in the **Federal Register**. The final EIS is scheduled to be available October 24, 2005.

The comment period on the draft EIS will be 45 days from the date the EPA publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of a draft EIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions [*Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978)]. Also, environmental objections that could be raised at the draft EIS stage but that are not raised until after completion of the final EIS may be waived or dismissed by the courts [*City of Angoon* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980)]. Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningful consider them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also help if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft EIS of the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

In the final EIS, the Forest Service is required to respond to substantive comments received during the comment period for the draft EIS. The Forest Service is the lead agency and the responsible official is the Forest Supervisor, Deschutes National Forest. The responsible official will decide where and whether or not to apply natural fuels treatments, thin stands, and reforest group cuts. The responsible official will also decide how to mitigate impacts of these actions and will determine when and how monitoring of effects will take place.

The Kelsey Vegetation Management decision and the reasons for the decision will be documented in the record of decision. That decision will be subject to Forest Service Appeal Regulations (35 CFR Part 215).

Dated: March 16, 2005.

Kevin Martin,

Deputy Forest Supervisor, Deschutes National Forest.

[FR Doc. 05–5292 Filed 3–17–05; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to procurement list.

SUMMARY: This action adds to the Procurement List a service to be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: Effective Date: April 17, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

For Further Information Or To Submit Comments Contact: Sheryl D. Kennerly,

Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov.*

SUPPLEMENTARY INFORMATION: On February 4, 2005, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (70 FR 5964) of proposed additions to the Procurement List. After consideration of the material presented to it concerning capability of qualified nonprofit agency to provide the service and impact of the additions on the current or most recent contractors, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service is added to the Procurement List:

Service

Service Type/Location: Custodial Services, Naval Base Ventura County, Ventura, California.

NPA: PRIDE Industries, Inc., Roseville, California.

Contracting Activity: ROICC/Naval Base Ventura County, Point Mugu, California.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E5–1191 Filed 3–17–05; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee For Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee is proposing to add to the Procurement List products and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received On Or Before: April 17, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

For Further Information Or To Submit Comments Contact: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions. If the Committee approves the proposed additions, the entities of the Federal Government identified in the notice for each product or service will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and service to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and service are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

Product/NSN: Antifoam Compound, Silicon, 6850–01–506–6533.

Product/NSN: Detergent, Laundry, 7930–01–506–7081.

NPA: East Texas Lighthouse for the Blind, Tyler, Texas.

Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, Pennsylvania.

Product/NSN: Gloves, Flyers', Summer, Type GS/FRP–2; GS/FPP–2 (Exigency or surge requirements up to 240,000 pairs annually which are over and above the current contractors' requirements for a period up to September 2007.

8415–01–029–0109—Type GS/FRP–2, Sage Green—Size 7
8415–01–029–0111—Type GS/FRP–2, Sage Green—Size 8
8415–01–029–0112—Type GS/FRP–2, Sage Green—Size 9
8415–01–029–0113—Type GS/FRP–2, Sage Green—Size 10
8415–01–029–0116—Type GS/FRP–2, Sage Green—Size 11
8415–01–040–1453—Type GS/FRP–2, Sage Green—Size 6
8415–01–040–2012—Type GS/FRP–2, Sage Green—Size 5
8415–01–461–4920—Type GS/FPP–2, Desert Tan—Size 5
8415–01–461–4922—Type GS/FPP–2, Desert Tan—Size 6
8415–01–461–4924—Type GS/FPP–2, Desert Tan—Size 7
8415–01–461–4932—Type GS/FPP–2, Desert Tan—Size 8
8415–01–461–4934—Type GS/FPP–2, Desert Tan—Size 9
8415–01–461–4940—Type GS/FPP–2, Desert Tan—Size 10
8415–01–461–4942—Type GS/FPP–2, Desert Tan—Size 11
8415–01–461–4962—Type GS/FRP–2, Black—Size 5
8415–01–461–4964—Type GS/FRP–2, Black—Size 6
8415–01–461–4966—Type GS/FRP–2, Black—Size 7
8415–01–461–4969—Type GS/FRP–2, Black—Size 8
8415–01–461–4970—Type GS/FRP–2, Black—Size 9
8415–01–461–4971—Type GS/FRP–2, Black—Size 10
8415–01–461–4981—Type GS/FRP–2, Black—Size 11
8415–01–482–8417—Type GS/FRP–2, Sage Green—Size 4
8415–01–482–8420—Type GS/FRP–2, Sage Green—Size 12
8415–01–482–8678—Type GS/FRP–2, Black—Size 4

8415–01–482–8684—Type GS/FRP–2, Black—Size 12
8415–01–482–8688—Type GS/FPP–2, Desert Tan—Size 4
8415–01–482–8690—Type GS/FPP–2, Desert Tan—Size 12
NPA: South Texas Lighthouse for the Blind, Corpus Christi, Texas.
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, Pennsylvania.
Product/NSN: Marker, Dry Erase, 7520–01–294–3791 (Black, Chisel Tip).
NPA: Dallas Lighthouse for the Blind, Inc., Dallas, Texas.
Contracting Activity: Office Supplies & Paper Products Acquisition Center, New York, NY.

Service

Service Type/Location: Document Destruction, USDA, Forest Service, 101 B Sun Avenue, NE., Albuquerque, New Mexico.
NPA: Adelante Development Center, Inc., Albuquerque, New Mexico.
Contracting Activity: USDA, Forest Service, Albuquerque, New Mexico.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E5–1192 Filed 3–17–05; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC 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: U.S. Census Bureau.

Title: Current Retail Sales & Inventory Survey.

Form Number(s): SM–44(00)S, SM–44(00)SE, SM–44(00)SS, SM–44(00)B, SM–44(00)BE, SM–44(00)BS, SM–44(00)L, SM–44(00)LE, SM–44(00)LS, SM–45(00)S, SM–45(00)SE, SM–45(00)SS, SM–45(00)B, SM–45(00)BE, SM–45(00)BS, SM–72(00)S, SM–20(00)I.

Agency Approval Number: 0607–0717.

Type of Request: Extension of a currently approved collection.

Burden: 13,364 hours.

Number of Respondents: 8,706.

Avg Hours Per Response: 7.7 minutes.

Needs and Uses: The U.S. Census Bureau requests an extension of the OMB approval of the Current Retail Sales and Inventory Survey. The Current Retail Sales and Inventory Survey provides estimates of monthly retail sales, end-of-month merchandise inventories, and quarterly e-commerce sales of retailers in the United States by selected kinds of business. Also, it provides monthly sales of food service establishments.

Sales and inventory data provide a current statistical picture of the retail portion of consumer activity. The sales and inventory estimates in the Current Retail Sales and Inventory Survey measure current trends of economic activity that occur in the United States. Also, the estimates compiled from the survey provide valuable information for economic policy decisions and actions by the government and are widely used by private businesses, trade organizations, professional associations, and others for market research and analysis. Sales are used by the Bureau of Economic Analysis (BEA) in determining the consumption portion of the Gross Domestic Product (GDP).

Retail and Food Services Sales during 2004 amounted to $4.1 trillion. The estimates produced in the Current Retail Sales and Inventory Survey are critical to the accurate measurement of total economic activity. The estimates of retail sales represent all operating receipts, including receipts from wholesale sales made at retail locations and services rendered as part of the sale of the goods, by businesses that primarily sell at retail. The sales estimates include sales made on credit as well on a cash basis, but exclude receipts from sales taxes and interest charges from credit sales. Also excluded is non-operating income from such services as investments and real estate.

The estimates of merchandise inventories owned by retailers represent all merchandise located in retail stores, warehouses, offices, or in transit for distribution to retail establishments. The estimates of merchandise inventories exclude fixtures and supplies not held for sale, as well as merchandise held on consignment owned by others. Inventories are used by the BEA in determining the investment portion of the GDP.

Retail e-commerce sales are estimated from the same sample used in the Current Retail Sales and Inventory Survey to estimate preliminary and final U.S. retail sales. The Current Retail Sales and Inventory sample is updated on an ongoing basis to account for new retail employer businesses (including those selling via the Internet), business deaths, and other changes to the retail business universe. Research was conducted to ensure that retail firms selected in the Current Retail Sales and Inventory Survey sample and engaged in e-commerce are representative of the universe of e-commerce retailers. Total e-commerce sales for 2003 were estimated at $56 billion.

We publish retail sales and inventory estimates based on the North American Industry Classification System (NAICS) which has been widely adopted throughout both the public and private sectors.

The BEA is the primary Federal user of data collected in the Current Retail Sales and Inventory Survey. BEA uses the information in its preparation of the National Income and Products Accounts, and its benchmark and annual input-output tables. Statistics provided from retail sales and inventory estimates are used in the calculation of the GDP. If the survey were not conducted, BEA would lack comprehensive data from the retail sector. This would adversely affect the reliability of the National Income and Products Accounts and the GDP.

The Bureau of Labor Statistics (BLS) uses the data as input to its Producer Price Indexes and in developing productivity measurements. The data are also used for gauging current economic trends of the economy. Private businesses use the retail sales and inventory data to compute business activity indexes. The private sector also uses retail sales as a reliable indicator of consumer activity.

Affected Public: Business or other for-profit.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. 182.

OMB Desk Officer: Susan Schechter, (202) 395–5103.

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 Susan Schechter, OMB Desk Officer either by fax (202–395–7245) or e-mail (*susan_schechter@omb.eop.gov*).

Dated: March 15, 2005.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 05–5425 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC 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: U.S. Census Bureau.

Title: Shipper's Export Declaration/ Automated Export System.

Form Number(s): 7525–V, AES.

Agency Approval Number: 0607–0152.

Type of Request: Revision of a currently approved collection.

Burden: 814,140 hours.

Number of Respondents: 223,213.

Avg. Hours Per Response: SED—11 minutes; AES—3 minutes.

Needs and Uses: The current clearance under Office of Management and Budget (OMB) Number 0607–0152 covers the paper Shipper's Export Declaration (SED) 7525–V, and its electronic equivalent, the Automated Export System (AES) and related documents (*e.g.*, Letter of Intent and AESDirect Registration and Certification). With this submission the U.S. Census Bureau (Census Bureau) is requesting continued clearance for the SED program.

The Census Bureau will accept the paper SED for only a limited period of time during the year 2005. This is due to the expected implementation of mandatory electronic filing of all export information. This requirement is mandated through Public Law 107–228, of the Foreign Relations Authorization Act of 2003.

This law authorizes the Secretary of Commerce with the concurrences of the Secretary of State and the Secretary of Homeland Security to require all persons who file export information according to Title 13, United States Code (U.S.C.), Chapter 9, to file such information through the AES. In June 2004 the Census Bureau and the U.S. Customs and Border Protection (CBP) implemented the redesign of the commodity module of the AES in anticipation of the implementation of the mandatory electronic reporting requirement. Since the implementation of the AES Commodity Redesign the following changes have taken place within the AES: Addition of the (1) Routed Transaction Indicator and the (2) Vehicle Identification Qualifier; and the removal of the (1) Waiver of Prior Notice and the (2) Date of Arrival indicators. Other changes that affect corporate business practices include the following: (1) Corrections must be performed with the ''change'' or ''replace'' functions rather than the ''delete/add'' functions; (2) use of new compliance alert conditions for late filings (3) changes to licensed or used vehicle shipments after departure; (4) commodity filing response messages that provide the text, identification, reason and resolution for conditional situations; (5) use of a verify condition message for sanctioned countries rather than the receipt of a warning message; (6) removal of the Internal Transaction Number (ITN) from the SC2 record for placement in the ES1 response message output record; and (7) inclusion of a severity indicator to the ES1 record. In addition to the changes, most warning error messages were converted to fatal errors. The revisions should not affect the average three-minute response time for the completion of the AES record. There will be no changes to the paper SED, therefore there is no expected change to the existing eleven-minute response time to complete this form.

The Census Bureau will allow the trade community to continue using the paper SED until the actual implementation of the mandatory electronic filing requirement occurs. This is expected later during the year 2005. Currently, the Census Bureau is involved in the rulemaking process that will notify the trade community of the mandatory requirement for electronic filing.

The SED form and its electronic equivalent the AES record provide the means for collecting data on U.S. exports. Title 13, U.S.C., Chapter 9, Sections 301–307, mandates the collection of these data. The regulatory provisions for the collection of these data are contained in the Foreign Trade Statistics Regulations, Title 15, Code of Federal Regulations (CFR), Part 30. The official export statistics collected from these tools provide the basic component for the compilation of the U.S. position on merchandise trade. These data are an essential component of the monthly totals on U.S. International Trade in Goods and Services, a principal economic indicator and primary component of the Gross Domestic Product (GDP).

The data collected from the SED and the AES record are also used for export control purposes under Title 50, U.S.C., Export Administration Act, to detect and prevent the export of certain items by unauthorized parties or to unauthorized destinations or end users.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C. Chapter 9; Title 15 CFR Part 30.

OMB Desk Officer: Susan Schechter, (202) 395–5103.

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 Susan Schechter, OMB Desk Officer either by fax (202–395–7245) or e-mail (*susan_schechter@omb.eop.gov*).

Dated: March 15, 2005.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 05–5426 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Current Industrial Reports Surveys—WAVE III (Mandatory and Voluntary Surveys)

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, 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)).

DATES: Written comments must be submitted on or before May 17, 2005.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to: Judy Dodds, Assistant Chief for Census and Related Programs, (301) 763–4587, Census Bureau, Manufacturing and Construction Division, Room 2101, Building #4,

Washington, DC 20233 (or via the Internet at *judy.m.dodds@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducts a series of monthly, quarterly, and annual surveys as part of the Current Industrial Reports (CIR) program. The CIR surveys deal mainly with the quantity and value of shipments of particular products and occasionally with data on production and inventories; unfilled orders, receipts, stocks and consumption; and comparative data on domestic production, exports, and imports of the products they cover. These surveys provide continuing and timely national statistical data on manufacturing. The results of these surveys are used extensively by individual firms, trade associations, and market analysts in planning or recommending marketing and legislative strategies.

The CIR program includes both mandatory and voluntary surveys. Typically, the monthly and quarterly surveys are conducted on a voluntary basis and annual collections are mandatory. The collection frequency of individual CIR surveys is determined by the cyclical nature of production, the need for frequent trade monitoring, or the use of data in Government economic indicator series. Some monthly and quarterly CIR surveys have an annual ''counterpart'' collection. The annual counterpart collects annual data on a mandatory basis from those firms not participating in the more frequent collection.

Due to the large number of surveys in the CIR program, for clearance purposes, the CIR surveys are divided into ''waves.'' One wave is resubmitted for clearance each year. This year the Census Bureau plans to submit mandatory and voluntary surveys of Wave III for clearance. The surveys in Wave III are:

Mandatory surveys	Voluntary survey
M311H—Fats and Oils (Warehouse)	*M336G—Civil Aircraft and Aircraft Engines.
M311L—Fats and Oils (Renderers).	
M311M—Fats and Oils (Consumers).	
M311N—Fats and Oils (Producers).	
MA327E—Consumer, Scientific, Technical, and Industrial Glassware.	
MA333D—Construction Machinery.	
MA333F—Mining, Machinery and Mineral Processing Equipment.	
** MA334B—Selected Instruments & Related Products.	
** MA334M—Consumer Electronics.	
MA334P—Communication Equipment.	
** MA334Q—Semiconductors, Printed Circuit Boards, and Other Electronic Components.	
MA334R—Computers and Office and Accounting Machines.	
** MA334S—Electromedical and Irradiation Equipment.	
** MA335A—Switchgear, Switchboard Apparatus, Relays, and Industrial Controls.	

* This voluntary survey has mandatory annual counterpart.
** Moved from another wave.

II. Method of Collection

The Census Bureau will use mail out/mail back survey forms to collect data. We ask respondents to return monthly report forms within 10 days, quarterly report forms within 15 days, and annual report forms within 30 days of the initial mailing. Telephone calls and/or letters encouraging participation will be mailed to respondents who have not responded by the designated time.

III. Data

OMB Number: 0607–0476.

Form Number: See Chart Above.

Type of Review: Regular Review.

Affected Public: Businesses, or other for-profit organizations.

Estimated Number of Respondents: 9,109.

Estimated Time Per Response: 1.4322 hours.

Estimated Total Annual Burden: 13,046 hours.

Estimated Total Annual Cost: The estimated cost to respondents for all the CIR reports in Wave III for fiscal year 2006 is $217,477.

Respondent's Obligation: The CIR program includes both mandatory and voluntary surveys.

Legal Authority: Title 13, United States Code, sections 61, 182, 224, and 225.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) 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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: March 15, 2005.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 05–5427 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of the Census

Request for Nominations of Member Organizations To Serve on the 2010 Census Advisory Committee

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Bureau of the Census (Census Bureau) invites and requests nominations of organizations for appointment to the 2010 Census Advisory Committee (2010 CAC). The **SUPPLEMENTARY INFORMATION** section for this notice provides information about the objectives and duties of the advisory committee and membership criteria.

DATES: Please submit nominations by April 8, 2005.

ADDRESSES: Please submit nominations to Jeri Green, Chief, Census Advisory Committee Office, U.S. Census Bureau, Room 3627, Federal Building 3, 4700 Silver Hill Road, Washington, DC 20233, telephone 301–763–6590. Nominations also may be submitted via fax (301–457–2642) or by e-mail to *jeri.green@census.gov.*

FOR FURTHER INFORMATION CONTACT: Jeri Green, Chief, Census Advisory Committee Office, Census Bureau, Room 3627, Federal Building 3, 4700 Silver Hill Road, Washington, DC 20233, telephone 301–763–6590, or e-mail to *jeri.green@census.gov.*

SUPPLEMENTARY INFORMATION: The 2010 CAC was established in accordance with the Federal Advisory Committee Act (Title 5, United States Code (U.S.C.), Appendix 2). The following provides information about the Committee, membership, and nomination process:

Objectives and Duties

1. The 2010 CAC considers the needs of the decennial census from the perspective of outside data users and other organizations having a substantial interest and expertise in the conduct and outcome of the decennial. The Committee will provide advice on how best the Census Bureau can effectively and efficiently accomplish its decennial goals and objectives.

2. The 2010 CAC addresses policy, research, and technical issues related to the design and implementation of the 2010 decennial census, including the American Community Survey.

3. The Committee functions solely as an advisory body under the Federal Advisory Committee Act.

Membership

1. The Secretary of Commerce appoints the member organizations and designates the Chair and Vice-Chair of the Committee.

2. The 2010 CAC consists of a Chair, Vice-Chair, and a designated representative from each member organization. The 2010 CAC is comprised of up to twenty (20) member organizations. Member organizations represent data users, general governmental entities, technology-based organizations, and entities with expertise in the statutory and constitutional uses of census data, including redistricting. Membership also will include ex-officio members representing U.S. Senate and House of Representatives' Committees with census oversight responsibilities. A representative from the Census Advisory Committees on Race and Ethnic Populations also serves as ex-officio member. Ex-officio members serve in a non-voting capacity.

3. Committee members are selected in accordance with applicable Department of Commerce guidelines. The Committee's composition should reflect a balance of viewpoints and perspectives, considering such factors as geography, diversity in the sectors represented (*i.e.*, business and industry, academia, consumers, etc.), and the public-at-large. The size and the scope of the member organization also are considered.

4. Committee members should have relevant backgrounds and experience to significantly assist and/or contribute to the overall functions, tasks, and missions of the decennial census. The members should bring diverse perspectives and be able to provide advice on policy and technical issues affecting the goals of ongoing decennial programs, surveys, and initiatives.

5. The Committee has the fewest number of members necessary to accomplish the objectives of the Charter. Committee membership will not duplicate other organizations, interests, or communities already represented on existing census advisory committees or census consultation groups (i.e., Census Information Centers or State Data Centers).

6. Committee members report to the Director of the Census Bureau.

Miscellaneous

1. Members of the Committee serve without compensation, but the Census Bureau will, upon request, reimburse travel expenses, as authorized by 5 U.S.C. 5701, *et seq.,* dealing with travel and subsistence expenses.

2. The Committee meets at least once a year. Meetings are one to two days in duration.

3. Committee meetings are open to the public.

Nomination Information

1. The Census Bureau is seeking nominations for membership on the 2010 CAC to include organizations that are knowledgeable about issues related to the statutory and/or constitutional uses of the census data, general governmental entities, data users, and research and technology-based organizations.

2. Member organizations shall initially serve a staggered term of either two or three years. Upon completion of the initial terms, all subsequent terms shall be three years. Members may be invited to serve a second subsequent term contingent upon the organization's active participation in advisory committee activities, overall advisory committee needs for that organization's expertise and specialized advice, and the status and schedule of decennial planning activities and implementation.

3. Nominations of organizations may come from individuals or organizations. Organizations also may self-nominate. A summary of the organization's qualifications and the experience that qualifies it for membership should be included in the nomination letter. Nominated organizations must be able to actively participate in the tasks of the Committee, including, but not limited to regular meeting attendance, review of materials, and participation in conference calls, working groups, and special committee activities. *All DCAC members included under the previous charter must apply for membership under the new 2010 CAC charter and structure.*

4. The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse Committee membership.

Dated: March 15, 2005.

Hermann Habermann,

Deputy Director and Chief Operating Officer, Bureau of the Census.

[FR Doc. 05–5392 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement (NAFTA), Article 1904 NAFTA Panel Reviews; Decision of the Panel

AGENCY: NAFTA secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of decision of NAFTA Panel.

SUMMARY: On March 10, 2005, the NAFTA Panel issued its decision in the matter of Certain Durum Wheat and Hard Red Spring Wheat CVD determination from Canada, Secretariat File No. USA–CDA–2003–1904–05.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement (''Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumpting and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for

Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686). The panel review in this matter was conducted in accordance with these Rules.

Background Information: On October 3, 2003, the Government of Canada filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Second requests were filed on behalf of the Canadian Wheat Board, the Government of Saskatchewan, and the Government of Alberta, respectively. Panel review was requested of the final affirmative Countervailing Duty determination made by the United States Department of Commerce, International Trade Administration, respecting Certain Durum Wheat and Hard Red Spring Wheat from Canada. This determination was published in the **Federal Register**, (68 FR 52747) on September 5, 2003. The NAFTA Secretariat assigned Case Number USA–CDA–2003–1904–05 to this request.

Panel Decision: The Panel affirmed in part and remanded in part. The panel determined that:

(1) The Commission's findings and determinations concerning the comprehensive financial risk coverage program are not in accordance with law and remanded this issue to the Commission for action consistent with its opinion;

(2) The Panel upheld the Commission's findings and determinations concerning the provision of government-owned and leased railcars in all respects and dismiss the appeal on this issue.

The Panel ordered the Commission to issue a determination on remand consistent with the instructions set forth in the Panel's decision within 90 days of the decision or not later than June 8, 2005.

Dated: March 14, 2005.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 05–5358 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–GT–M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Announcement of a Meeting To Explore Feasibility of Establishing a NIST/Industry Consortium on Fire Resistive Materials for Structural Steel

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of public meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) invites interested parties to attend a pre-consortium meeting on July 14, 2005 to be held on the NIST campus. The goal of the one-day meeting is to evaluate industry interest in creating a NIST/industry consortium focused on the materials science of fire resistive materials for structural steel. The goals of such a consortium would include the development of measurement methods for the thermal and adhesion properties of fire resistive materials, tools for the characterization of their three-dimensional microstructure, and linkages between microstructure and the above-mentioned performance properties. The consortium would be supervised and administered by NIST. Consortium research and development would be conducted by NIST staff members along with at least one technical representative from each participating member company. It is estimated that membership fees for participation in the consortium would be on the order of Twenty-five Thousand ($25,000) per year. The initial term of the consortium is intended to be three years.

DATES: The meeting will take place on July 14, 2005 at 8 a.m. to 5 p.m. Interested parties should contact NIST to confirm their interest at the address, telephone number or FAX number shown below.

ADDRESSES: The meeting will take place at the National Institute of Standards and Technology (NIST), 100 Bureau Drive, Administration Building (101), Lecture Room B, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Dale P. Bentz, Emmett P. O'Brien, or Christopher C. White, Building Research (226), Room B362, National Institute of Standards and Technology (NIST), Gaithersburg, MD 20899–8615. Telephone: 301–975–5865; FAX: 301–990–6891; e-mail: *dale.bentz@nist.gov*, *emmett.obrien@nist.gov*, *christopher.white@nist.gov*.

SUPPLEMENTARY INFORMATION: Any program undertaken will be within the scope and confines of The Federal Technology Transfer Act of 1986 (Pub. L. 99–502, 15 U.S.C. 3710a), which provides federal laboratories including NIST, with the authority to enter into cooperative research agreements with qualified parties. Under this law, NIST may contribute personnel, equipment, and facilities but no funds to the cooperative research program. This is not a grant program.

Dated: March 10, 2005.

Hratch G. Semerjian,

Acting Director.

[FR Doc. 05–5397 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Announcement of a Meeting To Discuss an Opportunity To Join a Cooperative Research and Development Consortium on Fire Retardant Foam Flammability

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of public meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) invites interested parties to attend a meeting on April 20, 2005 to discuss the possibility of setting up a cooperative research consortium. The objective is to develop high throughput foam preparation methods and flammability measurement methods to aid polyurethane manufacturers and additive suppliers in developing fire safe foams that are environmentally safe and cost effective. The primary outcome of this work being the creation of a structure-flammability property database for polyurethane foams.

DATES: The meeting will take place on April 20, 2005 at 9 a.m. Interested parties should contact NIST to confirm their interest at the address, telephone number or FAX number shown below.

ADDRESSES: The meeting will take place at the National Institute of Standards and Technology (NIST), 100 Bureau Drive, Polymer Building (224), Room B–245 Fire Science Division, Gaithersburg, MD 20899–8665.

FOR FURTHER INFORMATION CONTACT: Dr. Jeffrey W. Gilman, Polymers Building (224), Room A263, National Institute of Standards and Technology (NIST), Gaithersburg, MD 20899–8665. Telephone: 301–975–6573; FAX: 301–

975–4052; e-mail: *jeffrey.gilman@nist.gov*.

SUPPLEMENTARY INFORMATION: Any program undertaken will be within the scope and confines of The Federal Technology Transfer Act of 1986 (Pub. L. 99–502, 15 U.S.C. 3710a), which provides Federal laboratories including NIST, with the authority to enter into cooperative research agreements with qualified parties. Under this law, NIST may contribute personnel, equipment, and facilities but no funds to the cooperative research program. This is not a grant program.

Dated: March 10, 2005.

Hratch G. Semerjian,

Acting Director.

[FR Doc. 05–5396 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Announcing a Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App., notice is hereby given that the Information Security and Privacy Advisory Board (ISPAB) will meet Tuesday, March 29, 2005 from 8:30 a.m. until 5 p.m. and Wednesday, March 30, 2005 from 8:30 a.m. until 5 p.m. All sessions will be open to the public. The Advisory Board was established by the Computer Security Act of 1987 (Pub. L. 100–235) and amended by the Federal Information Security Management Act of 2002 (Pub. L. 107–347) to advise the Secretary of Commerce and the Director of NIST on security and privacy issues pertaining to federal computer systems. Details regarding the Board's activities are available at *http://csrc.nist.gov/ispab/*.

DATES: The meeting will be held on March 29, 2005, from 8:30 a.m. until 5 p.m. and March 30, 2005, from 8:30 a.m. until 5 p.m.

ADDRESSES: The meeting will take place at the Doubletree Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland.

Agenda:

—Welcome and Overview
—Customer Relations Management (CRM) Work Project
—SRA International Briefing on Radio Frequency Identification
—Office of Management and Budget Update on Computer Security
—National Information Assurance Partnership Program ''The Study
—Professional Credentialing Strategy
—Agenda Development for June 2005 ISPAB Meeting
—Wrap-Up

Note that agenda items may change without notice because of possible unexpected schedule conflicts of presenters.

Public Participation: The Board agenda will include a period of time, not to exceed thirty minutes, for oral comments and questions from the public. Each speaker will be limited to five minutes. Members of the public who are interested in speaking are asked to contact the Board Secretariat at the telephone number indicated below. In addition, written statements are invited and may be submitted to the Board at any time. Written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory, 100 Bureau Drive, Stop 8930, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930. It would be appreciated if 35 copies of written material were submitted for distribution to the Board and attendees no later than March 28, 2005. Approximately 15 seats will be available for the public and media.

FOR FURTHER INFORMATION CONTACT: Ms. Joan Hash, Board Secretariat, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930, telephone: (301) 975–3357.

Dated: March 14, 2005.

Hratch G. Semerjian,

Acting Director.

[FR Doc. 05–5398 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–CN–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 031405A]

Mid-Atlantic Fishery Management Council; Tilefish Fishery; Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of scoping meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council announces its intention to hold scoping meetings to seek public comment on issues to be addressed when developing Amendment 1 to the Tilefish Fishery Management Plan pursuant to the Magnuson Stevens Fishery Conservation and Management Act of 1976, as amended. The purpose of these scoping meetings is to solicit input on management issues to be included in Amendment 1. It is anticipated that the following issues will be discussed at these meetings: the possible implementation of an individual fishing quota system; consideration of possible new methods to collect landings information for the commercial fishery; recreational management measures; a required minimum hook size and/or hook configuration in the commercial tilefish fishery; and, methods to allow new entrants into the commercial fishery as the stock recovers.

DATES: Public scoping meetings will be held on Monday, March 21, 2005, at 7 p.m. and Tuesday, March 22, 2005, at 7 p.m.

ADDRESSES: The dates, times, and locations of the scoping meetings are listed as follows:

1. Monday, March 21, 2005, at 7 p.m.—The Southampton Inn, 91 Hill Street, Southampton, NY 11968 (telephone 631–283–6500).

2. Tuesday, March 22, 2005, at 7 p.m.—Clarion Hotel and Convention Center-Atlantic City West, 6821 Black Horse Pike, Atlantic City, EHT, NJ 08234 (telephone 800–782–9237 or 609–272–0200).

FOR FURTHER INFORMATION CONTACT: Mr. Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council, 300 S. New Street Suite 2115, Dover, Delaware 19904 (telephone 302–674–2331).

SUPPLEMENTARY INFORMATION:

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Debbie Donnangelo at the Mid-Atlantic Council, telephone (302) 674–2331, at least five days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 15, 2005.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1181 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 031505A]

National Marine Fisheries Service, Pacific Fishery Management Council; April 3–8, 2005, Council Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Council) and its advisory entities will hold public meetings. There will also be a Tuesday evening meeting between NMFS, states, and industry on the 2005 whiting exempted fishing permit and a Monday evening meeting sponsored by NMFS and the states to provide an update on the Pacific Groundfish Essential Fish Habitat EIS.

DATES: The Council and its advisory entities will meet April 3–8, 2005. The Council meeting will begin on Monday, April 4, at 3:30 p.m., reconvening each day through Friday. All meetings are open to the public, except a closed session will be held from 3:30 p.m. until 4:30 p.m. on Monday, April 4 to address litigation and personnel matters. The Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: The meetings will be held at the Sheraton Tacoma Hotel, 1320 Broadway Plaza, Tacoma, Washington 98402; telephone: 253–572–3200.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. McIsaac, Executive Director; telephone: 503–820–2280.

SUPPLEMENTARY INFORMATION: The following items are on the Council agenda, but not necessarily in this order:

A. Call to Order
1. Opening Remarks and Introductions
2. Roll Call
3. Executive Director's Report
4. Approve Agenda
C. Salmon Management
1. Identify Stocks Not Meeting Conservation Objectives
2. Methodology Review Process for 2005
3. Update on Essential Fish Habitat Review Process
4. Final Action on 2005 Salmon Management Measures
D. Pacific Halibut Management
1. Adopt Final 2005 Incidental Halibut Catch Regulations for Salmon Troll and Fixed Gear Sablefish Fisheries
E. Habitat
1. Current Habitat Issues
B. Groundfish Management
1. Vermillion Rockfish Assessment
2. Inseason Management Response Policy Final Adoption
3. NMFS Report
4. Terms of Reference for Groundfish Rebuilding Plan Review
5. Implementation of an Expanded Vessel Monitoring System
6. Status of 2005 Groundfish Fisheries and Inseason Adjustments
7. Longline Dogfish Fishery Control Date
F. Coastal Pelagic Species Management
1. NMFS Report
2. Fishery Management Plan Amendment 11–Sardine Allocation
G. Marine Protected Areas
1. Channel Islands National Marine Sanctuary (NMS), Cordell Bank NMS, Gulf of Farallones NMS, and Monterey Bay NMS Designation Document Comments and Proposed NMS Regulations
H. Enforcement Issues
1. U.S. Coast Guard Fishery Enforcement Report
I. Highly Migratory Species Management
1. NMFS Report
2. Fishery Management Plan Implementation
J. Administrative Matters
1. Report on ''Managing Our Fisheries II'' Conference
2. Legislative Matters
3. Appointments to Advisory Bodies, Standing Committees, and Other Forums
4. Work Load Priorities and Draft June 2005 Council Meeting Agenda

SCHEDULE OF ANCILLARY MEETINGS

SUNDAY, April 3, 2005
Klamath Fishery Management Council 3 p.m.
MONDAY, April 4, 2005
Council Secretariat 8 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Scientific and Statistical Committee 8 a.m.
Habitat Committee 10 a.m.
Legislative Committee 10:30 a.m.
Special Session: Salmon Ocean Ecology 1 p.m.
Enforcement Consultants 4:30 p.m.
Special Session: Essential Fish Habitat Environmental Impact Statement Review 7 p.m.
Klamath Fishery Management Council As necessary
Tribal Policy Group As necessary
Tribal and Washington Technical Group As necessary
TUESDAY, April 5, 2005
Council Secretariat 7 a.m.
California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Scientific and Statistical Committee 8 a.m.
Coastal Pelagic Species Management Team 1 p.m.
Coastal Pelagic Species Advisory Subpanel 1 p.m.
Special Sessions: Whiting EFP and Video
Monitoring Briefing 7 p.m.
Enforcement Consultants As necessary
Klamath Fishery Management Council As necessary
Tribal Policy GroupAs necessary
Tribal and Washington Technical Group As necessary
WEDNESDAY, April 6, 2005
Council Secretariat 7 a.m.
California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Coastal Pelagic Species Management Team 8 a.m.
Coastal Pelagic Species Advisory Subpanel 8 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Enforcement Consultants As necessary
Klamath Fishery Management Council As necessary
Tribal Policy Group As necessary
Tribal and Washington Technical Group As necessary
THURSDAY, April 7, 2005
Council Secretariat 7 a.m.
California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Enforcement Consultants As necessary
Tribal Policy Group As necessary
Tribal and Washington Technical Group As necessary
FRIDAY, April 8, 2005
Council Secretariat 7 a.m.
California State Delegation 7 a.m.

Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Enforcement Consultants As necessary
Salmon Advisory Subpanel As necessary
Salmon Technical Team As necessary
Tribal Policy Group As necessary
Tribal and Washington Technical Group As necessary

Although nonemergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at 503–820–2280 at least five days prior to the meeting date.

Dated: March 15, 2005.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1182 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 031505D]

Fisheries of the Exclusive Economic Zone Off Alaska; Application for an Exempted Fishing Permit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of exempted fishing permit application.

SUMMARY: This notice announces receipt of an application for an exempted fishing permit (EFP) from John Gauvin and John Gruver. If granted, this permit would be used to continue the development and testing of a salmon excluder device in the Bering Sea pollock trawl fishery. It is intended to promote the objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) by developing a method for reducing salmon bycatch in the Bering Sea pollock trawl fishery.

ADDRESSES: Copies of the EFP application are available by writing to Sue Salveson, Assistant Regional Administrator for Sustainable Fisheries, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Durall.

FOR FURTHER INFORMATION CONTACT: Melanie Brown, 907–586–7228 or *melanie.brown@noaa.gov*.

SUPPLEMENTARY INFORMATION: NMFS manages the domestic groundfish fisheries in the Bering Sea and Aleutian Islands Management Area (BSAI) under the FMP. The North Pacific Fishery Management Council (Council) prepared the FMP under the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing the groundfish fisheries of the BSAI appear at 50 CFR parts 600 and 679. The FMP and the implementing regulations at §§ 679.6 and 600.745(b) authorize issuance of EFPs to allow fishing that would otherwise be prohibited. Procedures for issuing EFPs are contained in the implementing regulations.

NMFS received an application for an EFP from John Gauvin, Principal Investigator and John Gruver of the United Catcher Boats Association. The purpose of the project is to improve the performance of the salmon excluder device developed under an EFP in 2004 and 2005, and to validate the performance of this device for pollock trawls. The goal is to develop a device for pollock trawls that reduces salmon bycatch without significantly lowering catch rates of pollock.

The EFP would allow for two types of testing of the salmon excluder device in fall 2005 and spring 2006. In the first experiment, a catcher vessel would be used to test minor adjustments to the current excluder device design to improve performance. The second experiment would be conducted using a catcher/processor for the paired-tow experiment to validate the performance of the excluder device. Depending on the results from the work in 2005 and 2006, the EFP may need to be modified to allow for an additional year of testing.

Exemptions from regulations for salmon bycatch limits, observer requirements, salmon savings area closure, the Catcher Vessel Operating Area (CVOA), and total allowable catch amounts (TACs) for groundfish would be necessary to conduct the work. The taking of salmon during the experiment is crucial for determining the effectiveness of the device. Salmon taken during the experiment would not be counted toward the chinook and chum salmon bycatch limits under §§ 679.21(e)(1)(vii) and (e)(1)(viii). Potentially, the amount of salmon bycatch by the pollock trawl industry during the EFP period could approach or exceed the salmon bycatch limits. The additional salmon taken during the experiment would create an additional burden on the pollock trawl industry and may lead to closures of the salmon savings areas, if the EFP salmon were counted toward the salmon bycatch limits. Approximately 2,500 chum salmon and 1,500 chinook salmon would be required to support the project.

The applicants also have requested an exemption from closures of the Chinook Salmon Savings Areas and the Chum Salmon Savings Area (§§ 679.21(e)(7)(vii) and (e)(7)(viii)). The experiment must be conducted in areas of salmon concentration to ensure a sufficient sample size. The salmon savings areas are areas of known concentration of salmon and provide an ideal location for conducting the experiment and ensuring that the vessels encounter concentrations of salmon.

Groundfish taken under the EFP would be exempt from the TACs specified in the annual harvest specifications (§ 679.20). A total of 2,500 metric tons (mt) of groundfish (primarily pollock) would be taken during the EFP work and would not be included in the harvest applied against the Bering Sea groundfish TACs, including the pollock TAC of approximately 1.5 million mt. The 2005 Bering Sea pollock acceptable biological catch is 1.960 million mt, well above the combined TAC and the additional harvest anticipated from the project. Because of the nature of groundfish bycatch in the pollock fishery, the harvest of other groundfish species during the project is expected to be very minor.

The experiment using the catcher/processor would require exemption from the CVOA restriction (§ 679.22(a)(5)) because of the location of the Chinook Salmon Savings Area in the CVOA. Catcher/processors are prohibited from operating in the CVOA during the B season. It would be necessary for the catcher/processor to conduct tows in this area to ensure encountering sufficient pollock and salmon.

The EFP would include an exemption from the observer requirements at § 679.50. The applicants would use ''sea samplers'' who are NMFS-trained observers. They would not be deployed

as NMFS observers, however, at the time of the experiment. The ''sea samplers'' would conduct the data collection and perform other observer duties that would normally be required for vessels directed fishing for pollock.

The activities under the EFP are not expected to have a significant impact on the marine environment, but the potential effects on the marine environment will be further analyzed during review of the application.

In accordance with § 679.6, NMFS has determined that the proposal warrants further consideration and has initiated consultation with the Council by forwarding the application to the Council. The Council will consider the EFP application during its April 4–11, 2005, meeting which will be held at the Hilton Hotel in Anchorage, AK. The applicants have been invited to appear in support of the application, if the applicants desire. Interested persons may comment on the application at the Council meeting during public testimony. A notice announcing the upcoming meeting will be published in the **Federal Register**.

A copy of the application is available for review from NMFS (see **ADDRESSES**).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 15, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1186 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 031505F]

Fisheries of the Exclusive Economic Zone Off Alaska; Application for an Exempted Fishing Permit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of amended application for an exempted fishing permit.

SUMMARY: NMFS has received an amended application for an exempted fishing permit (EFP) from William Thornton Smith of the North Pacific Longline Association (NPLA). If granted, this EFP would authorize the applicant to conduct an experiment to evaluate the integrated weight groundline as a potential seabird avoidance measure in the 2005 Pacific cod hook-and-line fishery in the Bering Sea and Aleutian Islands Management Area (BSAI). The project is intended to promote the objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) by reducing fishery interactions with the endangered short-tailed albatross (*Phoebastria albatrus*) and other seabird species.

ADDRESSES: Copies of the EFP application may be requested from Sue Salveson, Assistant Regional Administrator for Sustainable Fisheries, Alaska Region, NMFS, Attn: Lori Durall by: mail to P.O. Box 21668, Juneau, AK 99802; fax to 907–586–7557; or email to *Lori.Durall@noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Kim Rivera, 907–586–7424 or *Kim.Rivera@noaa.gov*.

SUPPLEMENTARY INFORMATION: NMFS manages the domestic groundfish fisheries in the BSAI under the FMP. The North Pacific Fishery Management Council (Council) prepared the FMP under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing the groundfish fisheries of the BSAI appear at 50 CFR parts 600 and 679. The FMP and the implementing regulations at §§ 679.6 and 600.745(b) authorize the issuance of EFPs to allow fishing that would otherwise be prohibited. Procedures for issuing EFPs are contained in the implementing regulations.

In June 2004, the Council approved the application for an EFP for this experiment which was submitted by the Washington Sea Grant Program (WSGP). The WSGP was unable to secure vessels for the work, and an EFP was not issued in 2004. In February 2005, NMFS received an amended application for this EFP from the NPLA. The purpose of this EFP is to authorize experimental fishing using integrated weight groundline to evaluate its effectiveness as a potential new seabird avoidance measure. The application calls for testing integrated weight groundlines against unweighted groundlines, with and without paired streamer lines. This proposed experiment builds on work that was completed in Alaska in 2002, and compliments efforts taking place in other fisheries. Information from this experiment could ultimately result in better and more effective seabird avoidance measures. The hook-and-line fishing industry appears especially interested in this experiment, because it may provide a better tool with which to avoid the incidental catch of the endangered short-tailed albatross and other seabird species. In addition, the integrated weight groundline may improve fishing efficiency with better gear handling characteristics and increased target catch rates resulting from getting baited hooks down more quickly. The U.S. Fish & Wildlife Service issued a Biological Opinion (September 2003) that includes a conservation recommendation for NMFS to support research efforts to develop new and novel deterrent technologies such as integrated weight groundlines. This experiment would fulfill such a recommendation.

The goal of the experiment is to reduce the incidental catch of the endangered short-tailed albatross and other seabird species in ways that are consistent with Magnuson-Stevens Act National Standard 9 which requires conservation and management measures to minimize bycatch and bycatch mortality and that the effects on birds should be considered when selecting these measures. A preliminary WSGP investigation in 2002 evaluated four weightings of integrated weight groundline (25g/m, 50g/m, 75g/m and 100 g/m). The four weighting treatments were compared to a control of unweighted groundline in the sablefish fishery in the Aleutian Islands and the Pacific cod fishery in the Gulf of Alaska. Preliminary results strongly suggest that 50g/m line was the optimal weighting. It was the most practical gear in terms of operational performance in mechanical baiting (auto-bait) hook-and-line systems, and it sank quickly beyond the range of seabirds.

Based on these initial results, NPLA proposes to continue this work by comparing the catch rates of all species, the abundance and behavior of seabirds, and the sink rate of groundlines under three scenarios: 50g/m integrated weight groundline, and un-weighted groundlines with and without paired streamer lines. Regulations at § 679.24(e)(4)(ii)(c) require the use of paired streamer lines by vessels greater than 55 ft (16.8 m) length overall (LOA). Because vessels used in the experiment would be greater than 55 ft (16.8 m) LOA, an EFP is necessary to conduct the experimental control treatments that call for the experimental gear to be deployed in the absence of paired streamer lines. Work will take place on two freezer-longliner vessels using auto-bait systems in the Pacific cod fishery in the BSAI during 2005 and 2006, if unforeseen circumstances prohibit completion of the work in 2005.

Amendments to the application approved in June 2004, include: (1) starting the experimental fishing a month earlier (July 15, 2005 instead of August 15, 2005), (2) allocating

specified amounts of Pacific cod and bycatch species to participating vessels, (3) harvesting Pacific cod beyond the total allowable catch and acceptable biological catch amounts specified for 2005, and (4) exemption from improved retention/improved utilization regulations at § 679.27.

These levels of harvest and manner of harvest are not expected to have a significant impact on the marine environment, but the potential effects on the marine environment will be further analyzed during review of the application.

In accordance with § 679.6, NMFS has determined that the application warrants further consideration and has initiated consultation with the Council by forwarding the amended application to the Council for consultation. The Council will consider the application during its April 4–11, 2005 meeting which will be held at the Hilton Hotel in Anchorage, AK. While the applicant has been invited to appear in support of the application, all interested parties may comment on the application at the meeting during public testimony. A notice announcing the upcoming meeting will be published in the **Federal Register**.

The vessels that would conduct the experimental fishing were not identified on the application, but would be identified on the EFP, once they have been selected for the project. The NMFS Regional Administrator may consider and attach additional terms and conditions to the EFP that are consistent with the purpose of the experiment. Public comment may help determine such conditions.

A copy of the amended application is available for review from NMFS (see **ADDRESSES**).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 15, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1193 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122104A]

Vessel Monitoring Systems; Approved Mobile Transmitting Units for use in the South Atlantic Rock Shrimp Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of vessel monitoring systems; approval.

SUMMARY: This document provides notice of vessel monitoring systems (VMS) approved by NOAA for use by vessels participating in the Rock Shrimp Fishery of the South Atlantic Region and sets forth relevant features of the VMS, and supersedes all previous type approval notices for the South Atlantic Rock Shrimp Fishery.

ADDRESSES: To obtain copies of the list of NOAA-approved VMS mobile transmitting units and NOAA-approved VMS communications service providers, or to obtain information regarding the status of VMS systems being evaluated by NOAA for approval, write to NOAA Fisheries Office for Law Enforcement (OLE), 8484 Georgia Avenue, Suite 415, Silver Spring, MD 20910.

To submit a completed and signed checklist, mail or fax it to NOAA Enforcement, 9721 Executive Center Drive North, Koger Building, St. Petersburg, FL 33702, fax 727–570–5355. For more addresses regarding approved VMS, see the **SUPPLEMENTARY INFORMATION** section, under the heading VMS Provider Addresses.

FOR FURTHER INFORMATION CONTACT: For current listing information contact Mark Oswell, Outreach Specialist, phone 301–427–2300, fax 301–427–2055. For questions regarding VMS installation, activation checklists, and status of evaluations, contact Jonathan Pinkerton, National VMS Program Manager, phone 301–427–2300, fax 301–427–2055. For questions regarding the installation checklist, contact Beverly Lambert, Southeast Division VMS Program Manager, NMFS Office for Law Enforcement, phone 727–570–5344.

The public may acquire this notice, installation checklist, and relevant updates via the OLE website *http://www.nmfs.noaa.gov/ole/vms.html*. Telephone requests can be made by calling 301–427–2300.

SUPPLEMENTARY INFORMATION:

I. VMS Mobile Transceiver Units

A. Inmarsat-C Transceivers

The Inmarsat-C satellite communications VMS transmitting units that meet the minimum technical requirements for the Rock Shrimp Fishery are the Thrane & Thrane Fishery ''Capsat'' (part number TT–3022D-NMFS) and the Thrane & Thrane Fishery ''Mini-C'' (part number TT–3026–NMFS). The address for the Thrane & Thrane distributor (Thrane & Thrane) dealer contact is provided in this notice under the heading VMS Provider Addresses.

Thrane & Thrane TT–3022D-NMFS features: The transceiver consists of an integrated GPS/Inmarsat-C unit in the wheelhouse and an antenna mounted atop the vessel. The unit is factory pre-configured for NMFS VMS operations (non-Global Maritime Distress & Safety System (non-GMDSS)). Satellite commissioning services are provided by Thrane & Thrane personnel.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is a car-radio-sized transceiver using a floating 10 to 32 VDC power supply. The unit is configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port). It allows for port stays without power drain or power shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The outside antenna, model TT–3005M, is a compact omni-directional Inmarsat-C/GPS antenna, providing operation down to +/-15 deg. angles.

A configuration option is available to automatically send position reports to a private address, such as a fleet management company. Another available option is the ability to send and receive private e-mail and other messages with the purchase and installation of an input device such as a laptop, personal computer, or message display terminal.

Thrane & Thrane TT–3026–NMFS features: The transceiver consists of an integrated GPS/Inmarsat-C unit mounted atop the vessel. The unit is factory pre-configured for NMFS VMS operations (non-Global Maritime Distress & Safety System (non-GMDSS)). Satellite commissioning services are provided by Thrane & Thrane personnel.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is an integrated transceiver/antenna/GPS design using a floating 10 to 32 VDC power supply. The unit is configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port). It allows for port stays without power drain or power shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The TT–3026–NMFS provides operation down to +/-15 degree angles. Although the unit has the capability of two-way communication to send and receive private e-mail and other messages, it can only use this capability when additional equipment - not

required by NMFS - is utilized (i.e., a laptop, personal computer, or message display terminal). A configuration option is available to automatically send position reports to a private address, such as a fleet management company.

A vessel owner may purchase either of these systems by contacting the entity identified under the heading VMS Provider Addresses. The owner should identify himself or herself as a vessel owner in the ''U.S. South Atlantic Rock Shrimp Fishery'' so the transceiver set can be configured for the Rock Shrimp Fishery.

To use the TT–3022D-NMFS or the TT–3026–NMFS, the vessel owner will need to establish an Inmarsat-C system use contract with an approved Inmarsat-C communications service provider. The owner will be required to complete the Inmarsat-C ''Registration for Service Activation for Maritime Mobile Earth Station.'' The owner should consult with Thrane & Thrane when completing this form.

Thrane & Thrane personnel will perform the following services before shipment: (1) configure the transceiver according to NOAA Fisheries Office for Law Enforcement specifications for the Rock Shrimp Fishery; (2) download the predetermined NMFS position reporting and broadcast command identification numbers into the unit; (3) test the unit to ensure operation when installation has been completed on the vessel; and (4) forward the Inmarsat service provider and the transceiver identifying information to the NOAA Fisheries Office for Law Enforcement.

B. ORBCOMM Transceivers

The ORBCOMM satellite communications VMS transmitting unit that meets the minimum technical requirements for U.S. South Atlantic Rock Shrimp Fishery requiring VMS is the Stellar ST2500G (part number ST2500G-NMFS). The address for ORBCOMM Value Added Resellers (VAR) and their regional sales outlets around the country are provided in this notice under the heading VMS Provider Addresses.

The Stellar ST2500G-NMFS transceiver consists of an integrated GPS/ORBCOMM satellite communicator mounted in the wheelhouse and antennas mounted atop the vessel. The unit is pre-configured and tested for NMFS VMS operations. Satellite commissioning services are available from several VMS providers.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is a car radio-sized transceiver powered by any 12 to 32 VDC power supply. It is factory configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port) which allows for port stays without power drain or unit shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The ST2500G has an omni-directional VHF antenna, providing operation from +/-5 degrees above the horizon. A configuration option is available to automatically send position reports to a private e-mail address or to a secure web site where the data is displayed on a map and in tabular form. Another available option is the ability to send and receive private e-mail from a laptop, personal computer or specific handheld devices. A complete list of devices, supported operating systems and available software solutions can be obtained from any ORBCOMM VAR.

Please note that any ''assistance'' or ''emergency'' functions integrated into a VMS unit are not supported by NOAA, although they may be supported by other parties.

A vessel owner wishing to purchase the Stellar ST2500G transceiver will be required to complete an ORBCOMM ''Provisioning'' form via the Internet at *www.orbcomm.com*. The owner should identify him or herself as a vessel owner in the ''U.S. South Atlantic Rock Shrimp Fishery.'' If assistance is required, the owner may consult with the VAR or one of the entities identified in this notice under the heading VMS Provider Addresses. The unit will be configured specifically for the U.S. South Atlantic Rock Shrimp Fishery.

The ORBCOMM VMS VAR will perform the following services before shipment: (1) configure the transceiver according to OLE specifications for the U.S. South Atlantic Rock Shrimp Fishery, (2) download the predetermined NMFS position reporting applications into the unit, (3) test the unit to ensure proper operation prior to shipping, and (4) forward the service provider and the transceiver identifying information to OLE and test the unit when the installation has been completed on the vessel.

II. Communications Service Providers

OLE has approved the below-listed communications service providers: ORBCOMM, Stratos, Telenor, and Xantic satellite communications services.

A. ORBCOMM

NMFS recommends, for vendor warranty and customer service purposes, that the vessel owner and the VAR have on record the following identifying information: (1) signed and dated receipts and contracts, (2) satellite communicator identification number, (3) VAR customer number, (identification number/unit surname name combination), (4) e-mail address of satellite communicator (*surname@ORBCOMM.net*), (5) owner name, (6) vessel name, and (7) vessel documentation or registration number.

VMS units must be installed in accordance with vendor instructions and specifications. Installation can be performed by experienced crew, a VAR, or an electronics specialist. All installation costs are paid by the owner. The vessel owner is required to fax or mail the Rock Shrimp Fishery Activation Fax directly to NOAA Enforcement, 9721 Executive Center Drive North, Koger Building, St. Petersburg, FL 33702, fax 727–570–5355.

The owner must confirm the Stellar ST2500G-NMFS operation and communications service to ensure that position reports are automatically sent to and received by OLE before leaving on their first fishing trip requiring VMS. OLE does not regard the fishing vessel as meeting the requirements until position reports are automatically received. For confirmation purposes, owners must contact the NOAA Enforcement, 9721 Executive Center Drive North, Koger Building, St. Petersburg, FL 33702, phone 727–570–5344, fax 727–570–5355.

ORBCOMM is a store-and-forward data messaging service allowing users to send and receive information virtually anywhere in the world. ORBCOMM supports a wide variety of applications including plain text Internet-based e-mail, position and weather reporting, and remote equipment monitoring and control. Mariners can use ORBCOMM free of charge to send critical safety at-sea messages as part of the U.S. Coast Guard's Automated Mutual-Assistance Vessel Rescue System. VMS services are being sold through specific ORBCOMM VARs.

ORBCOMM customer service supports the security and privacy of vessel accounts and messages by requiring password authentication of vessel owners or agents and OLE personnel to prevent unauthorized changes or inquiries, and by separating private messages from OLE messages. (OLE presently requires VMS-related position reports, only.)

Billing is separated between accounts for the vessel owner and OLE. VMS position reports and vessel-initiated messaging are paid by the vessel owner. Messaging initiated from OLE operations center is paid by OLE.

ORBCOMM provides customer service through its VARs to establish and support two-way transmission of transceiver unit configuration commands between the transceiver and land-based control centers. This supports OLE's message needs and, optionally, fishermen's private e-mail needs.

The owner should refer to and follow the configuration, installation, and service activation procedures for the Stellar ST2500G-NMFS satellite communicator.

B. INMARSAT-C Communications Providers

NMFS recommends, for vendor warranty and customer service purposes, that the vessel owner, Stratos, Telenor and Xantic have on record the following identifying information: (1) signed and dated receipts and contracts, (2) transceiver serial number, (3) Stratos, Telenor or Xantic customer number, user name and password, (4) e-mail address of transceiver, (5) Inmarsat identification number, (6) owner name, (7) vessel name, (8) vessel documentation or registration number, and (9) mobile earth station license (FCC license).

VMS units must be installed in accordance with vendor instructions and specifications and can be performed by experienced crew or by an electronics specialist; costs are paid by the owner. The vessel owner is required to fax or mail the VMS Activation Fax directly to NOAA Enforcement, 9721 Executive Center Drive North, Koger Building, St. Petersburg, FL 33702, phone 727–570–5344, fax 727–570–5355.

The owner must confirm the TT–3022D-NMFS or TT–3026–NMFS operation and communications service to ensure that position reports are automatically sent to and received by OLE before leaving on their first fishing trip under VMS. OLE does not regard the fishing vessel as meeting the requirements until position reports are automatically received. For confirmation purposes, contact NOAA Enforcement, 9721 Executive Center Drive North, Koger Building, St. Petersburg, FL 33702, phone 727–570–5344, fax 727–570–5355.

B1. Telenor Satellite Services

Inmarsat-C is a store-and-forward data messaging service. It allows users to send and receive information virtually anywhere in the world, on land, at sea, and in the air. Inmarsat-C supports a wide-variety of applications including Internet-based e-mail, position and weather reporting, a free daily news service, and remote equipment monitoring and control. Mariners can use Inmarsat-C free of charge to send critical safety at-sea messages as part of the U.S. Coast Guard's Automated Mutual-Assistance Vessel Rescue System and NOAA's Shipboard Environmental Acquisition System programs.

Telenor Vessel Monitoring System Services is being sold through Thrane & Thrane Inc. For the Thrane & Thrane and Telenor addresses, look in this notice under the heading VMS Provider Addresses.

B2. Xantic

Xantic is a provider of vessel monitoring services to the fishing industry. By installing an OLE-approved Inmarsat-C transceiver on the vessel, fishermen can send and receive e-mail, to and from land. The transceiver automatically sends vessel position reports to OLE, and is fully compliant with Coast Guard search and rescue centers. Xantic vessel monitoring system services are being sold through Thrane & Thrane Inc. For the Thrane & Thrane and Xantic addresses, look in this notice under the heading VMS Provider Addresses.

Telenor and Xantic products and services are offered through Thrane & Thrane who supports the security and privacy of vessel accounts and messages by requiring password authentication for vessel owners or agents, and OLE personnel to prevent unauthorized changes or inquiries, and separating of private messages from OLE messages. (OLE currently requires VMS-related position reports, only.)

Billing is separated between accounts for the vessel owner and the OLE. VMS position reports and vessel-initiated messaging are paid by the vessel owner. Messaging initiated from OLE operations center is paid by NOAA.

Thrane & Thrane provides customer service for Telenor and Xantic users to support and establish two-way transmission of transceiver unit configuration commands between the transceiver and land-based control centers. This supports OLE's message needs and, optionally, fishermen's private message needs. A configuration option is available to automatically send position reports to a private e-mail address, such as a fleet management company.

B3. Stratos

Stratos provides all Inmarsat services globally and has extensive experience in the provision of Inmarsat-C messaging and tracking services. Stratos has distributors situated throughout the United States that can provide equipment, installation, commissioning and all other necessary services in compliance with NMFS requirements.

By installing an OLE approved Inmarsat-C transceiver on the vessel in accordance with vendor instructions and specifications and OLE requirements, fishermen can also easily send and receive e-mail to and from land and can also setup individual crew member accounts onboard for e-mail to family and friends without billing to the vessel, but direct billing to crew member.

Vessel owners wishing to use Stratos, Telenor or Xantic services must purchase an Inmarsat-C transceiver approved for the fishery. The owner must complete an Inmarsat-C system use contract with Stratos, Telenor or Xantic; obtain a mobile earth station license (FCC requirement). The transceiver must be commissioned with Inmarsat according to Stratos, Telenor or Xantic's instructions. The owner should refer to and follow the configuration, installation, and service activation procedures for the specific transceiver purchased.

III. VMS Provider Addresses

For ORBCOMM and Stellar ST2500G-NMFS information, contact: ORBCOMM, LLC, 21700 Atlantic Boulevard, Dulles, VA 20166 USA; voice: 800–ORBCOMM (USA) or 703–433–6300; fax: 703–433–6400; or website: *www.ORBCOMM.com*.

For Stratos service or to locate the nearest Stratos distributor, contact *sales@stratosglobal.com*, 1–888–766–1313 or in Florida contact Roberto Darias, 1–954–217–2277, or e-mail: *roberto.darias@stratosglobal.com*.

For Thrane & Thrane TT–3022D-NMFS or TT–3026–NMFS information, contact Ronald Lockerby, Marine Products, Thrane & Thrane, Inc., 509 Viking Drive, Suite K, L & M, Virginia Beach, VA 23452; voice: 757–463–9557; fax: 757–463–9581, e-mail: *rdl@tt.dk.com*; website: *http://www.LandSeaSystems.com*.

For Telenor or Xantic information, contact Thrane & Thrane Inc., Donna Sherman, 509 Viking Drive, Suite K, L, M, Virginia Beach, VA 23452; voice: 757 463–9557; fax: 757 463–9581 e-mail: *airtime@landsea.com*. Telenor and Xantic Customer Service, contact the address above or e-mail: *rdl@tt.dk.com*. Alternate Telenor contacts include Courtney Coleman, Manager COMSAT-C Services Marketing, 6560 Rock Spring Dr., Bethesda, MD 20817; phone: 301–838–7720; e-mail: *courtney.coleman@telenor-usa.com*. Alternate Xantic contacts include Folef

Hooft Graafland, 6100 Hollywood Boulevard, Suite 410, Hollywood, FL 33024; voice: (954) 962–9908 ext. 11; fax: (954) 962–1164; cellular:(954) 214–2609; e-mail: *folef.hooftgraafland@Xantic.net*; and Andre Cortese, 1211 Connecticut Ave., NW, Suite 504, Washington, DC 20036; voice: 202–785–5615; e-mail: *andre.cortese@Xantic.net*.

Authority: 16 U.S.C. 1801, *et seq.*

Dated: March 14, 2005.

William T. Hogarth,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 05–5428 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Technology Administration

Department of Commerce Radio Frequency Identification (RFID) Workshop With Industry on April 6, 2005 From 9 a.m. to 1 p.m.

AGENCY: Technology Administration, U.S. Department of Commerce.

ACTION: Notice; U.S. Department of Commerce RFID workshop.

SUMMARY: The Technology Administration invites representatives from the high technology industry in the United States to participate in a half-day workshop to discuss the latest advances in Radio Frequency Identification (RFID) technology to include: the benefits of RFID, technology development efforts, current and future applications, and privacy and security considerations.

DATES: RSVP must be received at the address below by no later than March 30th, 2005.

ADDRESSES: Please submit names of attendees to Mr. Saul Summerall, Office of Technology Policy, Technology Administration, U.S. Department of Commerce, Room 4817, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Names of attendees may also be submitted by fax at 202–501–6849 or e-mail *saul.summerall@technology.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Sujata Millick, Technology Administration, telephone: 202–482–6804; fax: 202–501–6849, or e-mail: *Sujata.Millick@technology.gov.* Please direct media inquiries to the Office of Public Affairs, Technology Administration, Ms. Cheryl Mendonsa, Director, 202–482–8321.

SUPPLEMENTARY INFORMATION: The Department of Commerce's National Telecommunications and Information Administration and the Technology Administration held a workshop in April 2004 titled *From RFID to Smart Dust: The Expanding Market for Wireless Sensor Technologies*, looking at the market, the uses, and the policy issues related to Radio Frequency Identification (RFID) technologies. (*http://www.ntia.doc.gov/forums/sensors/index.html*). *RFID in 2005: Technology and Industry Perspectives* follows the 2004 workshop and aims to engage stakeholders and industry in discussions about the potential of the technology and its policy implications.

The primary objective of the workshop is to educate stakeholders and policymakers about the benefits of RFID technology, technology development efforts, current and future applications, and privacy and security considerations, as well as to understand industry's experiences in implementing RFID technologies. In this half-day workshop, industry panelists will give brief presentations on their development, use, or management of RFID technology. The final panel will address the challenge of responsible data policies to sustain RFID technology and develop consumer confidence and acceptance of RFID.

RFID technology applications have the immense potential to enhance commerce, personal and business security, and government and business processes. Market estimates for RFID applications range from about $1 billion in 2004 to almost $5 billion by 2008, with about 30% of all capital goods carrying RFID tags by 2008. This has important implications for businesses and consumers. Introduction of RFID technology into the marketplace requires an explanation of the benefits of the technology and discussions about actual and perceived challenges.

In the case of RFID: technical standards, spectrum, international operability, implementation costs, data privacy and security considerations are part of the current discourse on RFID. The Department of Commerce wants to use this workshop opportunity to ensure that RFID industry concerns and views are heard and that accurate information about the features and abilities of RFID are disseminated.

Dated: March 14, 2005.

Phillip J. Bond,

Under Secretary of Commerce for Technology.

[FR Doc. 05–5399 Filed 3–17–05; 8:45 am]

BILLING CODE 3510–GN–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11 a.m., Friday, April 1, 2005.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

FOR FURTHER INFORMATION CONTACT: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–5485 Filed 3–16–05; 11:47 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11 a.m., Friday, April 8, 2005.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

FOR FURTHER INFORMATION CONTACT: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–5486 Filed 3–16–05; 11:47 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11 a.m., Friday, April 15, 2005.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

FOR FURTHER INFORMATION CONTACT: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–5487 Filed 3–16–05; 11:47 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11 a.m., Friday, April 22, 2005.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

FOR FURTHER INFORMATION CONTACT: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–5488 Filed 3–16–05; 8:45 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11 a.m., Friday, April 29, 2005.

PLACE: 1155 21 St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

FOR FURTHER INFORMATION CONTACT: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–5489 Filed 3–16–05; 11:47 am]

BILLING CODE 6351–01–M

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 05–C0005]

Polaris Industries Inc.; Final Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Commission has finally accepted a Settlement Agreement with Polaris Industries Inc. containing a civil penalty of $950,000.

DATES: The Settlement Agreement was finally accepted and the Order issued on March 9, 2005.

FOR FURTHER INFORMATION CONTACT: Seth B. Popkin, Trial Attorney, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207.

SUPPLEMENTARY INFORMATION: On January 13, 2005, the Commission provisionally accepted a Settlement Agreement and Order in the matter of Polaris Industries Inc. and published it for comment in the **Federal Register** of January 21, 2005 (70 FR 3188). The Commission received two comments on the Provisional Settlement Agreement and Order. After considering those comments, the Commission voted on March 9, 2005, to finally accept the Settlement Agreement.

Dated: March 9, 2005.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

Order

Upon consideration of the Settlement Agreement entered into between Polaris Industries Inc. (''Polaris'') and the U.S. Consumer Product Safety Commission (''Commission'') staff, and the Commission having jurisdiction over the subject matter and over Polaris, and it appearing that the Settlement Agreement and Order is in the public interest, it is

Ordered, that the Settlement Agreement be, and hereby is, accepted; and it is

Further ordered, that Polaris shall pay a civil penalty in the amount of nine hundred and fifty thousand dollars ($950,000.00) within twenty (20) calendar days of service of the final Order upon Polaris. The payment shall be made by check payable to the order of the United States Treasury. Upon the failure of Polaris to make the foregoing payment when due, interest on the unpaid amount shall accrue and be paid by Polaris at the federal legal rate of interest set forth in the provisions of 28 U.S.C. 1961(a) and (b).

Provisionally accepted and Provisional Order issued on the 13th day of January 2005.

By order of the Commission:

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

Upon consideration of the Settlement Agreement between Polaris Industries Inc. and the staff and the comments received on the provisional Settlement Agreement and Order, the Consumer Product Safety Commission finally accepts the Settlement Agreement.

Final Order issued on the 9th day of March, 2005.

By order of the Commission:

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 05–5354 Filed 3–17–05; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 05–17]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/OPS–ADMIN, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 05–17 with attached transmittal and policy justification.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense

BILLING CODE 5001–06–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

10 MAR 2005
In reply refer to:
I-05/002457

The Honorable J. Dennis Hastert
Speaker of the House of Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 05-17, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Iraq for defense articles and services estimated to cost $132 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

Richard J. Millies
Deputy Director

Enclosures:
1. **Transmittal**
2. **Policy Justification**

Same ltr to: House Committee on International Relations
Senate Committee on Foreign Relations
House Committee on Armed Services
Senate Committee on Armed Services
House Committee on Appropriations
Senate Committee on Appropriations

Transmittal No. 05-17

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended

(i) **Prospective Purchaser: Iraq**

(ii) **Total Estimated Value:**

Major Defense Equipment*	$ 21 million
Other	$111 million
TOTAL	$132 million

(iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: six T-56A-7 engines and logistics support for C-130 aircraft to include supply and maintenance support, flares, software upgrades, pyrotechnics, spare and repair parts, support equipment, publications and documentation, personnel training and training equipment, fuel and fueling services, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics support.**

(iv) **Military Department: Air Force (QAC)**

(v) **Prior Related Cases, if any: none**

(vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none**

(vii) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: none**

(viii) **Date Report Delivered to Congress:**

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Iraq - T-56A-7 Engines and Logistics Support for C-130 Aircraft

The Government of Iraq has requested a possible sale of six T-56A-7 engines and logistics support for C-130 aircraft to include supply and maintenance support, flares, software upgrades, pyrotechnics, spare and repair parts, support equipment, publications and documentation, personnel training and training equipment, fuel and fueling services, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics support. The estimated cost is $132 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country. This proposed sale directly supports the Iraqi government and serves the interests of the Iraqi people and the U.S., as well as offering hope for a more stable and peaceful Middle East.

The Government of Iraq needs the spare engines, contractor technical support, maintenance, and logistical services to maintain the operational capabilities of its C-130E aircraft, previously procured from the United States. These C-130E aircraft will be used to provide airlift support. Additionally, this sale offers the U.S. the opportunity to facilitate the political transition currently underway and build additional links to the Iraqi military.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

There will be a competition between the contractors in joint negotiations for Contractor Engineering Technical Services. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale may require the assignment of up to four representatives to support Contractor Engineering Technical Services in Iraq for two years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 05–5430 Filed 3–17–05; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Department of Defense, Advisory Group on Electron Devices.

ACTION: Notice; meeting of the DOD advisory group on electron devices.

SUMMARY: The DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 1200, Monday, April 4, 2005.

ADDRESSES: The meeting will be held at Nellis AFB, 4370 N. Washington Blvd. Suite 223,Ne1lis AFB, NV 89191.

FOR FURTHER INFORMATION CONTACT: Ms. Vicky Schneider, Noesis, Inc. 4100 N. Fairfax Drive, Suite 800, Arlington, VA 22203.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition, Technology and Logistics to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency and the Military Departments in planning and managing an effective and

economical research and development program in the area of electron devices.

The AGED meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. The agenda for this meeting will include programs on microwave technology microelectronics, electro-optics, and electronics materials.

In accordance with Section 10(d) of Pub. L. No. 92–463, as amended, (5 U.S.C. App.2 § 10(d)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1), and that accordingly, this meeting will be closed to the public.

Dated: March 14, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–5432 Filed 3–17–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notification of an Open Meeting of the Board of Visitors (BOV), National Defense University

AGENCY: National Defense University.

ACTION: Notice; meeting of Board of Visitors (BOV) at NDU.

SUMMARY: The President, National Defense University has scheduled a meeting of the Board of Visitors. Request subject notice be published in the **Federal Register**. The National Defense University Board of Visitors is a Federal Advisory Board. The Board meets twice a year in proceedings that are open to the Public.

DATES: The meeting will be held on April 18 and 19, 2005 from 11 a.m. to 5 p.m. on the 18th and continuing on the 19th from 8:30 a.m. to 1:30 p.m.

Location: The Board of Visitors meeting will be held at Building 62, Marshall Hall, Room 155, National Defense University, 300 5th Avenue, Fort McNair, Washington, DC 20319–5066.

FOR FURTHER INFORMATION CONTACT: The point of contact for this notice of an ''Open Meeting'' is Ms. Tonya Barbee at (202) 6885–3539, Fax (202) 685–3935 or *barbee@ndu.edu*.

SUPPLEMENTARY INFORMATION: The future agenda will include discussions on Defense transformation, faculty development facilities, information technology, curriculum development, post 9/11 initiatives as well as other operational issued and areas of interests affecting the day-to-day operations of the National Defense University and its components. The meeting is open to the public; limited space made available for observers will be allocated on a first come, first served basis.

Dated: March 14, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–5431 Filed 3–17–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Non-Exclusive, Exclusive, or Partially Exclusive Licensing of U.S. Patent Concerning Trifluoromethylepinephrine Compounds and Methods of Making and Using Thereof

AGENCY: Department of the Army, DoD.

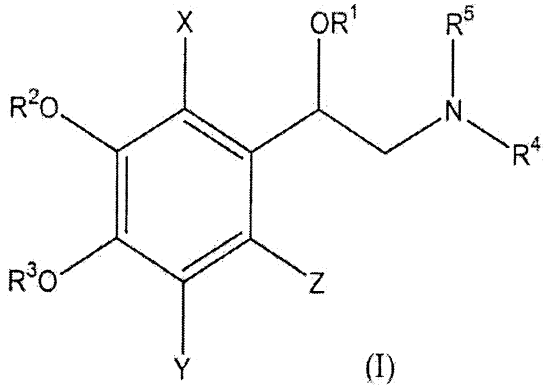
ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.6 and 404.7, announcement is made of the availability for licensing of U.S. Patent No. 6,825,382 entitled ''Trifluoromethylepinephrine Compounds and Methods of Making and Using Thereof,'' issued November 30, 2004. Foreign rights are also available (PCT/US03/05976). The United States Government, as represented by the Secretary of the Army, has rights in this invention.

ADDRESSES: Commander, U.S. Army Medical Research and Materiel Command, ATTN: Command Judge Advocate, MCMR–ZA–J, 504 Scott Street, Fort Detrick, Frederick, MD 21702–5012.

FOR FURTHER INFORMATION CONTACT: For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619–7808. For licensing issues, Dr. Paul Mele, Office of Research & Technology Assessment, (301) 619–6664, both at telefax (301) 619–5034.

SUPPLEMENTARY INFORMATION: Disclosed herein are trifluoromethylepinephrine compounds having the following structural forumula (I):



(I)

Wherein R^1—R^5 are each independently selected from the group consisting of H, alkyl, alkoxyl, aryl, heteroaryl, cycloalkyl, heterocycloalkyl, acyl, thioacyl, suffonyl mercapto, alkylthio, carboxy, amino, alkylamino dialkylamino, carbamoyl, arylthio, and heteroarylthio; wherein X, Y, and Z are each independently selected from the group consisting of H or trifluoromethyl with the proviso that at least one of which is trifluoromethyl. Also disclosed are pharmaceutical compositions comprising the trifluoromethylepinephrine compounds and methods of making and using thereof. Novel

trifluoromethylepinephrine intermediates are also disclosed.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

FR Doc. 05–5328 Filed 3–17–05; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP04–101–001]

Columbia Natural Resources, LLC; Notice of Compliance Filing

March 14, 2005.

Take notice that on February 25, 2005, Columbia Natural Resources, LLC pursuant with the Commission's ''Order on Petition for Declaratory Order,'' 110 FERC ¶ 61,062 (2005), filed a service agreement with Allegheny Power as a special rate schedule under section 154.112(a) of the Commission's regulations.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all the parties in this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. eastern time on April 4, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–1205 Filed 3–17–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–202–001]

Panhandle Eastern Pipe Line Company, LP; Notice of Proposed Changes in FERC Gas Tariff

March 11, 2005.

Take notice that on March 9, 2005, Panhandle Eastern Pipe Line Company, LP (Panhandle) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the revised tariff sheets in Appendix B attached to the filing, to become effective April 1, 2005.

Panhandle states that the purpose of this filing, made in accordance with section 24 (Fuel Reimbursement Adjustment) of the General Terms and Conditions in Panhandle's FERC Gas Tariff, Third Revised Volume No. 1, is to replace Appendix B, Page 6, which contained an incorrect amount for the projected annual throughput for the Market Zone.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–1176 Filed 3–17–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER03–256–004, et al.]

TXU Pedricktown Cogeneration Company LP, et al.; Electric Rate and Corporate Filings

March 11, 2005.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. TXU Pedricktown Cogeneration Company LP

[Docket No. ER03–256–004]

Take notice that on March 8, 2005, TXU Pedricktown Cogeneration Company LP (TXU Pedricktown) tendered for filing a compliance filing consisting of its triennial market power update and its third revised market-based rate schedule reflecting the incorporation of the reporting requirement adopted by the Commission in Order No. 652 issued February 10, 2005, *Reporting Requirement for Changes in Status for Public Utilities with Market-Based Rate Authority,* 110 FERC ¶ 61,097 (2005).

Comment Date: 5 p.m. eastern time on March 29, 2005.

2. FirstEnergy Solutions Corp.

[Docket No. ER04–652–003]

Take notice that on March 8, 2005, FirstEnergy Solutions Corp. (Solutions) submitted revisions to Service Schedule A-Reactive Supply and Voltage Control from Generation Sources Service under its tariff for sales of ancillary services

and interconnected operations services in compliance with the Commission's order issued February 14, 2005 in Docket No. ER05–652–002, *et al.,* 110 FERC ¶ 61,142.

Comment Date: 5 p.m. eastern time on March 29, 2005.

3. Tucson Electric Power Company and UNS Electric, Inc.

[Docket No. ER05–610–001]

Take notice that on March 8, 2005, Tucson Electric Power Company and UNS Electric Inc. tendered for filing revised tariff sheets as an addendum to their joint February 18, 2005 compliance filing in Docket No. ER05–610–000.

Comment Date: 5 p.m. eastern time on March 29, 2005.

4. WPS Energy Services, Inc.

[Docket No. ER05–686–000]

Take notice that on March 8, 2005, WPS Energy Services, Inc. (ESI) tendered for filing a Notice of Cancellation of the brokering and dispatch agreement between ESI and Sunbury Generation, LLC (Sunbury). ESI requests an effective date of December 31, 2004.

ESI states that copies of the filing were served upon Sunbury.

Comment Date: 5 p.m. eastern time on March 29, 2005.

5. Total Gas & Electricity (PA), Inc.

[Docket Nos. ER05–687–000]

Take notice that on March 8, 2005, Total Gas & Electricity (PA), Inc. (TG&E PA) tendered for filing a petition for acceptance of TG&E PA's proposed FERC Rate Schedule No. 1; waiver of certain requirements under Subparts B and C of Part 35 of the regulations; and the granting of blanket approvals normally accorded to sellers at market-based rates. TG&E PA states that it intends to act as a power marketer and that it and its affiliates do not own or control any electric generation facilities, transmission facilities, or any inputs to generation and does not have any franchised electric utility affiliates.

Comment Date: 5 p.m. eastern time on March 29, 2005.

6. Southwest Power Pool, Inc.

[Docket No. ER05–688–000]

Take notice that on March 8, 2005, Southwest Power Pool, Inc. (SPP) submitted for filing a letter agreement between Southwestern Public Service Company d/b/a Xcel Energy (Xcel) and Wildorado Wind, LP (Wildorado) (collectively, Parties) providing for the performance of certain engineering and design activities by Xcel and the payment for such activities by Wildorado relating to the proposed interconnection of a generating facility to be owned and constructed by Wildorado. SPP states that while it is not a party to the letter agreement, it is submitting the letter agreement on behalf of the Parties as the relevant Transmission Provider. SPP seeks an effective date of February 14, 2005.

Comment Date: 5 p.m. eastern time on March 29, 2005.

Standard Paragraph

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1180 Filed 3–17–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–58–000]

CenterPoint Energy Gas Transmission Company; Notice of Intent To Prepare an Environmental Assessment for the Proposed Chiles Dome Storage Expansion Project and Request for Comments on Environmental Issues

March 11, 2005.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Chiles Dome Storage Expansion Project involving construction and operation of facilities by CenterPoint Energy Gas Transmission Company (CenterPoint) in Coal, Atoka, Pittsburg, and Latimer Counties, Oklahoma. CenterPoint's project purpose is to increase its Chiles Dome storage reservoir working gas capacity by three billion cubic feet and its deliverability by 43,000,000 cubic feet per day. In general, the project consists of three wells, about 23.5 miles of pipeline, and auxiliary facilities at Centerpoint's existing Chiles Dome and Chandler Compressor Stations.

This notice announces the opening of the scoping period that will be used to gather environmental input from the public and interested agencies on the project. Please note that the scoping period will close on April 11, 2005.

This notice is being sent to potentially affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American Tribes, other interested parties; local libraries and newspapers. State and local government representatives are asked to notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The pipeline company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*http://www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is available for viewing on the FERC Internet Web site (*http://www.ferc.gov*).

Summary of the Proposed Project

Centerpoint proposes to construct and operate: [1]

(1) Three vertical wells in its Chiles Dome Storage Reservoir in Coal County, Oklahoma;

(2) About 23.4 miles of 24-inch-diameter pipeline that would extend eastward from the Chiles Dome Storage Reservoir to an existing CenterPoint 24-inch-diameter pipeline in Pittsburg County, Oklahoma. This would include:

- Two 24-inch mainline valve assemblies,
- Two blowdown stacks, and
- A pig launcher and receiver at each terminal;

(3) within its existing Chiles Dome Compressor Station in Coal County, Oklahoma:

- A pipeline liquid removal scrubber,
- A glycol dehydrator and reboiler,
- A gas cooler, filter-separator, and pressure reducing valve,
- About 400 feet of 20-inch-diameter pipe and 100 feet of 16-inch-diameter pipe, and
- Valves, fittings, and supports to connect to the proposed 24-inch-diameter pipeline; and

(4) Within its existing Chandler Compressor Station in Latimer County, Oklahoma:

- A 16-inch meter,
- An 8-inch pressure reducing valve,
- A 20-inch cross-over line, and
- About 450 feet of 20-inch-diameter pipe.

The general location of Centerpoint's proposed facilities is shown on the map attached as Appendix 1.[2]

Land Requirements for Construction

Construction of CenterPoint's proposed facilities would require about 255.0 acres of land for the well pads, construction right-of-way for the pipelines, additional temporary workspaces, and staging areas. The wells would require about 2.1 acres each for both construction and operation. The construction right-of-way for the pipelines would typically be 75 feet wide, except in agricultural areas or where specifically requested by landowners it could be 100 feet wide, to allow for topsoil segregation. Following construction, a 50-foot wide permanent right-of-way would be maintained.

The construction of the auxiliary facilities at the Chiles Dome and Chandler Compressor Stations would be performed within the existing CenterPoint facilities and would not require the clearing of additional land.

Construction access to CenterPoint's project would be via existing public and private roads. CenterPoint has identified 13 existing private access roads necessary for the construction of its project.

The EA Process

We [3] are preparing the EA to comply with the National Environmental Policy Act (NEPA) which requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission staff requests public comments on the scope of the issues to address in the EA. All comments received are considered during the preparation of the EA. By this notice, we are also asking Federal, state, and local agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. Agencies that would like to request cooperating status should follow the instructions for filing comments below.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

Currently Identified Environmental Issues

In the EA, we will discuss impacts that could occur as a result of the construction and operation of the project. We will also evaluate possible alternatives to the proposed project or portions of the project.

We have already identified some issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by CenterPoint. This preliminary list of issues may be changed based on your comments and our analysis.

Project-related impact on:

- Pipeline crossings of 12 perennial waterbodies.
- Five federally-listed threatened and endangered species potentially in the project area.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative locations and routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.
- Label one copy of the comments for the attention of Gas Branch 1.
- Reference Docket No. CP05–58–000.
- Mail your comments so that they will be received in Washington, DC on or before April 11, 2005.

Please note that the Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov under the* ''e-Filing'' link and the link to the User's

[1] CenterPoint's application was filed with the Commission under section 7 of the Natural Gas Act and Part 157 of the Commission's regulations.

[2] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of all appendices, other than appendix 1 (maps), are available on the Commission's Web site at the ''eLibrary'' link or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

[3] ''We'', ''us'', and ''our'', refer to the environmental staff of the Office of Energy Projects (OEP).

Guide. Before you can file comments you will need to create an account which can be created on-line.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding known as an ''intervenor''. Intervenors play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must send one electronic copy (using the Commission's e-Filing system) or 14 paper copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, see Appendix 2).[4] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

Magalie R. Salas,

Secretary.

[FR Doc. E5–1179 Filed 3–17–05; 8:45 am]

BILLING CODE 6717–01–P

[4] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Scoping Meetings, Technical Conference, Site Visit and Soliciting Scoping Comments

March 11, 2005.

Take notice that the following hydroelectric application has been filed with Commission and are available for public inspection:

a. *Type of Application:* New major license.

b. *Project No.:* 11882–002.

c. *Date filed:* May 27, 2004.

d. *Applicant:* Fall River Rural Electric Cooperative, Inc.

e. *Name of Project:* Hebgen Dam Hydroelectric Project.

f. *Location:* On the Madison River, near the town of West Yellowstone, Gallatin County, Montana. The project is located in the Gallatin National Forest and is within close proximity to Yellowstone National Park.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Brent L. Smith, Northwest Power Services, Inc. PO Box 535, Rigby, Idaho 83442; telephone (208) 745–0834 or by e-mail at *bsmith@nwpwrservices.com.*

i. *FERC Contact:* Kim A. Nguyen, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426; telephone (202) 502–6105 or by e-mail at *kim.nguyen@ferc.gov.*

j. *Deadline for filing scoping comments:* May 13, 2005.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Scoping comments may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. This application is not ready for environmental analysis at this time.

l. The Hebgen Dam Hydroelectric Project will consist of a powerhouse with a single turbine generator unit of approximately 6.7 megawatt capacity at the area downstream of the dam and immediately north of the present outlet discharge. The Applicant also proposes to install a new 9.4-mile, 25-kilovolt underground power transmission line to connect the powerhouse with the existing Fall River Rural Electric Cooperative's Hebgen substation located near Grayline, Montana. The Applicant proposes to utilize the existing Hebgen Dam, Hebgen Resevoir, outlet works, and spillway, currently owned and operated by Pennsylvania Power and Light Montana, LLC (PPL Montana) as a regulating reservoir under the Missouri-Madison Hydroelectric Project, FERC No. 2188.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Scoping Process.* The Commission intends to prepare an Environmental assessment (EA) on the project in accordance with the National Environmental Policy Act. The EA will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Scoping Meetings

FERC staff will conduct one daytime scoping meeting and one evening meeting. The daytime scoping meeting

will focus on resource agency and non-governmental organization concerns, while the evening scoping meeting is primarily for public input. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EA. The times and locations of these meetings are as follows:

Daytime Scoping Meeting

Date: Tuesday, April 12, 2005.
Time: 10 a.m. (m.s.t.).
Place: West Yellowstone Conference Center.
Address: 315 Yellowstone Avenue, West Yellowstone, Montana.

Evening Scoping Meeting

Date: Tuesday, April 12, 2005.
Time: 7 p.m.
Place: West Yellowstone Conference Center.
Address: 315 Yellowstone Avenue, West Yellowstone, Montana.

Copies of the Scoping Document (SD1) outlining the subject areas to be addressed in the EA were distributed to the parties on the Commission(s mailing list. Copies of the SD1 will be available at the scoping meeting or may be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link (*see* item m above).

Site Visit

The Applicant and FERC staff will conduct a project site visit beginning at 10 a.m. on April 13, 2005. All interested individuals, organizations, and agencies are invited to attend. All participants should meet at the Hebgen Dam. All participants are responsible for their own transportation to the site. Anyone with questions about the site visit should contact Kim Nguyen of FERC at (202) 502–6105 or Brent Smith of Fall River at (208) 745–0834.

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the EA; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the EA, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the EA; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Procedures

The meetings are recorded by a stenographer and become part of the formal record of the Commission proceeding on the project.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the EA.

Technical Conference

At the technical conference, we will discuss how the proposed project would affect PPL Montana's Missouri-Madison Project (FERC No. 2188). This technical conference will not be recorded by a court reporter, however, we will summarize the meeting in a filing of public record for the project.

Technical Conference

Date: Wednesday, April 13, 2005.
Time: 2 p.m.
Place: West Yellowstone Conference Center.
Address: 315 Yellowstone Avenue, West Yellowstone, Montana.

Magalie R. Salas,
Secretary.

[FR Doc. E5–1177 Filed 3–17–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, Protests, Recommendations, and Terms and Conditions

March 11, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Small Conduit Exemption.
b. *Project No.:* 12574–000.
c. *Date filed:* February 1, 2005.
d. *Applicant:* Santiam Water Control District (SWCD).
e. *Name of Project:* Stayton Hydroelectric Project.
f. *Location:* The Stayton Project is located on the Stayton Ditch in Marion County, Oregon. The Stayton Ditch conveys water diverted from the North Santiam River at the Lower Bennett Dam for agricultural, municipal, and industrial uses. At about one quarter mile downstream, flows in the Ditch are directed through a headgate and newly constructed fish screen that directs fish to a pipe that returns them to the North Santiam River. At the downstream end of the Stayton Ditch, SWCD has also constructed a barrier that restricts upstream migration of fish into the Ditch.
g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791a–825r.
h. *Applicant Contact:* Mr. Larry Trosi, Manager, Santiam Water Control District, 284 East Water Street, Stayton, OR 97383, (503) 769–2669.
i. *FERC Contact:* James Hunter, (202) 502–6086.
j. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.
k. *Deadline for filing responsive documents:* The Commission directs, pursuant to section 4.34(b) of the Regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments, motions to intervene, protests, recommendations, terms and conditions, and prescriptions concerning the application be filed with the Commission by April 11, 2005. All reply comments must be filed with the Commission by April 27, 2005.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. Description of Project: The existing hydroelectric project consists of: (1) An intake with trash racks at normal water surface elevation 447 feet mean sea level (msl), (2) a 27-foot by 28-foot powerhouse, (2) an Allis-Chalmers turbine and a 600-kilowatt generating unit; and (3) an outlet returning flow to the Stayton Ditch at normal water surface elevation 431 feet msl. With completion of the fish screen and barrier enabling power production during the spring fish migration season, the average annual energy production is expected to be 4,320 megawatt hours.

m. This filing is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street, NE., Washington, DC 20426. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, here P–12574, in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for review and reproduction at the address in item h. above.

n. Development Application—Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

q. All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' ''COMPETING APPLICATION,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and eight copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Office of Energy Projects, Federal Energy Regulatory Commission, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Magalie R. Salas,

Secretary.

[FR Doc. E5–1178 Filed 3–17–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6661–5]

Environmental Impact Statements; Notice of Availability Responsible

Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa.*

Weekly receipt of Environmental Impact Statements

Filed March 8, 2005 Through March 11, 2005

Pursuant to 40 CFR 1506.9.

EIS No. 050099, Draft EIS, AFS, OR, Big Butte Springs Timber Sales, To Implementation Management Direction, Roque River-Siskiyou National Forest, Butte Falls Ranger District, Cascade Zone, Jackson County, OR, Comment Period Ends: May 2, 2005, Contact: Joel T. King (541) 560–3400.

EIS No. 050100, Final EIS, HUD, CA, Marysville Hotel Demolition Project, Proposed Acquisition and Demolition of Building, City of Marysville, Yuba County, CA, Wait Period Ends: April 18, 2005, Contact: Gary Price (530) 749–3904.

EIS No. 050101, Final EIS, AFS, AZ, Arizona Snowbowl Facilities Improvements, Proposal to Provide a Consistent/Reliable Operating Season, Coconino National Forest, Coconino County, AZ, Wait Period Ends: April 18, 2005, Contact: Ken Jacobs (928) 774–1147.

EIS No. 050102, Final EIS, COE, OH, Mill Creek, Ohio Flood Damage Reduction Project, To Reduce Damages to Communities, Hamilton County, OH, Wait Period Ends: April 18, 2005, Contact: Barry Schueler (502) 315–6780.

EIS No. 050103, Draft EIS, HUD, CA, Stillwater Business Park, Development of Business Park, Annexation AN 1–01, Shastec Redevelopment Project Area, Airport Land Use Plan Amendment Pre-Zone, General Plan Amendment GPA–2–01, Funding and U.S. Army COE 404 Permit, City of Redding, Shasta County, CA, Comment Period Ends: May 2, 2005, Contact: Nathan Cherpeski (530) 225–4519.

EIS No. 050104, Draft EIS, AFS, CA, Golden Gate National Recreation Area (GGNRA) Fire Management Plan, Implementation, Muir Woods National Monument, Fort Point National Historic Site, San Mateo, San Francisco and Marin Counties, CA, Comment Period Ends: May 17, 2005, Contact: Alex Naar (415) 331–6374.

EIS No. 050105, Draft EIS, AFS, WI, PROGRAMMTIC EIS—Huron-Manistee National Forests, Proposed Land and Resource Management Plan, Implementation, Several Counties, WI, Comment Period Ends: May 2, 2005, Contact: Jeff Pullen (231) 775–2421.

EIS No. 050106, Final EIS, AFS, MT, Sheep Creek Salvage Project, Moving Current Resource Conditions and Trends Toward Desired Future Conditions, Beaverhead-Deerlodge National Forest, Beaverhead County, MT, Wait Period Ends: April 19, 2005, Contact: Jeffrey L. Trejo (406) 832–3178.

EIS No. 050107, Draft EIS, AFS, IL, Shawnee National Forest Proposed Land and Resource Management Plan Revision, Implementation, Alexander, Gallatin, Hardin, Jackson, Johnson, Massac, Pope, Union and Williamson Counties, IL, Comment Period Ends: June 16, 2005, Contact: Stephen Hupe (618) 253–7114.

EIS No. 050108, Final EIS, FTA, UT, Weber County to Salt Lake City Commuter Rail Project, Proposes a

Commuter Rail Transit Service with Nine Stations between Salt Lake City and Peasant View, Funding, Weber, Davis and Salt Lake Counties, UT, Wait Period Ends: April 18, 2005, Contact: Don Cover (720) 963–3332.

EIS No. 050109, Draft Supplement, NOA, PR, VI, Amendment to the Fishery Management Plans (FMPs), Amendment 2 for the Spiny Lobster Fishery; Amendment 1 for the Queen Conch Resources; Amendment 3 for the Reef Fish Fishery; Amendment 2 Corals and Reef Associated Invertebrates, U.S. Caribbean to Address Required Provisions MSFCMA, Puerto Rico and the U.S. Virgin Island, Comment Period Ends: May 2, 2005, Contact: Dr. Roy Crabtree (727) 824–5301.

Amended Notices

EIS No. 050018, Draft EIS, FAA, IL, O'Hare Modernization Program, Proposes Major Development, Chicago O'Hare International Airport, Airport Layout Plan (ALP), Federal Funding, U.S. Army COE Section 404 Permit, City of Chicago, IL, Comment Period Ends: April 6, 2005, Contact: Michael W. MacMullen (847) 294–8339. Revision of FR Notice Published on 1/28/05: CEQ Comment Period Ending 03/23/2005 has been Extended to 04/06/2005.

EIS No. 050063, Final EIS, AFS, UT, Monticello and Blanding Municipal Watershed Improvement Projects, Implementation, Manti-La Sal National Forest, Monticello Ranger District, San Juan County, UT, Wait Period Ends: March 21, 2005, Contact: Greg T. Montgomery (435) 636–3348. Revision of FR Notice Published on 2/18/2005: Correction to Contact Person Name and Telephone Number.

EIS No. 050068, Draft EIS, AFS, AK, OK, Ouachita National Forest, Proposed Revised Land and Resource Management Plan, Implementation, several counties, AR and LeFlore and McCurtain Counties, OK, Comment Period Ends: May 26, 2005, Contact: Bill Pell (501) 321–5320. Revision of FR Notice Published on 2/25/2005: CEQ Comment Period Ending on 4/11/2005 has been Extended to 5/26/2005.

Dated: March 15, 2005.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 05–5417 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6661–6]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7146. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in the **Federal Register** dated April 2, 2004 (69 FR 17403).

Draft EISs

ERP No. D–AFS–G65097–NM Rating LO, Tajique Watershed Restoration Project, Proposes Fuel Reduction and Restore Forest Health, Cibola National Forest, Torraine County, NM.

Summary: EPA expressed lack of objections to the preferred alternative.

ERP No. D–NPS–G02014–TX Rating EC2, Big Thicket National Preserve Oil and Gas Management Plan, Implementation, Hardin, Jefferson, Orange, Liberty, Tyler, Jasper and Polk Counties, TX.

Summary: EPA expressed environmental concerns with impacts to jurisdictional wetlands and requests additional information on the delineation of these wetlands be incorporated in the Final EIS.

Final EISs

ERP No. F–AFS–J65402–WY, Tongue Allotment Management Plan, Proposal to Continue Livestock Grazing on All or Portions of the 22 Allotment, Bighorn National Forest, Tongue and Medicine Wheel/Paintrock Ranger Districts, Johnson, Sheridan and Bighorn Counties, WY.

Summary: EPA continued to express concerns with potential adverse impacts to water quality and riparian zones from livestock grazing and recreation. EPA's request for additional evaluation, disclosure, and mitigation in the Final EIS and recommendation to eliminate grazing impacts near important aquatic resources were not addressed.

ERP No. F–AFS–L65405–AK, Shoreline Outfitter/Guide Plan, Commercial Permits Issuance for Shoreline-Based Activities on National Forest System Lands, Admiralty Island National Monument, Hoonah, Sitka and Juneau Ranger Districts, Tongass National Forest, AK.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–FHW–C40158–NY, Slingerlands Bypass Extension (NYS Route 85) (P.I.N. 1125.19) Route 140 (Cherry Avenue Extension) to the Albany City Line, Reconstruction Town of Bethlehem, Albany County, NY.

Summary: EPA continues to have environmental concerns with the preferred alternative regarding the adequacy of mitigation for impacts to forested wetlands.

ERP No. F–FHW–F40419–MN, MN–371 North Improvement Project, Reconstruction from the intersection of Crow Wing County Road 18 in Nisswa to the Intersection of Cass County Road 42 in Pine River, Funding, NPDES Permit, and U.S. Army COE Section 404 Permit Issuance, Crow Wing and Cass Counties, MN.

Summary: EPA has no objection to the action as proposed since previous comments were adequately addressed. Wetland mitigation issues will be pursued as part of the CWA Section 404 permit review.

ERP No. F–NIH–G84000–TX, Galveston National Laboratory for Biodefense and Emerging Infectious Diseases Research Facility at the University of Texas Medical Branch, Construction, Partial Funding, Grant, Galveston, TX.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–NRC–E09809–SC, Savannah River Site Construction and Operation of a Mixed Oxide (MOX) Fuel Fabrication Facility, NUREG–1767, Aiken, Barnwell and Allendale Counties, SC.

Summary: EPA continues to have environmental concerns about the project regarding the hazardous and radioactive wastes associated with the exhaust that will be generated during operation of the proposed facility. However, EPA acknowledges that NRC will address related air emissions issues during the Clean Air Act permitting process.

ERP No. F–SFW–L64050–00, Caspian Tern (*sterna caspia*) Management to Reduce Predation of Juvenile Salmonids in the Columbia River Estuary, To Comply with the 2002 Settlement Agreement, Endangered Species Act (ESA), Columbia River, WA, OR, ID and CA.

Summary: EPA's concerns associated with tern consumption of ESA-listed Salmonids, alternative nesting sites and water quality impacts were addressed in the Final EIS. However, EPA continued to express concerns over whether the proposed relocation of terns to newly

created nesting sites would be successful.

ERP No. F–UAF–G11045–TX, Relocation of the C–5 Formal Training Unit from Altus Air Force Base, Oklahoma to Lackland Air Force Base, Bexar County, TX.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–USA–G11044–00, Fort Bliss, Texas Proposed Leasing of Lands, Proposed Siting, Construction and Operation, by the City of EL Paso of a Brackish Water Desalination Plant and Support Facilities, EL Paso Water Utilities (EPWU), City of EL Paso, TX and New Mexico.

Summary: No formal comment letter was sent to the preparing agency.

Dated: March 15, 2005.

B. Katherine Biggs,

Associate Director, Office of Federal Activities.

[FR Doc. 05–5418 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7886–5]

Request for Proposals; Environmental Education Training Program

I. Overview

Federal Agency Name: U.S. Environmental Protection Agency, Office of Environmental Education.

Funding Opportunity Title: Environmental Education Training Program.

Announcement Type: New announcement.

Program Announcement Identifier: EPA–OEE–05–02.

Catalog of Federal Domestic Assistance: 66–950.

Application Deadline: Applications must be postmarked by the U.S. Postal Service or received by a commercial overnight delivery service no later than April 30, 2005.

Where to Send Applications: Kathleen MacKinnon, U.S. EPA Office of Environmental Education, 1200 Pennsylvania Ave., NW., (MC 1704A; RM 1426), Washington, DC. The zip code is 20460 when using the U.S. Postal Service; its 20004 when using a commercial overnight delivery service.

Authorizing Legislation: Section 5, National Environmental Education Act of 1990 (Pub. L. 101–619).

Purpose: To deliver environmental education training and long-term support to education professionals across the U.S. to enable them to effectively teach about environmental issues.

Eligible Applicants: U.S. institutions of higher education, not-for-profit institutions, or a consortia of such institutions.

Number of Awards: Only one cooperative agreement will be awarded to a U.S. institution of higher education, a not-for-profit institution, or a consortium of such institutions.

Funding Amount: $1,699,025 for the first year of the program (FY 2005 appropriations). For planning purposes, funding for years two and three should be estimated at $1.8 million (subject to Congressional appropriations).

Cost-Sharing Requirement: Applicant must provide non-Federal matching funds, or in-kind contributions, of at least 25% of the total cost of the project (a minimum of $566,342).

Project Period: October 1, 2005–September 30, 2006. The Agency intends, based upon annual performance reviews, the availability of funds, and if consistent with Agency policy, to execute supplemental funding agreements for up to four subsequent project periods.

Award Date: By September 30, 2005.

II. Full Text Announcement

Section I: Funding Opportunity Description

A. What Is the Purpose of This Notice?

The purpose of this notice is to invite eligible institutions to submit proposals to operate the national Environmental Education Training Program. This program is authorized under section 5 of the National Environmental Education Act of 1990 (the Act) (Pub. L. 101–619).

B. What Is Environmental Education?

Environmental education increases awareness and knowledge about environmental issues and provides the skills needed to make informed and responsible decisions. It enhances critical thinking, problem solving and effective decision making skills and teaches individuals how to weigh various sides of an environmental issue before making decisions. Environmental education does not advocate a particular viewpoint or course of action.

C. What Is Environmental Education Training and Long-Term Support?

Environmental education training refers to activities such as classes, on-line courses, workshops, seminars, and conferences which are designed to prepare education professionals to effectively teach about environmental issues. Long-term support refers to activities that support the actual training such as: The dissemination of environmental education guidelines; the development of state educator certification programs; and access to information about quality programs and resources.

D. What Is the History of This Program?

There have been three previous multi-year cooperative agreements awarded under this program. In 1992, the first award was made to a consortium headed by the University of Michigan entitled the ''National Consortium for Environmental Education and Training'' (NCEET). In 1995, the second award was made to a consortium headed by the North American Association for Environmental Education (NAAEE) entitled the ''Environmental Education and Training Partnership'' (EETAP). In 2000, the third award was made to a consortium headed by the University of Wisconsin-Stevens Point (UWSP) also entitled the ''Environmental Education and Training Partnership'' (EETAP). The current program is scheduled to be completed by March 31, 2006. The Web site for the current program is *http://www.eetap.org*.

E. What Is the Purpose of the Training Program?

The purpose of this program is to provide environmental education training and long-term support to education professionals across the U.S. to enable them to effectively teach about environmental issues. Note that long-term support for educators is as important as the training itself. Training and support must:

- Be provided for both formal and non-formal educators (*e.g.*, classroom teachers and faculty at colleges and universities as well as educators in museums, nature centers, and other venues);
- Occur in both pre-service (*e.g.*, for students and faculty in colleges of education) and in-service settings (*e.g.*, for classroom teachers and other practicing educators); and
- Reach geographically and culturally diverse audiences across the U.S. to the maximum extent possible. Educators from Mexico and Canada are also eligible to participate in this program.

F. What Are the Expected Outputs and Outcomes of the Program?

''Output'' refers to the activity or work product that the applicant proposes to undertake. ''Outcome'' refers to the result, effect or consequence that will occur from carrying out the activity or program. The outcomes must be quantitative and may be intermediate (occur during the project period) or long-term (may occur after the project closes). Because this is an education

program, the outcomes should be geared toward educational outcomes (especially in the intermediate term). The long-term outcomes may have a broader impact that goes beyond improving educator training such as impacting the public's behavior that may affect environmental quality.

Below is a list of the expected outputs of the program along with a general reference to possible outcomes. These outputs are not listed in any order of priority. The work plan must identify the outputs and provide specific intermediate and long-term outcomes. The outputs should include, but are not limited to, the following:

- Delivering in-service educator training that builds on existing quality environmental education programs. The intermediate outcome is better trained educators. The long-term outcome is a more environmentally literate public.
- Delivering pre-service educator training that enables students and faculty in education departments at colleges and universities to effectively include environmental education in their teaching. The intermediate outcome is better educated students (future educators) and faculty. The long-term outcome is a more environmentally literate public.
- Promoting the national environmental education guidelines that seeks to improve the quality of environmental education. This refers to the guidelines produced by the National Project for Excellence in Environmental Education for education materials, K–12 student outcomes, educator preparation and professional development, and non-formal programs (*see http://www.naaee.org/npeee.html*). These guidelines were produced with EPA funds. The intermediate outcome is better educational materials, more environmentally literate students, better trained educators, and better non-formal programs. The long-term outcome is a more environmentally literate public.
- Supporting state ''infrastructure'' that enables educators to effectively teach about environmental issues (referred to as ''state capacity building''). This may include, for example, state-directed efforts that produce K–12 instruction requirements, environmental education curriculum resources, correlations of environmental education materials to state standards, and environmental education guidelines. For more information on state capacity building *see http://eelink.net/capacitybuilding.html*. The intermediate outcome is educators that are better equipped with the materials, resources, and support they need to teach. The long-term outcome is a more environmentally literate public.
- Developing and institutionalizing a materials review process that identifies, evaluates, and promotes quality environmental education materials. The intermediate outcome is better educational materials. The long-term outcome is a more environmentally literate public.
- Supporting accreditation efforts to include environmental education in college and university teacher preparation programs such as through the National Council for the Accreditation of Teacher Education (NCATE). The intermediate outcome is better educated students (future educators). The long-term outcome is a more environmentally literate public.
- Supporting state educator certification efforts by assisting states that are developing their own certification programs. The intermediate outcome is better trained educators. The long-term outcome is a more environmentally literate public.
- Supporting Internet access to information and materials by building on existing Internet sites that provide electronic access to quality environmental education materials, resources, and information. The intermediate outcome is increased educator access to quality resources. The long-term outcome is a more environmentally literate public.

G. How Do These Outputs and Outcomes Support EPA's Strategic Plan?

''Goal 5: Compliance and Environmental Stewardship'' of EPA's Strategic Plan is designed to protect human health and the environment by improving environmental behavior through regulatory and non-regulatory means. This goal states that EPA will work to ensure that government, business and the public meet federal environmental requirements and will empower and assist them to do more. The goal also states that EPA programs are designed to, among other things, increase voluntary and self-directed actions to minimize or eliminate pollution before it is generated (pollution prevention) and promote environmental stewardship behavior. ''Objective 5.2.1: Prevent Pollution and Promote Environmental Stewardship by Government and the Public'' calls for raising the public's awareness of actions it can take to prevent pollution.

The purpose of the national Environmental Education Training Program is to provide educators with training and long-term support to enable them to effectively teach about environmental issues. The outputs of the program are geared toward delivering actual training as well as providing long-term support (*e.g.*, the use of national guidelines that discuss what constitutes quality environmental education materials and what a student needs to know about the environment in grades K–12 to become environmentally literate). The intermediate outcome is better trained educators. The long-term outcome is a more environmentally literate public. A more environmentally literate public is better able to understand complex environmental issues and to make responsible decisions that minimize adverse impacts on the environment. This knowledge and understanding enables the public to take actions that prevent pollution and to become effective environmental stewards.

Section II: Award Information

A. How Many Awards Will be Made?

Only one award will be made under this program to an eligible institution or consortium of such institutions. The award will be made as a one year cooperative agreement. The Agency intends, based upon annual performance reviews, the availability of funds, and if consistent with Agency policy, to execute supplemental funding agreements for up to four subsequent project periods.

B. What Is EPA's Role in the Program?

As a cooperative agreement, EPA will have substantial involvement in the program. This includes EPA participation in the development of an annual work plan and EPA approval of the annual work plan.

C. How Will the Program be Funded?

The program will be funded for an initial project period of one year. The Agency intends, based upon annual performance reviews, the availability of funds, and if consistent with Agency policy, to execute supplemental funding agreements for up to four subsequent project periods. The first year of the program will be provided with FY 2005 appropriations of $1,699,025.

Section III: Eligibility Information

A. Who Is Eligible To Apply To Operate This Program?

Only U.S. institutions of higher education, not-for-profit institutions, or a consortium of such institutions may apply to operate this program as specified under the Act.

B. Does EPA Encourage Applicants To Form a Consortia of Institutions?

Because of the broad and diverse nature of this program, EPA encourages eligible institutions to form a consortia to operate this program.

C. May an Institution be Part of or Submit More Than One Application?

Yes, eligible institutions may be a member of a consortium in more than one application. However, such institutions may not apply as the sole applicant or as the lead institution in a consortium in more than one application.

D. Is Cost-Sharing Required?

Yes, non-Federal matching funds of at least 25% of the total cost of the program are required. The source of matching funds must be identified in the application and may be provided in cash or by in-kind contributions. In-kind contributions often include salaries or other verifiable costs. All in-kind contributions must be for allowable and verifiable costs that are carefully documented. The matching non-Federal share is a percentage of the entire cost of the project. For example, the Federal portion of the project is $1,699,025 for the first year. Thus, the total cost of the project for year one would be a minimum of $2,265,367 if the applicant is providing the minimum 25% cost share of $566,342. Proposals that do not include the required non-Federal match will not be considered for funding.

Section IV: Application and Submission Information

A. Where Can I Get an Application?

You can download an application (SF 424 and SF 424A) from the EPA Office of Environmental Education Web site at *http://www.epa.gov/enviroed/educate.html*. If you cannot download the application, please contact Kathleen MacKinnon at 202–564–0454 or *mackinnon.kathleen@epa.gov*.

B. What Must be Included in the Application?

The application must include the following three components (*i.e.*, application, budget, and work plan). Only the finalist will be asked to submit additional federal forms needed to process the application (*e.g.*, certification regarding debarment and lobbying).

(1) *Application for Federal Assistance (SF 424):* This form requests basic information about proposals such as the name of the project and the amount of money requested. The SF 424 is required for all Federal grants and cooperative agreements. A completed SF 424 for the first year of the program must be submitted as part of the application.

(2) *Budget Information: Non-Construction Programs (SF 424A):* This form requests budget information by object class categories such as personnel, travel, and supplies. This form is also required for all Federal grants and cooperative agreements. A completed SF 424A for the first year of the program must also be submitted as part of the application. Note that additional budget information describing how the funds will be used for all major activities during the first year is also required under the budget section of the work plan discussed below.

(3) *Work Plan:* Include a detailed work plan which describes the goals, objectives, outputs, and outcomes of the program. The work plan also indicates how the program will be managed, implemented and evaluated during the first year. The work plan is limited to 20 pages (not including the appendices). The work plan must also discuss in general terms what the goals, objectives, and major outputs and outcomes will be for the second and third years of the program. The work plan is subject to final review, comment, and approval by the EPA Project Officer. The work plan must contain all four sections discussed below.

(a) *Summary:* A brief synopsis of no more than two pages identifying:

1. The institution requesting funding and its key partners (where the applicant is a consortium of institutions);
2. The goals, objectives, outputs, and outcomes of the program by the end of years one, two, and three;
3. How the proposed program builds on existing national efforts and programs;
4. The estimated number of education professionals to be reached as well as the expected demographics of the audiences reached; and
5. How the funds will be used.

(b) *Mission Statement:* A statement of the short (first year) and long-term (three to five year) goals, objectives, and expected outcomes of the program. Include a discussion about the needs of the environmental education and education communities and how these needs will be met.

(c) *Management and Implementation Plan:* A detailed plan of how the project will be managed and implemented in the first year of the program (plus a summary of the project in the second and third years). The plan must: (1) Identify the proposed training and long-term support; (2) discuss how these activities build on existing national efforts and programs; (3) identify all key outputs and outcomes of the project consistent with section II.F.; (4) describe the major responsibilities, qualifications, expertise, and abilities of the Program Director, Program Manager, and key staff as well as key partners where the applicant is a consortium to effectively manage and implement the program; and (5) include a matrix or table identifying all key goals, objectives, outputs, and outcomes, as well as a schedule for conducting and completing these outputs and outcomes during the first year. EPA will consider information provided by the applicant and may consider information from other sources, including Agency files, in evaluating programmatic capability.

(d) *Evaluation Plan:* A detailed plan on how the effectiveness of the program will be evaluated. It is important that the applicant demonstrate how the outputs and outcomes of their program will meet the goals of the program as well as the needs of the environmental education and education communities. The evaluation must be conducted by an institution that has appropriate credentials and expertise in evaluating education programs and is independent of the applicant and key partners where the applicant is a consortium.

(e) *Appendices:* Attachments to the work plan containing information on the budget, qualifications and experience of key personnel, and letters of commitment from key partners.

- *Budget:* A statement describing how funds will be used in the first year, including budget milestones for each major proposed output and a timetable showing the month/year of completion. Estimates must include the allocation of funding for all major outputs. Include indirect costs as well as a statement on the relative effectiveness of the program in terms of the ratio of indirect to direct costs.
- *Key Personnel and Letters of Commitment:* Include brief resumes of no more than three pages each for the Program Director, Program Manager, key staff, and key partners where the applicant is a consortium with major responsibilities for managing and implementing the program. Resumes should describe educational, administrative, management, and professional qualifications and experience. Also, include a one page ''letter of commitment'' from each key partner with major responsibilities in the program where the applicant is a consortium of institutions. ''Letters of endorsement'' from individuals or

institutions will not be considered in the evaluation process.

C. How Should the Application be Submitted?

The applicant must submit one original and two copies of the application (a signed SF 424, SF 424A, and a work plan). To help ensure the applications are readable and can be reproduced, please adhere to the following guidelines. Applications should not be bound. They should be on white paper with page numbers. Work plans must be limited to 20 pages (not including the appendices). Evaluators will not read work plans beyond the 20th page. A ''page'' refers to one side of a single-spaced typed page. The page should be letter sized (8 x 11 inches) with normal type size (10 or 12 cpi). To conserve paper, please provide double-sided copies of the work plan and appendices, where possible.

D. What is the Deadline for Submitting an Application and Where Should it be Sent?

Applications must be sent to EPA through the U.S. Postal Service or through a commercial overnight delivery service. The applications must be postmarked or received by the delivery service no later than April 30, 2005. Any application postmarked or received by the delivery service after this date will not be considered for funding. All applications must be sent to: Kathleen MacKinnon, U.S. EPA, Office of Environmental Education, 1200 Pennsylvania Ave, NW. (MC: 1704A, RM 1426), Washington, DC 20460 (zip code for U.S. Postal Service deliveries), 20004 (zip code for commercial overnight deliveries).

E. Can I Claim my Proposal as Confidential Business Information?

In accordance with 40 CFR 2.203, applicants may claim all or a portion of their application/proposal as confidential business information. EPA will evaluate confidentiality claims in accordance with 40 CFR part 2. Applicants must clearly mark applications/proposals or portions of applications/proposals they claim as confidential. If no claim of confidentiality is made, EPA is not required to make the inquiry to the applicant otherwise required by 40 CFR 2.204(c)(2) prior to disclosure.

F. Is Intergovernmental Review Required?

This program may be eligible for coverage under Executive Order 12372 ''Intergovernmental Review of Federal Programs.'' An applicant should consult the office or official designated as the single point of contact in his or her State for more information on the process the State requires to be followed in applying for assistance, if the State has selected the program for review. You may obtain additional information on intergovernmental review at *http://www.whitehouse.gov/omb/grants/spoc.html*.

Section V: Application Review Information

A. What Criteria Will be Used To Evaluate Proposals? How Will Proposals be Scored?

The following criteria will be used to evaluate the proposals. The evaluators will consider the extent to which the proposal:

(1) Demonstrates the capability to develop and deliver effective environmental education training programs and long-term support to education professionals that integrate environmental education: (i) Across the U.S. to a broad and diverse audience, (ii) in both formal and non-formal settings, and (iii) to pre-service and in-service professionals.

(2) Builds on existing national environmental education resources, programs, and long-term support effectively and efficiently, especially in the first year of the program.

(3) Provides a concise plan to track and measure progress toward achieving the outputs and outcomes identified in section I.F.

(4) Clearly describes how funds will be used; links the expenditure of funds to the goals, objectives, outputs and outcomes of the program; ensures the relative economic effectiveness of the program in terms of the ratio of overhead costs to direct services; and demonstrates effective use of public funds.

(5) Demonstrates the qualifications and expertise of the Program Director, Program Manager, and key staff in a range of appropriate disciplines to provide effective environmental education training and long-term support. If the applicant is a consortium of institutions, the applicant must also demonstrate the qualifications and expertise of the key partners in the consortium.

(6) Demonstrates the ability of the Program Director and Program Manager to effectively manage and implement the program by providing strong leadership in setting the direction of and properly overseeing a cohesive program. If the applicant is a consortium of institutions, the applicant must also demonstrate their ability to effectively oversee the work of multiple partner institutions.

The maximum score for each proposal is 120. The six criteria identified above are each worth 20 points.

B. Who Will Review the Proposals and Make the Final Decision?

Federal environmental education officials will evaluate the proposals. The evaluators' comments will enable EPA's Office of Environmental Education to recommend which proposal to fund. This recommendation will be forwarded to the Associate Administrator for the Office of Public Affairs for concurrence.

C. When Will the Award Be Made?

The award will be made by September 30, 2005.

Section VI: Award Administration Information

A. How Will the Grantee and Other Applicants Be Notified?

EPA's Grants Administration Division will provide official notification of the award to the applicant's Project Director by mail by September 30, 2005. EPA's Office of Environmental Education will notify other applicants of their status within 15 calendar days after the final selection is made.

B. How Will Disputes be Resolved?

Assistance agreement competition-related disputes will be resolved in accordance with the dispute resolution procedures published in 70 FR (**Federal Register**) 3629, 3630 (January 26, 2005) which can be found at *http://www.epa.gov/ogd/competition/index.htm*. Copies of these procedures can also be obtained by contacting Kathleen MacKinnon, U.S. EPA Office of Environmental Education, at 202–564–0454 or *mackinnon.kathleen@epa.gov*.

C. What Administrative Requirements Apply to This Grant?

This award will include the standard administrative conditions that apply to all EPA grants and cooperative agreements. Information on these requirements can be obtained by contacting EPA's Grants Administration Division at *ogdweb.gad@epa.gov* or 202–564–5325.

D. What Post-award Reports are Required?

The award notice will specify the reporting requirements. A detailed progress report is due to the EPA Project Officer bi-annually. A final report is due at the end of the project period.

Section VII: Agency Contact

Please contact Kathleen MacKinnon, U.S. EPA Office of Environmental Education, at 202–564–0454 or *mackinnon.kathleen@epa.gov* if you have any administrative questions about the solicitation notice. EPA can address only administrative questions and can not provide advice nor interpret the content of the solicitation notice.

Section VIII: Other Information

A. Where Can I Get Additional Information About the Current Training Program?

For information on the current program, visit EPA's environmental education Web site at *http://www.epa.gov/enviroed/educate.html* or the Environmental Education and Training Partnership's Web site at *http://www.eetap.org*.

B. What is the Relationship Between the EPA's Environmental Education Training Program and EPA's Environmental Education Grant Program?

This notice applies only to the training program authorized under section 5 of the Act. This notice does not apply to the Environmental Education Grant Program authorized under section 6 of the Act. For information on the Office of Environmental Education, go to *http://www.epa.gov/enviroed*.

Dated: March 11, 2005.

Cece Kremer,

Deputy Associate Administrator, Office of Public Affairs.

[FR Doc. 05–5413 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7886–6]

Partnership to Promote Innovation in Environmental Practice, Notice of Availability and Request for Proposals—Clarification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of solicitation for proposals.

SUMMARY: The Environmental Protection Agency's National Center for Environmental Innovation (NCEI) is amending its March 7, 2005 (70 FR 11011) notice to clarify that the purpose of its solicitation is to solicit proposals from institutions that are interested in promoting innovations that can improve environmental results from State programs. NCEI is also clarifying that the Web site address for the full solicitation is *http://www.epa.gov/innovation/symposia.htm*. NCEI is extending the application period until May 2, 2005.

DATES: Interested applicants have until May 2, 2005 to submit a proposal.

ADDRESSES: Due to heightened security requirements, there may be substantial delays in mail service to EPA. Hence, EPA strongly encourages applicants to send applications electronically. Electronic applications must be sent to *State_Innovation_Grants@epa.gov*. Applicants choosing to submit paper applications should mail one original and two copies to the EPA contact, Sandy Germann. Please also note that the delivery address varies depending on whether you are using regular mail or using a delivery service (*e.g.*, Federal Express, Courier, UPS). If you are using a delivery service, send it to Sandy Germann, U.S. EPA, Room 645C, 4930 Page Road, Research Triangle Park, NC 27703. If you are sending the application via regular mail, send it to Sandy Germann, U.S. EPA, MC C604–02, Research Triangle Park, NC 27711.

FOR FURTHER INFORMATION CONTACT: Sandy Germann, U.S. EPA, MC C604–02, RTP, NC 27711, (919 541–3061), *germann.sandy@epa.gov*.

Dated: March 10, 2005.

Elizabeth Shaw,

Director, Office of Environmental Policy Innovation.

[FR Doc. 05–5414 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7886–9]

Science Advisory Board Staff Office; Notification of an Upcoming Meeting of the Science Advisory Board Metals Risk Assessment Framework Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference of the SAB Metals Risk Assessment Framework Review Panel.

DATES: The public teleconference will be held on April 5, 2005, from 12 p.m. to 3 p.m. (eastern time).

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain the teleconference call-in number and access code to participate in the teleconference may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), U.S. EPA Science Advisory Board by telephone/voice mail at (202) 343–9995, or via e-mail at *armitage.thomas@epa.gov*. The SAB Mailing address is: U.S. EPA, Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. General information about the SAB may be found in the SAB Web site at *http://www.epa.gov/sab*.

SUPPLEMENTARY INFORMATION: *Background:* Pursuant to the Federal Advisory Committee Act, Pub. L. 92–463, notice is hereby given that the SAB Metals Risk Assessment Framework Review Panel will hold a public teleconference to discuss its draft review report on EPA's Framework for Inorganic Metals Risk Assessment. The Panel conducted a peer review of the Framework at a public meeting held on February 1–3, 2005 and has prepared a draft report to EPA. Background information on the Panel and its review of the Framework for Inorganic Metals Risk Assessment was provided in **Federal Register** notices published on July 29, 2004 (69 FR 45314–45315), and January 11, 2005 (70 FR 1888–1889). The Panel is holding the teleconference to review its draft report and identify any clarifications needed for the final draft report to the SAB. The teleconference agenda and the draft advisory report will be posted on the SAB Web site prior to the teleconference. EPA's draft Framework for Inorganic Metals Risk Assessment may be found at: *http://cfpub2.epa.gov/ncea/raf/recordisplay.cfm?deid=88903*.

Procedures for Providing Public Comment: It is the policy of the EPA Science Advisory Board (SAB) Staff Office to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA SAB Staff Office expects that public statements presented at the Metals Risk Assessment Framework Review Panel teleconference will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general, each individual or group requesting an oral presentation at a conference call meeting will be limited to no more than three minutes per speaker and no more than fifteen minutes total. Interested parties should contact the DFO in writing via e-mail at least one week prior to the teleconference in order to be placed on the public speaker list. *Written Comments:* Although written comments are accepted until the date of

the teleconference (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the teleconference date so that the comments may be made available to the committee or panel for their consideration. Comments should be supplied to the DFO at the address/contact information above in the following formats: One hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 95/98 format)).

Meeting Accommodations: Individuals requiring special accommodation to access the teleconference, should contact the relevant DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: March 11, 2005.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–5415 Filed 3–17–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Technological Advisory Council; Charter Renewal

AGENCY: Federal Communications Commission.

ACTION: Notice of charter renewal.

SUMMARY: The Federal Communications Commission has renewed the charter for the Technological Advisory Council (''TAC'') for a 2-year period, through November 19, 2006. The Council is a federal advisory committee under the Federal Advisory Committee Act (Pub. L. 92–463).

DATES: Renewed through November 19, 2006.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Commission Meeting Room (TW–C305), Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jeffery Goldthorp, the Designated Federal Officer (DFO), Office of Engineering and Technology, (202) 418–1096 (voice), (202) 418–2989 (TTY), or e-mail *Jeffery.Goldthorp@fcc.gov.*

SUPPLEMENTARY INFORMATION:

Technological Advisory Council Charter

A. The Committee's Official Designation

The official designation of this federal advisory committee is the ''Technological Advisory Council'' (''TAC'').

B. The Committee's Objective and Scope of Its Activity

Rapid advances in technology have resulted in innovations in how telecommunications services are provided to, and are accessed by, users of those services. Many of these advances are increasing the rate of convergence among categories of services that have traditionally been viewed as distinct, such as cable television services, telephony, data services, and internet services. Regulations must be examined in light of these technology advances, and the Federal Communications Commission (''FCC'') must remain abreast of new developments in technology so that it can effectively fulfill its responsibilities under the Communications Act.

The purpose of the TAC is to provide technical advice to the Federal Communications Commission and to make recommendations on the issues and questions presented to it by the FCC. The TAC will address questions referred to it by the FCC Chairman, by the FCC Chief Office of Engineering and Technology or by the TAC Designated Federal Officer. The questions referred to the TAC will be directed to technological and technical issues in the field of communications.

Each scheduled TAC meeting will be organized according to a particular technical theme to be decided in advance by the TAC Chairman and the TAC Designated Federal officer. The TAC Chairman will make the necessary arrangements to have presenters from different segments of the telecommunications industry present points of view on the theme. The objective of the meeting will be to educate the FCC on new technology trends and to advise the FCC of potential regulatory obstacles to their development and deployment.

C. Period of Time Necessary for the Committee To Carry Out Its Purpose

Under its renewed charter, the TAC shall convene for a period that terminates two (2) years from the date on which the renewed charter is field. The charter may be renewed for an additional two years prior to the charter termination date.

D. Official to Whom the Committee Reports

Chairman, Federal Communications Commission.

E. Agency Responsible for Providing Necessary Support

The Federal Communications Commission will provide the facilities and staff support necessary to conduct meetings in Washington, DC. Private sector members of the committee will serve without any government compensation, and will not be entitled to travel expenses, per diem or subsistence allowances.

F. Description of the Duties for Which the Committee Is Responsible

The duties of the TAC will be to gather data and information and perform those analyses that are necessary to respond to the questions referred to it.

G. Estimated Annual Operating Costs in Dollars and Staff Years

Annual operating costs associated with supporting the TAC's functions are estimated to be $100,000 and one full-time regular government employee.

H. Estimated Number and Frequency of Committee Meetings

The Council will meet three to five times per year, with the possibility of more frequent meetings by informal subcommittees.

I. Committee's Termination Date

The Council will terminate two years from the date on which this renewed charter is filed, unless renewed before that date for an additional term. Upon renewal, the present charter termination date is November 19, 2006.

J. Membership

Members will be selected to balance the expertise and viewpoints that are necessary to address effectively the new technology issues that will be referred to the TAC.

Members should be prepared to attend three to five meetings per year in Washington D.C. and are responsible for all associated expenses. The TAC will maintain a website and members are expected members are expected to be able to devote some time each week to electronic deliberations. As members of a collegial federal advisory committee, members should be prepared for vigorous debate with their peers on TAC as well as with FCC Commission and staff. Members will have an initial and continuing obligation to disclose any interests in, or connections to, persons or entities who are, or will, be regulated by or who have interests before the FCC.

K. Charter Filing Date

November 19, 2004.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–5403 Filed 3–17–05; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, March 17, 2005, 10 a.m. meeting open to the public. This meeting was cancelled.

DATE AND TIME: Tuesday, March 22, 2005 at 3 p.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: March 24, 2005, 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. 2005 Legislative Recommendations. Notice of Proposed Rulemaking on the Internet: Definitions of ''Public Communication'' and ''Generic Campaign Activity,'' and Disclaimers. Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Robert Biersack, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 05–5479 Filed 3–16–05; 11:01 am]

BILLING CODE 6717–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may obtain copies of agreements by contacting the Commission's Office of Agreements at 202–523–5793 or via e-mail at *tradeanalysis@fmc.gov.* 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.: 011908.

Title: CSAV/Maruba Cross Slot Charter Agreement.

Parties: Maruba S.A. and Compania Sudamericana de Vapores S.A.

Filing Party: Walter H. Lion, Esq.; McLaughlin & Stern, LLP; 260 Madison Avenue; New York, New York 10016.

Synopsis: The agreement permits CSAV and Maruba to cross charter space in the trade between the United States Pacific Coast and the Pacific Coasts of Mexico and Canada.

Dated: March 15, 2005.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 05–5423 Filed 3–17–05; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 05–02]

SAT International Corporation v. Great White Fleet (US), Ltd.; Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission (''Commission'') by SAT International Corporation (''SAT'' or ''Complainant'') against Great White Fleet (US), Ltd. (''Great White'' or ''Respondent''). Great White, acting as a VOCC, transported cargo for SAT from the United States to Guatemala. Complainant contends that Respondent violated section 10(b)(4)(E) of the Shipping Act of 1984, 46 U.S.C. app. § 1709(b)(4)(E), by engaging in unfair and unjustly discriminatory practices relating to the adjustment and settlement of claims. Complainant also contends that Respondent violated section 10(d)(1) of the Shipping Act of 1984, 46 U.S.C. app. § 1709(d)(1), by failing to establish, observe, and enforce just and reasonable regulations and practices relating to the handling of SAT's goods. Complainant claims that it has suffered damages in the amount of at least $69,520. Complainant seeks an order directing Respondent to cease and desist from such unlawful activities and compelling Respondent to make reparations to SAT in an amount to be proved at an administrative hearing, plus interest, costs, and reasonable attorneys' fees.

This proceeding has been assigned to the Office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by March 9, 2006 and the final decision of the Commission shall be issued by July 7, 2006.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 05–5424 Filed 3–17–05; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–05–0414X]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 371–5983 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Human Resources and Housing Branch, Office of Management and Budget by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Ecology of Bats in Households: A Survey for Assessing Knowledge, Attitudes, and Health Risks—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

Bats are associated with many different kinds of infectious diseases that may be pathogenic to humans. Anthropogenic change from urban

sprawl provides new roosts for bats in homes and buildings while reducing available natural roosts and putting humans in more frequent contact with bats. The largest public health concern with respect to bat exposure is the transmission of rabies virus—about 75% of human rabies deaths are from bat-associated rabies variants. The current U.S. guidelines for animal rabies prevention and control recommend that bats be excluded from houses and adjacent structures to prevent direct association with humans. While direct association with bats is certainly a risk factor for rabies transmission, little is known about the effects of indirect association with bats and potential adverse health effects. This is of public health concern because many organizations actually promote interactions between bats and humans, without consideration of public health consequences.

The questionnaire will establish bat exposure history, general personal health history including frequency of post-exposure prophylaxis for rabies and knowledge and attitudes pertaining to bat roosts. The Colorado State University/United States Geological Survey (USGS) study provides both a background for bat and rabies virus ecology in the Fort Collins area, and the ability of conservation and health issues to be relayed to the public.

We will evaluate health outcomes among household members by administering a survey focused on frequency and nature of hospital/clinic visits, frequency of bat exposure, and frequency of post-exposure prophylaxis (PEP) for rabies.

The list of households with roosts is provided by Colorado State University bat researchers, identified through radio-tagging of bats. We plan to improve the knowledge of the ecology of bats and associated rabies transmission by assimilating rabies prevalence data in a bat population with data regarding the roost ecology and bat/human interaction ecology in a rapidly sprawling suburban area, Ft. Collins, Colorado. There is no cost to the respondents other than their time. The total annualized burden hours are 178.

ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
Households with Bats (n=45)	81	1	30/60
Households without Bats (n=153)	275	1	30/60

Dated: March 14, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–5384 Filed 3–17–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

General Notice.

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

Background

This notice supplements the summer 2004 HRSA Preview which announced the availability of fiscal year (FY) 2005 funding for new and competing continuation applications for Healthy Start. Healthy Start, authorized under section 330H of the Public Health Service Act, strengthens communities to effectively address the causes of infant mortality, low birth weight and other poor perinatal outcomes for women and infants. Recently, new guidance became available with regards to funding FY 2005 Healthy Start programs.

SUMMARY: Following the Senate Committee's recommendation, the Health Resources and Services Administration (HRSA) will give funding preference during the FY 2005 competition to current and former Healthy Start grantees, including those whose Healthy Start grant application was approved but not funded in FY 2004.

Senate Report 108–345 at 54 (2004) accompanying the Consolidated Appropriations Act, 2005 (Pub. L. 108–447) states ''The Committee urges HRSA to give preference to current and former grantees with expiring or recently expired project periods. This should include grantees whose grant applications were approved but not funded during fiscal year 2004.''

FOR FURTHER INFORMATION CONTACT: Maribeth Badura, Director, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, Room 18–20, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–0543; e-mail *MBadura@hrsa.gov*.

Dated: March 14, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–5378 Filed 3–17–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC).

Dates and Times: April 21, 2005, 9 a.m. to 5 p.m., April 22, 2005, 9 a.m. to 5 p.m.

Place: Ronald Reagan Building and International Trade Center, 1300 Pennsylvania Avenue, NW., Washington, DC 20004.

Status: The meeting will be open to the public with attendance limited to space availability.

Purpose: The Advisory Committee provides advice and recommendations concerning the grants and projects authorized under the Heritable Disorders Program and technical information to develop policies and priorities for this program that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders. Specifically, the Advisory Committee shall advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies,

guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders.

Agenda: Presentations will include a discussion of the report from the American College of Medical Genetics; reports from the Laboratory Standards and Procedures; Education and Training; and Follow-Up Subcommittees; a discussion on the educations process for parents and an assessment system and guidelines for state newborn screening follow-up.

Proposed agenda items are subject to change as priorities indicate.

Public Comments: Time will be provided each day for public comment. Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACHDGDNC Executive Secretary, Michele A. Lloyd-Puryear, M.D., Ph.D. (contact information provided below).

Contact Person: Anyone interested in obtaining a roster of members or other relevant information should write or contact Michele A. Lloyd-Puryear, M.D., Ph.D., Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1080. Information on the Advisory Committee is available at *http://mchb.hrsa.gov/programs/genetics/committee*.

Dated: March 11, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–5377 Filed 3–17–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following 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 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 Cancer Institute Special Emphasis Panel, SBIR Topic 212 Phase I & SBIR Topic 181 Phase II.

Date: April 1, 2005.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8057, MSC 8329, Bethesda, MD 20892–8329, 301–496–7421, *kerwinm@mail.nih.gov.*

This notice notice is being published less than 15 days prior to meeting due to scheduling conflicts.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 11, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–5371 Filed 3–17–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 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 Cancer Institute Special Emphasis Panel, SBIR Topic 211 Phase I.

Date: April 1, 2005.

Time: 8 a.m. to 11 a.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8057, MSC 8329, Bethesda, MD 20892–8329, 301–496–7421, *kerwinm@mail.nih.gov.*

This meeting is being published less than 15 days prior to meeting due to scheduling conflicts.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 11, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–5372 Filed 3–17–05; 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 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 Child Health and Human Development Special Emphasis Panel, The Center for Repreocutive Biological Research/Transcription Factors in Reproduction.

Date: April 12, 2005.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852, (Telephone conference call.)

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100

Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435–6884, *ranhandj@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;a 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 11, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–5369 Filed 3–17–05; 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 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 Child Health and Human Development Special Emphasis Panel, Autism and Related Disorders: Development and Outcome.

Date: April 13, 2005.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Marita R. Hopmann, Phd, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hopmannm@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: March 11, 2005.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–5370 Filed 3–17–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1549–DR]

Alabama; Amendment No. 10 to Notice of a Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Alabama (FEMA–1549–DR), dated September 15, 2004, and related determinations.

DATES: *Effective Date:* March 2, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 2, 2005, the President amended the cost sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), in a letter to Michael D. Brown, Under Secretary for Emergency Preparedness and Response, Federal Emergency Management Agency, Department of Homeland Security as follows:

I have determined that the damage in certain areas of the State of Alabama, resulting from Hurricane Ivan beginning on September 13, 2004, and continuing through September 30, 2004, is of sufficient severity and magnitude that special conditions are warranted regarding the cost sharing arrangements concerning Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act).

Therefore, I amend my declaration of September 15, 2004, to authorize Federal funds for Public Assistance, including direct Federal assistance, at 90 percent of total eligible costs, except those categories, including direct Federal assistance, previously approved at 100 percent for a limited time period.

This adjustment to State and local cost sharing applies only to Public Assistance costs and direct Federal assistance eligible for such adjustments under the law. The law specifically prohibits a similar adjustment for funds provided to States for Other Needs Assistance (Section 408), and the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

Please notify the Governor of Alabama and the Federal Coordinating Officer of this amendment to my major disaster declaration.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–5373 Filed 3–17–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1578–DR]

Kentucky; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Kentucky (FEMA–1578–DR), dated February 8, 2005, and related determinations.

DATES: *Effective Date:* March 10, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Kentucky is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 8, 2005:

Todd and Trigg Counties for Public Assistance.

Todd and Trigg Counties for emergency protective measures (Category B) under the Public Assistance program for a period of 48 hours.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individual and Household Housing; 97.049, Individual and Household Disaster Housing Operations; 97.050, Individual and Household Program-Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–5374 Filed 3–17–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1583–DR]

Nevada; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Nevada (FEMA–1583-DR), dated March 7, 2005, and related determinations.

EFFECTIVE DATE: March 7, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 7, 2005, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Nevada, resulting from heavy rains and flooding on January 7–13, 2005, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Nevada.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation in the designated areas; and any other forms of assistance under the Stafford Act you may deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs. If Other Needs Assistance under Section 408 of the Stafford Act is later warranted, Federal funding under that program will also be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Philip Parr, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Nevada to have been affected adversely by this declared major disaster:

Clark and Lincoln Counties for Public Assistance.

Clark and Lincoln Counties in the State of Nevada are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–5376 Filed 3–17–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1580–DR]

Ohio; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Ohio (FEMA–1580–DR), dated February 15, 2005, and related determinations.

EFFECTIVE DATE: March 9, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Ohio is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 15, 2005:

Darke, Fairfield, Guernsey, Hocking, Holmes, Licking, Richland, Stark, and Tuscarawas Counties for Individual Assistance (already designated for Public Assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–5375 Filed 3–17–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4980–N–11]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, room 7266, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homelesss Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Heather Ranson, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available for suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: COMMERCE: Mr. Lance Feiner, Office of Real Estate, 14th & Constitution Avenue, NW., Room 1036, Washington, DC 20230; (202) 482–3580; COAST GUARD: Commandant (G–SEC), United States Coast Guard, Attn: Teresa Sheinberg, 2100 Second St., SW., Rm. 6109, Washington, DC 20593–0001; (202) 267–6142; ENERGY: Mr. Andy Duran, Department of Energy, Office of Engineering & Construction Management, ME–90, 1000 Independence Ave., SW., Washington, DC 20585; (202) 586–4548; GSA: Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW., Washington, DC 20405; (202) 501–0084; INTERIOR: Ms. Linda Tribby, Acquisition & Property Management, Department of the Interior, 1849 C Street, NW., MS5512, Washington, DC 20240; (202) 219–0728; NAVY: Mr. Charles C. Cocks, Department of the Navy, Real Estate Policy Division, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374–5065; (202) 685–9200; (These are not toll-free numbers).

Dated: March 10, 2005.

Mark R. Johnston,

Director, Office of Special Needs Assistance Programs.

Title V, Federal Surplus Property Program Federal Register Report For 3/18/2005

Suitable/Available Properties

Buildings (by State)

Illinois

SSA Building
2628 N. Knoxville
Peoria Co: IL 61604–
Landholding Agency: GSA
Property Number: 54200510011
Status: Excess
Comment: 9154 sq. ft., most recent use—office
GSA Number: 1–G–IL–731

New Hampshire

Bldg. 288
Naval Shipyard
Portsmouth Co: NH 03804–5000
Landholding Agency: Navy
Property Number: 77200510018
Status: Excess
Comment: 3600 sq. ft., presence of asbestos/lead paint, most recent use—ship filters shop, off-site use only

Bldg. 344
Naval Shipyard
Portsmouth Co: NH 03804–5000
Landholding Agency: Navy
Property Number: 77200510019
Status: Excess
Comment: 1406 sq. ft., presence of asbestos/lead paint, most recent use—riggers shop, off-site use only

Bldg. 346
Naval Shipyard
Portsmouth Co: NH 03804–5000
Landholding Agency: Navy
Property Number: 77200510020
Status: Excess
Comment: 545 sq. ft., presence of asbestos/lead paint, most recent use—locker bldg., off-site use only

Bldg. M–17
Naval Shipyard
Portsmouth Co: NH 03804–5000
Landholding Agency: Navy
Property Number: 77200510021
Status: Excess
Comment: 760 sq. ft., presence of asbestos/lead paint, most recent use—garage, off-site use only

North Carolina

Caretaker's Residence
101 Pivers Island Road
Beaufort Co: Carteret NC 28506–
Landholding Agency: Commerce
Property Number: 27200510001
Status: Excess
Comment: 1900 sq. ft., off-site use only

Pennsylvania

SSA Building
200 Ferry Street
Easton Co: Bucks PA 18042–3674
Landholding Agency: GSA
Property Number: 54200510013
Status: Excess
Comment: 5800 sq. ft., most recent use—office
GSA Number: 4–G–PA–0796

Texas

SSA Building
1000 Burnett Street
Wichita Falls Co: TX 76301–
Landholding Agency: GSA
Property Number: 54200510014
Status: Excess
Comment: 6930 sq. ft., most recent use—office
GSA Number: 7–G–TXndash;1086

Wyoming

Naval Reserve Center
4700 Ocean Loop
Cheyenne Co: Laramie WY 82009–5604
Landholding Agency: GSA
Property Number: 54200510015
Status: Surplus
Comment: 11,858 sq. ft., most recent use—training center/offices, subject to existing easements
GSA Number: 7–N–WY–0542

Suitable/Unavailable Properties

Buildings (by State)

Maryland

Social Security Building
688 Easst Main Street
Salisbury Co: MD
Landholding Agency: GSA
Property Number: 54200510016
Status: Surplus
Comment: Republished: 7200 sq. ft., needs repair, most recent use—office
GSA Number: 4–G–MD–618

Land (by State)

Hawaii

Property 111017
Naval Station
890 Valkenburgh Street
Pearl Harbor Co: Honolulu HI 96818–
Landholding Agency: Navy
Property Number: 77200510017
Status: Unutilized
Comment: 5.16 acres

Unsuitable Properties

Buildings (by State)

California

Quarter #90
Sequoia National Park
Three Rivers Co: Tulare CA 93271–
Landholding Agency: Interior
Property Number: 61200510004
Status: Unutilized
Reason: Extensive deterioration

Bryan Park Military Housing
Naval Weapons Station
Concord Co: Contra Costa CA
Landholding Agency: Navy
Property Number: 77200510024
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material

Connecticut

Bldg. CT380
Naval Submarine Base
Groton Co: New London CT 06340–
Landholding Agency: Navy
Property Number: 77200510016
Status: Unutilized
Reason: Extensive deterioration

Georgia

Whitesburg Rain Gage Station
Yates Co: Coweta GA 30263–
Landholding Agency: GSA
Property Number: 54200510009
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 4–D–GA–0875

Idaho

Bldg. TRA 618
Idaho National Laboratory
Scoville Co: Butte ID 83415–
Landholding Agency: Energy
Status: Excess
Reason: Extensive deterioration

Project Office Bldg.
214 Broadway Avenue
Boise Co: Ada ID 83702–
Landholding Agency: GSA
Property Number: 54200510010
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 9–1–ID–556

Illinois

Bldg. 202 ''W'' Wing
Argonne National Laboratory
Argonne Co: DuPage IL 60439–
Landholding Agency: Energy
Property Number: 41200510001
Status: Excess
Reason: Contamination

Bldg. 128
FERMILAB
Batavia Co: DuPage IL 60510–
Landholding Agency: Energy
Property Number: 41200510002
Status: Excess
Reason: Extensive deterioration

Bldg. 261
FERMILAB
Batavia Co: DuPage IL 60510–
Landholding Agency: Energy
Property Number: 41200510003
Status: Excess
Reason: Extensive deterioration

Michigan

U.S. Coast Guard Station
101 South Lakeshore Drive
Ludington Co: Mason MI 49431–
Landholding Agency: GSA
Property Number: 54200510012
Status: Surplus
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 1–U–MI–537–D

Admin. Bldg.
Station Saginaw River
Essexville Co: Bay MI 48732–
Landholding Agency: Coast Guard
Property Number: 88200510001
Status: Unutilized
Reasons: Secured Area. Extensive deterioration

Nevada

69 Units
Naval Air Station
Fallon Co: Churchill NV 89496–
Landholding Agency; Navy
Property Number: 77200510022
Status: Underutilized
Reason: Secured Area

New Mexico

Bldg. 99650
Sandia National Laboratory
Albuquerque Co: Bernalillo NM 87185–
Landholding Agency; Energy
Property Number: 41200510004
Status: Unutilized
Reason: Secured Area

North Carolina

Bldg. 124
Marine Corps Air Station
Cherry Point Co: Craven NC 28533–
Landholding Agency: Navy
Property Number: 77200510023
Status: Underutilized
Reason: Secured Area

[FR Doc. 05–5042 Filed 3–17–05; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Notice of Proposed Changes to Procedures; Request for Comments

SUMMARY: These proposed changes to procedures modify the Departmental Manual at 516 DM 2.5, *Cooperating Agencies* (40 CFR 1501.6). These proposed procedures clarify the responsibility of managers to offer this status to qualified agencies and governments, and to respond to requests for this status. These proposed procedures also make clear the role of cooperating agencies in the implementation of the Department's National Environmental Policy Act (NEPA) compliance process. When adopted, these procedures will be

published and added to the Electronic Library of Interior Policies (ELIPS). ELIPS is located at: *http://elips.doi.gov/.*

The proposed changes to the procedures are necessary to emphasize the importance of working with Federal and State agencies and Tribal and local governments through cooperating agency relationships in preparing environmental impact statements under NEPA.

DATES: Submit comments on or before April 18, 2005.

ADDRESSES: Comments may be mailed to: Department of the Interior; NEPA Revised Implementing Procedures; c/o Office of Environmental Policy and Compliance; U.S. Department of the Interior; MS 2342—MIB, 1849 C St NW., Washington DC 20240. Comments may also be faxed to the Office of Environmental Policy and Compliance (OEPC) at: 202/208–6970. Finally comments may be e-mailed to the OEPC: *DOINEPA@ios.doi.gov.*

FOR FURTHER INFORMATION CONTACT: Willie R. Taylor, Director, Office of Environmental Policy and Compliance; 1849 C Street, NW.; Washington, DC 20240. Telephone: 202–208–6661. e-mail: *willie_taylor@ios.doi.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION: *General:* In an Executive Order (EO 13352) on Facilitation of Cooperative Conservation, the President seeks to ensure that certain Federal agencies, including the Department of the Interior, implement laws relating to the environment and natural resources in a manner that promotes cooperative conservation. The EO emphasizes appropriate local participation in Federal decision-making, in accordance with agencies' respective agency missions, policies, and regulations.

In an effort to carry out the intent of EO 13352, the Department of the Interior is proposing to strengthen its National Environmental Policy Act (NEPA) implementing procedures which appear in part 516 of the Departmental Manual (DM) at 516 DM 2.5 on Cooperating Agencies. Consistent with both EO 13352 and the Secretary of the Interior's ''4C's'' policy, that is, Conservation through Communication, Consultation, and Cooperation, these revised procedures will reinforce existing bureau procedures that encourage the types of cooperation envisioned in the EO 13352. The Department of the Interior long has promoted, and has successfully implemented, partnerships with States, Tribes, local governments, and private landowners to advance conservation. Such partnerships serve to preserve open space, restore habitat for wildlife, and protect endangered species, among other things.

The proposed changes provide Department-wide direction to proactively engage States, Tribes and local governments in the development of all environmental impact statements.

Background and Purpose: Current Departmental policy emphasizes the importance of forming partnerships with Federal and State agencies, tribal and local, and private landowners to ensure effective participation in the management of Federal lands. These proposed procedural changes clarify the Department's expectation that bureaus will ensure that qualified Federal and non-Federal agencies have meaningful opportunities to participate as cooperating agencies when a bureau develops an environmental impact statement, in accordance with NEPA. These proposed procedures will strengthen the Department's commitment to employ all practicable means for facilitating cooperation, collaboration, and consultation. The Department believes that cooperative conservation is an important tool for working with other agencies and governments, Tribes, and private landowners.

These proposed changes to cooperating agency procedures:

- Require bureaus to invite eligible governmental entities to participate as cooperating agencies when the bureau is developing an environmental impact statement;
- Require bureaus to consider any requests by governmental entities to participate as a cooperating agency with respect to a particular environmental impact statement; and
- Ensure that throughout the development of an environmental impact statement, the bureau will collaborate with all cooperating agencies, to the fullest extent practicable.

These proposed changes do not affect any other public participation requirements of the Department. The collaboration between the Department's bureaus and cooperating agencies envisioned by these proposed changes will supplement existing requirements to engage the public in the decision making process.

Because cooperating agencies are government agencies, meetings between the Department's bureaus and offices and agencies that hold cooperating agency status would not normally be subject to the requirements of the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix 1. This is because section 204 (b) of the Unfunded Mandates Reform Act of 1995, Pub. L. 104–4, provides that FACA does not apply to meetings held exclusively between Federal officials and officers of State, tribal and local governments.

In accordance with 1507.3 of the CEQ Regulations, this Department is consulting with CEQ and is hereby requesting public review and comment on the proposed procedures.

Procedural Requirements: The following list of procedural requirements has been assembled and addressed to contribute to this open review process. Today's publication is a notice of draft, internal Departmental action and not a rulemaking. However, we have addressed the various procedural requirements that are generally applicable to proposed and final rulemaking to show how they would affect this notice if it were a rulemaking.

Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993) it has been determined that this action is the implementation of policy and procedures applicable only to the Department of the Interior and not a significant regulatory action. These policies and procedures would not impose a compliance burden on the general economy.

Administrative Procedures Act

This document is not subject to prior notice and opportunity to comment because it is a general statement of policy and procedure [(5 U.S.C. 553(b)(A)]. However, notice and opportunity to comment is required by the CEQ Regulations [40 CFR 1507.3(a)].

Regulatory Flexibility Act

This document is not subject to notice and comment under the Administrative Procedures Act, and, therefore, is not subject to the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This document provides the Department with policy and procedures under NEPA and does not compel any other party to conduct any action.

Small Business Regulatory Enforcement Fairness Act

These policies and procedures do not comprise a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The document will not have an annual effect on the economy of $100 million or more

and is expected to have no significant economic impacts. Further, it will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions and will impose no additional regulatory restraints in addition to those already in operation. Finally, the document does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States based enterprises to compete with foreign based enterprises.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*), this document will not significantly or uniquely affect small governments. A Small Government Agency Plan is not required. The document does not require any additional management responsibilities. Further, this document will not produce a Federal mandate of $100 million or greater in any year, that is, it is not a significant regulatory action under the Unfunded Mandates Reform Act. These policies and procedures are not expected to have significant economic impacts nor will they impose any unfunded mandates on other Federal, State, or local government agencies to carry out specific activities.

Federalism

In accordance with Executive Order 13132, this document does not have significant Federalism effects; and, therefore, a Federalism assessment is not required. The policies and procedures will not have substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. However, this policy will likely improve, and enhance, state and local relationships with Federal agencies. No intrusion on State policy or administration is expected, roles or responsibilities of Federal or State governments will not change, and fiscal capacity will not be substantially, directly affected. Therefore, the document does not have significant effects or implications on Federalism.

Paperwork Reduction Act

This document does not require information collection as defined under the Paperwork Reduction Act. Therefore, this document does not constitute a new information collection system requiring Office of Management and Budget (OMB) approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

National Environmental Policy Act

The Council on Environmental Quality does not direct agencies to prepare a NEPA analysis or document before establishing agency procedures that supplement the CEQ regulations for implementing NEPA. Agency NEPA procedures are internal procedural guidance to assist agencies in the fulfillment of agency responsibilities under NEPA, but are not the agency's final determination of what level of NEPA analysis is required for a particular proposed action.

Essential Fish Habitat

We have analyzed this document in accordance with section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and determined that issuance of this document will not affect the essential fish habitat of Federally managed species; and, therefore, an essential fish habitat consultation on this document is not required.

Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175 of November 6, 2000, and 512 DM 2, we have assessed this document's impact on tribal trust resources and have determined that it does not directly affect tribal resources since it describes the Department's procedures for its compliance with NEPA. However, this policy will likely improve and enhance the tribal relationship with Federal agencies.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 of May 18, 2001, requires a Statement of Energy Effects for significant energy actions. Significant energy actions are actions normally published in the **Federal Register** that lead to the promulgation of a final rule or regulation and may have any adverse effects on energy supply, distribution, or use. We have explained above that this document is an internal Departmental Manual part which only affects how the Department conducts its business under the National Environmental Policy Act. This manual part is not a rulemaking; and, therefore, not subject to Executive Order 13211.

Actions To Expedite Energy-Related Projects

Executive Order 13212 of May 18, 2001, requires agencies to expedite energy-related projects by streamlining internal processes while maintaining safety, public health, and environmental protections. Today's publication is in conformance with this requirement as it promotes early collaboration and cooperation amongst agencies with jurisdiction or expertise in activities requiring an environmental impact study (including some energy-related projects).

Government Actions and Interference With Constitutionally Protected Property Rights

In accordance with Executive Order 12630 (March 15, 1988) and Part 318 of the Departmental Manual, the Department has reviewed today's notice to determine whether it would interfere with constitutionally protected property rights. Again, we believe that as internal instructions to bureaus on the implementation of the National Environmental Policy Act, this publication would not cause such interference.

Authority: NEPA, the National Environmental Quality Improvement Act of 1970, as amended (42 U.S.C. 4371 *et seq.*); E.O. 11514, March 5, 1970, as amended by E.O. 11991, May 24, 1977; and CEQ Regulations 40 CFR 1507.3

Christopher B. Kearney,

Deputy Assistant Secretary for Policy and International Affairs.

Departmental Manual

Effective Date:
Series: Environmental Quality.
Part 516: National Environmental Policy Act of 1969.
Chapter 2: Initiating the NEPA Process.
Originating Office: Office of Environmental Policy and Compliance.
516 DM 2

2.5 Cooperating Agencies (40 CFR 1501.6 and 1508.5)

A. Upon the request of a bureau, the OEPC will assist bureaus in determining cooperating agencies and coordinating requests from non-Interior agencies.

B. Bureaus will inform the OEPC of any requests to become a cooperating agency or any declinations to become a cooperating agency pursuant to 40 CFR 1501.6(c). Bureaus will consider requests to participate as a cooperating agency with respect to a particular environmental impact statement and will either accept or deny such requests given the bureau's other program commitments and the bureau's expertise. If such a request is denied, the bureau will respond in writing as provided for in 40 CFR 1501.6(c),

C. Upon the request of the lead agency, any Federal agency that is qualified to participate in the NEPA process as a cooperating agency as provided for in 40 CFR 1501.6 and 1508.5 by virtue of its jurisdiction by law, as defined in 40 CFR 1508.15, shall be a cooperating agency. In addition, upon request of the lead agency, any Federal agency that is qualified

to participate in the NEPA process as a cooperating agency as provided for in 40 CFR 1501.6 and 1508.5 by virtue of its special expertise, as defined in 40 CFR 1508.26, may be a cooperating agency. Any non-Federal agency (State, tribal, or local) with similar qualifications may by agreement be a cooperating agency. Bureaus will consult with the Solicitor's Office in cases where such non-Federal agencies are also applicants before the Department to determine relative lead/cooperating agency responsibilities. (CEQ guidance to agencies dated July 28, 1999, and January 30, 2002, urges agencies to more actively solicit participation of Federal, State, tribal, and local governments as cooperating agencies.)

D. Bureaus will invite governmental entities that are qualified to participate as cooperating agencies when the bureau is developing an environmental impact statement in accordance with the requirements of NEPA and the CEQ regulations. Bureaus will also consider any requests by eligible governmental entities to participate as a cooperating agency with respect to a particular environmental impact statement, and will either accept or deny such requests. If such a request is denied, bureaus will respond in writing to the requestor and provide a summary of the request and reasons for such denial within the environmental impact statement.

E. Throughout the development of an environmental impact statement, the bureau will collaborate, to the fullest extent practicable, with all cooperating agencies, concerning those issues relating to their jurisdiction and/or special expertise. Collaboration will be to:

(1) identify issues to be addressed in the environmental impact statement;

(2) arrange for the collection and/or assembly of necessary resource, environmental, social, economic, and institutional data;

(3) analyze data;

(4) develop alternatives;

(5) evaluate alternatives and estimate the effects of implementing each alternative; and

(6) carry out any other task necessary for the development of the environmental impact statement.

F. Bureaus and governmental entities that are potential cooperating agencies are required to express in a memorandum of understanding their respective roles, assignment of issues, schedules, and staff commitments so that the process of preparing an environmental impact statement remains on track and within the time schedule.

[FR Doc. 05–5416 Filed 3–17–05; 8:45 am]

BILLING CODE 4310–RG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–957–00–1420–BJ: GP05–0078]

Filing of Plats of Survey: Oregon/Washington

March 9, 2005.

AGENCY: Bureau of Land Management.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands were officially filed in the Oregon State Office, Portland, Oregon, on December 15, 2004.

Willamette Meridian

Oregon

T. 37 S., R. 8 W., accepted November 1, 2004.
T. 31 S., R. 8 W., accepted November 1, 2004.

Washington

T. 28 N., R. 38 E., accepted November 1, 2004.

The plats of survey of the following described lands were officially filed in the Oregon State Office, Portland, Oregon, on December 20, 2004.

Willamette Meridian

Oregon

T. 23 S., R. 6 W., accepted, November 3, 2004.
T. 25 S., R. 3 W., accepted, November 3, 2004.
T. 29 S., R. 7 W., accepted , November 3, 2004.
Tps. 29 & 29½ S., Rgs. 7 & 8 W., accepted November 3, 2004.
T. 29 S., R. 6 W., accepted November 3, 2004.
T. 26 S., R. 2 W., accepted November 3, 2004.
T. 24 S., R. 4 W., accepted November 3, 2004.
T. 24 S., R. 6 W., accepted November 3, 2004.
T. 30 S., R. 6 W. accepted November 3, 2004.
T. 30 S., R. 15 W. accepted November 15, 2004.
T. 27 S., R. 9 W., accepted November 15, 2004.
T. 28 S., R. 9 W., accepted November 15, 2004.
T. 32 S., R. 7 W., accepted November 15, 2004.
T. 27 S., R. 11 W., accepted November 15, 2004.
T. 8 W., R. 8 W., accepted November 15, 2004.

Washington

T 22 N., R. 11 W., accepted November 1, 2004.

The plats of survey of the following described lands were officially filed in the Oregon State Office, Portland, Oregon, on February 11, 2005.

Willamette Meridian

Oregon

T. 1 S., R. 8 W., accepted November 2, 2004.
T. 20 S., R. 1 W., accepted November 15, 2004.
T. 31 S., R. 6 W., accepted November 15, 2004.
T. 25 S., R. 8 W., accepted December 6, 2004.
T. 29 S., R. 3 W., accepted December 6, 2004.
T. 1 S., R. 38 E., accepted December 17, 2004.
T. 25 S., R. 5 W., accepted January 14, 2005.

A copy of the plat may be obtained from the Public Room at the Oregon State Office, Bureau of Land Management, 333 SW. 1st Avenue, Portland, Oregon 97204, upon required payment. A person or party who wishes to protest against a survey must file a notice that they wish to protest (at the above address) with the State Director, Bureau of Land Management, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Chief, Branch of Geographic Sciences, Bureau of Land Management, (333 SW. 1st Avenue) P.O. Box 2965, Portland, Oregon 97208.

Robert D. DeViney, Jr.,

Branch of Realty and Records Services.

[FR Doc. 05–5355 Filed 3–17–05; 8:45 am]

BILLING CODE 4310–33–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–514]

In the Matter of Certain Plastic Food Containers; Notice of Commission Decision To Review an Initial Determination Finding a Violation of Section 337 and That the Domestic Industry Requirement is Met; Schedule for Written Submissions

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review an initial determination (''ID'') (Order No. 8) issued by the presiding administrative law judge (''ALJ'') finding a violation of section 337 and that the domestic industry requirement has been met in the above-captioned investigation. The review is for the limited purpose of examining possible formatting and typographical errors contained on one page of the ID.

FOR FURTHER INFORMATION CONTACT: Michael Diehl, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 205–3095. Copies of all nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://*

edis.usitc.gov. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: By a notice published on June 22, 2004, the Commission instituted an investigation into alleged violations of section 337 in the importation and sale of certain plastic food containers by reason of infringement of certain claims of U.S. Patent No. 6,056,138; of U.S. Patent No. 6,196,404; and of U.S. Design Patent No. D 415,420. 69 FR 34691 (June 22, 2004).

On August 19, 2004, complainant Newspring Industrial Corp. (Newspring) moved for an order directing that respondents Taizhou Huasen Household Necessities, Co., Ltd. (''Taizhou'') and Jiangsu Sainty Corporation, Ltd. (''Jiangsu'') show cause as to why they should not be found in default for failure to respond to the complaint and notice of investigation. Complainant also asked for an order finding respondents in default if they failed to show cause. On August 30, 2004, the ALJ issued Order No. 5, directing respondents to show cause no later than September 17, 2004, why they should not be held in default. Neither respondent responded to the order.

On September 9, 2004, before the ALJ ruled on the motions for default, Newspring filed motions for summary determinations that there has been a violation of section 337 and that a domestic industry has been established with respect to each of the asserted patents. Newspring sought a recommendation for the issuance of a general exclusion order. On September 23, 2004, the Investigative Attorney (''IA'') filed a response in support of the motions, although he contended that a genuine issue of material fact exists as to whether certain accused products infringe two of the patents in issue.

On October 12, 2004, the ALJ issued an Initial Determination (ID) (Order No. 7), finding the respondents in default. No party petitioned for review of the ID. The Commission subsequently issued a notice of determination not to review the ID.

On February 10, 2005, the ALJ issued an ID (Order No. 8), granting Newspring's motions for summary determinations in part. He determined that a domestic industry had been established with respect to each of the asserted patents, and that respondent Jiangsu had violated section 337 with respect to each asserted patent as well. He determined that respondent Taizhou had violated section 337 with respect to the '420 patent, but denied the motion as to Taizhou with respect to the '138 and '404 patents. No party petitioned for review of the ID. The ALJ also recommended the issuance of a general exclusion order. He also recommended that the bond permitting temporary importation during the Presidential review period be set at 100 percent of the value of the infringing imported product.

The Commission has determined to review the subject ID (Order No. 8). The scope of the review is limited to possible formatting and typographic errors on page 15 of the ID. The Commission notes that the Complainant, on September 28, 2004, filed a corrected version of what is apparently the figure that appears on page 15 of the ID. The Commission requests comments from the parties regarding whether the widths labeled ''A'' and ''B'' in the figure in the ID correspond to the widths described in the text of the ID, and whether the indicated widths are incorrectly placed in the figure. Comments should also address what action, if any, the Commission should take if it finds the labeling incorrect and whether all references to ''Figure 1'' on page 15 of the ID should be changed to ''Figure 5.''

In connection with the final disposition of this investigation, the Commission may issue an order that could result in the exclusion of the subject articles from entry into the United States. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, it should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *In the Matter of Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

When the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider in this investigation include the effect that an exclusion order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues under review. The parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the February 10, 2005, recommended determination by the ALJ on remedy and bonding. Complainant and the Commission's investigative attorney are also requested to submit proposed orders for the Commission's consideration. Complainant is further requested to state the expiration dates of the patents at issue. Main written submissions and proposed orders must be filed no later than close of business on March 29, 2005. Reply submissions, if any, must be filed no later than the close of business on April 5, 2005. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons that the Commission should grant such treatment. *See* section 201.6 of the Commission's Rules of Practice and Procedure, 19 CFR 201.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, and sections 210.16, 210.42, 210.44 of the

Commission's Rules of Practice and Procedure, 19 CFR 210.16, 210.42, 210.44.

Issued: March 14, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–5389 Filed 3–17–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. Singapore FTA 103–10]

Certain Yarns and Fabrics: Effect of Modification of U.S.-Singapore FTA Rules of Origin for Goods of Singapore

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and request for written submissions.

EFFECTIVE DATE: March 14, 2005.

SUMMARY: Following receipt of a request on March 2, 2005, from the Acting United States Trade Representative (USTR) under authority delegated by the President and pursuant to section 103 of the United States-Singapore Free Trade Agreement (USSFTA) Implementation Act (19 U.S.C. 3805 note), the Commission instituted Investigation No. Singapore FTA 103–10, *Certain Yarns and Fabrics: Effect of Modification of U.S.-Singapore FTA Rules of Origin for Goods of Singapore.*

FOR FURTHER INFORMATION CONTACT: Information may be obtained from Robert W. Wallace, Office of Industries (202–205–3458, *robert.wallace@usitc.gov*); for information on legal aspects, contact William Gearhart of the Office of the General Counsel (202–205–3091, *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819, *margaret.olaughlin@usitc.gov*).

Background: Chapter 3 and Annex 3-A of the USSFTA contain the rules of origin for textiles and apparel for application of the tariff provisions of the USSFTA. These rules are set forth for the United States in general note 25 to the Harmonized Tariff Schedule (HTS). According to the request letter, U.S. negotiators have recently reached agreement in principle with representatives of the Government of Singapore to modify the USSFTA rules of origin for certain yarns and fabrics (as described below). If implemented, the proposed rules of origin would apply to U.S. imports from and exports to the USSFTA parties. Section 202(o)(2)(B)(i) of the United States-Singapore Free Trade Agreement Implementation Act (the Act) authorizes the President, subject to the consultation and layover requirements of section 103 of the Act, to proclaim such modifications to the rules of origin as are necessary to implement an agreement with Singapore pursuant to Article 3.18.4(c) of the Agreement. One of the requirements set out in section 103 of the Act is that the President obtain advice from the United States International Trade Commission.

The request letter asked that the Commission provide advice on the probable effect of the proposed modification of the USSFTA rules of origin for the four textile articles described below on U.S. trade under the USSFTA, on total U.S. trade, and on domestic producers of the affected articles. As requested, the Commission will submit its advice to USTR by May 27, 2005, and soon thereafter, issue a public version of the report with any confidential business information deleted. Additional information concerning the articles and the proposed modifications can be obtained by accessing the electronic version of this notice at the Commission Internet site (*http://www.usitc.gov*). The current USSFTA rules of origin applicable to U.S. imports can be found in general note 25 of the 2005 HTS (*see* ''General Notes'' link at *http://www.usitc.gov/tata/hts/bychapter/index.htm*).

The articles of Singapore covered by the investigation are (1) ring spun single yarn of nm 51 and 85, containing 50 percent or more, but less than 85 percent, by weight of 0.9 denier or finer micro modal fiber, mixed solely with U.S. origin extra long pima cotton, classified in HTS subheading 5510.30.0000, for use in women's and girls' knit blouses, shirts, lingerie, and underwear; (2) 100 percent cotton woven flannel fabrics, of yarns of different colors, containing ring-spun yarns of nm 21 through nm 36, of 2 x 2 twill weave construction, classified in HTS subheading 5208.43.0000, for use in apparel other than gloves; (3) fabrics of cotton classified in HTS subheadings 5210.21 and 5210.31, not of square construction, containing more than 70 warp ends and filling picks per square centimeter, of average yarn number exceeding 70 nm, for use in women's and girls' blouses; and (4) micro-denier 30 singles and 36 singles solution dyed, open-end spun, staple spun viscose yarn, classified in HTS subheading 5510.11.0000, for use in apparel.

Written Submissions: No public hearing is planned. However, interested parties are invited to submit written statements concerning the matters to be addressed by the Commission in this investigation. Submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. To be assured of consideration by the Commission, written statements related to the Commission's report should be submitted to the Commission at the earliest practical date and should be received no later than the close of business on April 20, 2005. All written submissions must conform with the provisions of section 201.8 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 of the rules requires that a signed original (or copy designated as an original) and fourteen (14) copies of each document be filed. In the event that confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential business information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the rules (*see* Handbook for Electronic Filing Procedures, *ftp://ftp.usitc.gov/pub/reports/electronic_filing_handbook.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000 or *edis@usitc.gov*).

Any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''nonconfidential'' version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties.

The Commission may include some or all of the confidential business information submitted in the course of this investigation in the report it sends to the USTR and the President. As requested by the Acting USTR, the Commission will publish a public version of the report. However, in the public version, the Commission will not publish confidential business information in a manner that would

reveal the operations of the firm supplying the information.

The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) *http://edis.usitc.gov.* Hearing impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Issued: March 15, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–5390 Filed 3–17–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Sunshine Act Meeting; Notice

[USITC SE–05–008]

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: March 23, 2005 at 9:30 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436; Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 731–TA–1071 and 1072 (Final) (Magnesium from China and Russia)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before April 4, 2005.)
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: March 16, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–5516 Filed 3–16–05; 1:19 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Re-establishment, Advisory Committee on Apprenticeship (ACA)

AGENCY: Employment and Training Administration, Labor.

ACTION: Re-establishment of the Advisory Committee on Apprenticeship.

SUMMARY: Notice is hereby given that after consultation with the General Services Administration, the Department of Labor has determined that the re-establishment of a national advisory committee on apprenticeship is necessary and in the public interest. Accordingly, the Employment and Training Administration has re-chartered the Advisory Committee on Apprenticeship (ACA). The charter for the ACA expired on February 13, 2005. The current charter was signed March 2, 2005, and will expire two years from that date.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Swoope, Administrator, Office of Apprenticeship Training, Employer and Labor Services, Employment and Training Administration, U.S. Department of Labor, Room N–4671, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 693–2796 (this is not a toll-free number).

Signed in Washington, DC, this 14th day of March, 2005.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

[FR Doc. 05–5357 Filed 3–17–05; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment Standards Administration

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment Standards Administration is soliciting comments concerning the proposed collection: Miner's Claim for Benefits Under the Black Lung Benefits Act; Employment History (CM–911 and CM–911a). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before May 17, 2005.

ADDRESSES: Ms. Hazel M. Bell, U.S. Department of Labor, 200 Constitution Ave., NW., Room S–3201, Washington, DC 20210, telephone (202) 693–0418, fax (202) 693–1451, e-mail *bell.hazel@dol.gov*. Please use only one method of transmission for comments (mail, fax, or e-mail).

SUPPLEMENTARY INFORMATION:

I. Background

The Black Lung Act of 1977, as amended, 30 U.S.C. 901 *et seq.*, provides for the payment of benefits to a coal miner who is totally disabled due to pneumoconiosis (black lung disease) and to certain survivors of the miner who died due to pneumoconiosis. A miner who applies for black lung benefits must complete the CM–911 (application form). The completed CM–911 gives basic identifying information about the applicant and is the beginning of the development of the black lung claim. An applicant filing for black lungs benefits must also complete a CM–911a at the same time the black lung application form is submitted. The CM–911a when completed is formatted to render a complete history of employment and helps to establish if the miner currently or formerly worked in the nation's coal mines. The Black Lung Benefits Act as amended, 30 U.S.C. *et seq.* and 20 CFR 725.304a, necessitates the collection of this information. This information collection is currently approved for use through August 31, 2005.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks the extension of approval to collect this information in order to carry out its responsibility to determine eligibility for black lung benefits.

Type of Review: Extension.

Agency: Employment Standards Administration.

Title: Miner's Claim for Benefits under the Black Lung Benefits Act; Employment History.

OMB Number: 1215–0052.

Agency Number: CM–911 and CM–911a.

Affected Public: Individuals or households; business or other for profit.

Total Respondents: 9,000.

Total Annual responses: 9,000.

Estimated Total Burden Hours: 6,333.

Frequency: On occasion.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $1,000.00.

Forms	Respondents/responses	Time per response (minutes)	Burden hours
CM–911	4,000	45	3,000
CM–911a	5,000	40	3,333
Total	9,000		6,333

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: March 11, 2005.

Bruce Bohanon,

Chief, Branch of Management Review and Internal Control, Division of Financial Management, Office of Management, Administration and Planning, Employment Standards Administration.

[FR Doc. 05–5356 Filed 3–17–05; 8:45 am]

BILLING CODE 4510–CK–P

DEPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from the date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or government agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration be the Department.

Further information and self-eplanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of

publication in the **Federal Register** are in parentheses following the decision being modified.

Volume I

New Jersey
NJ20030005 (Jun. 13, 2003)

Volume II

None

Volume III

None

Volume IV

None

Volume V

Oklahoma
OK20030016 (Jun. 13, 2003)
OK20030017 (Jun. 13, 2003)
OK20030034 (Jun. 13, 2003)

Volume VI

Washington
WA20030001 (Jun. 13, 2003)
WA20030002 (Jun. 13, 2003)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts.'' This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *http://www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Service *http://davisbacon.fedworld.gov* of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed in Washington, DC this 9th day of March, 2005.

John Frank,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 05–5030 Filed 3–17–05; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (05–054)]

NASA International Space Station Strategic Roadmap Committee Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA International Space Station Strategic Roadmap Committee.

DATES: Thursday, April 7, 2005, 8:30 a.m. to 5:30 p.m., Friday, April 8, 2005, 8:30 a.m. to 5 p.m. eastern standard time.

ADDRESSES: The Magnolia Hotel, 818 17th St., Denver, Colorado 80202.

FOR FURTHER INFORMATION CONTACT: Ms. Stacey Edgington, 202–358–4519.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the meeting room. Attendees will be requested to sign a register.

The agenda for the meeting is as follows:

—Exploration Systems Mission Directorate update.
—Progress of other Roadmap Committees:
  —Exploration Transportation System (''Strategic Roadmap'');
  —Robotic and Human Lunar Exploration (''Strategic Roadmap'');
  —Human Health and Support Systems (''Capability Roadmap'').
—NASA Policies on Risk Management.
—Budget Overviews.
—Report Drafting.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Dated: March 14, 2005.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–5395 Filed 3–17–05; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 05–055]

NASA Nuclear Systems Strategic Roadmap Committee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Nuclear Systems Strategic Roadmap Committee.

DATES: Tuesday, April 5, 2005, 8 a.m. to 6 p.m.; Wednesday, April 6, 2005, 8 a.m. to 6 p.m., eastern standard time.

ADDRESSES: Hilton, Washington Dulles Airport, 13869 Park Center Rd., Herndon, VA 20171.

FOR FURTHER INFORMATION CONTACT: Ms. Victoria Friedensen, Exploration Systems Mission Directorate, National Aeronautics and Space Administration, Washington, DC 20546, (202) 358–1916.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the meeting room. Attendees will be requested to sign a register. The agenda for the meeting includes the following topics:

—Review of previous meeting.
—Interim reports from other NASA Strategic Roadmap efforts.
—Risk Management and Communication.
—Lessons learned from previous space nuclear systems experience.
—International participation.
—Review and deliberation of first draft report.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Dated: March 14, 2005.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–5394 Filed 3–17–05; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: The National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Daniel Schneider, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential and/or information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* April 1, 2005.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review applications for Special Projects, submitted to the Division of Public Programs at the February 3, 2005 deadline.

2. *Date:* April 4, 2005.
Time: 8:30 a.m. to 5:30 p.m.
Room: 426.
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of Public Programs at the February 3, 2005 deadline.

3. *Date:* April 8, 2005.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review applications for Humanities Projects in Libraries, submitted to the Division of Public Programs at the February 3, 2005 deadline.

4. *Date:* April 11, 2005.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of Public Programs at the February 3, 2005 deadline.

5. *Date:* April 15, 2005.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review applications for Special Projects, submitted to the Division of Public Programs at the February 3, 2005 deadline.

6. *Date:* April 18, 2005.
Time: 8:30 a.m. to 5:30 p.m.
Room: 426.
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of Public Programs at the February 3, 2005 deadline.

7. *Date:* April 18, 2005.
Time: 9 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Summer Seminars and Institutes for School Teachers, submitted to the Division of Education Programs at the March 1, 2005 deadline.

8. *Date:* April 19, 2005.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for ''We the People'' Challenge Grants, submitted to the Office of Challenge Grants at the February 1, 2005 deadline.

9. *Date:* April 21, 2005.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for ''We the People'' Challenge Grants, submitted to the Office of Challenge Grants at the February 1, 2005 deadline.

10. *Date:* April 21, 2005.
Time: 9 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Summer Seminars and Institutes for School Teachers, submitted to the Division of Education Programs at the March 1, 2005 deadline.

11. *Date:* April 22, 2005.
Time: 9 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Summer Seminars and Institutes for College and University Teachers, submitted to the Division of Education Programs at the March 1, 2005 deadline.

12. Date: April 26, 2005.
Time: 9 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Summer Seminars and Institutes for College and University Teachers, submitted to the Division of Education Programs at the March 1, 2005 deadline.

13. *Date:* April 27, 2005.
Time: 9 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Summer Seminars and Institutes for School Teachers, submitted to the Division of Education Programs at the March 1, 2005 deadline.

14. *Date:* April 28, 2005.
Time: 9 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Summer Seminars and Institutes for College and University Teachers, submitted to the Division of Education Programs at the March 1, 2005 deadline.

15. Date: April 29, 2005.
Time: 9 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Summer Seminars and Institutes for School Teachers, submitted to the Division of Education Programs at the March 1, 2005 deadline.

Daniel Schneider,
Advisory Committee Management Officer.

[FR Doc. 05–5404 Filed 3–17–05; 8:45 am]
BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board and Its Subdivisions; Sunshine Act Meeting

DATE AND TIME: March 29–30, 2005.

March 29, 2005; 7:30 a.m.–5:30 p.m.

Concurrent Sessions

7:30 a.m.–8 a.m. Closed
8 a.m.–9 a.m. Open
9:15 a.m.–10 a.m. Open
10 a.m.–11:30 a.m. Open
11:30 a.m.–12 noon Closed
1 p.m.–2 p.m. Open
2 p.m.–3:30 p.m. Open
3:30 p.m.–5 p.m. Closed
5 p.m.–5:15 p.m. Open
5:15 p.m.–5:30 p.m. Closed

March 30, 2005; 7:45 a.m.–3:15 p.m.

Concurrent Sessions

7:45 a.m.–8:30 a.m. Executive Closed
8:30 a.m.–10 a.m. Open
10 a.m.–12 noon Open
12:30 p.m.–1 p.m. Executive Closed
1:00 p.m.–1:15 p.m. Closed
1:15 p.m.–3:15 p.m. Open

PLACE: National Science Foundation, 4201 Wilson Blvd, Room 1235, Arlington, VA 22230.

PUBLIC MEETING ATTENDANCE: All visitors must report to the NSF's visitor's desk at the 9th and N. Stuart Streets entrance to receive a visitor's badge.

CONTACT INFORMATION: Please refer to the National Science Board Web site *(http://www.nsf.gov/nsb)* for updated schedule. NSB Office: (703) 292–7000.

STATUS: Part of this meeting will be closed to the public, Part of this meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Tuesday, March 29, 2005

Open

Committee on Programs & Plans Subcommittee on Polar Issues (8 a.m.–9 a.m.) Room 1235
- Approval of Minutes
- International Polar Year
- Antarctic Season Logistics Highlights
- Arctic Education and Outreach
- IceCube Report

Task Force on Transformative Research [TR] (9:15 a.m.–10 a.m.) Room 1235
- Approval of Minutes
- Background Presentations
  - ''Chemical Bonding Centers: A Program to Support Transformative Research in the Chemical Sciences''
  - ''Information Visualization Tools''
- General discussion on implementing TR actions to address charter objectives
- Summary of TR milestone and timeline

Committee on Audit & Oversight (10 a.m.–11:30 a.m.) Room 1235
- Approval of Minutes
- NSB Chairman's Remarks
- Update on Plan to address Reportable Conditions of FY2004 Audit
  - Post-award Administration
  - Contract Monitoring
- Congressional request for NSB examination of the NSF Merit Review System
- FY 2004 Merit Review Report
- Business Analysis update [items related to Merit Review]
- Chief Financial Officer's Update
  - FY 2004 audit—Management letter status report
  - OMB Circular A–123 ''Managements'' Responsibility for Internal Control
- Sarbanes-Oxley Act and implications for the NSF
- Process of selecting financial statement auditors

Committee on Strategy & Budget (1 p.m.–2 p.m.) Room 1235
- Approval of Minutes
- Summary of Congressional budget testimony for President's FY 2006 NSF budget request to Congress
- Overview of FY 2007 budget process, with emphasis on NSB action items and time

Committee on Programs & Plans (2 p.m.–3:30 p.m.) Room 1235
- Approval of Minutes
- Status Reports
  - Long-lived Data Collections
  - Transformative Research Task Force
  - Subcommittee on Polar Issues
- Discussion on Major Research Facilities
  - Public Comments on joint NSB/NSF Response on priority setting for large facilities
  - Review of draft Facilities Plan
  - NSF Annual Major Facilities Plan Review

Executive Committee (5 p.m.–5:15 p.m.) Room 1235
- Approval of Minutes
- Updates or new business from Committee Members

Closed

Committee on Programs & Plans Subcommittee on Polar Issues (7:30 a.m.–8 a.m.) Room 1235
- Antarctic icebreaker—future budget issues

Committee on Audit & Oversight (11:30 a.m.–12 noon) Room 1235
- Pending Investigations

Committee on Programs & Plans (3:30 p.m.–5 p.m.) Room 1235
- Action Items
- Information Item

Executive Committee (5:15 p.m.–5:30 p.m.) Room 1235
- Board Member Proposal
- Director's Items: Specific Personnel Matters and Future Budgets

Wednesday, March 30, 2005

Open

Education & Human Resources Subcommittee on S&E Indicators (8:30 a.m.–10 a.m.) Room 1235
- Approval of Minutes
- Discussion of Elementary and Secondary Education Chapter
- Discussion of State Indicators Chapter
- Discussion of possible topics for Board Companion Piece
- Important dates for Board Companion Piece

Committee on Education & Human Resources (10 a.m.–12 noon) Room 1235
- Approval of Minutes
- AAAS Presentation: ''Diversifying STEM: Policy and Practice Derived from Standing Our Ground'
- Reports and staff presentations
  - Subcommittee on S&E Indicators
  - NSB items
  - NSF EHR activity update
  - Integration of Research and Education
- Discussion items
  - Proposal for a workshop on Engineering Education
  - Update on Industry Panel

Executive Closed

Ad hoc committee for the 2005 Vannevar Bush Award (7:45 a.m.–8:30 a.m.) Room 1235
- Review and discussion of candidates
- Balloting

Plenary Session of the Board (12:30 p.m.–3:15 p.m.)

Executive Closed Plenary Session of the Board (12:30 p.m.–1 p.m.) Room 1235
- Approval of Executive Closed Minutes
- Board Member Proposal
- Approval of Honorary Awards
  - Alan T. Waterman Award
  - Vannevar Bush Award
  - NSB Public Service Award

Closed Plenary Session of the Board (1–1:15 p.m.) Room 1235
- Approval of Closed Session Minutes
- Awards and Agreements (Resolutions)
- Closed Committee Reports

Open Plenary Session of the Board (1:15p.m.–3:15 p.m.) Room 1235
- Approval of Open Session Minutes
- Resolution to Close May 2005 Meeting
- NSB Chairman's Report
- NSF Director's Report
- Committee Reports

Michael P. Crosby,

Executive Officer, NSB.

[FR Doc. 05–5467 Filed 3–16–05; 8:47 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* Extension.

2. *Current OMB approval number:* 3150–0026.

3. *How often the collection is required:* On occasion.

4. *Who is required or asked to report:* NRC employees, contractors, licensees, and applicants who marry after completing NRC's Personnel Security forms, or marry after having been granted an NRC access authorization or employment clearance.

5. *The number of annual respondents:* 60.

6. *The number of hours needed annually to complete the requirement or request:* Total Burden 12 hours (.20 hour per response).

7. *Abstract:* Completion of the NRC Form 354 is a mandatory requirement for NRC employees, contractors, licensees, and applicants who marry after submission of the Personnel Security Forms, or after receiving an access authorization or employment clearance to permit the NRC to assure there is no increased risk to the common defense and security.

Submit, by May 17, 2005, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft 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 about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–7233, or by Internet electronic mail to *infocollects@nrc.gov.*

Dated at Rockville, Maryland, this 14th day of March 2005.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 05–5367 Filed 3–17–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection: Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 241, ''Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters.''

2. *Current OMB approval number:* 3150–0013.

3. *How often the collection is required:* NRC Form 241 must be submitted each time an Agreement State licensee wants to engage in or revise its activities involving the use of radioactive byproduct material in a non-Agreement State, areas of exclusive Federal jurisdiction, or offshore waters. The NRC may waive the requirements for filing additional copies of NRC Form 241 during the remainder of the calendar year following receipt of the initial form from a licensee engaging in activities under the general license.

4. *Who is required or asked to report:* Any licensees who holds a specific license from an Agreement State and wants to conduct the same activity in non-Agreement States, areas of exclusive Federal jurisdiction, or offshore waters under the general license in 10 CFR 150.20.

5. *The estimated number of annual respondents:* 167 respondents.

6. *The number of hours needed annually to complete the requirement or request:* 1,033 hours (6.18 hours per response).

7. *Abstract:* Under the reciprocity provisions of 10 CFR part 150, any Agreement State licensee who engages in activities (use of radioactive material) in non-Agreement States, areas of exclusive Federal jurisdiction, or offshore waters, under the general license in section 150.20, is required to file four copies of NRC Form 241, ''Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters,'' and four copies of its Agreement State license at least 3 days before engaging in such activity. This mandatory notification permits NRC to schedule inspections of the activities to determine whether the activities are being conducted in accordance with requirements for protection of the public health and safety.

Submit, by May 17, 2005, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft 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 about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T–5 F52, Washington, DC 20555–0001, by telephone at 301–415–7233, or by Internet electronic mail to *infocollects@nrc.gov.*

Dated at Rockville, Maryland, this 14th day of March 2005.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 05–5368 Filed 3–17–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–348 and 50–364]

Southern Nuclear Operating Company, Inc (SNC), Joseph M. Farley Nuclear Power Plant, Units 1 and 2; Notice of Availability of the Final Supplement 18 to the Generic Environmental Impact Statement for the License Renewal of Joseph M. Farley Nuclear Power Plant, Units 1 and 2

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has published a final plant-specific supplement to the Generic Environmental Impact Statement (GEIS), NUREG–1437, regarding the renewal of operating licenses NPF–2 and NPF–8 for an additional 20 years of operation at Joseph M. Farley Nuclear Power Plant (FNP). FNP is located in Houston County, Alabama, approximately 16.5 miles east of the City of Dothan, Alabama. Possible alternatives to the proposed action (license renewal) include no action and reasonable alternative energy sources.

Section 9.3 of the final supplement 18 states:

> Based on: (1) The analysis and findings in the GEIS (NRC 1996; 1999), (2) the environmental report submitted by SNC (SNC 2003), (3) consultation with Federal, State, Tribal, and local agencies, (4) the staff's own independent review, and (5) the staff's consideration of public comments, the recommendation of the staff is that the Commission determine that the adverse environmental impacts of license renewal for Farley Units 1 and 2, are not so great that preserving the option of license renewal for energy planning decision makers would be unreasonable.

The final Supplement 18 to the GEIS is available for public inspection in the NRC Public Document Room (PDR) located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, between 7:30 a.m. and 4:15 p.m. or from the Publicly Available Records (PARS) component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC's Web site at *http://www.nrc.gov/reading-rm/adams.html* (the Public Electronic Reading Room). Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to pdr@nrc.gov. In addition, the Houston Love Memorial Library, 212 West Burdeshaw Street, Dothan, Alabama, and the Lucy Maddox Memorial Library, 11880 Columbia Street, Blakely, Georgia, have agreed to make the final plant-specific supplement to the GEIS available for public inspection.

FOR FURTHER INFORMATION CONTACT: Mr. Jack Cushing, License Renewal and Environmental Impacts Program, Division of Regulatory Improvement Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Mr. Cushing may be contacted at 301–415–1424 or via e-mail at *JXC9@nrc.gov.*

Dated in Rockville, Maryland, this 9th day of March, 2005.

For the Nuclear Regulatory Commission.

Pao-Tsin Kuo,

Program Director, License Renewal and Environmental Impacts Program, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.

[FR Doc. 05–5365 Filed 3–17–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–424 and 50–425]

Southern Nuclear Operating Company, Vogtle Electric Generating Plant, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an exemption from Title 10 of the Code of Federal Regulations (10 CFR) part 50, Appendix G, for Renewed Facility Operating License Nos. NPF–68 and NPF–81, issued to Southern Nuclear Operating Company (the licensee), for operation of the Vogtle Electric Generating Plant (Vogtle), Units 1, and 2, located in Waynesboro, Georgia. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action: The proposed action would exempt the licensee from the requirements of 10 CFR part 50, Appendix G, footnote 2 to table 1, and allow the licensee to use the methodology in Westinghouse Commercial Atomic Power Report (WCAP), WCAP–16142, Revision 1, ''Reactor Vessel Closure Head/Vessel Flange Requirements Evaluation for Vogtle Units 1 and 2,'' to justify eliminating the reactor vessel/head flange region when determining pressure-temperature (P–T) limits for the reactor vessel.

The proposed action is in accordance with the licensee's application dated February 26, 2004, as supplemented on July 8, and October 22, 2004.

The Need for the Proposed Action: Appendix G of 10 CFR part 50, contains requirements for P–T limits for the primary system, and requirements for metal temperature of the closure head flange and vessel flange regions. The P–T limits are to be determined using the methodology of American Society of Mechanical Engineers Boiler and Pressure Vessel Code (ASME Code), Section XI, Appendix G, but the flange temperature requirements are specified in 10 CFR part 50, Appendix G. This rule states that the metal temperature at the closure flange regions must exceed the material unirradiated RT_{NDT} by at least 120 °F for normal operation when the pressure exceeds 20 percent of the pre-service hydrostatic test pressure.

This requirement was originally based on concerns about the fracture margin in the closure flange region. During the boltup process, outside surface stresses in this region typically reach over 70 percent of the steady state stress, without being at steady state temperature. The margin of 120 °F and the pressure limitation of 20 percent of hydrostatic pressure were developed in the mid-1970s using the K_{Ia} fracture toughness to ensure that appropriate margins would be maintained.

Improved knowledge of fracture toughness and other issues that affect the integrity of the reactor vessel have led to the recent change to allow the use of K_{Ic} in the development of P–T curves, as contained in ASME Code Case N–640, ''Alternative Reference Fracture Toughness for Development of P–T Limit Curves for Section XI, Division 1.'' ASME Code Case, N–640 has been approved for use without conditions by the NRC staff in Regulatory Guide 1.147, ''Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1,'' published in June 2003.

However, P–T limit curves can still produce operational constraints by limiting the operational range available to the operator during heatup and cooldown of the plant, especially when considering requirements in the closure head flange and the vessel flange regions. Implementing the P–T curves that use K_{Ic} material fracture toughness without exempting the flange requirement of 10 CFR part 50, Appendix G, would place a restricted

operating window in the temperature range associated with the closure head flange and reactor vessel flange, without a commensurate increase in plant safety.

Environmental Impacts of the Proposed Action: The NRC has completed its safety evaluation of the proposed action and concludes that the more conservative minimum temperature requirements related to footnote (2) to Table 1 of 10 CFR part 50, Appendix G are not necessary to meet the underlying intent of 10 CFR part 50, Appendix G, to protect the Vogtle, Units 1 and 2 RPVs from brittle fracture during normal operation under both core critical and core non-critical conditions and RPV hydrostatic and leak test conditions.

The details of the NRC staffs safety evaluation will be provided in the amendment and exemption that will be issued as part of letter to the licensee approving the amendment and exemption to the regulation.

The proposed action will not significantly increase the probability or consequence of accidents, no changes are being made in the types of effluents that may be released off-site, and there is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does not have a potential to affect any historic sites. It does not affect non-radiological plant effluents and has no other environmental impact. Therefore, there are no significant nonradiological environmental impacts associated with the proposed action.

Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action: As an alternative to the proposed action, the NRC staff considered denial of the proposed action (*i.e.*, the ''no-action'' alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources: The action does not involve the use of any different resource than those previously considered in NUREG–1087, ''Final Environmental Statement related to the operation of the Vogtle Electric Generating Plant, Units 1 and 2,'' dated December 1985.

Agencies and Persons Consulted: On January 6, 2005, the NRC staff consulted with the Georgia State official, Mr. Jim Hardeman of the Department of Natural Resources, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated February 26, 2004, as supplemented on July 8, and October 22, 2004. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 10th day of March, 2005.

For the Nuclear Regulatory Commission.

John Nakoski,

Chief, Section 1, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 05–5366 Filed 3–17–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

DATE: Week of March 14, 2005.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of March 14, 2005

Wednesday, March 16, 2005

9:25 a.m. Affirmation Session (Public Meeting) (Tentative).

a. Private Fuel Storage (Independent Spent Fuel Storage Installation) Docket No. 72–22–ISFSI (Tentative).

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Dave Gamberoni, (301) 415–1651.

* * * * *

ADDITIONAL INFORMATION: By a vote of 5–0 on March 15, 2005, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that ''Affirmation of Private Fuel Storage (Independent Spent Fuel Storage Installation) Docket No. 72–22–ISFSI'' be held March 16, 2005, and on less than one week's notice to the public.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at (301) 415–7080, TDD: (301) 415–2100, or by e-mail at *aks@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301) 415–1969. In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: March 15, 2005.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 05–5468 Filed 3–16–05; 9:25 am]

BILLING CODE 7590–01–M

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of Section 3506(c)(2)(A) of

the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and Purpose of Information Collection

Application for Reimbursement for Hospital Insurance Services in Canada; OMB 3220–0086. Under section 7(d) of the Railroad Retirement Act (RRA), the RRB administers the Medicare program for persons covered by the railroad retirement system. Payments are provided under section 7(d)4) of the RRA for medical services furnished in Canada to the same extent as for those furnished in the United States. However, payments for the services furnished in Canada are made from the Railroad Retirement Account rather than from the Federal Hospital Insurance Trust Fund, with the payments limited to the amount by which insurance benefits under Medicare exceed the amounts payable under Canadian Provincial plans.

Form AA–104, Application for Canadian Hospital Benefits Under Medicare—Part A, is provided by the RRB for use in claiming benefits for covered hospital services received in Canada. The form obtains information needed to determine eligibility for, and the amount of any reimbursement due the applicant. One response is requested of each respondent. Completion is required to obtain a benefit.

No changes are proposed to Form AA–104.

Number of respondents: 50.

Estimated completion time: 10 minutes.

Estimated annual burden hours: 8.

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363 or send an e-mail request to *Charles.Mierzwa@RRB.GOV.* Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or send an e-mail to *Ronald.Hodapp@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Clearance Officer.

[FR Doc. 05–5419 Filed 3–17–05; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of March 21, 2005:

A Closed Meeting will be held on Tuesday, March 22, 2005 at 2:30 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), (9)(B), and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Glassman, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the Closed Meeting scheduled for Tuesday, March 22, 2005, will be:

Formal orders of investigations; Institution and settlement of injunctive actions; and Institution and settlement of administrative proceedings of an enforcement nature.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: March 15, 2005.

Jonathan G. Katz,

Secretary.

[FR Doc. 05–5463 Filed 3–15–05; 4:18 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51366; File No. SR–CBOE–2004–75]

Self-Regulatory Organizations; Order Approving Proposed Rule Change and Amendments No. 1 and 2 Thereto by the Chicago Board Options Exchange, Incorporated Relating to the Introduction of Remote Market-Makers

March 14, 2005.

I. Introduction

On November 22, 2004, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to the introduction of Remote Market-Makers (''RMMs''). On January 10, 2005, CBOE filed Amendment No. 1 to the proposed rule change.[3]

On January 21, 2005, CBOE filed Amendment No. 2 to the proposed rule change.[4] The proposed rule change and Amendments No. 1 and 2 were published for comment in the **Federal Register** on February 4, 2005.[5] The Commission received no comment letters on the proposal. This order approves the proposed rule change and Amendments No. 1 and 2.

II. Discussion

CBOE's Hybrid Trading System merges the electronic and open outcry trading models, offering market participants the ability to stream electronically their own firm disseminated market quotes representing their trading interest. The current Hybrid rules allow market makers to stream electronic quotes only when they are physically present in their appointed trading stations. This requirement prevents ''remote market making,'' a practice whereby market

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 replaces and supersedes CBOE's original 19b–4 filing in its entirety.

[4] Amendment No. 2 replaces and supersedes CBOE's original 19b–4 filing and Amendment No. 1 in their entirety.

[5] Securities Exchange Act Release No. 51107 (January 31, 2005), 70 FR 6051.

makers may submit quotes from locations outside of the physical trading station for that class.

The proposed rule change would accommodate remote market making, by authorizing a new membership status called RMM. RMMs would have the ability to submit quotes to the CBOE from a location outside of the physical trading station for the subject class. To accommodate RMMs, the Exchange proposes to amend existing, and adopt new, rules addressing RMM obligations, RMM appointments, Priority and Allocation of Trades, and Evaluation of RMMs.

After careful review, 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[6] and, in particular, the requirements of Section 6 of the Act.[7] Specifically, the Commission finds that the proposal to add a new category of options market-making participant, RMMs, to the CBOE Hybrid trading platform is consistent with Section 6(b)(5) of the Act[8] in that the proposal has been designed to promote just and equitable principles of trade, and to protect investors and the public interest.

A. Registration and Appointment of RMMs

The Exchange proposes to adopt new Rule 8.4 to address the definitional, registration, affiliation, and appointment issues relating to RMMs.[9] Proposed CBOE Rule 8.4(a) defines an RMM as an individual member or member organization registered with the Exchange that makes transactions as a dealer-specialist from a location other than the physical trading station for the subject class.[10] The rule also proposes that transactions of RMMs that are executed on the Exchange are deemed market maker transactions for purposes of Chapter VIII of the CBOE Rules and CBOE Rules 3.1 and 12.3(f).

Proposed Rule 8.4(b), Registration and Approval of RMMs, provides that the registration and approval of RMMs would be in accordance with CBOE Rule 8.2.[11] As a result, RMMs would be approved in the same manner that other market makers are approved and any member approved as a market maker would be approved as an RMM upon requesting RMM status with the Exchange's Membership department. Importantly, the Commission notes that CBOE has no authority under its rules to discriminate among applicants. An RMM retains its approval to act as an RMM until the RMM requests the Exchange to relieve it of its approval to act as an RMM and the Exchange grants such approval or until the Exchange terminates its approval to act as an RMM pursuant to Exchange Rules.[12]

Paragraph (d) of CBOE Rule 8.4 provides that an RMM may choose either a Physical Trading Crowd (''PTC'') or Virtual Trading Crowd (''VTC'') appointment.

A PTC Appointment would correspond to the location of a physical trading station on the floor of the CBOE. An RMM that chooses a PTC appointment would have the right to quote electronically (and not in open outcry): 30 Hybrid 2.0 Platform (''Hybrid 2.0'' or ''Hybrid 2.0 Platform'') products traded in that specific trading station for each Exchange membership it owns;[13] or 20 Hybrid 2.0 products traded in that specific trading station for each Exchange membership it leases.[14]

A VTC Appointment would confer the right to quote electronically (and not in open outcry) an appropriate number of products selected from ''tiers'' that have been structured according to trading volume statistics. By being able to choose the products it wishes to trade, an RMM would have flexibility in choosing and structuring its appointment. As proposed, RMMs would be able to choose from all products included in the Hybrid 2.0 Platform. Of those products, Tier A would consist of the 20% most actively-traded products over the preceding three calendar months, Tier B the next 20%, etc., through Tier E, which would consist of the 20% least actively-traded products. All products within a specific Tier would be assigned an ''appointment cost'' depending upon its Tier location. Each Tier A product would have an ''appointment cost'' of .10, each Tier B product would be .0667, each Tier C product would be .05, each Tier D product would be .04, and each Tier E product would be .033. An RMM as part of its VTC appointment may select for each membership it owns or leases any combination of Hybrid 2.0 products whose aggregate ''appointment cost'' does not exceed 1.0. For example, an RMM could request six ''A Tier'' products (6x.10), four ''C Tier'' products (4x.05), and five ''D Tier'' products (5x.04) to constitute its VTC appointment.

The Exchange would rebalance the ''tiers'' once each calendar quarter, which may result in additions or deletions to their composition. When a product changes ''tiers'' it would be assigned the ''appointment cost'' of that tier. Upon rebalancing, each RMM with a VTC appointment would be required to own or lease the appropriate number of Exchange memberships reflecting the revised ''appointment costs'' of the products constituting its appointment. The Commission believes the proposed PTC and VTC appointment rules are consistent with the Act.

B. Affiliations Among Market Makers

Proposed CBOE Rule 8.4 (c) provides that, except as specified in the rule, an RMM may not have an appointment as an RMM in any class in which it or its member organization serves as Designated Primary Market-Maker (''DPM''), electronic DPM (''e-DPM''), RMM, or market maker on CBOE. The Commission believes this prohibition is important because of the potential under CBOE's rules for allocations of trades to be based, in part, on an equal allocation methodology. Under an equal allocation methodology, a participant can be allocated contracts based solely on its quote or order at the best bid or offer, regardless of the size of such participant's quote or order. Accordingly, absent a prohibition, there could be an incentive for affiliated market makers to each post separate quotes to increase their total contract allocation.

1. Affiliated Floor Market-Maker Pilot Program

CBOE Rule 8.4(b) would provide exception to this general prohibition to allow a CBOE Member or Member Firm operating as an RMM in a class to have, as part of an 18-month pilot program, one market maker affiliated with the RMM organization trading in open outcry in any specific option class

[6] The Commission has considered the amended proposed rule change's impact on efficiency, competition, and capital formation.15 U.S.C. 78c(f).

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

[9] The Exchange also proposes to amend Rule 8.3 to clarify its non-applicability to RMMs.

[10] The Exchange proposes to amend CBOE Rule 8.1 to eliminate from the definition of Market-Maker the requirement that transactions be effected on the trading floor. Transactions by market makers that comply with the requirements of CBOE Rule 8.7.03 would be considered market maker transactions.

[11] The Exchange proposes a corresponding change to CBOE Rule 8.2(a) to provide that applicants must pass a member's exam as opposed to a floor member's exam.

[12] The termination of an RMM's approval to act as an RMM would be pursuant to proposed CBOE Rules 8.61 or 8.4(e).

[13] The Exchange proposes in CBOE Rule 1.1(aaa) definitions for Hybrid Trading System and Hybrid 2.0 Platform.

[14] For purposes of this rule, the term ''product'' refers to all options of the same single underlying security/value.

allocated to the RMM.[15] The Commission is approving this limited exception on a pilot basis because CBOE represents that firms do not want to have an RMM and a market maker to increase their allocation of contracts in electronic trades, but instead to be able to both make electronic markets remotely and to participate outcry trading.

2. Multiple Aggregation Units

CBOE Rule 8.4(c) would also allow a CBOE Member or Member Firm to have, as part of a 12-month pilot program, multiple aggregation units operating as separate RMMs within the same class, provided specific criteria are satisfied. CBOE has stated there are three primary instances in which this proposed multiple aggregation unit exception would be utilized.

• First, large broker-dealers are frequently divided into desks that pursue separate trading strategies, and each of these trading desks may be interested in serving in an RMM capacity. Without an aggregation unit exception, each broker-dealer would be limited to only one RMM, regardless of the number of trading desks it employs and regardless of the degree of autonomy or separation between each desk.

• Second, a common organizational structure utilized by CBOE market makers involves a common financial backer providing capital to multiple independent, unaffiliated market makers. Each of these market makers trades independently and has its own profit-loss account that is separate and distinct from that of the other market makers receiving financial backing from the same entity. Without an aggregation unit exception, these independent market makers could be viewed as affiliated and thus be precluded from being RMMs in the same classes.

• Third, given the rapidly escalating costs of acquiring sophisticated quoting technology, many market makers, in an effort to reduce their operating costs, have pooled resources to acquire such technology. Despite the shared expenses and pooled resources, these market makers continue to operate independently with their own separate profit-loss accounts, which are unaffected by the profitability (or lack thereof) of others with whom they have shared costs/pooled resources. Without the ability for each market maker to be treated as an aggregation unit, these market makers would be precluded from trading as RMMs within the same classes.

In this regard, CBOE proposes to allow multiple aggregation units to operate as RMMs in the same class provided they comply with the following criteria:[16]

• The member or member firm has a written plan of organization that identifies each aggregation unit, specifies its trading objective(s), and supports its independent identity. The independence of aggregation units may be evidenced by separate management structures, location, business purpose, or separate profit-and-loss treatment within the member firm. Each aggregation unit must maintain all trading activity of that aggregation unit in a segregated account, which would be reported to the Exchange as such.

• Each aggregation unit must operate independently of other aggregation units of the member or member firm. Moreover, all traders in an aggregation unit may pursue only the trading objectives or strategy(ies) of that aggregation unit and may not transmit or otherwise share information relating to those trading objectives or strategies to the member's or member firm's other aggregation units. The member or member firm may have risk management personnel outside of the RMM aggregation units view the positions of the multiple RMMs within the entity and direct position adjustments for risk management purposes. However, such persons may not transmit information to traders in an RMM aggregation unit about the trading strategies, objectives, or positions of another RMM aggregation unit.[17] Prior to being approved in an RMM capacity, each member or member organization operating multiple Aggregation Units would be required to certify that it is aware of these prohibitions, that it would comply with these prohibitions, and that it would ensure continued compliance with these prohibitions.

• Individual traders are assigned to only one aggregation unit at any time; and

• The member or member firm as part of its compliance and/or internal audit routines establishes and maintains surveillance and audit procedures that facilitate the review and surveillance programs of the firm and CBOE to ensure the independent operation of the separate aggregation units operating as RMMs. As part of these routines, the member or member firm must retain written records of information concerning the aggregation units, including, but not limited to, trading personnel, names of personnel making trading decisions, unusual trading activities, disciplinary action resulting from a breach of the member or member firm's systems firewalls and information-sharing policies, and the transfer of securities between the members or member firm's aggregation units, which information would be promptly made available to the Exchange upon its request. The member or member firm must promptly provide to the Exchange a written report at such time there is any material change with respect to the aggregation units, at which point the Exchange would reexamine its status.

The Commission believes that the proposed rules are designed to ensure that affiliated RMMs are sufficiently independent to allow them to operate as separate RMMs. The Commission believes such separation in important because, as stated above, CBOE's rules allocate trades among market makers quoting at the same price based, in part, on an equal allocation methodology unrelated to the size of each market makers quote. Thus, multiple RMMs at the same firm could be used to increase total allocation to that firm without a commensurate increase in the total size of its quote. The Commission notes that the proposed rule obligates the Exchange to conduct surveillance to ensure the independent operation of the multiple units operating as RMMs.

C. Integrated Market Making and Side-by-Side Market Making

RMMs who effect transactions in a particular option may be affiliated with market makers or specialists who trade the underlying security (*i.e.,* integrated market making). The Exchange has

[15] As part of the pilot program, CBOE represents that it would confidentially provide the Commission with data on: (1) The size of orders that RMMs and affiliated market makers both trade with electronically; (2) the price and size of the RMM's and the affiliated market maker's respective quotes; (3) the price and size of quotes of other participants in classes where an RMM and an affiliate are quoting; and (4) a breakdown of how orders are allocated to the RMM, the affiliated market maker, and any other participants. The Commission will use this data to consider whether the practice of allowing a member organization to receive more of an allocation of orders based solely on the number of market-makers that it has quoting in an option class is unfairly discriminatory in any way to other quoting market participants, and to determine whether to extend or permanently approve this practice.

[16] The Exchange based these criteria on the criteria contained in Regulation SHO, which was recently adopted by the Commission. Securities Exchange Act Release No. 50103 (July 28, 2004), 69 FR 48008 (August 6, 2004) (File No. S7–23–03).

[17] Senior risk management personnel are prohibited from engaging in any of the following activities with respect to the Aggregation Units they oversee: (i) Establishing quoting parameters for any trader including but not limited to delta and volatility values; (ii) directing the submission of specific quotes by any trader; or (iii) directing the timing of a trader's trading activities with anything other than general, nonspecific timeframes.

indicated that CBOE Rule 4.18, which governs the use of material, non-public information would apply to RMMs. The Exchange represents that this rule would require RMMs to maintain information barriers that are reasonably designed to prevent the misuse of material, non-public information by such member with any affiliates that may act as a specialist or market maker in any security underlying the options for which the CBOE member acts as an RMM.[18] The Commission believes that the requirement that there be an information barrier between the RMM and its affiliates with respect to transactions in the option and the underlying security serve to reduce the opportunity for unfair trading advantages or misuse of material, non-public information.

D. Limitations on Access Due to Systems Constraints

Because of limited systems bandwidth capacity, the Exchange proposes to limit the number of members quoting electronically in each product traded on Hybrid or Hybrid 2.0. The number of members permitted to quote in each product is specified in proposed CBOE Rule 8.3A.01.[19] The methodology for determining which members would be able to quote electronically in a product is governed by proposed CBOE Rule 8.3A(a)–(c).

The CBOE proposes that the DPM and e-DPMs (if applicable[20]) assigned to the product on January 6, 2005,[21] and market makers who: (1) Are in good standing with the Exchange; and (2)(i) have transacted at least 80% of their Market-Maker contracts and transactions in-person in each of the three immediately preceding calendar months prior to January 6, 2005 in option products traded in the trading station; or (ii) were physically present in the trading station acting in the capacity of a market maker on January 6, 2005, would be entitled to quote electronically in those products for as long as they maintain an appointment of those products.[22]

All other market makers, RMMs, and approved e-DPMs that request the ability to submit quotes electronically in the subject product would be entitled to quote electronically in that product in the order in which they so request provided the number of members quoting electronically in the product does not exceed the CQL. When the number of members in the product quoting electronically equals the CQL, all other members requesting the ability to quote electronically in that product would be wait-listed in the order in which they submitted the request.

The waiting list would operate based on time priority. When the product can accommodate another electronic quoter (whether due to attrition or an increase in the CQL), the member at the ''top'' of the list (*i.e.,* the member that has been on the waiting list the longest amount of time) would have priority. Once a member is wait-listed, the Exchange may not alter his/her position on the wait-list other than to improve such position (*i.e.,* the Exchange may not place other members ahead of a previously wait-listed member). If a wait-listed member is offered, yet refuses, the ability to quote electronically in the subject product, the member would be removed from that waiting list.

With respect to a product that is added to the Hybrid 2.0 Platform after January 6, 2005, the DPM and e-DPMs appointed to the product would also be entitled to quote electronically. All market makers quoting in the product prior to its addition to the Hybrid 2.0 Platform would be entitled to quote electronically provided that: (1) They have transacted at least 80% of their market maker contracts and transactions in-person in each of the three immediately preceding calendar months prior to the product being added to the Hybrid 2.0 Platform in option products traded in the trading station; or (2) they were physically present in the trading station acting in the capacity of a market maker on the day prior to the product being added to the Hybrid 2.0 Platform. The Exchange believes that these standards, which also are contained in paragraph (a) of this rule, would ensure that market makers that maintained a presence in the class prior to its conversion to the Hybrid 2.0 Platform would be guaranteed the ability to quote electronically upon conversion to Hybrid 2.0. If at the time a product is added to the Hybrid 2.0 Platform the aggregate number of DPMs, e-DPMs, and market makers entitled to quote electronically in the product exceeds the CQL, then the product would have an ''increased CQL,'' as described in proposed Interpretations and Policies .01(a). Reduction of any ''increased CQL'' would be in accordance with the procedures described in proposed Interpretations and Policies .01(a).

All other members would be entitled to quote electronically in that product in the order in which they so request provided the number of members quoting electronically in the product does not exceed the CQL. When the number of members quoting electronically in the product equals the CQL, all other members would be wait-listed in the order in which they request the ability to quote electronically. The wait-list would operate as described in proposed CBOE Rule 8.3A(a).

Finally, with respect to a new product that commences trading on the Hybrid Trading System after January 6, 2005, the assigned DPM would be entitled to quote electronically. Thereafter, all other members would be entitled to quote electronically in that product in the order in which they so request provided the number of members

[18] Telephone conversation between Stephen M. Youhn, Managing Senior Attorney, and Elizabeth King, Associate Director, Division of Market Regulation, March 10, 2005. *See also* Exchange Act Release No. 47628 (Apr. 10, 2003), 68 FR 17697 (order approving CBOEdirect).

[19] CBOE proposes that the CQL for all products trading on the Hybrid Trading System would be twenty-five (25).The CQLs for products trading on the Hybrid 2.0 Platform would vary based on trading volume over the preceding calendar quarter. The CQL for all products newly-listed on the Exchange after January 6, 2005 would be 25 until such time that the CQL increases in accordance with Rule 8.3A.01. The Exchange would announce all changes regarding CQLs to the membership via Information Circular. The Exchange may increase the CQL levels by submitting to the SEC a rule filing pursuant to Section 19(b)(3)(A) of the Act. The Exchange may decrease the CQL levels established above upon SEC approval of a rule filing submitted pursuant to Section 19(b)(2) of the Act.

When exceptional circumstances warrant, the President of the Exchange (or in his absence his designee, who must be a Senior Vice President of the Exchange or higher) may increase the CQL for an existing or new product. ''Exceptional circumstances'' refers to substantial trading volume, whether actual or expected (*e.g.,* in the case of a new product or a major news announcement). The Exchange does not intend for this discretion (*i.e.,* to increase the CQL) to be exercised on an intra-day basis. Rather, the primary instance for which the Exchange anticipates this discretion being exercised is for the addition of new products to Hybrid or Hybrid 2.0 for where the standard CQL is not high enough to accommodate the anticipated trading volume and member demand. When the CQL increases pursuant to the President exercising his authority in accordance with this paragraph, members on the wait-list (if applicable, with respect to a product already trading on Hybrid), would have first priority and remaining capacity would be filled on a time priority basis. Upon cessation of the exceptional circumstances, the President (or his designee), in his discretion, may determine to reduce the CQL. Any reduction in the CQL must be undertaken in accordance with the procedure established for lowering the ''increased CQL.'' Any actions taken by the President of the Exchange pursuant to this paragraph (to increase or decrease the CQL) would be submitted to the Commission in a rule filing pursuant to Section 19(b)(3)(A) of the Act.

[20] Non-Hybrid 2.0 classes do not have e-DPMs.

[21] The Commission understands that the CBOE currently intends to file a proposed rule change to change the January 6, 2005 date to a later date.

[22] CBOE represents that the practical effect of this rule is to ensure that the DPM, all market makers, and all e-DPMs would be guaranteed the ability to quote electronically in products trading at their primary trading stations as of January 6, 2005. CBOE further represents that there were no products as of this date for which the number of members quoting electronically exceeded the CQL for that product.

quoting electronically does not exceed the CQL. When the number of members quoting electronically in the product equals the CQL, all other members would be wait-listed in the order in which they request the ability to quote electronically. The wait-list would operate as described in proposed CBOE Rule 8.3A(a).

The Commission believes that CBOE's proposal to limit the number of market makers quoting in each options class is not unfairly discriminatory and is otherwise consistent with the Act.

E. Obligations of RMMs

The Exchange proposes to amend CBOE Rule 8.7 to clarify the obligations applicable to RMMs. RMMs would not be able to quote in open outcry. Accordingly, the Exchange proposes to amend paragraph (b)(iii) to specify the permissible methods by which in-crowd market makers and RMMs may quote or submit orders.

The Exchange also proposes to amend paragraph (d) of CBOE Rule 8.7, Market Making Obligations Applicable in Hybrid Classes, to exclude RMMs from the application of this paragraph. RMMs instead would be subject to the obligations contained in new paragraph (e), which are based on the Hybrid obligations in CBOE Rule 8.7(d). Specifically, RMMs would be required to provide continuous two-sided, 10-up, legal-width quotations in 60% of the series of their appointed classes.[23] The Exchange would be permitted to consider exceptions to this quoting requirement based on demonstrated legal or regulatory requirements or other mitigating circumstances (e.g., excused leaves of absence, personal emergencies, or equipment problems). In addition, proposed CBOE Rule 8.4(f) provides that RMMs are subject to CBOE Rule 8.7.03A with respect to trading in appointed classes. CBOE Rule 8.7.03A requires at least 75% of a Market-Maker's total contract volume (measured quarterly) be in his/her appointed classes. RMMs may not enter quotations in option classes that are not included within their appointments although they may submit orders in non-appointed classes.

The Commission believes that these obligations for RMMs are consistent with the Act. In particular, the Commission believes that RMMs' affirmative obligations are sufficient to justify the benefits they receive as market makers.[24] In this regard, the Commission believes that CBOE rules impose such affirmative obligations on RMMs.

F. Priority and Allocation of Trades for CBOE Hybrid System

The Exchange proposes to amend certain portions of CBOE Rule 6.45A regarding allocation of trades on Hybrid. The first change is to expand the introductory paragraph definition of ''market participant'' to include RMMs. The second proposed change is to clarify in paragraph (a), Allocation of Incoming Electronic Orders, that market participants may enter quotes or orders and receive allocations pursuant to the Ultimate Matching Algorithm.

The third proposed change is to amend paragraph (b), Allocation of Orders Represented in Open Outcry, to clarify that only in-crowd market participants would be eligible to participate in open outcry trade allocations. This is consistent with the prohibitions in CBOE Rules 8.4 and 8.7 that prevent an RMM from trading in open outcry. The Exchange also proposes to limit the duration of paragraph (b) to six months from the date of approval of this proposal, unless otherwise extended.

The Commission believes that the trade allocation algorithm that would apply to RMMs is consistent with the Act. The Commission believes that treating RMMs and other CBOE Hybrid market participants the same under CBOE Rule 6.45A(a) should encourage RMMs to quote competitively.

G. CBOE Membership Rules

CBOE proposes to amend CBOE Rule 3.2 to make clear that a member is deemed to have an authorized trading function if the member is approved to act as a nominee or person registered for an RMM organization. This would ensure under CBOE Rule 3.9(g) that the RMM nominee completes CBOE's Member Orientation Program and passes CBOE's Trading Member Qualification Exam. The proposed amendments to CBOE Rules 3.2 and 3.3 would also clarify that a member may elect membership status as an RMM.

CBOE also proposes to amend CBOE Rule 3.8(a)(ii), which currently states that ''if the member organization is the owner or lessee of more than one such membership, the organization must designate a different individual to be the nominee for each of the memberships (except that this subparagraph would not apply to memberships designated for use in an e-DPM capacity pursuant to CBOE Rule 8.92 by a member organization approved as an e-DPM).'' Proposed CBOE Rule 3.8.02 would accommodate the creation of RMMs by allowing a member organization to designate one individual to be the nominee of the memberships that are designated for use in an RMM capacity and an e-DPM capacity, provided that a member organization may not have more than one RMM appointment in an option class (except to the extent provided in CBOE Rule 8.4(c)) and may not have an RMM appointment in an option class in which the organization serves as a DPM, e-DPM, or Market-Maker on the Exchange (except to the extent provided in CBOE Rule 8.4(c)).

The Commission believes that this exception to the general rule that a member organization must designate a different individual to be the nominee for each of the memberships would not be inappropriate given that RMMs operate from locations outside of the trading crowds for their applicable option classes, thereby making it possible for a member to act as an nominee on more than one membership.[25]

Proposed CBOE Rule 3.8.02(ii) would also permit an individual to act as a nominee of an organization with respect to one membership utilized in an RMM capacity and a membership not utilized in an RMM or e-DPM capacity in order to allow the nominee to use those memberships to simultaneously trade as an in-crowd Market-Maker and in an RMM capacity (but not in the same classes), provided that the RMM trading activity of the nominee is from a location other than the physical trading station for any of the classes traded by the nominee in an RMM capacity.

The Commission believes that this provision is reasonable and should accommodate members who choose to take advantage of their remote market making privileges while on the Exchange floor.

[23] If the underlying primary market disseminates a 100-share quote, an RMM's undecremented quote may be for as low as 1-contract (''1-up''), however, this ability is expressly conditioned on the process being automated (*i.e.,* an RMM may not manually adjust its quotes to reflect 1-up sizes). Quotes must automatically return to at least 10-up when the underlying primary market no longer disseminates a 100-share quote. RMMs that have not automated this process may not avail themselves of the relief provided herein. The ability to quote 1-up would operate on a pilot basis and would terminate on August 17, 2005, which is the same expiration date contained in CBOE Rules 8.7(d)(i)(B) and (d)(ii)(B) for Hybrid trading.

[24] For example, a lender may extend credit to a broker-dealer without regard to the restrictions in Regulation T of the Board of Governors of the Federal Reserve if the credit is to be used to finance the broker-dealer's activities as a specialist or market maker on a national securities exchange. *See* 12 CFR 221.5(c)(6).

[25] The Commission notes that it would not be possible for an in-crowd market participant to act as nominee on more than one membership because such participant would be unable to physically be present in more than one trading crowd.

For the foregoing reasons, the Commission finds that the proposed rule change, as amended, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with Section 6(b)(5) of the Act.[26]

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[27] that the proposed rule change (SR–CBOE–2004–75), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[28]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E5–1185 Filed 3–17–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51365; File No. SR–FICC–2004–15]

Self-Regulatory Organizations; The Fixed Income Clearing Corporation; Notice of Filing of an Amended Proposed Rule Change Relating to Trade Submission Requirements and Pre-Netting

March 14, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on March 4, 2005, The Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') an amendment to a proposed rule change as described in Items I, II, and III below. Prior to being amended the proposed rule change was published in the **Federal Register** on November 4, 2004.[2] The Commission is publishing this notice to solicit comments on the proposed rule change as amended.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

As previously noticed, the proposed rule change would amend the rules of FICC's Government Securities Division (''GSD'') to broaden its trade submission requirements and to prohibit pre-netting activities of certain affiliates of its members. As amended, the proposed rule change would also require netting members to report foreign affiliate trades to FICC.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC 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. FICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed rule change as originally filed would require GSD members of FICC to submit data on trades executed or whose settlement is cleared and guaranteed by affiliates of GSD members that are registered broker-dealers, banks, or futures commission merchants organized in the U.S. Because the proposed rule would define a covered affiliate as an entity organized in the U.S., the rule would not apply to trades executed by non-U.S. affiliates of GSD members.

FICC has filed an amendment to the proposed rule change that would require a netting member to report foreign affiliate trades to FICC. The trades would be reported to FICC on an annual basis in the format and within the timeframe specified by guidelines to be issued by FICC. The reporting requirement would not apply to foreign affiliate trades of a foreign affiliate that has executed less than an average of 30 or more foreign affiliate trades per business day during any one-month period within the prior year.

The amendment proposes to add definitions of ''foreign affiliate'' and ''foreign affiliate trade'' to GSD's rules. A ''foreign affiliate'' would be defined as an affiliate of a netting member that is not itself a netting member and is a foreign person. A ''foreign affiliate trade'' would be defined as a trade executed by a ''foreign affiliate'' of a netting member that satisfies the following criteria: (i) The trade is eligible for netting pursuant to GSD's rules and (ii) the trade is executed with another netting member, with a covered affiliate, or with a ''foreign affiliate'' of another netting member. ''Foreign affiliate trade'' would not include a trade that is executed between a member and its affiliate or between affiliates of the same member. For purposes of this definition, the term ''executed'' shall include trades that are cleared and guaranteed as to their settlement by the foreign affiliate.

The proposed rule change is consistent with the requirements of Section 17A of the Act[4] and the rules and regulations thereunder applicable to FICC because the proposed rule change should reduce systemic risk in the government securities marketplace and therefore facilitate the establishment of a national system for the prompt and accurate clearance and settlement of securities transactions.

(B) Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change would have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty five 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 ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve the proposed rule change; or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

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[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78s(b)(2).

[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 50607 (October 29, 2004), 69 FR 64343.

[3] The Commission has modified the text of the summaries prepared by FICC.

[4] 15 U.S.C. 78q–1.

Electronic Comments

- Use the Commission's Internet comment form *(http://www.sec.gov/rules/sro.shtml)* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–FICC–2004–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–FICC–2004–15. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.ficc.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2004–15 and should be submitted on or before April 8, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E5–1184 Filed 3–17–05; 8:45 am]

BILLING CODE 8010–01–P

[5] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51360; File No. SR–PCX–2005–15]

Self-Regulatory Organizations; Pacific Exchange, Inc.; Order Granting Approval of Proposed Rule Change Relating to Primary Only Orders

March 11, 2005.

On February 1, 2005, the Pacific Exchange, Incorporated (''PCX'' or ''Exchange''), through its wholly-owned subsidiary, PCX Equities (''PCXE''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (';Act'')[1] and Rule 19b–4 thereunder,[2] to amend PCXE Rule 7.31(x), to provide that Primary Only Orders (''PO Orders'') may apply to Nasdaq securities traded on the Archipelago Exchange (''ArcaEx'') facility, and may be either market or limit orders. The proposed rule change was published for comment in the **Federal Register** on February 9, 2005.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

After careful review, the Commission finds that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[4] and, in particular, the requirements of Section 6 of the Act[5] and the rules and regulations thereunder. The Commission finds specifically that the proposed rule change is consistent with Section 6(b)(5) of the Act[6] because it is designed 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, and, in general, to protect investors and the public interest.

As proposed, PCXE Rule 7.31(x) would define a PO Order as a market or limit order that is to be routed to the primary market, until a cut-off time periodically determined by PCXE, and would expand the PO Order applicability from exclusively exchange-listed securities to include Nasdaq Stock Market, Inc. (''Nasdaq'') securities. The Commission notes that PO market orders in Nasdaq securities received prior to 6:28 a.m. PT will be marked On-Open and will be routed to Nasdaq for possible participation in Nasdaq's Opening Cross. As such, the Commission believes that implementing these changes may provide market participants with more choices for executing orders on the opening. In addition, the Commission believes that expanding the applicability of PO Orders to limit orders and to Nasdaq listed securities should enhance the opportunity for ArcaEx users to have their orders executed on the primary market.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[7] that the proposed rule change (SR–PCX–2005–15) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E5–1183 Filed 3–17–05; 8:45 am]

BILLING CODE 8010–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 51125 (February 2, 2005), 70 FR 6914.

[4] In approving this proposed rule change, 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).

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(2).

[8] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending March 4, 2005

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days after the filing of the application.

Docket Number: OST–2005–20535.

Date Filed: March 3, 2005.

Parties: Members of the International Air Transport Association.

Subject: PTC3 0829 dated 4 March 2005, Mail Vote 443—Resolution 010o—Special Amending Resolution from Japan to South East Asia. r1–r6, Intended effective date: 1 April 2005.

Renee V. Wright,

Acting Program Manager, Docket Operations, Alternate Federal Register Liaison.

[FR Doc. 05–5353 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending March 4, 2005

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–2005–20491.
Date Filed: February 28, 2005.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: March 21, 2005.
Description: Application of NetJets Transportes Aereos, S.A., requesting a foreign air carrier permit authorizing it to: (a) Conduct charter air transportation of persons and property between any point or points in Portugal and any point or points in the United States; (b) conduct charter air transportation of persons and property between any point or points in the United States and any point or points in a third country or countries, provided that such service constitutes part of a continuous operation, with or without a change of aircraft, that includes service to Portugal for the purpose of carrying local traffic between Portugal and the United States; (c) conduct other charters pursuant to Part 212; and (d) exercise all other rights enumerated in the Air Transport Agreement between the United States of America and the Republic of Portugal.

Docket Number: OST–2005–20492.
Date Filed: February 28, 2005.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: March 21, 2005.
Description: Application of Executive Jet Management, Inc., requesting commuter air carrier authority to operate scheduled passenger service between the New York, NY metropolitan area and the Chicago, IL metropolitan area, and between the New York, NY metropolitan area and the Los Angeles, CA area.

Docket Number: OST–2005–20570.
Date Filed: March 4, 2005.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: March 25, 2005.
Description: Application of Tradewind Aviation, LLC, requesting a certificate of public convenience and necessity authorizing it to provide interstate charter air transportation of persons, property, and mail.

Renee V. Wright,

Acting Program Manager, Docket Operations, Alternate Federal Register Liaison.

[FR Doc. 05–5352 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice: Receipt of Noise Compatibility Program and Request for Review

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by Capital Region Airport Authority for Capital City Airport under the provisions of 49 U.S.C. 47501 *et seq.* (Aviation Safety and Noise Abatement Act) and 14 CFR Part 150 are in compliance with applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program that was submitted for Capital City Airport under Part 150 in conjunction with the noise exposure map, and that this program will be approved or disapproved on or before August 5, 2005.

DATES: *Effective Date:* The effective date of the FAA's determination on the noise exposure maps and of the start of its review of the associated noise compatibility program is February 7, 2005. The public comment period ends April 8, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Katherine S. Jones, Federal Aviation Administration, Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, Michigan, phone number (734) 229–2958. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Capital City Airport are in compliance with applicable requirements of Part 150, effective February 7, 2005. Further, FAA is reviewing a proposed noise compatibility program for that airport which will be approved or disapproved on or before August 5, 2005. This notice also announces the availability of this program for public review and comment.

Under 49 U.S.C. 47503 (the Aviation Safety and Noise Abatement Act, hereinafter referred to as ''the Act''), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

Capital Region Airport Authority submitted to the FAA on February 1, 2005 noise exposure maps, descriptions and other documentation that were produced during the Capital City Airport FAR Part 150 Noise Compatibility Study Update, January 2005. It was requested that the FAA review this material as the noise exposure maps, as described in section 47503 of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 47504 of the Act.

The FAA has completed its review of the noise exposure maps and related descriptions submitted by Capital Region Airport Authority. The specific documentation determined to constitute the noise exposure maps includes: Noise Exposure Map Existing Conditions (2003), Noise Exposure Map Future (2008) with Runway Extension, FAR Part 150 Noise Compatibility Study Update Volume I contains the required information for Section 47503 and section A150.101 including the following specific references: Current and forecast operations in Table II–9;

fleet mix and nighttime operations in Tables IV–2, IV–3, IV–4, and IV–5; flight patterns in Exhibits IV–3, IV–4, Iv–5, IV–6, IV–7, IV–8, IV–9, IV–10, and land use in Exhibits III–2 and III–3. The FAA has determined that these maps for Capital City Airport are in compliance with applicable requirements. This determination is effective on February 7, 2005. FAA's determinations on an airport operator's noise exposure maps is limited to a finding that the maps are developed in accordance with the procedures contained in appendix A of FAR Part 150. Such determination does not constitute approval of the applicant's data, information or plans, or constitute a commitment to approve a noise compatibility program or to find the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 47503 of the Act. The FAA has relied on the certification by the airport operator, under section 150.21 of FAR Part 150, that the statutorily required consultation has been accomplished.

The FAA has formally received the noise compatibility program for Capital Region Airport Authority, also effective on February 7, 2005. Preliminary review of the submitted material indicates that in conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before August 6, 2005.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, section 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or by reasonably consistent with obtaining the goal of reducing existing non-compatible land uses and preventing the introduction of additional non-compatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, Michigan 48174

Capital Region Airport Authority, Capital City Airport, 4100 Capital City Boulevard, Lansing, Michigan 48906

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Romulus, Michigan, on February 7, 2005.

Irene R. Porter,

Manager, Detroit Airports District Office, Great Lakes Region.

[FR Doc. 05–5341 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Meeting With Interested Persons To Discuss the Proposed Federal Aviation Administration Policy (Draft Order 8110.RC) for the Certification of Restricted Category Aircraft

AGENCY: Federal Aviation Administration (DOT).

ACTION: Notice of public meeting.

SUMMARY: The FAA will hold three informational meetings to discuss the proposed policy (Draft Order 8110.RC) that the FAA's Aircraft Certification Service personnel, Flight Standards Service Personnel, persons designated by the Administrator, and organizations associated with the certification process required by Title 14 of the Code of Federal Regulations (14 CFR) will use during the certification evaluation of restricted category aircraft. These public meetings will be a continuation of information gathering for the evaluation of Restricted Category Aircraft Applications originally offered to the public for comments in the **Federal Register**, dated October 8, 2004, Page 60454 (Volume 69, Number 195). This meeting, the third and final public meeting will be held at the Federal Aviation Administration's (FAA) Orlando Florida's Flight Standards District Office, located at 5950 Hazeltine National Drive, Suite 500, Orlando, Florida. To obtain additional information and details about this meeting, please contact Mr. Graham Long via the information listed in the paragraph titled **FOR FURTHER INFORMATION CONTACT**. Notes from this informational meeting will be posted on the Internet at: *http://www.faa.gov/Certification/Aircraft/DraftDoc/Comments.htm.*

DATES: This meeting will be held on Thursday, April 7, 2005, from 9 a.m. to 12 noon.

ADDRESSES: This third meeting will be held at the FAA's Orlando Flight Standards District Office, Suite 500, 5950 Hazeltine National Drive, Orlando, FL 32822.

FOR FURTHER INFORMATION CONTACT: To obtain additional details on this and the two previous meetings, please contact Mr. Graham Long, AIR–110, Room 815, Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, 800 Independence Avenue, SW., Washington, DC 20591, Telephone (202) 267–3715, FAX: (202) 237–5340, or e-mail: *9-awa-air110-gn12@faa.gov.*

Issued in Washington, DC, on March 11, 2005.

Susan J.M. Cabler,

Assistant Manager, Aircraft Engineering Division, Aircraft Certification Service.

[FR Doc. 05–5339 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Policy Statement No. ANE–2004–33.4–4]

Policy for Design Approval Procedures for Parts Manufacturer Approval of Critical Engine and Propeller Parts

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of issuance; policy statement.

SUMMARY: The Federal Aviation Administration (FAA) announces the availability of policy for Design

Approval Procedures for Parts Manufacturer Approval of Critical Engine and Propeller Parts.

DATES: The FAA issued policy statement number ANE–2004–33.4–4 on March 4, 2005.

FOR FURTHER INFORMATION CONTACT: Karen M. Grant, FAA, Engine and Propeller Standards Staff, ANE–110, 12 New England Executive Park, Burlington, MA 01803; e-mail: *karen.m.grant@faa.gov;* telephone: (781) 238–7119; fax: (781) 238–7199. The policy statement is available on the Internet at the following address: *http:://www.airweb.faa.gov/rgl.* If you do not have access to the Internet, you may request a copy of the policy by contacting the individual listed in this section.

SUPPLEMENTARY INFORMATION: The FAA published a notice in the **Federal Register** on November 8, 2004 (69 FR 64805) to announce the availability of the proposed policy and invite interested parties to comment.

We have filed in the docket all comments we received, as well as a report summarizing each substantive public contact with FAA personnel concerning this policy. The docket is available for public inspection. If you wish to review the docket in person, go to the above address between 9 a.m. and 5 p.m.. Monday through Friday, except Federal holidays.

Background

This policy memorandum provides guidance to Aircraft Certification Offices when establishing their process for evaluating Parts Manufacturer Approval (PMA) applications for critical engine and propeller parts. This policy also requires applicants to complete a safety assessment and to consider a continuous operational safety plan for all engine and propeller PMA proposed parts.

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

Issued in Burlington, Massachusetts, on March 4, 2005.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 05–5340 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–13–M

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.

Metro North Railroad (MNCW)

(Docket Number FRA–2005–20314)

The Metro North Railroad (MNCW) seeks a waiver of compliance from docket number, FRA–2005–20314, with the Passenger Equipment Safety Standards, 49 CFR part 238, section 309(b) periodic brake equipment maintenance, as it pertains to scheduled 1,104 day clean, repair, and test intervals for a MU locomotive that is part of a fleet that is 100% equipped with air driers and also equipped with one of the approved brake systems, RT–5A. MNCW is requesting permission to extend the 1,104 day intervals by 184 days for 144 M1–A MU rail cars. MNCW explains in their request that the M1–A cars were slated for retirement prior to coming due for the 1,104 day maintenance but because they are not receiving new M7 cars on time, they are unable to do this.

As part of the request, the railroad will perform a 368 day inspection, which will include the same maintenance and overhaul to the M1–A air compressor and air quality system as required as part of the 1104 day maintenance. Also, at this time, they will renew the emergency brake valve portion, the J–1 Relay valve, and the electro-pneumatic emergency valve, and perform a single car test, to assure the emergency brake functions as intended.

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 (FRA–2005–20314) 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*.

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). The Statement may also be found at *http://dms.dot.gov*.

Issued in Washington, DC on March 14, 2005.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 05–5364 Filed 3–17–05; 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.

Norfolk Southern Corporation

(Waiver Petition Docket Number FRA–2005–20384)

The Norfolk Southern Corporation (NS) seeks a waiver of compliance for locomotives assigned to operate over the hump yard retarders at its Bellevue, OH, and Roanoke, VA, yards, from the requirements of the *Locomotive Safety Standards*, 49 CFR 229.123, which requires each lead locomotive be equipped with an end plate, pilot plate, or snow plow, that extends across both rails at a maximum clearance of six inches. NS indicates that due to the height of the retarders, it is not uncommon for locomotive pilots or

snow plows to strike them when operating over the hump. If the waiver is granted, NS would raise the height of the pilot plates or snow plow to allow more clearance and would re-adjust the height whenever it is necessary for a hump assigned locomotive to be moved from Bellevue or Roanoke yards.

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 (FRA–2005–20384) 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*.

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). The Statement may also be found at *http://dms.dot.gov*.

Issued in Washington, DC on March 14, 2005.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 05–5363 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number: MARAD 2004–17114]

Availability of a Finding of No Significant Impact

AGENCY: Department of Transportation, Maritime Administration.

ACTION: Notice of the availability of a finding of no significant impact.

SUMMARY: The purpose of this notice is to make available to the public the Finding of No Significant Impact (FONSI) derived from the Environmental Assessment (EA) regarding the Port of Anchorage (Port) Marine Terminal Redevelopment Project. The purpose of the project is to improve and enhance the existing dock and terminal capability at the Port to facilitate the transportation of goods and people within the State of Alaska.

FOR FURTHER INFORMATION CONTACT: Daniel E. Yuska, Jr., Environmental Protection Specialist, Office of Environmental Activities, U.S. Maritime Administration, 400 7th Street, SW., Room 7209, Washington, DC 20590; telephone (202) 366–0714, fax (202) 366–6988.

SUPPLEMENTARY INFORMATION: The Maritime Administration, in cooperation with the Port of Anchorage, completed an EA that studied potential environmental effects associated with the redevelopment of the marine terminal used by the Port. The EA considered potential effects to the natural and human environments including: Air quality; water quality; geology and soils; coastal resources; terrestrial resources; aquatic resources; navigation; hazardous materials; cultural and historic resources; visual and aesthetic resources; and other topics associated with the proposed action. The FONSI is based on the analysis presented in the Marine Terminal Redevelopment EA.

The FONSI and the EA are available for review at Loussac Library in Anchorage or online at *http://www.portofanchorage.org* and *http://dms.dot.gov.*

(Authority: 49 CFR 1.66.)

By Order of the Maritime Administrator.

Dated: March 11, 2005.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 05–5335 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2000–6940]

Anthropomorphic Test Devices; Denial of Petition for Reconsideration Regarding the Hybrid III 5th Percentile Female Test Dummy, Alpha Version

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

ACTION: Denial of petition for reconsideration.

SUMMARY: This notice denies an August 29, 2002, petition for reconsideration submitted by DaimlerChrysler. The petitioner asked the agency to delay the effective date of the Hybrid III 5th Percentile Female Test Dummy, specified in the 49 CFR Part 572, Subpart O final rule, ''Response to Petitions for Reconsideration'' (67 FR 46400).

FOR FURTHER INFORMATION CONTACT: For non-legal issues: Mr. Sean Doyle, Office of Crashworthiness Standards, NVS–111, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Telephone: (202) 366–1740. Facsimile: (202) 473–2629. Electronic Mail: *Sean.Doyle@nhtsa.dot.gov.*

For legal issues: Mr. Christopher Calamita, Office of Chief Counsel, NCC–112, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Telephone: (202) 366–2992. Facsimile: (202) 366–3820. Electronic Mail: *Christopher.Calamita@nhtsa.dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

DaimlerChrysler petitioned the National Highway Traffic Safety Administration (NHTSA), in a letter dated August 29, 2002, to delay the September 13, 2002, effective date for the dummy specified in the Part 572, Subpart O final rule (67 FR 46400) until all issues related to the neck are resolved.

In the mid 1990's, there had been serious concern regarding air bag related fatalities and injuries to small female drivers seated close to deploying air bags in low speed crashes. Crash data showed that small-stature women often experienced a higher potential for serious injury in low speed crashes, even when properly restrained. To help deal with these concerns, NHTSA published a notice of proposed rulemaking (NPRM) on September 18, 1998, to upgrade Federal Motor Vehicle

Safety Standard (FMVSS) No. 208, ''Occupant crash protection'' (63 FR 49958). The NPRM proposed that vehicles be equipped with advanced air bags that meet new and more rigorous performance requirements. The NPRM proposed alternative options for complying with the new set of performance requirements to ensure that new air bags were designed to avoid causing injury to a broad array of occupants. After receiving public comments, the agency published a supplemental notice of proposed rulemaking (SNPRM) on November 5, 1999, for FMVSS No. 208 (64 FR 60556) outlining the proposed Nij neck injury criterion. DaimlerChrysler submitted comments on December 23, 1999, (NHTSA Docket No. NHTSA–99–6407) in response to the SNPRM citing its concerns over the need and usefulness of the Nij specification as an adequate neck injury measure in the advanced air bag rule, and questioning the sufficiency of the Hybrid III neck to measure appropriately the injury producing forces and movements as they relate to the human neck.

Complementing the November 5, 1999, proposed rulemaking, the agency incorporated in 49 CFR Part 572 the specifications for the Hybrid III 5th Percentile Female Test Dummy (65 FR 10961) on March 1, 2000. This dummy was incorporated to permit assessment of the potential for injury to small-stature adults and teenagers in frontal crashes and to facilitate the development of technologies that would minimize the risk of injury from deploying air bags, in part, through application of Nij as an injury assessment measure. In response to the March 1, 2000, final rule, DaimlerChrysler submitted a petition for reconsideration on April 14, 2000, again stating its concern with the need for and use of Nij and the adequacy of the HIII 5th Percentile Female Dummy's neck.

After consideration of DaimlerChrysler's and others' comments to the November 1999 SNPRM, the agency published a final rule amending FMVSS No. 208 on May 12, 2000 (65 FR 30680), adopting the proposed neck injury criteria. Since the publication of the advanced air bag final rule, DaimlerChrysler has submitted additional petitions to FMVSS No. 208 on June 26, 2000, and February 1, 2002, reiterating its previous objection regarding Nij and the Hybrid III 5th Percentile Female Test Dummy's neck.

The agency first addressed DaimlerChrysler's petitions for reconsideration concerning the adequacy of the Nij and the Hybrid III 5th Percentile Female Test Dummy's neck in the response to petitions for reconsideration of the advanced air bag rulemaking published on December 18, 2001 (66 FR 65376). On July 15, 2002, the agency likewise denied the DaimlerChrysler petition for reconsideration (submitted April 14, 2000) of the adoption of the Hybrid III 5th Percentile Female into 49 CFR Part 571, Subpart O (67 FR 46400).

Analysis

In its petition for reconsideration dated August 29, 2002, DaimlerChrysler claimed that it either did not clearly communicate its position in its April 14, 2000, petition for reconsideration of the final rule (Subpart O) or NHTSA misinterpreted what DaimlerChrysler was attempting to convey. In particular DaimlerChrysler stated that:

1. DaimlerChrysler only petitioned to discontinue use of the Nij in conjunction with the Hybrid-III neck and did not petition to discontinue use of the neck;
2. The agency believes that DaimlerChrysler contends that the neck muscles do not contribute to global moments of the neck, when DaimlerChrysler's position is that moments generated due to neck muscles do not contribute to injury; and
3. The agency did not address DaimlerChrysler's claim that the basis of the moment component of the Nij is the local moments, and that the global moments (the moments measured by the Hybrid III [neck]) cannot be used to estimate the local moments.
4. DaimlerChrysler questioned the accuracy of the response of the Hybrid III dummy neck with regards to the moments recorded when there was little head rotation.

After consideration of DaimlerChrysler's August 29, 2002, petition for reconsideration of 49 CFR Part 572, Subpart O final rule, NHTSA concludes that there is no reasonable justification to delay the implementation date of the Hybrid III 5th Percentile Female Test Dummy final rule as the petitioner requested. The issues in this petition for reconsideration were raised by DaimlerChrysler previously, twice in petitions of FMVSS No. 208 (June 26, 2000, Docket No. 00–7013 and February 1, 2002, Docket No. 01–1110) and once in a petition of 49 CFR Part 572 (April 14, 2000, Docket No. 00–6940). The agency fully understood and considered the issues raised by DaimlerChrysler when it denied those three previous petitions. The agency does not believe it is appropriate to challenge the validity of Nij in a petition for reconsideration of a rule implementing or amending 49 CFR Part 572, Subpart O, since the Nij neck injury criteria is specified in FMVSS No. 208 and is not relevant to 49 CFR Part 572.

NHTSA fully understands that DaimlerChrysler only petitioned to discontinue use of the Nij in conjunction with the Hybrid III neck and did not petition to completely discontinue use of the neck. NHTSA acknowledges the likelihood that injury causing moments are those of the ligamentous spine when some moment levels are exceeded, as does the agency acknowledge that the global neck moments, measured by the Hybrid III dummy neck, may include some contribution from the muscle pairs, as well as the local moment at the occipital condyle (OC). However, the agency disagrees that Nij cannot be used with the Hybrid III dummy neck, since the criteria was developed and validated for that particular dummy neck.[1] Furthermore, the Nij was adjusted to account for possible muscle contribution.

DaimlerChrysler also questioned the accuracy of the response of the Hybrid III dummy neck with regards to the moments recorded when there was little head rotation. The agency's analysis of air bag loading patterns with the Hybrid III neck showed that in nearly all cases with high moments at the OC, there was also a corresponding high shear force caused by direct contact between the air bag and the neck. This correlation between a high OC moment and high shear force measured by the upper and lower neck load cells were recorded only when the air bag directly contacted the neck. Moreover, this direct neck contact did not always result in significant head rotation. The agency, therefore, believes the moments being recorded are appropriate because they are partly accounted for by the shear force that is occurring during contact.

Lastly, the Transportation Equity Act (TEA 21) initially specified the implementation of advanced air bags by September 1, 2002. The agency used provisions allowed in the Act to extend the implementation date from September 1, 2002 to September 1, 2003, (January 1, 2003, Docket No. 02–14270). To further ease the transition, a phase-in period was established with the first year of implementation reduced

[1] ''Development of Improved Injury Criteria for the Assessment of Advanced Automotive Restraint Systems—II'' and ''Supplemental: Development of Improved Injury Criteria for the Assessment of Advanced Automotive Restraint Systems—II'' (NHTSA Docket # 1999–6407).

to 20% of the vehicle production.[2] Consequently, 20% of the vehicle fleet already complies with the advanced air bag requirements, and within the next few months the majority of the vehicle fleet (65% of model year 2005 vehicles) will comply with the advanced air bag requirements. To date, there have been no manufacturers unable to meet the FMVSS No. 208 Nij requirements.

Conclusion

Inasmuch as the DaimlerChrysler's petition did not provide further test data to support its petition, and the Nij limits are practicable and have contributed to the elimination of special risks for small-statured occupants, the agency finds no reason or justification for giving the DaimlerChrysler petition further consideration. Accordingly, the DaimlerChrysler Petition for Reconsideration of August 29, 2002, is hereby denied.

Authority: 49 U.S.C. 30162; delegations of authority at 49 CFR 1.50 and 49 CFR 501.8.

Issued on: March 14, 2005.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 05–5342 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–59–P

[2] The second year of the phase-in requires 65% of the production to comply with the advanced air bag requirement.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2005–20649]

Notice of Receipt of Petition for Decision That Nonconforming 2003–2004 Porsche Cayenne Multipurpose Passenger Vehicles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 2003–2004 Porsche Cayenne multipurpose passenger vehicles are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 2003–2004 Porsche Cayenne multipurpose passenger vehicles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards, are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is April 18, 2005.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW., Washington, DC 20590. [Docket hours are from 9 a.m. to 5 p.m.]. 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.*

FOR FURTHER INFORMATION CONTACT: Coleman Sachs, Office of Vehicle Safety Compliance, NHTSA (202–366–3151).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

US SPECS of Aberdeen, Maryland (Registered Importer 03–321) has petitioned NHTSA to decide whether nonconforming 2003–2004 Porsche Cayenne multipurpose passenger vehicles are eligible for importation into the United States. The vehicles which US SPECS believes are substantially similar are 2003–2004 Porsche Cayenne multipurpose passenger vehicles that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 2003–2004 Porsche Cayenne multipurpose passenger vehicles to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

US SPECS submitted information with its petition intended to demonstrate that non-U.S. certified 2003–2004 Porsche Cayenne multipurpose passenger vehicles as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 2003–2004 Porsche Cayenne multipurpose passenger vehicles are identical to their U.S-certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect,* 103 *Windshield Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 106 *Brake Hoses,* 113 *Hood Latch System,* 116 *Motor Vehicle Brake Fluids,* 119 *New Pneumatic Tires for Vehicles Other than Passenger Cars,* 124 *Accelerator Control Systems,* 135 *Passenger Car Brake Systems,* 201 *Occupant Protection in Interior Impact,* 202 *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 207 *Seating Systems,* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Mounting,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* and 302 *Flammability of Interior Materials.*

The petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* Replacement or conversion of the speedometer to read in miles per hours.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* Installation, on vehicles that are not already so equipped, of U.S.-model headlamps, front side marker lamps,

taillamp assemblies that incorporate rear side marker lamps, a high-mounted stoplamp assembly, and front and rear side reflex reflectors.

Standard No. 111 *Rearview Mirrors:* Installation of a U.S.-model passenger side rearview mirror, or inscription of the required warning statement on the face of the passenger side rearview mirror.

Standard No. 114 *Theft Protection:* Installation, on vehicles that are not already so equipped, of a supplemental key warning buzzer system to meet the requirements of this standard.

Standard No. 118 *Power-Operated Window, Partition, and Roof Panel Systems:* Reprogramming and rewiring the vehicle's systems, as required, to ensure compliance with the standard.

Standard No. 120 *Tire Selection and Rims for Motor Vehicles Other than Passenger Cars:* Installation of a tire information placard.

Standard No. 206 *Door Locks and Door Retention Components:* Inspection of all vehicles and installation, on vehicles that are not already so equipped, of U.S.-model components, or modification of existing components, as necessary, to meet the requirements of this standard.

Standard No. 208 *Occupant Crash Protection:* (a) Inspection of all vehicles and replacement of any non U.S.-model seat belts, air bag control units, air bags, sensors, and knee bolsters with U.S.-model components on vehicles that are not already so equipped, and (b) installation of a supplemental seat belt warning buzzer system, if required, to meet the requirements of this standard.

The petitioner states that the occupant restraints used in these vehicles consist of dual front airbags and combination lap and shoulder belts at the front and rear outboard seating positions. These manual systems are automatic, self-tensioning, and are released by means of a single red push-button.

Standard No. 209 *Seat Belt Assemblies:* Inspection of all vehicles and replacement of non-U.S. model seat belt assemblies with U.S.-model components.

Standard No. 225 *Child Restraint Anchorage Systems:* Inspection of all vehicles and installation of U.S.-model components, on vehicles that are not already so equipped, to meet the requirements of this standard.

Standard No. 301 *Fuel System Integrity:* Inspection of all vehicles and installation of U.S.-model components, on vehicles that are not already so equipped, to ensure compliance with the standard.

The petitioner also states that a vehicle identification plate must be affixed to the vehicles near the left windshield post to meet the requirements of 49 CFR part 565.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW., Washington, DC 20590. [Docket hours are from 9 a.m. to 5 p.m.]. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 05–5420 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2005–20645]

Notice of Receipt of Petition for Decision That Nonconforming 1981 BMW R100 Motorcycles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1981 BMW R100 motorcycles are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1981 BMW R100 motorcycles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is 30 days after publication in the **Federal Register**.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW., Washington, DC 20590. [Docket hours are from 9 a.m. to 5 p.m.] 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.*

FOR FURTHER INFORMATION CONTACT: Coleman Sachs, Office of Vehicle Safety Compliance, NHTSA (202–366–3151).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**

US SPECS of Aberdeen, Maryland (Registered Importer 03–321) has petitioned NHTSA to decide whether non-U.S. certified 1981 BMW R100 motorcycles are eligible for importation into the United States. The vehicles that US SPECS believes are substantially similar are 1981 BMW R100 motorcycles that were manufactured for

sale in the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1981 BMW R100 motorcycles to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

US SPECS submitted information with its petition intended to demonstrate that non-U.S. certified 1981 BMW R100 motorcycles as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1981 BMW R100 motorcycles are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 106 *Brake Hoses,* 116 *Brake Fluid,* 119 *New Pneumatic Tires for Vehicles other than Passenger Cars,* and 122 *Motorcycle Brake Systems.*

The petitioner further contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated below:

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* Inspection of all vehicles and replacement of the following with U.S.-model components on vehicles not already so equipped: (a) Headlamps; (b) front and rear side reflex reflectors; (c) rear reflex reflector; (d) tail lamp assembly; and (e) front and rear turn signal lamps.

Standard No. 111 *Rearview Mirrors:* Installation of a U.S.-model passenger side rearview mirror, or inscription of the required warning statement on the face of that mirror.

Standard No. 120 *Tire Selection and Rims for Vehicles other than Passenger Cars:* Installation of a tire information placard.

Standard No. 123 *Motorcycle Controls and Displays:* (a) Installation of a U.S.-model speedometer and odometer, or modification of the speedometer and odometer so that they read in miles per hour and miles traveled; and (b) installation of an ignition switch label.

Standard No. 205 *Glazing Materials:* Inspection of all vehicles, and removal or replacement of the glazing with U.S.-model components on vehicles not already so equipped.

Comments should refer to the docket number and be submitted to: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 05–5421 Filed 3–17–05; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–290 (Sub-No. 260X)]

Tennessee Railway Company—Abandonment Exemption—in Scott County, TN

On February 28, 2005, Tennessee Railway Company (TNR), a wholly owned subsidiary of Norfolk Southern Railway Company, filed with the Surface Transportation Board a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon an approximately 27.01-mile line of railroad between milepost TE–0.95 near Oneida, and milepost TE–27.96 near Nicks Creek, in Scott County, TN. The line traverses United States Postal Service Zip Codes 37756 and 37841, and includes the stations of Stanley, Newtown, Winona, Norma, Laco, and Smoky Junction. Service will continue to the station of Oneida.

The line does not contain federally granted rights-of-way. Any documentation in TNR's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by June 17, 2005.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,200 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than April 7, 2005. Each trail use request must be accompanied by a $200 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–290 (Sub-No. 260X) and must be sent to: (1) Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001, and (2) James R. Paschall, Three Commercial Place, Norfolk, VA 23510. Replies to the TNR petition are due on or before April 7, 2005.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1539. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary), prepared by SEA, will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: March 9, 2005.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 05–5215 Filed 3–17–05; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8842

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, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8842, Election To Use Different Annualization Periods for Corporate Estimated Tax.

DATES: Written comments should be received on or before May 17, 2005 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6516, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202) 622–3634, Internal Revenue Service, room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Election To Use Different Annualization Periods for Corporate Estimated Tax.

OMB Number: 1545–1409.

Form Number: 8842.

Abstract: Form 8842 is used by corporations, tax-exempt organizations subject to the unrelated business income tax, and private foundations to annually elect the use of an annualization period under Internal Revenue Code section 6655(e)(2)(C)(i) or (ii) for purposes of figuring the corporation's estimated tax payments under the annualized income installment method.

Current Actions: There are no changes being made to the Form 8842 at this time.

Type of Review: Extension of a current OMB approval.

Affected Public: Business, or other for-profit organizations.

Estimated Number of Respondents: 1700.

Estimated Time Per Respondent: 3 hrs., 33 min.

Estimated Total Annual Burden Hours: 4335.

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: March 11, 2005.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–1187 Filed 3–17–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 99–17

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 99–17, Mark to Market Election for Commodities Dealers and Securities and Commodities Traders.

DATES: Written comments should be received on or before May 17, 2005 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, Room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of revenue procedure should be directed to R. Joseph Durbala, (202) 622–3634, Internal Revenue Service, Room 6516, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Mark to Market Election for Commodities Dealers and Securities and Commodities Traders.

OMB Number: 1545–1641.

Revenue Procedure Number: Revenue Procedure 99–17.

Abstract: This revenue procedure prescribes the time and manner for dealers in commodities and traders in securities or commodities to elect to use the mark-to-market method of accounting under sections 475(e) and (f) of the Internal Revenue Code. The collections of information in this revenue procedure are required by the IRS in order to facilitate monitoring taxpayers changing accounting methods resulting from making the elections under Code section 475(e) or (f).

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

The reporting burden for the collections of information in section 5.01–5.04 of this revenue procedure is as follows:

Estimated Number of Respondents/Recordkeepers: 1,000.

Estimated Time Per Respondent/Recordkeeper: 30 minutes.

Estimated Total Annual Reporting/Recordkeeping Hours: 500.

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 beretained 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: March 11, 2005.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–1189 Filed 3–17–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8050

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8050, Direct Deposit of Corporate Tax Refund.

DATES: Written comments should be received on or before May 17, 2005, to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202) 622–3634, Internal Revenue Service, room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Direct Deposit of Corporate Tax Refund.

OMB Number: 1545–1762.

Form Number: 8050.

Abstract: Form 8050 is used to request that the IRS deposit a tax refund of ($1 million or more) directly into an account at any U.S. bank or other financial institution (such as a mutual fund, credit union, or brokerage firm) that accepts direct deposits.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals or households.

Estimated Number of Respondents: 210,000.

Estimated Time Per Respondent: 1 hour, 40 minutes.

Estimated Total Annual Burden Hours: 348,600.

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: March 11, 2005.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–1190 Filed 3–17–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Low Income Taxpayer Clinic Grant Program; Availability of 2005 Supplementary Grant Application Package

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This document contains a notice that the IRS has made available a supplemental period within which organizations may apply for a Low Income Taxpayer Clinic (LITC) matching grant for the remainder of the 2005 grant cycle (the 2005 grant cycle runs January 1, 2005, through December 31, 2005). The supplemental application period shall run from March 15, 2005, to April 15, 2005.

As a result of increased funding made available by enactment of the Consolidated Appropriations Act of 2005, Public Law 108–447, the IRS now has an additional $500,000 available to be awarded to qualifying organizations, subject to the limitations of Internal Revenue Code section 7526, for Low Income Taxpayer Clinic matching grants.

Despite the IRS's efforts to foster parity in availability and accessibility in the selection of organizations receiving LITC matching grants and the continued increase in clinic services nationwide, there remain communities that are underrepresented by clinics. For the supplemental application cycle, the IRS will focus on those geographic areas where there is limited or no clinic representation.

The IRS will award up to $500,000 in additional funding to new qualifying organizations in the following underserved or underrepresented states or areas within a state:

State	Areas
Alabama	Montgomery & south of Birmingham.
Alaska	Statewide excluding Anchorage area.
Arizona	Statewide.
Colorado	Statewide.
District of Columbia	Districtwide.
Idaho	Southern sections.
Iowa	Statewide excluding Des Moines area.
Maryland	Statewide.
Mississippi	Western & southern sections.
Missouri	Eastern & central sections including St. Louis.
Montana	Eastern sections.
Nebraska	Statewide excluding Omaha area.
New Mexico	Statewide.
North Dakota	Northern sections.
Puerto Rico	San Juan & eastern sections.
Texas	Western sections & Dallas.
Utah	Statewide.
Wisconsin	Statewide.
Wyoming	Statewide.

DATES: Grant applications for the remainder of the 2005 grant cycle must be electronically filed or received no later than 4 p.m. on April 15, 2005.

ADDRESSES: Send completed grant applications to: Internal Revenue Service, Taxpayer Advocate Service, LITC Grant Program Administration Office, Mail Stop 211–D, 401 W. Peachtree St., NW., Atlanta, GA 30308. Copies of the 2005 Grant Application Package and Guidelines, IRS Publication 3319 (Rev. 5–2004), can be downloaded from the IRS Internet site at *http://www.irs.gov/advocate* or ordered from the IRS Distribution Center by calling 1–800–829–3676. Applicants can also file electronically at *http://www.grants.gov.* For applicants applying through the Federal Grants Web site, the Funding Number is TREAS–GRANTS–032005–002.

FOR FURTHER INFORMATION CONTACT: The LITC Program Office at 404–338–7185 (not a toll-free number) or by e-mail at *LITCProgramOffice@irs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 7526 of the Internal Revenue Code authorizes the IRS, subject to the availability of appropriated funds, to award organizations matching grants of up to $100,000 for the development, expansion, or continuation of qualified low income taxpayer clinics. Section 7526 authorizes the IRS to provide grants to qualified organizations that represent low income taxpayers in controversies with the IRS or inform individuals for whom English is a second language of their tax rights and responsibilities. The IRS may award grants to qualifying organizations to fund one-year, two-year or three-year project periods. Grant funds may be awarded for start-up expenditures incurred by new clinics during the grant period.

The 2005 *Grant Application Package and Guidelines,* Publication 3319 (Rev. 5–2004), includes several changes that are being implemented to improve delivery of clinic services, including additional oversight and assistance with the technical components of the LITC Program by the LITC Program Office. Among the changes, the LITC Program Office has established work groups, clarified the comprehensive Program standards, improved communications, and increased the emphasis on education and outreach programs to taxpayers for whom English is a second language.

The costs of preparing and submitting an application are the responsibility of each applicant. Each application will be given due consideration and the LITC Program Office will mail notification letters to each applicant.

Selection Consideration

Applications that pass the eligibility screening process will be numerically ranked based on the information contained in their proposed program plan. Please note that the IRS Volunteer Income Tax Assistance (VITA) and Tax Counseling for the Elderly (TCE) Programs are independently funded and separate from the LITC Program. Organizations currently participating in the VITA or TCE Programs may be eligible to apply for a LITC grant if they meet the criteria and qualifications outlined in the 2005 *Grant Application Package and Guidelines,* Publication 3319 (Rev. 5–2004). Organizations that seek to operate VITA and LITC Programs, or TCE and LITC Programs, must maintain separate and distinct programs even if co-located to ensure proper cost allocation for LITC grant funds and adherence to the rules and regulations of the VITA, TCE and LITC Programs, as appropriate.

Comments

Interested parties are encouraged to provide comments on the IRS's administration of the grant program on an ongoing basis. Comments may be sent to Internal Revenue Service, Taxpayer Advocate Service, Attn: W. R. Swartz, LITC Program Office, 290 Broadway, 14th Floor, New York, NY 10007.

Christopher Wagner,

Deputy National Taxpayer Advocate, Internal Revenue Service.

[FR Doc. 05–4881 Filed 3–15–05; 1 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open meeting of the Area 6 Taxpayer Advocacy Panel (including the States of Arizona, Colorado, Idaho, Montana, New Mexico, North Dakota, Oregon, South Dakota, Utah, Washington and Wyoming)

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Area 6 committee of the Taxpayer Advocacy Panel will be conducted (via teleconference). The Taxpayer Advocacy Panel (TAP) is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. The TAP will use citizen input to make recommendations to the Internal Revenue Service.

DATES: The meeting will be held Monday, April 18, 2005.

FOR FURTHER INFORMATION CONTACT: Dave Coffman at 1–888–912–1227, or (206) 220–6096.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Area 6 Taxpayer Advocacy Panel will be held Monday, April 18, 2005 from 10:30 a.m. Pacific time to 12 p.m. Pacific time via a telephone conference call. The public is invited to make oral comments. Individual comments will be limited to 5 minutes. If you would like to have the TAP consider a written statement, please call 1–888–912–1227 or (206) 220–6096, or write to Dave Coffman, TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174 or you can contact us at *http://www.improveirs.org.* Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Dave Coffman. Mr. Coffman can be reached at 1–888–912–1227 or (206) 220–6096.

The agenda will include the following: Various IRS issues.

Dated: March 14, 2005.

Martha Curry,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. E5–1188 Filed 3–17–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0068]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement, without change, of a previously approved collection for which approval has expired, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine a claimant's eligibility for service disabled insurance.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before May 17, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Please refer to ''OMB Control No. 2900–0068'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles: Application for Service–Disabled Insurance, VA Form 29–4364 and Application for Service—Disabled Veterans Insurance, VA Form 29–0151.

OMB Control Number: 2900–0068.

Type of Review: Extension of a currently approved collection.

Abstract: Claimants complete VA Forms 29–4364 and 29–0151 to apply for service–disabled insurance and service–disabled veterans insurance, to designate a beneficiary and to select an optional settlement. VA uses the data collected to determine the claimant's eligibility for insurance.

Affected Public: Individuals or households.

Estimated Annual Burden: 2,833 hours.

Estimated Average Burden Per Respondent: 40 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 4,250.

Dated: March 11, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1194 Filed 3–17–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0085]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Board of Veterans' Appeals, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Board of Veterans' Appeals (BVA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information required in processing appeals from denial of VA benefits and in regulation of representatives' fees.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before May 17, 2005.

ADDRESSES: Submit written comments on the collection of information to Sue Hamlin, Board of Veterans' Appeals (01C), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *sue.hamlin@mail.va.gov*. Please refer to ''OMB Control No. 2900–0085'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Sue Hamlin at (202) 565–5686.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, BVA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of BVA's functions, including whether the

information will have practical utility; (2) the accuracy of BVA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles

a. Appeal to Board of Veterans' Appeals, VA Form 9.
b. Withdrawal of Services by a Representative.
c. Filing of Representative's Fee Agreements and Motions for Review of Such Agreements.
d. Motion for Review of Representative's Charges for Expenses.
e. Request for Changes in Hearing Date.
f. Motion for Reconsideration.

OMB Control Number: 2900–0085.

Type of Review: Extension of a currently approved collection.

Abstract

a. Appeal to Board of Veterans' Appeals, VA Form 9, may be used by appellants to complete their appeal to the Board of Veterans' Appeals (BVA) from a denial of VA benefits. The information is used by BVA to identify the issues in dispute and prepare a decision responsive to the appellant's contentions and the legal and factual issues raised.

b. Withdrawal of Services by a Representative: When the appellant's representative withdraws from a case, both the appellant and the BVA must be informed so that the appellant's rights may be adequately protected and so that the BVA may meet its statutory obligations to provide notice to the current representative.

c. Filing of Representative's Fee Agreements and Motions for Review of Such Agreements: Agreements for fees charged by individuals or organizations for representing claimants and appellants before VA are filed with, and reviewed by, the Board of Veterans' Appeals. The information is used to determine whether such fees are excessive or unreasonable.

d. Motion for Review of Representative's Charges for Expenses: Expense reimbursements claimed by individuals and organizations for representing claimants and appellants before VA have been monitored for fairness for many years. The information is used to review changes by claimants' representatives for expenses to afford protection to such claimants from overreaching by unscrupulous representatives and is useful in monitoring fees charged by representatives and to ensure that fee limitations are not avoided by mischaracterizing fees as expenses.

e. Request for Changes in Hearing Date: VA provides hearings to appellants and their representatives, as required by basic Constitutional due-process and by Title 38 U.S.C. 7107(b). From time to time, hearing dates and/or times are changed, hearing requests withdrawn and new hearings requested after failure to appear at a scheduled hearing. The information is used to comply with the appellants' or their representatives' requests.

f. Motion for Reconsideration: Decisions by BVA are final unless the Chairman orders reconsideration of the decision either on the Chairman's initiative, or upon motion of a claimant. The Board Chairman, or his designee, uses the information provided in deciding whether reconsideration of a Board decision should be granted.

Affected Public: Individuals or households, business or other for profit, and not for profit institutions.

Estimated Total Annual Burden: 49,700 hours.

a. Appeal to Board of Veterans' Appeals, VA Form 9—46,592 hours.
b. Withdrawal of Services by a Representative—183 hours.
c. Filing of Representative's Fee Agreements and Motions for Review of Such Agreements—283 hours.
d. Motion for Review of Representative's Charges for Expenses—4 hours.
e. Request for Changes in Hearing Date—1,761 hours.
f. Motion for Reconsideration—877 hours.

Estimated Average Burden Per Respondent

a. Appeal to Board of Veterans' Appeals, VA Form 9—1 hour.
b. Withdrawal of Services by a Representative—20 minutes.
c. Filing of Representative's Fee Agreements and Motions for Review of Such Agreements—1 hour (contract modifications), 10 minutes (basic filing), 2 hours (filing motion or response).
d. Motion for Review of Representative's Charges for Expenses—4 hours (2 hours for motion and 2 hours for response to motion).
e. Request for Changes in Hearing Date—15 minutes (basic request), 1 hour (requests requiring preparation of a motion).
f. Motion for Reconsideration—1 hour.

Frequency of Response: On occasion.

Estimated Total Number of Respondents: 53,874.

a. Appeal to Board of Veterans' Appeals, VA Form 9—46,592.
b. Withdrawal of Services by a Representative—550.
c. Filing of Representative's Fee Agreements and Motions for Review of Such Agreements—1,279.
d. Motion for Review of Representative's Charges for Expenses—2.
e. Request for Changes in Hearing Date—4,574.
f. Motion for Reconsideration—877.

Dated: March 11, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1195 Filed 3–17–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0131]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to this notice. This notice solicits comments on information needed to determine the insured's eligibility to reinstate or change government life insurance.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before May 17, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov*. Please refer to ''OMB Control No. 2900–0131'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Request for Supplemental Information on Medical and Nonmedical Applications, VA Form Letter 29–615.

OMB Control Number: 2900–0131.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 29–615 used by the insured to apply for new issue, reinstatement or change of plan on Government Life Insurance policies.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,000 hours.

Estimated Average Burden Per Respondent: 20 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 9,000.

Dated: March 11, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1196 Filed 3–17–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0024]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to authorize VA to deduct premiums, loans and/or lien payment.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before May 17, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov*. Please refer to ''OMB Control No. 2900–0024'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Insurance Deduction Authorization (For Deduction from Benefit Payments), VA Form 29–888.

OMB Control Number: 2900–0024.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 29–888 is completed by the insured or their representative to authorize VA to deduct payment for premiums, loans and/or liens on his or her insurance contract from their VA compensation check.

Affected Public: Individuals or households.

Estimated Annual Burden: 622 hours.

Estimated Average Burden Per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 3,732.

Dated: March 11, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1197 Filed 3–17–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0422]

Agency Information Collection Activities Under OMB Review

AGENCY: Office of Management, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501–3521), this notice announces that the Office of Management (OM), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before April 18, 2005.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Information Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030 or FAX (202) 273–5981. Please refer to ''OMB Control No. 2900–0422.''

Send comments and recommendations concerning any aspect of the information collection to VA's Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0422'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, (OM) invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of (OM)'s functions, including whether the information will have practical utility; (2) the accuracy of (OM)'s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles

a. Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236–72, Performance of Work by the Contractor.

b. Department of Veterans Affairs Acquisition Regulation (VAAR) Alternate I to Clause 852.236–80, Subcontracts and Work Coordination.

c. Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236–82, Payments Under Fixed-Price Construction Contracts (without NAS), including Alternate 1.

d. Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236–83, Payments Under Fixed-Price Construction Contracts (with NAS), including Alternate 1.

e. Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236–84, Schedule of Work Progress.

f. Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236–88, Contract Changes, Supplements FAR Clause 52.243–4, Changes.

OMB Control Number: 2900–0422.

Type of Review: Extension of a currently approved collection.

Abstract

The information contained Department of Veterans Acquisition Regulation (VAAR) Clauses 852.236–72, Alternate I to 852.236–80, 852.236–82, 852.236–83, 852.236–84, and 852.236–88 is necessary for VA to administer construction contracts, and to carry out its responsibility to construct, maintain and repair real property for the Department.

a. VAAR Clause 852.236–72, Performance of Work by the Contractor, requires contractors awarded a construction contract containing Federal Acquisition Regulation (FAR) clause 52.236–1, to submit a statement designating the branch or branches of contract work to be performed by the contractor's own forces. The VAAR clause implements the FAR clause by requiring the contractor to provide information to the contracting officer on how the contractor intends to fulfill this contractual obligation. The contracting officer uses this information to ensure that the contractor complies with the contract requirements.

b. Alternate I to Clause 852.236–80, Work Coordination, requires construction contractors, on contracts involving complex mechanical-electrical work, to furnish coordination drawings showing the manner in which utility lines will fit into available spaces and relate to each other and to the existing building elements. The information is used by the contracting officer and VA engineer assigned to the project to resolve any problems relating to the installation of utilities on construction contract.

c. VAAR Clause 852.236–82, Payments Under Fixed-Price Construction Contracts (without NAS), requires construction contractors to submit a schedule of costs for work to be performed under the contract. If the contract includes guarantee period services, Alternate I requires contractor to submit information on the total and itemized costs of the guarantee period services and to submit a performance plan/program. The information is needed to allow the contracting officer to determine the correct amount to pay the contractor as work progresses and to properly proportion the amount paid for guarantee period services.

d. VAAR Clause 852.236–83, Payments Under Fixed-Price Construction Contracts (with NAS), requires construction contractors to submit a schedule of costs for work to be performed under the contract. If the contract includes guarantee period services, Alternate I requires contractor to submit information on the total and itemized costs of the guarantee period services and to submit a performance plan/program. The information is needed to allow the contracting officer to determine the correct amount to pay the contractor as work progresses and to properly proportion the amount paid for guarantee period services. The difference between this clause and the one above 852.236–82 is that this clause requires the contractor to use a computerized Network Analysis System (NAS) to prepare the cost estimate.

e. VAAR Clause 852.236–84, Schedule of Work Progress, requires construction contractors, on contracts that do not require the use of a NAS, to submit a progress schedule. The information is used by the contracting officer to track the contractor's progress under the contract and to determine whether or not the contractor is making satisfactory progress.

f. VAAR Clause 852.236–88, Contract Changes, Supplements FAR Clause 52.243–4, Changes. FAR Clause 52.243–4 authorizes the contracting officer to order changes to a construction contract but does not specifically require the contractor to submit cost proposals for those changes. VAAR Clause 852.236–88 requires contractors to submit cost proposal for changes ordered by the contracting officer or for changes proposed by the contractor. This information is needed to allow the contracting officer and the contractor to reach a mutually acceptable agreement on how much to pay the contractor for the proposed changes to the contract. It is also used by the contracting officer to determine whether or not to authorize the proposed changes or whether or not additional or alternate cost proposals for changes are needed.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on December 23, 2004, at pages 76975–76976.

Affected Public: Business or other for-profit, Individuals and households, Not-for-profit institutions.

Estimated Annual Burden

a. VAAR Clause 852.236–72, Performance of Work by the Contractor—36 hours.

b. VAAR Alternate I to Clause 852.236–80, Subcontracts and Work Coordination—1,190 hours.

c. VAAR Clause 852.236–82, Payments Under Fixed-Price Construction Contracts (without NAS), including Alternate 1—1,397.

d. VAAR Clause 852.236–83, Payments Under Fixed-Price Construction Contracts (with NAS), including Alternate 1—59 hours.

e. VAAR Clause 852.236–84, Schedule of Work Progress—2,095 hours.

f. VAAR Clause 852.236–88, Contract Changes, Supplements FAR Clause 52.243–4, Changes—807 hours.

Estimated Annual Burden Per Respondent

a. VAAR Clause 852.236–72, Performance of Work by the Contractor—1 hour.

b. VAAR Alternate I to Clause 852.236–80, Subcontracts and Work Coordination—10 hours.

c. VAAR Clause 852.236–82, Payments Under Fixed-Price Construction Contracts (without NAS), including Alternate 1—1 hour.

d. VAAR Clause 852.236–83, Payments Under Fixed-Price Construction Contracts (with NAS), including Alternate 1—30 minutes.

e. VAAR Clause 852.236–84, Schedule of Work Progress—1 hour.

f. VAAR Clause 852.236–88, Contract Changes, Supplements FAR Clause 52.243–4, Changes—3 hours.

Frequency of Response: On occasion.

Estimated Number of Respondents

a. VAAR Clause 852.236–72, Performance of Work by the Contractor—36.

b. VAAR Alternate I to Clause 852.236–80, Subcontracts and Work Coordination—119.

c. Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236–82, Payments Under Fixed-Price Construction Contracts (without NAS), including Alternate 1—1,397.

d. VAAR Clause 852.236–83, Payments Under Fixed-Price Construction Contracts (with NAS), including Alternate 1—119.

e. VAAR Clause 852.236–84, Schedule of Work Progress—1,397.

f. VAAR Clause 852.236–88, Contract Changes, Supplements FAR Clause 52.243–4, Changes—269.

Dated: March 10, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1198 Filed 3–17–05; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register

Vol. 70, No. 52

Friday, March 18, 2005

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

MISSISSIPPI RIVER COMMISSION

Sunshine Act Meetings

Correction

In notice document 05–4818 appearing on page 12019 in the issue of Thursday, March 10, 2005, make the following correction:

In the second column, in the second line from the top, under **MATTERS TO BE CONSIDERED**, in the eighth line, ''Vicksburg'' should read ''Memphis.''

[FR Doc. C5–4818 Filed 3–17–05; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–19581; Airspace Docket No. 04–ACE–71

Establishment of Class E2 Airspace; and Modification of Class E5 Airspace; Ankeny, IA

Correction

In rule document 05–4654 beginning on page 11853 in the issue of Thursday, March 10, 2005, make the following corrections:

§ 71.1 [Corrected]

1. On page 11854, in the first column, in §71.1 under the heading **ACE IA E2 Ankeny, IA**, in the seventh line, ''0.46°'' should read ''046°.''

2. On the same page, in the second column, in the same section, in the sixth line from the top, ''7600'' should read ''700.''

[FR Doc. C5–4654 Filed 3–17–05; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,
March 18, 2005

Part II

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Part 331 and 9 CFR Part 121
Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331 and 9 CFR Part 121

[Docket No. 02–088–4]

RIN 0579–AB47

Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are adopting as a final rule, with changes, an interim rule that established regulations governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal health, to plant health, or to animal or plant products. This action is necessary to protect animal and plant health, and animal and plant products.

DATES: *Effective Date:* The amendments to the list of PPQ select agents and toxins in 7 CFR 331.3(b) are effective March 10, 2005. The remaining provisions of this final rule are effective April 18, 2005.

FOR FURTHER INFORMATION CONTACT: For information concerning the regulations in 7 CFR part 331, contact Dr. Charles L. Divan, Senior Agricultural Microbiologist, Pest Permit Evaluations, Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236, (301) 734–8758.

For information concerning the regulations in 9 CFR part 121, contact Dr. Lee Ann Thomas, Director, Animals, Organisms and Vectors, and Select Agents, VS, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231, (301) 734–5960.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). Title II of Pub. L. 107–188, ''Enhancing Controls on Dangerous Biological Agents and Toxins'' (sections 201 through 231), provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services (subtitle A, sections 201–204) and the Department of Agriculture (subtitle B, sections 211–213), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). Subtitle D (section 231) provides for criminal penalties regarding certain biological agents and toxins. For the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) has been designated as the agency with primary responsibility for implementing the provisions of the Act; the Animal and Plant Health Inspection Service (APHIS) is the agency fulfilling that role for the Department of Agriculture (USDA). The Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation has been designated as the agency with primary responsibility for implementing the Attorney General's responsibilities under the Act (*i.e.*, the security risk assessments).

In subtitle B (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to below as the Act), section 212(a) provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act further requires (under section 213(b)) that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of that regulation, notify the Secretary of such possession.

In accordance with these statutory requirements, on August 12, 2002, we published in the **Federal Register** (67 FR 52383–52389, Docket No. 02–082–1) an interim rule that established the initial lists of biological agents and toxins and set out the manner in which persons in possession of listed agents and toxins were to provide notice of such possession.

Section 212 of the Act also required the Secretary to provide by regulation for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of listed biological agents and toxins in order to protect animal and plant health, and animal and plant products. Specifically, sections 212(b) and (c) required that the Secretary:

- Establish and enforce safety procedures for listed agents and toxins, including measures to ensure proper training and appropriate skills to handle agents and toxins, and proper laboratory facilities to contain and dispose of agents and toxins;
- Establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose;
- Establish procedures to protect animal and plant health, and animal and plant products, in the event of a transfer or potential transfer of a listed agent or toxin in violation of the safety procedures and safeguard and security measures established by the Secretary; and
- Ensure appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

In an interim rule published in the **Federal Register** on December 13, 2002 (67 FR 76908–76938, Docket No. 02–088–1) and effective on February 11, 2003, we established regulations in 7 CFR part 331 and 9 CFR part 121 governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal or plant products. These CFR parts are referred to below as the regulations. We solicited comments concerning the interim rule for 60 days ending February 11, 2003. We received 36 written comments. They were from academic institutions, professional associations, corporations, nonprofit organizations, individuals, and representatives of State and Federal Governments. These comments, as well as oral comments presented at a public meeting on December 16, 2002, are discussed by topic below.

Also on December 13, 2002, CDC published in the **Federal Register** (67 FR 76886–76905) an interim rule that established the standards and procedures governing the possession, use, and transfer of certain biological agents and toxins (referred to by CDC as select agents and toxins) (42 CFR part 73).

On November 3, 2003, APHIS and CDC published in the **Federal Register** (68 FR 62218–62221, Docket No. 02–088–3; and 68 FR 62245–62247) interim rules that amended both agencies' regulations in order to allow for the issuance of provisional registration certificates for individuals and entities and provisional grants of access to listed biological agents and toxins for individuals. These provisional measures provided additional time for the Attorney General to complete security risk assessments for those individuals and entities for which the Attorney General received, by November 12, 2003, all of the information required to conduct a security risk assessment. We solicited comments concerning the

interim rules for 60 days ending January 2, 2004. We did not receive any comments by that date.

APHIS and CDC collaborated closely on the December 13, 2002, and November 3, 2003, interim rules, as well as on this final rule and CDC's final rule also issued in today's **Federal Register**. Below is a summary of the changes we are making to the regulations in this final rule. We refer to the regulations in place prior to the effective date of this final rule as the ''interim'' regulations, or ''interim'' 7 CFR 331.4, for example, when we need to distinguish between the regulations established by the interim rules of December 2002 and November 2003 and this final rule.

Summary of Changes Made in Final Rule

1. We are revising the format of the regulations in 7 CFR part 331 and 9 CFR part 121 so that the sections numbers and, to the extent possible, the section titles and the information contained in each section is the same in 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73.

2. We are changing the terms ''biological agents and/or toxins,'' ''listed agents and/or toxins,'' and ''high consequence livestock pathogens'' to ''select agents and toxins'' or ''select agents or toxins'' throughout 7 CFR part 331 and 9 CFR part 121. In addition, in 9 CFR part 121, we are removing the term ''overlap agents'' each time it appears and adding ''overlap select agents and/or toxins'' in its place.

3. We are changing the title of 7 CFR part 331 and 9 CFR part 121 from ''Possession, Use, and Transfer of Biological Agents and Toxins'' to ''Possession, Use, and Transfer of Select Agents and Toxins.''

4. We are removing *Phakopsora pachyrhizi* and plum pox *potyvirus* from the list of PPQ select agents and toxins.

5. We are removing Newcastle disease virus (VVND) from the list of VS select agents and toxins and adding Newcastle disease virus (velogenic) in its place to make it clear that we are regulating all of the velogenic strains.

6. We are removing *Clostridium botulinum* from the list of overlap select agents and toxins but we are continuing to list Botulinum neurotoxin producing species of *Clostridium*.

7. We are adopting CDC's approach for genetic elements and, therefore, we will consider the following to be select agents and toxins:

- Nucleic acids that can produce infectious forms of any of the select agent viruses listed in either 7 CFR part 331 or 9 CFR part 121;
- Recombinant nucleic acids that encode for the functional forms of any toxin listed in either 7 CFR part 331 or 9 CFR part 121 if the nucleic acids: (1) Can be expressed *in vivo* or *in vitro*; or (2) are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*; and
- Select agents and toxins listed in either 7 CFR part 331 or 9 CFR part 121 that have been genetically modified.

8. We are broadening the scope of the overlap toxin exclusion to cover overlap toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor.

9. We are amending the exemption provisions by requiring, as another condition of exemption, that the select agent or toxin be secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin.

10. We are amending the exemption provisions in 9 CFR part 121 by requiring immediate reporting after identification of specified select agents and toxins; identification of the other select agents and toxins must be reported within 7 calendar days after identification.

11. We are amending the exemption provisions to allow the Administrator to make exceptions to the timeframes for transfer or destruction of a select agent or toxin, as necessary.

12. We are amending the registration sections to set out a new framework for submitting registration applications to APHIS or CDC.

13. We are amending the registration sections in 7 CFR part 331 and 9 CFR part 121 to provide:

- Federal, State, or local governmental agencies, including public institutions of higher education, are exempt from the security risk assessment for the entity and the individual who owns or controls such entity.
- For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.
- For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual: (1) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock; or (2) is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.
- An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

14. We are amending the registration sections to provide that a certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the responsible official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

15. We are amending the registration sections to require that, prior to any change, the responsible official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.

16. We are amending the registration sections to provide that an entity must immediately notify APHIS or CDC if it loses the services of its responsible official. An entity may continue to possess or use select agents or toxins only if it appoints as the responsible official another individual who has been approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of the regulations.

17. We are amending the sections pertaining to denial, revocation, and suspension of registration by requiring that, upon notification of suspension or revocation, an individual or entity must:

- Immediately stop all use of each select agent or toxin covered by the revocation or suspension order;
- Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release; and
- Comply with all disposition instructions issued by the Administrator for each select agent or toxin covered by the revocation or suspension.

18. We are amending the responsible official sections to require the responsible official to report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification. We are also amending the responsible official section in 9 CFR 121.9 to require the responsible official to report the identification and final disposition of any select agent or toxin

contained in a specimen presented for proficiency testing.

19. We are amending the provisions relating to access approvals to state that an individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (*e.g.*, carries, uses, or manipulates) or the ability to gain possession of a select agent or toxin.

20. We are amending the provisions pertaining to access approval to provide that an individual's access approval may be revoked if the individual is within any of the categories specified in the regulations.

21. We are amending the security sections to clarify that the security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

22. We are adding the provisions for restricted experiments to 7 CFR part 331 and we are amending these provisions in 7 CFR part 331 and 9 CFR part 121 to indicate that these experiments must be conducted under any conditions prescribed by the Administrator.

23. We are amending the training sections to require that information and training on biocontainment/biosafety and security be provided to each individual with access approval from the Administrator or the HHS Secretary before he/she has access and to each individual not approved for access by the Administrator or the HHS Secretary before he/she works in or visits areas where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.).

24. We are amending the transfer section in 9 CFR 121.16 to set out the requirements for transfer of a select agent or toxin contained in a specimen for proficiency testing.

25. We are amending the transfer sections to provide that, on a case-by-case basis, the Administrator may authorize a transfer of a select agent or toxin not otherwise eligible for transfer under the regulations under conditions prescribed by the Administrator.

26. We are amending the transfer sections to provide that an authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization changes (*e.g.*, change in the certificate of registration for the sender or recipient, change in the application for transfer).

27. We are amending the records sections to require the maintenance of an accurate, current inventory for each toxin held and for each select agent held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials).

28. We are amending the section pertaining to notification of theft, loss, or release in 7 CFR part 331 to require that APHIS or CDC be notified immediately upon discovery of a release of a select agent or toxin outside of the primary barriers of the biocontainment area and we are amending this section in 9 CFR part 121 to require that APHIS or CDC be notified immediately upon discovery of a release of a select agent or toxin causing occupational exposure or a release outside of the primary barriers of the biocontainment area.

29. We are amending the administrative review sections to allow an individual to appeal revocation of access approval.

Format of the Regulations

APHIS and CDC are revising the format of the regulations in the final rules so that the section numbers and, to the extent possible, the section titles and the information contained in each section is the same in 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73. These changes should make the regulations easier to use and facilitate compliance. The chart below sets out the format of 7 CFR part 331 and 9 CFR part 121 set by the interim rules (interim regulations) and the new format for the regulations in 7 CFR part 331 and 9 CFR part 121 (final rule).

Interim regulations	Final rule
331.0 *Effective and applicability dates*	
121.0 *Effective and applicability dates*	
331.1 *Definitions*	331.1 *Definitions.*
121.1 *Definitions*	121.1 *Definitions.*
331.2 *Purpose and scope*	331.2 *Purpose and scope.*
121.2 *Purpose and scope*	121.2 *Purpose and scope.*
331.3 *List of biological agents and toxins*	331.3 *PPQ select agents and toxins.*
121.3 *List of biological agents and toxins*	121.3 *VS select agents and toxins.*
331.4 *Exemptions*	331.4 *[Reserved].*
121.4 *Exemptions for overlap agents or toxins*	121.4 *Overlap select agents and toxins.*
331.5 *Registration; who must register*	331.5 *Exemptions.*
121.5 *Exemptions for animal agents and toxins*	121.5 *Exemptions for VS select agents and toxins.*
331.6 *Registration; general provisions*	331.6 *[Reserved]*
121.6 *Registration; who must register*	121.6 *Exemptions for overlap select agents and toxins.*
331.7 *Denial, revocation, or suspension of registration*	331.7 *Registration and related security risk assessments.*
121.7 *Registration; general provisions*	121.7 *Registration and related security risk assessments.*
331.8 *Registration; how to register*	331.8 *Denial, revocation, or suspension of registration.*
121.8 *Denial, revocation, or suspension of registration*	121.8 *Denial, revocation, or suspension of registration.*
331.9 *Responsibilities of the responsible official*	331.9 *Responsible official.*
121.9 *Registration; how to register*	121.9 *Responsible official.*
331.10 *Restricting access to biological agents and toxins*	331.10 *Restricting access to select agents and toxins; security risk assessments.*
121.10 *Responsibilities of the responsible official*	121.10 *Restricting access to select agents and toxins; security risk assessments.*
331.11 *Biocontainment and security plan*	331.11 *Security.*
121.11 *Restricting access to biological agents and toxins*	121.11 *Security.*
331.12 *Training*	331.12 *Biocontainment.*
121.12 *Biosafety and security plan*	121.12 *Biosafety.*
331.13 *Transfer of biological agents and toxins*	331.13 *Restricted experiments.*
121.13 *Training*	121.13 *Restricted experiments.*
331.14 *Records*	331.14 *Incident response.*
121.14 *Transfer of biological agents and toxins*	121.14 *Incident response.*
331.15 *Inspections*	331.15 *Training.*

Interim regulations	Final rule
121.15 *Records*	121.15 *Training.*
331.16 *Notification in the event of theft, loss, or release of a biological agent or toxin.*	331.16 *Transfers.*
121.16 *Inspections*	121.16 *Transfers.*
331.17 *Administrative review*	331.17 *Records.*
121.17 *Notification in the event of theft, loss, or release of a biological agent or toxin.*	121.17 *Records.*
121.18 *Administrative review*	331.18 *Inspections.*
	121.18 *Inspections.*
	331.19 *Notification of theft, loss, or release.*
	121.19 *Notification of theft, loss, or release.*
	331.20 *Administrative review.*
	121.20 *Administrative review.*

General Comments

A commenter suggested that APHIS and CDC adopt consistent terminology when referring to biological agents and toxins. The commenter pointed out that the regulations use the following terms: biological agents and toxins, select agents and toxins, overlap agents, and high consequence pathogens.

We agree that APHIS and CDC should use consistent terminology. Therefore, in this final rule, we are removing the terms ''biological agents and/or toxins,'' ''listed agents and/or toxins,'' and ''high consequence livestock pathogens'' each time they appear in 7 CFR part 331 and/or 9 CFR part 121 and adding ''select agents and/or toxins'' in their place. In addition, in 9 CFR part 121, we are removing the term ''overlap agents'' each time it appears and adding ''overlap select agents and/or toxins'' in its place. To reflect this change in terminology, we are also changing the title of both parts from ''Possession, Use, and Transfer of Biological Agents and Toxins'' to ''Possession, Use, and Transfer of Select Agents and Toxins.'' In accordance with these changes, we will be using the term ''select agent and/or toxin'' throughout the preamble of this rule. When it is necessary to specify the type of select agent or toxin, we will use the following terms: ''PPQ select agent and/or toxin'' (for the plant agents and toxins), ''VS select agent and/or toxin'' (for the animal agents and toxins), or ''overlap select agent and/or toxin.'' Unless otherwise specified, the term ''select agent and/or toxin'' will refer to all agents or toxins listed by APHIS.

One commenter stated that APHIS and CDC should harmonize the regulations and provide consistent guidance to entities. This commenter also recommended close collaboration between the agencies for registration, enforcement, and compliance assistance. Another commenter recommended that APHIS and CDC establish one regulatory and reporting mechanism and one office of compliance assistance and enforcement in order to enhance coordination between APHIS and CDC.

We agree that APHIS and CDC should harmonize the regulations and provide consistent guidance to entities. APHIS and CDC have worked closely together to identify and resolve differences between the regulations. This final rule is consistent with CDC's final rule in both structure and substance. APHIS and CDC have also established procedures that will allow an entity to interact with only one agency—either APHIS or CDC—with respect to most matters involving select agents and toxins. These changes will ensure the close coordination of APHIS and CDC and create a uniform and consistent approach to the regulation of select agents and toxins. APHIS and CDC are also developing a single shared web-based system that will allow the regulated community to conduct transactions electronically with APHIS and CDC via a single web portal. By providing a single web portal, APHIS and CDC will be able to interact efficiently and effectively with the regulated community while reducing the burden on the public. We envision that this system will enable the entity to dynamically communicate with APHIS and CDC in a digitally secured environment using a single web portal. The web portal will provide a platform for electronic exchange of information. It will allow entities to access data related to their own registration data and allow them to create, amend, and submit registration applications; requests for approvals for transfers, exemptions, or exclusions; and any other required forms without the need to print, mail, or e-mail hard copies. Hard copy registration materials and other required forms will still be accepted. The single web portal will be available in winter 2005.

A number of commenters expressed concern about the effect of the regulations on the scientific community. Several commenters stated that the regulations will limit the free exchange of scientific information and make it difficult to recruit foreign researchers and technical workers in areas of short supply in the United States. Several commenters asserted that the costs of the regulations (especially the security requirements) will result in the termination of important research projects and the destruction of specimens. One commenter stated that research programs will be terminated because researchers will not want to deal with the new regulatory requirements or their institutions will not want to be liable for violations of the regulations. This commenter also noted that the costs of adhering to the regulations will limit the money available for the research. Another commenter stated that scientists will end up spending more time dealing with bureaucratic requirements rather than working in the laboratory or supervising their employees.

The Act requires the Secretary to establish, by regulation, standards and procedures governing the possession, use, and transfer of listed biological agents and toxins in order to protect animal and plant health, and animal and plant products. In an interim rule published in the **Federal Register** on December 13, 2002, and effective on February 11, 2003, APHIS established the regulations required under the Act. To date, the commenters' concerns about the costs or difficulties of complying with the regulations have failed to materialize. Accordingly, we are making no changes in response to these comments.

Several commenters requested that APHIS and CDC create a grant program to assist entities with the costs of implementing the security requirements.

At this time APHIS is unable to assist entities with the costs of implementing the security requirements because

Congress has not appropriated any funds to establish such a grant program. Accordingly, we are making no change based on these comments.

One commenter requested that APHIS specify in the final rule that it is the regulatory agency for the veterinary biologics industry.

An entity in the veterinary biologics industry may be regulated by APHIS and/or CDC, depending on the agent or toxin that it possesses, uses, or transfers—overlap select agents and toxins are regulated by both APHIS and CDC, while VS select agents and toxins are regulated only by APHIS. For this reason, we are making no change in response to this comment.

A commenter stated that the regulations should be revoked and replaced with prohibitions on owning, working with, or importing any of the agents or products. This commenter recommended that the penalty for possession of a select agent be a fine of $500,000 or imprisonment for up to 25 years.

The Act does not authorize APHIS to prohibit the possession, use, or transfer of biological agents and toxins. Rather, section 212 of the Act directs APHIS to establish, by regulation, standards and procedures governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal or plant products. The Act also sets forth the civil and criminal penalties for violations of the Act. For these reasons, we are making no changes based on this comment.

One commenter warned of the potential for international travelers to bring biological ''suitcase bombs'' into the United States from countries with bovine spongiform encephalopathy, foot-and-mouth disease, or other exotic animal disease pathogens.

This commenter appears to be concerned about the introduction of animal disease pathogens into the United States in the luggage of international travelers. This comment is outside the scope of this rulemaking. However, we note that VS select agents or toxins and overlap select agents or toxins may only be imported into the United States in accordance with 9 CFR parts 121 and 122. We are making no change based on this comment.

Protection of Information Collected by APHIS

Several commenters expressed concern about APHIS' ability to protect the information collected under the regulations. One commenter asked how APHIS would store and protect the information collected. Another commenter stated that USDA should ensure that the information collected is not available through Freedom of Information Act requests.

Section 212(h) of the Act sets forth the requirements relating to the disclosure of information by APHIS and other Federal agencies. Specifically, section 212(h)(1) provides that the specified Federal agencies may not disclose under 5 U.S.C. 552 any of the following: (1) Any registration or transfer documentation, permits issued prior to the enactment of the Act, or information derived therefrom to the extent that it identifies the agent or toxin possessed, used, or transferred by a specific person or discloses the identity or location of a specific person; (2) the national database or any other compilation of the registration or transfer information to the extent that such compilation discloses site-specific registration or transfer information; (3) any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to agents and toxins; (4) any notification of a theft, loss, or release of an agent or toxin; and (5) any portion of an evaluation or report of an inspection of a specific registered person that identifies the agent or toxin possessed by a specific registered person if the agency determines that public disclosure of the information would endanger animal or plant health, or animal or plant products. We believe the Act provides sufficient protection for the information collected under the regulations. Accordingly, we are making no changes based on these comments.

A commenter stated the rule should explicitly state that the security risk assessment is confidential.

As previously noted, we believe the Act provides sufficient protection for the information collected under the regulations. We do not believe it is necessary to state in the regulations that the security risk assessment is confidential. Therefore, we are making no change based on this comment.

Another commenter asserted that the information collected by APHIS for the security risk assessment should not be used more broadly than to determine who is a ''restricted person.'' The commenter noted that California State law prohibits discrimination in employment based upon citizenship and prohibits the disclosure of citizenship information to a third party in a manner that links that information to the individual, except in limited and compelling circumstances. The commenter expressed concern that the data collected for registration or a security risk assessment might be used inappropriately by a Federal agency to assess a proposal for funding. The commenter recommended that APHIS, CDC, and the Department of Justice take steps to ensure the security and confidentiality of submitted information.

In accordance with the Act, the information submitted by an individual as part of a security risk assessment may only be used to determine if an individual is a restricted person under 18 U.S.C. 175b or is reasonably suspected by any Federal law enforcement or intelligence agency of (1) committing a crime set forth in 18 U.S.C. 2332b(g)(5), (2) knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or (3) being an agent of a foreign power as defined in 50 U.S.C. 1801. We believe that the Act and other applicable Federal laws, such as the Privacy Act, are sufficient to ensure the confidentiality of the submitted information. We are making no change in response to this comment.

A commenter asked how APHIS inspectors will mark and protect their inspection reports. APHIS inspection reports and related documents will be protected in accordance with the Act and agency and departmental policies.

Economic Impact

Several commenters argued that the costs of compliance were grossly understated in the economic analysis for the December 2002 interim rule. One commenter stated that the one-time cost to retrofit existing facilities will easily exceed $1 million and that recurring annual costs could top $100,000.

Although the commenter didn't specify, we believe that the commenter is referring to the costs to upgrade security. In our December 2002 economic analysis, we provided estimates of the costs of the interim security requirements. However, we noted that these estimates may not apply to every entity due to the diversity in existing security levels and security needs, as well as the various methods of meeting the interim security requirements. In the economic analysis in this final rule, we reiterate that the costs to comply with the security requirements are site specific and will vary accordingly.

Another commenter stated that the interim rule ignored or grossly underestimated financial costs,

including the costs of verifying the baseline inventory and the costs of responding to lost vial reports. The commenter estimated that the one-time cost to verify the baseline inventory will be $2 million with recurring costs of about $1 million per year. The commenter also estimated that it will cost about $5 million per year to respond to reports of lost vials of select agents because the response would require, at least, a verification of the inventory.

In response to this comment, the economic analysis in this final rule provides more information about the costs of the inventory recordkeeping requirements. In this final rule, we estimate that it would cost an entity $7,200 to create a baseline inventory (assuming an average of 10 freezers and 3 toxin containers per entity). Assuming that registered entities would have to re-inventory one-half of their freezers each year to maintain an accurate and current inventory, we estimate the total yearly inventory cost for all affected entities to be $274,000. Finally, in the event of a theft or loss, we expect an entity would conduct an inventory of the affected storage freezer or toxin container. We estimate that such an inventory would cost $560 per occurrence.

Effective and Applicability Dates

Interim 7 CFR 331.0 and 9 CFR 121.0 provided that the regulations in each part became effective on February 11, 2003. To minimize the disruption of research or educational projects, both sections also provided additional time for individuals and entities to reach full compliance with the regulations in each part (*i.e.*, a phase-in period). Finally, as established in the November 3, 2003, interim rule, both sections provided for the issuance of provisional certificates of registration and provisional grants of access for individuals under certain conditions.

A number of commenters requested clarification of the provisions for the phase-in period and several commenters requested additional time to comply with certain provisions. Given that all of the dates in 7 CFR 331.0 and 9 CFR 121.0 have passed, the sections are no longer applicable and the issues raised by the commenters are moot. Accordingly, in this final rule, we are removing 7 CFR 331.0 and 9 CFR 121.0.

Definitions

In 7 CFR 331.1 and 9 CFR 121.1, we define the terms used in the regulations. We are adding definitions of *diagnosis* and *verification* in both sections in this final rule. *Diagnosis* is defined as ''the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.'' *Verification* is defined as ''the demonstration of obtaining established performance (*e.g.*, accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.'' In addition, in 9 CFR 121.1, we are amending the definition of *proficiency testing. Proficiency testing* is defined as ''the process of determining the competency of an individual or laboratory to perform a specified test or procedure.'' Finally, we are deleting the definition for *diagnostic laboratory* in both sections and we are deleting the definition for *clinical laboratory* in 9 CFR 121.1. These changes will clarify the exemption provisions and help to ensure that APHIS and CDC consistently apply these provisions.

To be consistent with CDC's definitions, we are adopting CDC's definitions for *HHS Secretary* and *HHS select agent and/or toxin* in both sections in this final rule. *HHS Secretary* is defined as ''the Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.'' *HHS select agent and/or toxin* is defined as ''a biological agent or toxin listed in 42 CFR 73.3.''

A commenter suggested that APHIS and CDC adopt consistent terminology when referring to biological agents and toxins. As previously noted, in this final rule we are adopting the terms ''select agents and/or toxins'' and ''overlap select agents and/or toxins.'' To reflect this change in terminology, we are adding several additional definitions to the regulations.

In 7 CFR 331.1 and 9 CFR 121.1, we are adding a definition for the term *select agent and/or toxin.* However, due to differences between the plant-related regulations in 7 CFR part 331 and the animal-related regulations in 9 CFR part 121, the term *select agent and/or toxin* is defined differently in both parts. In 7 CFR 331.1, *select agent and/or toxin* is defined as ''a biological agent or toxin listed in § 331.3'' while in 9 CFR 121.1 it is defined as ''unless otherwise specified, all of the biological agents and toxins listed in §§ 121.3 and 121.4.'' The latter definition takes into account the fact that overlap select agents and toxins are also regulated under 9 CFR part 121.

In 9 CFR 121.1, we are removing the definition for *overlap agent or toxin* and adding a definition for *overlap select agent and/or toxin* in its place. *Overlap select agent and/or toxin* is defined as ''a biological agent or toxin that is listed in 9 CFR 121.4 and 42 CFR 73.4.'' We are also adding definitions for *VS* and *VS select agent and/or toxin* in § 121.1. *VS* is defined as ''the Veterinary Services Programs of the Animal and Plant Health Inspection Service'' and *VS select agent and/or toxin* is defined as ''a biological agent or toxin listed in § 121.3.''

One commenter claimed that the term ''entity'' is subject to interpretation. The commenter stated that it does not make sense for a large multi-campus university to base cumulative limits on toxins or the designation of the responsible official on the entity when the actual labs are separated by hundreds of miles. Another commenter stated the definition of ''entity'' should be amended to permit a responsible official to discharge his or her responsibilities at several adjacent addresses.

These issues are addressed below in the registration section. We are making no change to the definitions section in 7 CFR 331.1 and 9 CFR 121.1 based on these comments.

One commenter recommended that APHIS and CDC adopt a common definition for the term ''responsible official.'' The commenter noted that APHIS defines the term ''responsible official'' but CDC does not. The commenter stated that APHIS indicates a responsible manager should be the responsible official for an entity, while CDC would allow a biosafety officer to assume this role. The commenter stated that, in general, a biosafety officer would not have direct control over either the affected staff or budgets in order to ensure compliance with the regulations.

We agree that APHIS and CDC should adopt a common definition for the term ''responsible official.'' Accordingly, we are amending the definition for *responsible official* in this final rule. In 7 CFR 331.1 and 9 CFR 121.1, we define *responsible official* as ''the individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.'' CDC is adopting the same definition in its final rule.

A commenter stated that APHIS should clarify the term ''facility.'' The commenter said the term appears to refer to a complete building or complex in some parts of the rule but to an individual laboratory/room in other parts of the rule.

APHIS uses the term ''facility'' in the definition for *diagnostic laboratory* in 7 CFR 331.1 and in the definitions for *clinical laboratory* and *diagnostic*

laboratory in 9 CFR 121.1. The term does not appear elsewhere in the regulations. Accordingly, we are making no change based on this comment.

A commenter recommended that APHIS define the term ''access'' to mean actual, physical contact with the agent or the realistic opportunity for same.

This issue is addressed below in the sections relating to security risk assessments and security. We are making no change to the definitions in 7 CFR 331.1 or 9 CFR 121.1 based on this comment.

One commenter stated that 9 CFR 121.1 should define the term ''exotic'' so that the term can be removed from the list of agents.

This issue is addressed below in the section relating to the lists of VS and overlap select agents and toxins. Therefore, we are making no change to the definitions in 9 CFR 121.1 in response to this comment.

Purpose and Scope

Interim 7 CFR 331.2 and 9 CFR 121.2 set out the purpose and scope of the regulations. Specifically, 7 CFR 331.2(a) stated that part 331 sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to plant health or plant products, while 9 CFR 121.2(a) stated that part 121 sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to both human and animal health, or to animal health or animal products. Both sections noted that the purpose of the regulations is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

In this final rule, we are amending both sections to clarify that each part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002. Furthermore, we are amending 9 CFR 121.2 to clarify that overlap select agents and toxins are subject to regulation by both APHIS and CDC.

In interim 7 CFR 331.2 and 9 CFR 121.2, paragraphs (b) and (c) summarized the regulatory requirements. Since these provisions are already set forth in other sections of the regulations, we believe it is unnecessary to summarize them in these sections. Therefore, in this final rule, we are removing paragraphs (b) and (c) in 7 CFR 331.2 and 9 CFR 121.2, and removing the paragraph designation for paragraph (a) in both sections since it is no longer necessary.

List of Biological Agents and Toxins

In accordance with the Act, interim 7 CFR 331.3 and 9 CFR 121.3 listed certain biological agents and toxins.

Section 212(a)(2) of the Act requires that the lists of biological agents and toxins be reviewed and republished biennially, or more often as needed, and revised as necessary. In addition, the Act requires that, when determining whether to include an agent or toxin, the Secretary shall consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups.

This final rule serves as APHIS' republication of the lists of select agents and toxins in 7 CFR 331.3 and 9 CFR 121.3, and in newly designated 9 CFR 121.4. As part of APHIS' review of the lists of agents and toxins, we reviewed current scientific information and studies and consulted with other Federal agencies. We also reviewed and considered the comments to the December 2002 interim rule on the lists of agents and toxins.

As previously noted, in this final rule, we are amending the structure of both parts to be consistent with CDC's select agent regulations. In 9 CFR part 121, we are creating separate sections for the lists of VS select agents and toxins and overlap select agents and toxins—§§ 121.3 and 121.4, respectively. We are also adding a new paragraph (a) to 7 CFR 331.3, containing introductory text, so that the format of the section is consistent with the format in 9 CFR 121.3 and 9 CFR 121.4.

One commenter recommended that APHIS include in the regulations a summary of the risk assessment data that supports the listing of each agent and toxin. The commenter stated that the data will heighten awareness of the risk characteristics of the listed agents and will promote safe practice and proficiency in handling such agents.

APHIS does not include risk assessment data in the regulations; rather, such information is discussed in a rule's preamble. As noted in the preamble of the August 2002 interim rule, the Act requires APHIS to consider the following criteria in determining whether to list an agent or toxin: (1) The effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products; (2) the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants; (3) the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and (4) any other criteria the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

We do not believe it is necessary to provide a summary of the risk assessment data that supports the listing of each select agent or toxin in order to heighten awareness of the risk characteristics of such agents and toxins and promote safe practice and proficiency in handling of such agents and toxins. Information about the risk characteristics of a select agent or toxin and safe handling practices is available in scientific literature and other publications (*e.g.*, the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories''). For these reasons, we are making no change based on this comment.

Interim 7 CFR 331.3(a) (newly designated § 331.3(b)) listed the biological agents and toxins that have been determined to pose a severe threat to plant health or to plant products (PPQ select agents and toxins).

In this final rule, we are removing *Phakopsora pachyrhizi,* also known as Asian soybean rust, from the list of PPQ select agents and toxins. Asian soybean rust has been introduced into the United States by natural means and now it would have virtually no impact if used as a weapon of terrorism. Asian soybean rust was detected in the United States in November 2004. All available evidence suggests that spores were blown into the United States during a series of hurricanes in 2004. Detection surveys indicate that it is present in at least nine southeastern States; however, USDA is conducting additional surveys to determine the full extent of the introduction. Because Asian soybean rust has a host range of more than 90 plant species and its spores disperse naturally on wind currents, this disease will continue to spread naturally and it cannot be controlled effectively. We expect that this disease will quickly reach the full extent of its ecological range in the United States. As a result, there is an urgent need for timely research on effective means to manage the disease in the United States. For all of these reasons, we are removing *Phakopsora pachyrhizi* from the list of PPQ select agents and toxins. However, we note that a permit will still be required for importation or interstate movement of Asian soybean rust (7 CFR part 330).

A commenter claimed that, pursuant to the rules of the International Code of Nomenclature of Bacteria, two bacteria

have been renamed; thus, *Liberobacter africanus* should be *Candidatus* Liberobacter africanus, and *Liberobacter asiaticus* should be *Candidatus* Liberobacter asiaticus.

We agree. Therefore, in this final rule, we are replacing the entry for *Liberobacter africanus* with *Candidatus* Liberobacter africanus and replacing *Liberobacter asiaticus* with *Candidatus* Liberobacter asiaticus. In addition, we are placing *Candidatus* Liberobacter africanus and *Candidatus* Liberobacter asiaticus on separate lines in order to make it clear that each one is a select agent.

One commenter argued that plum pox *potyvirus* should not be listed as a select agent because it is only naturally transmitted by aphids, and, without the insect vector to transmit the disease from one plant to another, the possibility of the virus being used as a weapon of terrorism is extremely small. The commenter stated that laboratory research of this agent, in the absence of its natural vector and only known means of transmission, poses little to no risk to plant health or plant products.

We agree that plum pox *potyvirus* (PPV) has limited potential as a weapon of terrorism given its biological characteristics. PPV is not easily transmitted and does not spread easily. The natural host range is limited to plants in the genus *Prunus* (*e.g.*, plums and other stone fruits). The natural spread of the disease requires insect vectors (aphids), and is a complex biological process, and artificial spread requires grafting, which is labor intensive and time-consuming. PPV is not spread by pollen or seed. While systemic treatments are not completely effective at mitigating the disease, destruction of infected trees mitigates the effects of the disease, removal of the diseased trees and other susceptible hosts removes the source of infection, and transmission can be halted by removing host material from the area. Furthermore, most strains of PPV attack only a few varieties of stone fruits, which limits the affect of an outbreak on the production and marketability of stone fruits. For these reasons, in this final rule, we are removing plum pox *potyvirus* from the list of PPQ select agents and toxins. However, we note that PPV continues to be a quarantine pest under the domestic plant regulations (7 CFR 301.74 through 301.74–5).

Another commenter asserted that *Ralstonia solanacearum,* race 3, biovar 2, should not be listed as a select agent. This commenter stated that the bacterium is unlikely to become established in the northern United States, where potatoes are commercially grown, because it is intolerant of freezing and does not generally survive winters in regions with sustained temperatures below 20 °F. The commenter claimed that, even if the bacterium became established, it is unlikely to cause an economically damaging disease outbreak in the climactic conditions characteristic of North America. The commenter went on to note that the bacterium has been repeatedly introduced into the United States without impact.

APHIS has determined that *Ralstonia solanacearum,* race 3, biovar 2, has the potential to pose a severe threat to plant health or plant products. The bacterium is known to attack a number of economically significant hosts (*e.g.*, geraniums and tomatoes), not just potatoes. Some of the known hosts are grown in greenhouses (*e.g.*, geraniums), which protect them from local climatic conditions, and some hosts are grown in fields throughout the United States (*e.g.*, tomatoes and potatoes). With regard to potatoes, scientific data indicate the potential range of the bacterium would include the potato-growing regions in the United States. *Ralstonia solanacearum,* race 3, biovar 2, occurs in Europe as far north as the 56th parallel (southern Scandinavia), which parallels regions of Canada. Furthermore, there are a number of wild hosts that would contribute to the spread of the bacterium if it were introduced into the United States. For these reasons, we are making no changes based on this comment.

Interim 9 CFR 121.3(d) (newly designated § 121.3(b)) listed the biological agents and toxins that have been determined to have the potential to pose a severe threat to animal health or to animal products (VS select agents and toxins).

A commenter asserted that listing Japanese encephalitis virus (JEV) as a select agent will negatively impact research on this disease, as well as on West Nile virus and dengue virus. This commenter stated that there does not appear to be sufficient justification for making Japanese encephalitis virus a select agent.

We disagree that there is insufficient justification for listing Japanese encephalitis virus as a VS select agent. The virus can cause severe disease in horses and swine for which there is no effective treatment and no domestically available veterinary vaccine. While the select agent regulations may affect research on JEV, we expect it will have a negligible effect on associated research on West Nile virus and dengue virus. For these reasons, we are making no change in response to this comment.

Several commenters questioned the inclusion of malignant catarrhal fever virus (exotic) on the list of select agents. One commenter stated the disease malignant catarrhal fever virus is caused be a variety of herpes viruses, none of which is known as malignant catarrhal fever virus. The commenter stated that Alcelaphine herpesvirus type 1 infects most wildebeest and spreads to domestic cattle causing malignant catarrhal fever in Africa. The commenter argued that malignant catarrhal fever virus (exotic) should be replaced with Alcelaphine herpesvirus type 1. Another commenter argued that the biological features of malignant catarrhal fever viruses prevent them from being effective bioterror agents. The commenter noted that Alcelaphine herpesvirus type 1 can only be transmitted by parenteral injection and cow-to-cow transmission does not occur under natural conditions. This commenter also argued that it is misleading to label malignant catarrhal fever as ''exotic'' since it is present wherever there are wildebeests, from zoos to exotic game farms.

We agree that clarification is needed with regard to the term malignant catarrhal fever virus. Accordingly, in this final rule we are replacing the entry for malignant catarrhal fever virus with malignant catarrhal fever virus (Alcelaphine herpesevirus type 1). However, we disagree that the biological features of malignant catarrhal fever viruses prevent them from being effective bioterror agents. Malignant catarrhal fever virus (Alcelaphine herpesevirus type 1) causes severe disease in cattle, and it may be possible for the virus to be transmitted from cow to cow. Currently, this virus is not found in U.S. cattle populations, and a widespread outbreak of the disease would likely result in widespread animal movement restrictions that could be long term, at least with respect to exports. We are making no change in response to this comment.

One commenter suggested that Newcastle disease virus (VVND) be replaced with Newcastle disease virus (velogenic). The commenter stated the background information indicated that only velogenic strains are to be regulated; however, the acronym VVND indicates viscerotropic, velogenic Newcastle disease.

In the December 2002 interim rule, we replaced the entry for Newcastle disease virus (exotic) with Newcastle disease virus (VVND) to make it clear that we are regulating only velogenic strains. Viscerotropic, velogenic Newcastle

disease (VVND) is a velogenic strain. To ensure that we are regulating all of the velogenic strains, in this final rule we are replacing the entry for Newcastle disease virus (VVND) with Newcastle disease virus (velogenic).

A commenter stated the distinction between domestic and exotic vesicular stomatitis virus cannot be justified scientifically. Therefore, it would be more logical to list all vesicular stomatitis viruses except specific viruses that are generally recognized as attenuated (*e.g.*, the VSV-Indiana Lab strain).

We do not believe it is necessary to regulate all strains of vesicular stomatitis virus, especially those strains that have limited morbidity and mortality in the United States. Therefore, we are making no change based on this comment.

Interim 9 CFR 121.3(b) (newly designated § 121.4(b)) listed the biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products (overlap select agents and toxins).

Several commenters pointed out that *Clostridium botulinum* is listed in the APHIS regulations but not in the CDC regulations.

APHIS inadvertently listed both *Clostridium botulinum* and Botulinum neurotoxin producing species of *Clostridium* as overlap agents in the December 2002 interim rule. We always intended to only list Botulinum neurotoxin producing species of *Clostridium* in order to be consistent with CDC. Accordingly, we are removing *Clostridium botulinum* from the list of overlap select agents and toxins in this final rule.

A number of commenters argued that overlap agents that are endemic, widespread, and easily isolated from natural sources should not be included in the list of overlap select agents. For these reasons, one commenter recommended that *Francisella tularensis* and *Coxiella burnetii* be removed from the list of overlap agents. Several commenters stated that *Coccidioides immitis* should not be included in the list of overlap select agents because it is endemic in California's Central Valley and is found in many areas of the southwest. Another commenter argued that *Coxiella burnetii* should be removed from the overlap list because ''it is so ubiquitous in nature that its identification as a select agent is meaningless.'' One commenter argued that Eastern equine encephalitis virus should be removed from the overlap list because it is endemic and even if it were intentionally introduced into people, horses, or other domestic animals, there would be little or no chance of spread to cause an adverse agricultural event.

We agree that *Coxiella burnetii, Coccidioides immitis,* and *Francisella tularensis* are endemic, widespread, and easily isolated from natural sources. However, these factors are not sufficient reason to remove these agents from the list of overlap select agents and toxins. Furthermore, we disagree that there is little risk of an adverse agricultural event involving Eastern equine encephalitis virus because it can cause high mortality in horses, and there is no mandatory vaccination program in the United States. We are making no changes based on this comment.

A commenter stated that it is pointless to regulate trichothecenes such as T–2 toxin as select agents if highly toxigenic strains of the toxin-producing organism are not also regulated.

We are regulating T–2 toxin, and not the organism that produces it, because we believe the toxin has the potential to pose a severe threat to public health and safety, to animal health, and to animal products. Accordingly, we are making no change in response to this comment.

Interim 7 CFR 331.3(c)(2), 9 CFR 121.3(c), and 9 CFR 121.3(f)(2) (newly designated 7 CFR 331.3, 9 CFR 121.3, and 9 CFR 121.4) set out the provisions for genetic elements.

One commenter stated there are differences between the APHIS and CDC regulations regarding genetic elements. For example, the regulations seem to imply that no bacterial sequences are regulated, except those from animal agents.

We agree. In the interim regulations, CDC provided that infectious viral sequences of HHS and overlap select agents are regulated, while APHIS provided that infectious viral sequences of overlap agents are regulated and infectious viral and bacterial sequences of PPQ and VS select agents are regulated. To resolve these differences, in this final rule we are adopting CDC's approach for genetic elements. Specifically, newly designated 7 CFR 331.3, 9 CFR 121.3, and 9 CFR 121.4 provide that the following will be considered select agents and toxins:

- Nucleic acids that can produce infectious forms of any of the select agent viruses listed in either 7 CFR part 331 or 9 CFR part 121;
- Recombinant nucleic acids that encode for the functional forms of any toxin listed in either 7 CFR part 331 or 9 CFR part 121 if the nucleic acids: (1) Can be expressed *in vivo* or *in vitro;* or (2) are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*; and
- Select agents and toxins listed in either 7 CFR part 331 or 9 CFR part 121 that have been genetically modified.

Another commenter stated that interim 9 CFR 121.3(c) and 121.3(f) conflict—§ 121.3(c) seems to include fragments, while § 121.3(f) exempts them. The commenter pointed out that all genetic elements that cause disease can be fragmented into pieces that cannot cause disease, but that can be reconstituted simply and quickly.

We believe the changes in this final rule will address the differences identified by this commenter. Accordingly, we are making no change based on this comment. However, we note that fragments are not subject to the regulations until reconstituted.

One commenter asked if cDNA is regulated. This commenter also asked how sequence data of select agents will be protected, since it can be used to make a select agent.

A cDNA fragment will be subject to the regulations if it can produce either an infectious form of toxin or a select agent. Sequence data of select agents is already in the public domain, and APHIS cannot protect this information. However, we note that an individual or entity that uses sequence data to produce an infectious agent or toxin will be subject to the select agent regulations. We are making no changes based on this comment.

Interim 7 CFR 331.3(b) and 9 CFR 121.3(e) stated that any biological agent or toxin that is in its naturally occurring environment will not be subject to the requirements of either part, provided that the biological agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

To be consistent with CDC, we are adopting the phrase ''excluded from the requirements of this part'' in place of the phrase ''will not be subject to the requirements of this part.'' Thus, in this final rule, newly designated 7 CFR 331.3(d)(1), 9 CFR 121.3(d)(1), and 9 CFR 121.4(d)(1) state that a select agent or toxin that is in its naturally occurring environment is excluded from the requirements of the regulations, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

One commenter stated that the naturally occurring environment of a virus is its host. The commenter pointed out that *Coxiella burnetii* can be found in milk samples and asked if the truck moving milk to a processing plant would be subject to the regulations or if

the milk sample submitted to a laboratory for mastitis testing would be subject to the regulations as the milk sample is being collected.

Coxiella burnetii that is contained in milk in a truck or in a diagnostic sample is considered to be in its naturally occurring environment as long as it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. We are making no changes in response to these comments.

Another commenter stated that the regulations suggest that an agent found in the lymph node of a slaughtered animal (found on histopathology but not cultivated or extracted) is in its naturally occurring environment and, therefore, exempt from notification.

This comment appears to combine the requirements for exclusions and exemptions. A select agent or toxin that has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source is considered to be in its naturally occurring environment and, therefore, excluded from the requirements of the regulations. The exemption provisions for overlap select agents and toxins are set forth in newly designated 9 CFR 121.6. Histopathology alone is not a definitive identification of a select agent. However, a select agent that has been identified by a histopathology method that has been validated would need to be reported to APHIS or CDC in accordance with the regulations. We are making no changes in response to this comment.

A commenter stated that any naturally occurring organism expressing a Shigatoxin should be specifically excluded from the list of select agents and toxins.

As previously noted, we are regulating the toxin and not the organisms that produce the toxin. Therefore, it is not necessary to exclude from the requirements of the regulations any naturally occurring organism expressing a Shigatoxin. However, we note that Shigatoxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor is excluded from the requirements of 9 CFR part 121 if the aggregate amount does not, at any time, exceed 100 mg (newly designated 9 CFR 121.4(d)(3)).

Interim 7 CFR 331.3(c)(1) (newly designated 7 CFR 331.3(d)(2)) provided that nonviable agents that are, bear, or contain listed agents or toxins will not be subject to the requirements of the part because they do not have the potential to pose a severe threat to plant health or plant products. Similarly, interim 9 CFR 121.3(f) (newly designated 9 CFR 121.3(d)(2) and 121.4(d)(2)) provided that nonviable agents or fixed tissues that are, bear, or contain listed agents or toxins will not be subject to the requirements of the part because they do not have the potential to pose a severe threat to both human and animal health, or to animal health or animal products.

In this final rule, we are amending both sections to clarify that these provisions apply to nonviable agents and nonfunctional toxins. These changes will make the provisions in the APHIS and CDC regulations consistent.

A commenter requested clarification of the terms ''nonviable'' and ''nonfunctional'' select agents or toxins. The commenter noted that some organisms can survive in nature, others only under lab conditions, and others not under any conditions.

A nonviable agent is not capable of replicating, infecting a plant or animal, or causing disease, while a nonfunctional toxin is not able to produce a toxic effect. These terms are generally understood in the scientific community, and we do not believe that further clarification is needed in the regulations. Therefore, we are making no change in response to this comment.

Footnotes in interim 9 CFR 121.3 stated that the importation and interstate movement of nonviable agents and genetic elements are subject to the permit requirements under 9 CFR part 122.

One commenter asked why a permit is needed for nonviable agents and genetic elements that are excluded from regulation under 9 CFR part 121. The commenter argued that nonviable agents and genetic elements that are not capable of causing disease do not meet the definition of ''organism'' in part 122. Another commenter requested clarification of the permit requirement for nonviable agents or fixed tissues. The commenter stated that the provision seems to suggest that, for as long as you retain the tissues, you would need to get yearly interstate transport permits even though no further receipt/transport is taking place.

The regulations in 9 CFR part 122 pertain to the movement of organisms and vectors. A nonviable agent or genetic material could serve as a vector of a disease agent through ineffective or insufficient processing methods, and, therefore, require a permit for importation or interstate movement. However, since a permit may not always be required, in this final rule we are revising the footnotes so that, in newly designated 9 CFR 121.3 and 121.4, they state that a permit may be needed for nonviable agents and genetic elements. We note that permits may contain restrictions that extend beyond the expiration of the permit if the agent/genetic element is not destroyed. If so, an individual or entity would be required to obtain a new permit as long as the nonviable agent or genetic element is possessed by the permittee.

A commenter asked if a positive chain reaction (PCR) test done on formalin fixed tissue that detects Eastern equine encephalitis virus would be exempt because it is nonviable.

This comment is not entirely clear. We believe the commenter is asking about the reporting requirements for identifications of a select agent or toxin. If Eastern equine encephalitis virus is identified from formalin tissue, an individual or entity must report the identification to APHIS in accordance with either newly designated 9 CFR 121.6 or 121.9, whichever is applicable. However, nonviable overlap select agents or nonfunctional toxins are excluded from the regulations (newly designated 9 CFR 121.4(d)(2)). We are making no changes in response to this comment.

Interim 9 CFR 121.3(f)(3) provided an exclusion from the regulations for ''[o]verlap toxins under the control of a principal investigator (or equivalent), if the total aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins (types A–G), 100 mg of *Clostridium perfringens* epsilon toxin, 100 mg of Shigatoxin, 5 mg of Staphylococcal enterotoxins, and 1,000 mg of T–2 toxin.

APHIS and CDC have determined that this exclusion is too narrow and has the unintended consequence of requiring treating physicians or veterinarians and commercial manufacturers or distributors that possess, use, or transfer otherwise excluded toxins to register. Accordingly, in this final rule, we are broadening the scope of the overlap toxin exclusion to cover overlap toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor (newly designated § 121.4(d)(3)). To be consistent with CDC, we are also removing the words ''(types A–G)'' after Botulinum neurotoxins.

One commenter requested that APHIS clarify that there is no limit to the amount of overlap toxins an individual or entity may possess or use, as long as the amount of toxin under the control of each principal investigator does not exceed the specified amounts.

We believe that newly designated § 121.4(d)(3) clearly indicates that the exclusion is based upon the amount of

overlap toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor. Therefore, we are making no change based on this comment.

Another commenter asked if the toxin amounts refer to quantities of isolated toxin (*i.e.*, toxin that has been extracted and is separate from the cell) or toxin that is in the process of being produced by living cells and may increase in quantity. The commenter stated that measuring the exact quantities of a toxin can only reasonably be achieved if the toxin has been isolated from the cell.

We agree that an exact measurement of a toxin can only reasonably be achieved if the toxin has been isolated from the cell. The amounts listed in newly designated § 121.4(d)(3) refer to the amount of toxin that has been isolated from the cell, not the amount of toxin that is being produced in living cells. We are making no change based on this comment.

Interim 9 CFR 121.3(g) (newly designated §§ 121.3(e) and 121.4(e)) provided a procedure by which an individual or entity may request a determination by the Administrator that an attenuated strain of a biological agent does not pose a severe threat to both human and animal health, or to animal health or animal products.

In this final rule, we are adding this provision to 7 CFR 331.3 so that the regulations in part 331 are consistent with the regulations in 9 CFR part 121. We are also amending both parts to clarify the requirements and streamline the process for excluding an attenuated strain of a select agent or toxin. Specifically, paragraph (e) in 7 CFR 331.3, 9 CFR 121.3, and 9 CFR 121.4 provides that an individual or entity may apply for an exclusion by submitting a written request and supporting scientific information. A written decision granting or denying the request will be issued and the exclusion will be effective upon notification of the applicant. Exclusions will be published periodically in the notice section of the **Federal Register** and will be listed on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.* Paragraph (e) also provides that, if an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of each part. This has always been the way the exclusion for attenuated strains has been interpreted; however, we are adding this provision to both parts to facilitate compliance.

One commenter claimed that the microbiological community, not just government agency representatives, must be involved in the process for excluding attenuated strains. The commenter recommended the establishment of a broadly representative group to act as an advisory body to APHIS and CDC. This commenter also stated that the regulations should state that determinations regarding overlap agents require the concurrence of APHIS and CDC.

APHIS may exclude attenuated strains of select agents or toxins after consultation with subject matter experts, including those in the microbiology community. For overlap select agents and toxins, APHIS may exclude attenuated strains after consultation with subject matter experts and CDC. We do not believe it is necessary to include these administrative procedures in the regulations. Accordingly, we are making no change based on this comment.

A commenter stated that APHIS should specify the criteria for exclusion of attenuated strains because the current standard (''poses a severe threat'') is insufficiently specific.

The Act requires APHIS to regulate the possession, use, and transfer of biological agents and toxins that have been determined to pose a severe threat to public health and safety, to animal health, to plant health, or to animal or plant products. Thus, the Act establishes the standard by which APHIS may exclude an attenuated strain (*i.e.*, the strain does not pose a severe threat). We are making no change to the regulations in response to this comment.

A commenter asserted that the excluded attenuated strains should be listed in the regulations so that an entity may be able to determine if an agent is excluded before registering the strain and installing any additional security.

APHIS is not including the lists of excluded attenuated strains of select agents or toxins in the regulations because any change to the lists of exclusions would require rulemaking. To minimize the potential delays related to rulemaking, in this final rule we are providing that exclusions will be published periodically in the notices section of the **Federal Register** and will be listed on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.* We believe these measures will provide sufficient notice to the public.

A commenter stated that the exclusion for attenuated strains would not make agents such as the Sterne strain of *Bacillus anthracis* and the vaccine strain of *Brucella abortus* available for the critical need of quality control, without registration of the laboratory.

An attenuated strain of a select agent may be excluded from the requirements of regulations based upon a determination that the attenuated strain does not pose a severe threat to plant health or plant products (newly designated 7 CFR 331.3(e)) or to public health and safety, to animal health, or animal products (newly designated 9 CFR 121.3(e) and 121.4(e)). Once an attenuated strain of a select agent has been excluded, it may be used for quality control or for other purposes, as long as its virulence is not restored or enhanced. To date, a number of attenuated strains have been excluded, including *Bacillus anthracis* Sterne, $pX01^{+}pX02^{-}$ and *Brucella abortus* strain RB51 (vaccine strain). For these reasons, we are making no change in response to this comment.

One commenter asked if the TC–83 vaccine strain of Venezuelan equine encephalitis is subject to the regulations. The commenter pointed out that the CDC regulations specifically exclude this strain from regulation but the APHIS regulations do not.

Both APHIS and CDC have excluded the TC–83 vaccine strain of Venezuelan equine encephalitis virus from the requirements of the regulations. We note that a current list of exclusions is available on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index/html.* We are making no change based on this comment.

To address concerns raised by Federal law enforcement agencies related to seizures (*i.e.*, possession) of select agents or toxins, in this final rule we are adding a new paragraph (f) to 7 CFR 331.3, 9 CFR 121.3, and 9 CFR 121.4 to address situations in which the select agents or toxins have been identified prior to seizure. In the event that a Federal law enforcement agency seizes a suspected select agent or toxin or unknown material, this material will be regarded as a specimen presented for diagnosis or verification and, therefore, will not be subject to the regulations until it has been identified as a select agent or toxin.

Paragraph (f) provides that any select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of the regulations during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

- As soon as practicable, the Federal law enforcement agency transfers the

seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process;

- The Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release and reports any theft, loss, or release of such agent or toxin; and
- The Federal law enforcement agency reports the seizure of the select agent or toxin to APHIS or CDC.

This provision will allow Federal law enforcement agencies to conduct certain law enforcement activities (*e.g.*, collecting evidence from a laboratory crime scene) without being in violation of the regulations. We note, however, that this provision does not authorize the seizure of a select agent or toxin by a Federal law enforcement agency; rather, it establishes the conditions under which a Federal law enforcement agency may seize a select agent or toxin without violating the regulations. Seizure of a select agent or toxin by a Federal law enforcement agency would have to be in accord with that agency's statutory authority.

Exemptions

Interim 7 CFR 331.4, 9 CFR 121.4, and 9 CFR 121.5 (newly designated 7 CFR 331.5, 9 CFR 121.5, and 9 CFR 121.6) set out exemptions.

Interim 9 CFR 121.4(a) provided that clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of part 121, provided that the identification of such agents or toxins is immediately reported to APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and, within 7 days after identification, such agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC. Interim 7 CFR 331.4(a) and 9 CFR 121.5(a) contained similar exemption provisions for diagnostic laboratories (the term clinical laboratories is not applicable to the plant-related regulations in 7 CFR part 331 or the animal-related regulations in 9 CFR part 121). Exemption provisions for laboratories and other entities that perform proficiency testing were set out in interim 9 CFR 121.4(b) and 121.5(b).

In this final rule, we are amending both parts to clarify the exemption provisions related to clinical or diagnostic laboratories and other entities (for overlap select agents and toxins) and diagnostic laboratories and other entities (for PPQ and VS select agents and toxins). Specifically, paragraph (a) in newly designated 7 CFR 331.5 and paragraphs (a) and (b) in newly designated 9 CFR 121.5 and 121.6 make clear that laboratories and other entities must meet the exemption requirements for each select agent or toxin contained in a specimen that it possesses, uses, or transfers. This change takes into account situations in which a diagnostic laboratory or other entity could be registered for a select agent or toxin but still meet the exemption requirements for other select agents or toxins contained in specimens. We are also amending both parts to clarify that, as a condition of exemption, clinical or diagnostic laboratories and other entities must transfer a select agent or toxin in accordance with the transfer requirements in each part (newly designated 7 CFR 331.16 and 9 CFR 121.16, respectively) or destroy the agent or toxin on-site by a recognized sterilization or inactivation process.

In this final rule, we are also deleting in both parts the requirement that the identification of a select agent or toxin be reported to appropriate authorities when required by Federal, State, or local law (interim 7 CFR 331.4, 9 CFR 121.4, and 9 CFR 121.5). Because this provision merely indicates that additional reporting requirements may exist under Federal, State, or local law, it is not necessary to include this provision in the regulations. It is the entity's responsibility to be familiar with all legal requirements for select agents and toxins.

In addition, newly designated 9 CFR 121.5 and 121.6 require immediate reporting after identification for specified select agents and toxins; identification of the other select agents and toxins must be reported within 7 calendar days after identification. This change will reduce the reporting burden on the public while continuing to provide information that will help us to identify outbreaks and to monitor activities related to select agents and toxins.

Finally, we are deleting footnote 1 in interim 7 CFR 331.4 (newly designated 7 CFR 331.5) because this information is contained in the transfer section in this final rule (newly designated § 331.16). We are also deleting the application and contact information contained in footnotes in interim 7 CFR 331.4, 9 CFR 121.4, and 9 CFR 121.5 because addresses and telephone numbers are subject to change. Information about the submission of forms, notices, and requests for exemptions or exclusions is available on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index/html.*

A commenter asserted that clinical or diagnostic laboratories should be required to secure the agent or toxin prior to transfer or destruction.

We agree. Taking into account the risks posed by select agents and toxins and the security requirements for registered entities, it is reasonable to require that a clinical or diagnostic laboratory or other entity secure the agent or toxin prior to transfer or destruction. Furthermore, we believe it is reasonable to require that a clinical or diagnostic laboratory or other entity report any theft, loss, or release of a select agent or toxin prior to transfer or destruction. Therefore, newly designated 7 CFR 331.5, 9 CFR 121.5, and 9 CFR 121.6 require, as another condition of exemption, that the select agent or toxin be secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and that any theft, loss, or release of such agent or toxin be reported.

Another commenter argued that the exemptions for clinical and diagnostic laboratories should require, at the very least, that employees of such labs be subject to security risk assessments by the Attorney General.

The Act does not require security risk assessments for employees of entities that are exempt from registration under the regulations (section 212(e)). We believe that the conditions for exemption in this final rule provide adequate safeguard and security measures to protect animal and plant health, and animal and plant products. Accordingly, we are making no change based on this comment.

One commenter requested that APHIS define the term ''identification.'' The commenter asked if a PCR positive reaction constituted identification or simply detection. This commenter also wondered if an entity must report an identification done on a nonviable organism.

If a PCR test is recognized in the scientific community as an identification method, then a result utilizing this test must be reported. If not, reporting is not required. An individual or entity must report an identification done on a nonviable organism in accordance with the regulations. We require this reporting in order to obtain surveillance information about select agents or toxins. We are making no changes in response to this comment.

Several commenters argued that the requirement to transfer an agent or toxin

within 7 calendar days of identification was unrealistic. One commenter stated that delays in transfer approval by APHIS or CDC could result in delays in shipping the samples. Several commenters expressed concern about this deadline due to the unreliability of shippers. Another commenter stated that it is unreasonable and counterproductive to require diagnostic labs to destroy or transfer select agents within 7 days after identification. The commenter said that some labs may process hundreds or thousands of samples each week and generate large numbers of select agent isolates, and transferring these isolates to a qualified lab within 1 week will be very difficult and costly. The commenter claimed that most labs will simply destroy the isolates and that such destruction will result in the loss of valuable scientific material.

Based on information provided by CDC and APHIS' National Veterinary Services Laboratories (NVSL), and taking into consideration the risks posed by select agents and toxins, we believe that 7 days will provide ample time after identification to destroy the agent or toxin, or to make transfer arrangements and to transfer the agent or toxin. However, in this final rule, we are amending newly designated 7 CFR 331.5(a) and 9 CFR 121.5(a) to allow the Administrator to make exceptions to these timeframes, as necessary. We are also amending newly designated 9 CFR 121.6(a) to allow the Administrator or the HHS Secretary to make exceptions to these timeframes for overlap select agents or toxins, as necessary. Finally, we are making similar changes to newly designated 9 CFR 121.5(b) and 9 CFR 121.6(b) to allow for exceptions to the timeframes for proficiency testing, which require that an agent or toxin be transferred or destroyed within 90 calendar days of receipt.

Another commenter recommended a longer holding period for agents and toxins before mandatory inactivation—30 to 45 days instead of 7 days—because the destruction of isolates of select agents after only 7 days is counter to good quality control in labs, which often specifies that isolates and specimens be kept for 30 days, and labs often have cases pending for at least 30 days awaiting additional results. The commenter went on to note that it is good lab practice to maintain the original sample until a case is complete, and labs often maintain samples so that additional testing can be done as needed.

The exemption provisions in interim 7 CFR 331.4(a), 9 CFR 121.4(a), and 9 CFR 121.5(a) (newly designated 7 CFR 331.5(a), 9 CFR 121.5(a), and 9 CFR 121.6(a)) do not require mandatory inactivation of a select agent or toxin. To qualify for an exemption, an individual or entity must satisfy the conditions for exemption, including transferring or destroying the select agent or toxin within 7 calendar days of identification unless directed otherwise by the Administrator or HHS Secretary. However, an individual or entity could continue to hold a select agent or toxin if it registers with APHIS or, for overlap select agents and toxins, if it registers with APHIS and CDC. While we recognize that the select agent regulations may have an effect on internal quality assurance procedures, lengthening the time that a diagnostic laboratory or other entity can possess a sample without being registered is inconsistent with the intent of the Act. We are making no changes based on this comment.

One commenter asked if diagnostic facilities could preregister for potential isolates they might obtain from future diagnostic cases. The commenter stated the regulations suggest that a facility has to have the agent before it can register. The commenter stated that, once an agent is isolated, it appears that the facility would only have 7 days to become registered before it would have to destroy or transfer the agent. The commenter noted that even the process to amend a certificate of registration would likely take longer than 7 days.

The regulations do not preclude preregistration for a select agent or toxin. A certificate of registration may be issued to an entity as long as the entity meets the regulatory requirements for such agent or toxin, even if the entity does not currently possess that particular agent or toxin.

The regulations (interim 7 CFR 331.4(b) and 9 CFR 121.5(f); newly designated 7 CFR 331.5(b) and 9 CFR 121.5(f)) provide that the Administrator may grant exemptions from the requirements of 7 CFR part 331 and 9 CFR part 121 upon a showing of good cause and a determination that such an exemption is consistent with protecting animal or plant health or animal or plant products.

A commenter stated that APHIS should establish timelines for responding to requests for exemptions. APHIS is committed to processing requests for exemptions in a timely manner. We do not believe it is necessary to include in the regulations timelines for responding to requests for exemptions. Therefore, we are making no change based on this comment.

Interim 9 CFR 121.4(c) and 121.5(d) provided that, unless the Administrator by order determines that additional regulation is necessary to protect animal health, or animal products, an individual or entity possessing, using, or transferring products that are, bear, or contain agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of the Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

In this final rule, newly designated §§ 121.5(d) and 121.6(c) clarify that the product is exempt from the requirements of the regulations. This change is designed to address those situations in which an entity produces an exempt product but conducts other activities that would require registration under this part.

A commenter requested that APHIS and CDC provide a list of agents exempted under the Federal laws listed in interim 9 CFR 121.4(c) so that investigators would know if the agents they possess or wish to study are exempt.

It is not administratively feasible for APHIS to maintain a list of select agents exempted under the Federal laws described above. The regulations provide sufficient information for an individual or entity to determine if the agents they possess or wish to study are exempt. Accordingly, we are making no changes based on this comment.

In interim 9 CFR 121.5(c), we provided that an individual or entity receiving diagnostic reagents and vaccines that are, bear, or contain select agents or toxins that are produced at USDA diagnostic facilities will be exempt from the requirements of part 121.

A commenter stated that agents approved by APHIS' Center for Veterinary Biologics for use in USDA licensed facilities should be exempt from the requirements of the rule.

We disagree. We included this provision in the regulations in order to exempt products, not agents, that would be cleared, approved, licensed, or registered pursuant to the Virus-Serum-Toxin Act (21 U.S.C. 151–159), but for the fact that they are produced by USDA. In order to clarify that this exemption applies to products, in this final rule, newly designated 9 CFR 121.5(c) provides that diagnostic reagents and vaccines that are, bear, or contain VS select agents or toxins that

are produced at USDA diagnostic facilities will be exempt from the requirements of this part.

The regulations (interim 9 CFR 121.4(e); newly designated § 121.6(e)) provide that the Administrator may exempt an individual or entity from the requirements of the part for 30 days if it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap agent or toxin. This exemption may be extended for an additional 30 days.

One commenter argued that the 30-day special exemption granted during an emergency is insufficient to deal with a foreign animal or outbreak emergency. This commenter stated that neither exotic Newcastle disease or the low pathogenic avian influenza outbreaks were resolved in 60 days.

Section 212(g)(1)(D) of the Act sets forth the exemption for agricultural emergencies involving overlap select agents and toxins. The Act specifies that such exemptions may not exceed 60 days. Accordingly, we are making no changes based on this comment.

Registration

Interim 7 CFR 331.5, 331.6, and 331.8 and 9 CFR 121.6, 121.7, and 121.9 (newly designated 7 CFR 331.7 and 9 CFR 121.7) set out registration requirements and procedures.

One commenter stated that the regulations do not contemplate or address a situation where an entity has employees that possess, use, or transfer select agents at locations owned and controlled by another entity. The commenter stated that it is a nonprofit organization that provides medical research personnel to Federal agencies. The commenter asserted that the regulations and the registration application should be revised to require registration for the entity that owns or controls the location where agents and toxins are used and stored.

This final rule requires that, unless exempted under the regulations, an individual or entity that possesses, uses, or transfers select agents or toxins must register with APHIS or, for overlap select agents or toxins, APHIS and CDC. The regulations provide for both individuals and entities, even though we expect that most registrants will be entities. Using the example given by the commenter, the Federal agency that possesses, uses, or transfers select agents or toxins would be required to register and restrict access to such agents or toxins to only those individuals approved by the Administrator or HHS Secretary following a security risk assessment by the Attorney General. We are making no change based on this comment.

One commenter requested that USDA and CDC consider a single clearinghouse for registration of select agents. The commenter said the rules require an entity that possesses only human and animal/plant agents (no overlaps) to register separately with each agency; however, this would place an undue burden on the entity by requiring dual registration packages and safety/security plans. Another commenter recommended that APHIS indicate what an entity can do to assist or mitigate conflict between APHIS and CDC on registration applications for overlap agents.

To simplify the registration process and minimize the burden on the public, APHIS and CDC have established a framework by which individuals and entities with various combinations of select agents and toxins may submit their registration applications to either APHIS or CDC. For instance, to apply for a certificate of registration for only PPQ or VS select agents or toxins, or for PPQ and VS select agents or toxins, an individual or entity must submit the registration application package to APHIS. However, to apply for a certificate of registration for overlap select agents or toxins, overlap select agents or toxins and any combination of PPQ or VS select agents or toxins, or HHS select agents or toxins and any combination of PPQ or VS select agents or toxins, an individual or entity must submit the registration application package to APHIS or CDC, but not both. In this final rule, we are amending both sections to set out this new framework for submitting registration applications (newly designated 7 CFR 331.7(d) and 9 CFR 121.7(d)).

As previously discussed, APHIS and CDC are also developing a single shared web-based system that will allow the regulated community to conduct transactions electronically with either agency via a single web portal. By providing a single web portal, APHIS and CDC will be able to interact efficiently and effectively with the regulated community while reducing the burden on the public. We envision that this system will enable the entity to dynamically communicate with APHIS and CDC in a digitally secured environment using a single web portal. The web portal will provide a platform for electronic exchange of information. It will allow entities to access data related to their own registration data and allow them to create, amend, and submit registration applications; requests for approvals for transfers, exemptions, or exclusions; and any other required forms without the need to print, mail, or e-mail hard copies. Hard copy registration materials and other required forms will still be accepted. The single web portal will be available in winter 2005.

Several commenters requested more information about the registration process. One commenter asked how long will it take to receive a certificate of registration after all the paperwork has been submitted. The commenter urged APHIS to promptly process registration applications so as not to disrupt valuable research and impede academic planning. Another commenter suggested that APHIS add information to the final rule to indicate when an entity should submit renewal applications (*i.e.*, at least 90 days prior to expiration).

We are committed to promptly processing initial registration applications and renewal applications. The time needed to process a registration application and issue a certificate of registration depends on the complexity and completeness of the application. However, to provide more guidance about the submission of renewal applications, we recommend that the registration application and the information necessary to conduct the required security risk assessments be submitted at least 8 weeks prior to the expiration of the date of the certificate of registration.

Interim 7 CFR 331.6(b)(1) and 9 CFR 121.7(b)(1) (newly designated 7 CFR 331.7 and 9 CFR 121.7) indicated that, as one of the conditions of registration, the owner or controller of an entity must be approved by APHIS following a security risk assessment by the Attorney General.

A commenter asked who would be deemed to own or control the entity in the context of an academic institution. Another commenter thought the phrase ''individual who controls the facility'' meant the senior administrators to whom the responsible official reports and not the members of the Board of Trustees.

The determination of who is an owner or controller of an academic institution (*i.e.*, institution of higher education) depends on whether it is a public or private institution of higher education. Federal, State, or local governmental agencies, including public institutions of higher education, are exempt from the security risk assessment for the entity and the individual who owns or controls such entity. However, for a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with

regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity. We consider an entity to be an institution of higher education if it is an institution of higher education as defined in the Higher Education Act of 1965 (20 U.S.C. 1001(a)) or an organization described in the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)). Because entities that meet this criteria do not have an owner, the individual(s) in control of the entity must be approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General. For all other entities, an individual will be deemed to own or control the entity if the individual: (1) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or (2) is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

To clarify the requirements for owners or controllers of an entity, we are making several changes to the registration sections in this final rule. We are making clear that the individuals must be approved by the Administrator or HHS Secretary based on a security risk assessment by the Attorney General (7 CFR 331.7(c)(1) and 9 CFR 121.7(c)(1)). We are also moving the information contained in footnote 4 in interim 7 CFR 331.6 and footnote 7 in interim 9 CFR 121.7 to a new paragraph in both sections, 7 CFR 331.7(c)(2) and 9 CFR 121.7(c)(2), which states that Federal, State, or local governmental agencies, including public institutions of higher education, are exempt from the security risk assessment for the entity and the individual who owns or controls such entity. In addition, we are adding the following paragraphs to both 7 CFR 331.7 and 9 CFR 121.7 to clarify who will be deemed to own or control an entity and to indicate the criteria by which an entity will be considered an institution of higher education:

- For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.
- For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual: (1) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock; or (2) is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.
- An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

Finally, we are adding a footnote to 7 CFR 331.7 and 9 CFR 121.7 to clarify that more than one individual may meet the criteria for ownership or control of an entity.

Interim 7 CFR 331.6(b)(2) and 9 CFR 121.7(b)(2) provided that APHIS may issue a certificate of registration if, among other things, the Administrator approves an entity's biosafety, containment, and security.

In drafting this provision, we intended to stress to the regulated community the importance of the biosafety, containment, and security requirements. However, we did not intend to suggest that an individual or entity did not have to meet the other requirements of the regulations. Since the issuance of a certificate of registration is an administrative action taken by APHIS, it is not necessary to include this provision in the regulations. Accordingly, we are deleting this provision in both sections.

Interim 7 CFR 331.6(b)(3) and 9 CFR 121.7(b)(3) provided that APHIS may issue a certificate of registration if, among other things, the Administrator determines that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer agents or toxins.

One commenter stated that it is unclear how APHIS will determine if the entity has an unlawful purpose to possess, use, or transfer select agents. The commenter asked what information APHIS will use to make this determination.

To determine whether an entity has a lawful purpose to possess, use, or transfer select agents or toxins, APHIS will consider the information contained in the registration application and any other information available to APHIS about the entity. This determination will be made on a case-by-case basis. However, since this is an administrative action taken by APHIS, it is unnecessary to include this provision in the regulations. Accordingly, we are deleting this provision in both sections. In addition, we are amending newly designated 7 CFR 331.7(f) and 9 CFR 121.7(f) to clarify that the issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biocontainment/biosafety plan, incident response plan, or any other documents required to be prepared under each part. These changes will make the APHIS and CDC regulations consistent.

In interim 7 CFR 331.5(b) and 9 CFR 121.6(b), we provided that each entity must designate an individual to be its responsible official and that this individual must have the authority and control to ensure compliance with the regulations. Furthermore, in interim 7 CFR 331.6(c) and 9 CFR 121.7(d), we provided that a certificate of registration will be valid for only the specific agents or toxins and specific activities and locations listed on the certificate.

One commenter stated an entity should be able to apply for a single certificate of registration to cover activities at all buildings on a campus or site under the control and authority of the responsible official, which would include both contiguous and dispersed sites within a local geographical area. The commenter stated that it is overly burdensome to require separate registrations for each general physical location (defined as a building or a complex of buildings at a single mailing address). The commenter claimed that the administrative and control functions at research and academic institutions are efficiently managed by a centralized department responsible for more than one physical location. Similarly, a commenter stated that the provisions concerning location should be amended to cover a single administrative organization under a single responsible official. Another commenter requested that the final regulations allow campuses to designate responsible officials with responsibility for an entire campus.

APHIS designed these provisions to ensure that the responsible official has the requisite authority and control to ensure compliance with the select agent regulations. We reasoned that a responsible official would be better able to ensure compliance with the regulations if he/she managed only one general physical location. While we still believe that to be true, we recognize that some responsible officials will be able to ensure compliance for an entire campus or business complex. Therefore, in this final rule, the registration sections (newly designated 7 CFR 331.7(g) and 9 CFR 121.7(g)) provide that a certificate

of registration will be valid for one physical location (a room, a building, or a group of buildings) where the responsible official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities. We believe this change will provide more flexibility and guidance to entities seeking to register.

In interim 7 CFR 331.6(d) and 9 CFR 121.7(e), we provided that a certificate of registration may be amended to reflect changed circumstances and that the responsible official must immediately notify APHIS of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

A commenter said that it is unclear how great a change would require notification of APHIS or CDC. The commenter suggested that investigators should instead submit annual reports of projects done and projects planned. Another commenter stated that there is no specific information in the regulations about what information must be reported and what constitutes immediately (*i.e.*, within 24 hours). The commenter indicated that, if the entire registration application must be resubmitted, then APHIS should allow a minimum of 7 to 10 business days.

To clarify the requirements for amending a registration application and a certificate of registration, in this final rule we are deleting the provisions of interim 7 CFR 331.6(d) and 9 CFR 121.7(e). In their place, we are adding a new paragraph (e) in newly designated 7 CFR 331.7 and 9 CFR 121.7 that requires the responsible official to provide prompt notification of any changes in the registration application by submitting the relevant page(s) of the registration application. In addition, we are adding a new paragraph (h) in both sections to require that, prior to any change, the responsible official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. Finally, to clarify the requirements for when an entity loses the services of its responsible official, we are adding a new paragraph (i) in both sections to require an entity to immediately notify APHIS or CDC if it loses the services of its responsible official. These paragraphs also provide that an entity may continue to possess or use select agents or toxins only if it appoints as the responsible official another individual who has been approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of the regulations.

Interim 7 CFR 331.6(e) and 9 CFR 121.7(f) stated that a responsible official who wishes to discontinue possessing, using, or transferring an agent or toxin may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered entity. Both sections further provided that APHIS must be notified 5 business days prior to a planned inactivation so that APHIS may have the opportunity to observe the inactivation.

One commenter asked when APHIS will observe the destruction of a select agent. Another commenter asked if a responsible official for a diagnostic laboratory is required to notify APHIS 5 business days prior to destroying a select agent or toxin.

In the final rule, we are deleting these paragraphs and simply providing that a certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered (newly designated 7 CFR 331.7(j) and 9 CFR 121.7(j)). This change should eliminate any confusion between this reporting requirement and the reporting requirements for diagnostic exemptions.

The regulations (interim 7 CFR 331.6(f) and 9 CFR 121.7(g); newly designated 7 CFR 331.7(k) and 9 CFR 121.7(k)) state that a certificate of registration will be valid for a maximum of 3 years.

A commenter recommended that certificates of registration be valid for 5 years to be consistent with the security risk assessments, simplify paperwork requirements for the entity, and reduce cost to government.

We believe it is reasonable to provide that a certificate of registration will be valid for a maximum of 3 years. A 3-year registration period takes into consideration the burden on the public and the risks posed by select agents and toxins. In addition, it is consistent with APHIS' permit systems and other established programs for laboratory certification or registration (e.g., Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists (CAP)), which are generally valid for 2 to 3 years. Accordingly, we are making no change based on this comment.

Denial, Revocation, and Suspension of Registration

Interim 7 CFR 331.7(a)(3) and 9 CFR 121.8(a)(3) provided that APHIS may deny an application for registration or revoke registration if the responsible official does not have a lawful purpose to possess, use, or transfer listed agents or toxins. In addition, interim 7 CFR 331.7(a)(4) and 9 CFR 121.8(a)(4) provided that APHIS may deny an application for registration or revoke registration if the responsible official is an individual who handles or uses listed agents or toxins and he/she does not have the necessary training or skills to handle such agents or toxins. To be consistent with CDC, we are deleting these provisions in this final rule.

Interim 7 CFR 331.7(a)(5) provided that APHIS may deny an application for registration or revoke registration if the entity does not meet the containment and security requirements prescribed by the Administrator, while interim 9 CFR 121.8(a)(5) provided that APHIS may deny an application for registration or revoke registration if the entity does not meet the biosafety, containment, and security requirements prescribed by the Administrator. In addition, interim 7 CFR 331.7(a)(6) provided that APHIS may deny an application for registration or revoke registration if there are egregious or repeated violations of the containment or security requirements, while interim 9 CFR 121.8(a)(6) provided that APHIS may deny an application for registration or revoke registration if there are egregious or repeated violations of the biosafety, containment, or security requirements.

In drafting these provisions, we wished to stress to the regulated community the importance of the biosafety, containment, and security requirements. However, we never intended to suggest that an entity did not have to meet the other requirements of each part. Therefore, we are amending these provisions in this final rule to provide that an application may be denied or a certificate of registration revoked or suspended if the individual or entity does not meet the requirements of the applicable part (newly designated 7 CFR 331.8(a)(3) and 9 CFR 121.8(a)(3)). These changes will clarify the registration requirements and make both sections consistent with CDC's regulations.

In addition, in this final rule, we are clarifying the actions an entity must take in the event that APHIS suspends or revokes a certificate of registration. Specifically, we are adding a paragraph to require that, upon notification of suspension or revocation, an individual or entity must: (1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order; (2) immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release; and (3) comply with all disposition instructions issued

by the Administrator for each select agent or toxin covered by the revocation or suspension (newly designated 7 CFR 331.8(b) and 9 CFR 121.8(b)).

In a footnote to interim 7 CFR 331.7(a)(5) and 9 CFR 121.8(a)(5), we indicated that APHIS may provide technical assistance and guidance on the biosafety, containment, and security requirements. A commenter requested information on when and to what degree APHIS will provide such assistance.

As discussed below in the biocontainment/biosafety and security sections, in this final rule we are providing a list of documents in each part that an entity should consider in developing a biocontainment/biosafety or security plan. We recommend that an entity review these documents before contacting APHIS for technical assistance. We will provide technical assistance and guidance upon request.

Interim 7 CFR 331.7(b) and 9 CFR 121.8(b) provided that APHIS may summarily revoke or suspend registration for any of the reasons set forth in each section.

To clarify the provisions for denial, suspension, and revocation of registration, in this final rule, we are deleting interim paragraph (b) in both sections and simply providing that an application may be denied or a certificate of registration revoked or suspended for the reasons set forth in each section (newly designated 7 CFR 331.8(a) and 9 CFR 121.8(a)).

Interim 7 CFR 331.7(d) and 9 CFR 121.9(d) provided that the denial of an application for registration, revocation of registration, and suspension of registration may be appealed under each part. In this final rule, newly designated 7 CFR 331.8(c) and 9 CFR 121.8(c) provide that the denial of an application for registration and revocation of registration may be appealed under each part. Furthermore, both paragraphs provide that any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered. These changes will clarify the status of an application for registration or a certificate of registration during the appeal process.

Responsibilities of the Responsible Official

To facilitate compliance with the regulations, the regulations (interim 7 CFR 331.9 and 9 CFR 121.10; newly designated 7 CFR 331.9 and 9 CFR 121.9) set out the responsibilities of the responsible official.

One commenter stated that the APHIS and CDC regulations should have the same responsibilities for the responsible official and that these responsibilities should be better defined.

We agree that the APHIS and CDC regulations should contain the same provisions for the responsible official. Therefore, in this final rule, we are amending newly designated 7 CFR 331.9(a) and 9 CFR 121.9(a) to require that an individual or entity required to register under each part designate an individual to be the responsible official. Paragraph (a) further requires that the responsible official:

- Be approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General;
- Be familiar with the requirements of this part;
- Have the authority and responsibility to act on behalf of the entity;
- Ensure compliance with the requirements of this part; and
- Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

In addition, we are deleting the provision for the alternate responsible official(s) from the registration section and adding it to the responsible official section (newly designated 7 CFR 331.9(b) and 9 CFR 121.9(b)). These changes will make the APHIS and CDC regulations consistent.

A commenter recommended that APHIS add the following language to the regulations: ''This does not preclude the assignment of activities in §§ 121.10(a)(1) through 121.10(a)(8) to other individuals, provided the activities are performed or supervised by a person approved under § 121.11 and the results are reviewed and approved by the Responsible Official or Alternate Responsible Official.'' The commenter stated that it would be inappropriate for the responsible official to participate in the actual transferring of an agent or to perform data entry to maintain records.

In response to this comment, in this final rule we are amending the regulations to provide that the individual or entity required to register under each part, and not the responsible official, must provide training, maintain records, and provide notice of theft, loss, or release of select agents or toxins (newly designated 7 CFR 331.15 and 9 CFR 121.15, 7 CFR 331.17 and 9 CFR 121.17, and 7 CFR 331.19 and 9 CFR 121.19). This change will allow the responsible official to delegate certain responsibilities. For instance, interim 7 CFR 331.14(a) and 9 CFR 121.15(a) stated that the responsible official must maintain complete, up-to-date records of information necessary to give an accounting of all of the activities related to listed agents or toxins. In this final rule, we are amending the regulations to require the individual or entity to maintain such records (newly designated 7 CFR 331.17 and 9 CFR 121.17).

Interim 7 CFR 331.9(b) and 9 CFR 121.10(b) (newly designated 7 CFR 331.9 and 9 CFR 121.9) required the responsible official for a diagnostic laboratory, or other entity possessing, using, or transferring listed agents or toxins that are contained in specimens presented for diagnosis to immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law. Furthermore, both paragraphs provided that the Administrator may require less frequent reporting during agricultural emergencies or outbreaks, or in endemic areas.

In this final rule, we are amending newly designated 7 CFR 331.9(c) and 9 CFR 121.9(c) to require the responsible official to report the identification and final disposition of any select agent or toxin contained in a specimen for diagnosis or verification. In addition, we are adding a new paragraph (d) to 9 CFR 121.9 to require the responsible official to report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. This information will help us to identify outbreaks and to monitor activities related to select agents and toxins.

We are also amending newly designated 9 CFR 121.9(c) to require the responsible official to immediately report the identification of specified select agents and toxins with a report of the final disposition of the agent or toxin due within 7 calendar days after identification. The responsible official must report the identification and final disposition of the other select agents and toxins within 7 calendar days after identification. This will make the reporting requirements for registered entities consistent with those in the exemption sections (newly designated 9 CFR 121.5 and 121.6). Finally, we are deleting in both sections the requirement that the identification of a select agent or toxin be reported to appropriate authorities when required

by Federal, State, or local law (interim 7 CFR 331.9(b) and 9 CFR 121.10(b)). This change corresponds to a similar change made in the exemption sections (interim 7 CFR 331.4, 9 CFR 121.4, and 9 CFR 121.5).

One commenter requested clarification of the diagnostic exemptions and the provisions of interim 9 CFR 121.10(b) requiring the responsible official for a diagnostic laboratory to report identifications. The commenter noted that exempt diagnostic laboratories are not required to have a responsible official.

The reporting requirements in interim 9 CFR 121.10(b) (newly designated 7 CFR 331.9(c) and 9 CFR 121.9(c)) pertain to *registered* diagnostic laboratories. The regulations require that both exempt and registered entities report the identification of a select agent or toxin. We adopted these reporting requirements because this information will help us to identify outbreaks and to monitor activities related to select agents and toxins. Accordingly, we are making no change in response to this comment.

Restricting Access/Security Risk Assessments

Interim 7 CFR 331.10 and 9 CFR 121.11 stated that an individual may not have access to listed agents and toxins unless approved by APHIS or, for overlap agents, APHIS or CDC. Both sections provided that APHIS will grant, limit, or deny access approval and, interim 9 CFR 121.11, provided that APHIS or CDC will make this determination for overlap agents or toxins. Interim 7 CFR 331.10 and 9 CFR 121.11 further provided that the responsible official is responsible for ensuring that only approved individuals within the entity have access to agents or toxins.

In this final rule, we are amending these sections to clarify that an individual must be approved for access by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General (newly designated 7 CFR 331.10 and 9 CFR 121.10). In addition, we are deleting the provision that the responsible official is responsible for ensuring that only approved individuals have access to select agents or toxins. This change will make it clear that the registrant and the individual are responsible for ensuring that the individual does not have access to any select agent or toxin unless approved by the Administrator or the HHS Secretary.

Several commenters requested information about the security risk assessments conducted by the Attorney General.

To obtain a security risk assessment, an individual or entity must submit a completed FBI Form FD–961 and two legible fingerprint cards, printed by a local law enforcement agency, to the Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation. Fingerprint cards and FBI Form FD–961 may be obtained by calling (304) 625–4900. FBI Form FD–961 is also available on the Internet at *http://www.fbi.gov/terrorinfo/bioterrorfd961.htm.* It would be impractical to include this information in the regulations because the Attorney General determines the information and processes required for a security risk assessment. Accordingly, we are making no change based on these comments.

One commenter recommended that security risk assessments be completed within 2 weeks. Another commenter stated that a person should be permitted to work with select agents or toxins under the direct supervision of an approved person if the individual subject to the background check suffers a delay in excess of 10 working days.

Security risk assessments are conducted by the Attorney General, not APHIS. The time required to complete a security risk assessment depends on the completeness of the application and the results of the database search. In general, a security risk assessment may be completed in 45 days. However, in certain cases, additional time may be needed to verify the results of the database search. We are making no changes based on these comments.

A commenter asserted that personnel screening should include, at a minimum, a criminal background check, credit check, and random drug screening.

In accordance with the Act, each individual identified by the responsible official must undergo a security risk assessment. The Act does not require a credit check or random drug screening. However, this does not preclude an entity from having more stringent personnel screening for individuals with access to select agents or toxins. Accordingly, we are making no changes based on this comment.

Interim 7 CFR 331.10(b) and 9 CFR 121.11(b) required the responsible official to request access approval for only those individuals who have a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents and toxins.

APHIS received a number of comments dealing with the term ''access.'' A commenter stated that judgments about an individual's need to handle agents and the adequacy of their training and skills is a matter for the responsible official, not APHIS. This commenter recommended that APHIS rely upon the responsible official to make informed judgments about an individual's need for access and their proficiency in handling select agents and toxins. One commenter noted the term ''access'' is used to describe two distinct situations—access to select agents and toxins by individuals who are authorized to handle and use them, and approved entry to an area where select agents or toxins are present by individuals who are not authorized to handle or use such agents or toxins. Several commenters recommended that APHIS define the term ''access'' as the ''ability to gain physical control of select agents and toxins.'' Another commenter suggested the word ''access'' be changed to ''handle or use'' throughout the regulations. The commenter noted that many people may have access to a containment space but never handle or use agents or toxins. Similarly, one commenter argued that the regulations are conceptually flawed because they focus on restricting access to the laboratory rather than to the select agent or toxin. The commenter said that numerous individuals need to access lab space for a variety of reasons and that it is unnecessary and burdensome to require that they be continually escorted or undergo security risk assessments. Another commenter recommended that APHIS define the term ''entry,'' which would refer to admission of unapproved individuals into an area where select agents and toxins are present.

In the December 2002 interim rule, we provided that an individual may not have access to listed agents or toxins unless approved by APHIS or, for overlap agents or toxin, APHIS or CDC. We required access approval for each individual with a legitimate need to handle or use agents or toxins, and the necessary training and skills to handle such agents or toxins. We continue to believe that individuals that handle or use select agents or toxins must be approved for such access. However, we agree with the commenters that access approval should also be required for individuals who have the ability to gain possession. Therefore, this final rule provides that an individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (*e.g.,* carries, uses, or manipulates) or the ability to gain possession of a select agent or toxin (newly designated 7 CFR 331.10(b) and 9 CFR 121.10(b)). In addition, we are

requiring in both sections that each individual with access to select agents or toxins have the appropriate education, training, and/or experience to handle or use such agents or toxins (newly designated 7 CFR 331.10(c) and 9 CFR 121.10(c)). However, in this final rule, we are removing the requirement that the responsible official submit information about an individual's training and skills to APHIS (interim 7 CFR 331.10(e) and 9 CFR 121.11(e)). These changes will make it clear that the registered individual or entity, and not APHIS, is responsible for ensuring that an individual with access to select agents or toxins has the appropriate education, training, and/or experience to handle such agents or toxins.

Several commenters argued that access approval should be portable from entity to entity, from location to location, and from project to project for the duration of the valid period. A commenter stated that delays in access approval could be avoided if an individual's approval was portable. Another commenter asked if an individual will need a new security risk assessment if he or she has already been cleared at one entity but will visit another entity to conduct research.

We do not believe it is necessary to make an individual's access approval portable in order to avoid delays in such approval. The Administrator or the HHS Secretary may grant access approval to an individual following a security risk assessment by the Attorney General. A security risk assessment may be completed in 45 days unless additional time is needed to verify the database search results. However, in recognition of the need for flexibility for visiting researchers, APHIS, CDC, and the Attorney General have developed procedures by which an approved individual may visit another registered entity without having to undergo another security risk assessment by the Attorney General. Specific guidance on these procedures is available on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index/html.* We note that an individual who ceases to be employed by the entity at which he/she originally received access approval must obtain new access approval through his/her new employer. We are making no changes to the regulations in response to these comments.

A commenter asserted that the L or Q clearances (or their equivalent) granted in Department of Energy laboratories should be considered synonymous with the security risk assessment, and, therefore, approved.

Section 212(e) of the Act requires that registered persons provide access to select agents and toxins to only those individuals that have a legitimate need to handle or use such agents and toxins, and that those individuals undergo a security risk assessment by the Attorney General. The Act provides no exemption for Federal clearances. Accordingly, we are making no change based on this comment.

The regulations (interim 7 CFR 331.10(f) and 9 CFR 121.11(f); newly designated 7 CFR 331.10(e) and 9 CFR 121.10(e)) provide that the access approval process for individuals may be expedited upon request by the responsible official and a showing of good cause.

Several commenters stated that APHIS and the Attorney General should establish timelines for responding to requests for expedited review for security risk assessments.

We do not believe it is necessary to establish timelines for responding to requests for expedited review for security risk assessments. In our experience, an expedited security risk assessment can be completed within a week, barring any complications. Therefore, we are making no change based on this comment.

Another commenter asked what constituted ''good cause'' for expedited review of access approval. This commenter asserted that Federal clearances should be a reason for expedited review.

This final rule cites several examples of good cause to expedite a security risk assessment (*e.g.,* public health or agricultural emergencies, national security, a short-term visit by a prominent researcher). We do not believe that a Federal clearance alone is sufficient reason to expedite a security risk assessment. Thus, we are making no change in response to this comment.

Interim 7 CFR 331.10(h) and 9 CFR 121.11(h) provided that APHIS may deny or limit access of an individual to agents or toxins if:

- The Attorney General identifies the individual as a restricted person under 18 U.S.C. 175b;
- The Attorney General identifies the individual as reasonably suspected by any Federal law enforcement or intelligence agency of (1) committing a crime set forth in 18 U.S.C. 2332b(g)(5), (2) knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or (3) being an agent of a foreign power as defined in 50 U.S.C. 1801;
- The Administrator determines that the individual does not have a legitimate need to handle listed agents or toxins;
- The individual does not have the necessary training and skills to handle listed agents or toxins; or
- The Administrator determines that such action is necessary to protect plant health or plant products, or animal health or animal products.

In this final rule, newly designated 7 CFR 331.10(f) and 9 CFR 121.10(f) provide that an individual's access approval may be denied, limited, or *revoked* if the individual is a restricted person under 18 U.S.C. 175b or is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power as defined in 50 U.S.C. 1801. This has always been the way these provisions have been interpreted; however, we are making this change to both sections for clarification purposes.

To be consistent with a change made in the section pertaining to denial, revocation, or suspension of registration (newly designated 7 CFR 331.8 and 9 CFR 121.8), in this final rule we are deleting the provision that the Administrator may deny, limit, or revoke an individual's access approval if the individual does not have a legitimate need to handle select agents or toxins. In addition, we are deleting the provision pertaining to an individual's training and skills to be consistent with CDC's regulations.

A commenter stated that limited access, whereby the individual can only handle or use the agent or toxin under the direct supervision of an approved individual, is impractical. The commenter noted that each faculty member, postdoctoral fellow, or student who is a member of a research team is expected to make significant, independent contributions to research; also, it would be too burdensome for institutions to track whether individuals have full or limited access. The commenter stated that provisions for limited access would be unnecessary if the regulations included a precise definition of access.

Section 212(e)(2) of the Act provides for limited access approval. The Administrator will determine what constitutes limited access on a case-by-case basis. The determination will take into consideration all of the facts at

hand and be commensurate with the risks posed by the select agent or toxin. We are making no change based on this comment.

One commenter argued that the Attorney General should allow the research community to comment on how the definition of ''restricted person'' will be interpreted and applied. This commenter stated that, while the Attorney General is bound by statutory language in the respective categories, interpretation will be required to make the definitions operational. For instance, the commenter asked if a scientist who has fled political persecution in another country, and who may therefore have an outstanding foreign arrest warrant, would be considered a restricted person. Another commenter recommended that the Administrator reserve the authority, in exceptional circumstances, to allow individuals deemed ineligible to have access to select agents and toxins for a limited time. The commenter stated that it is in the national interest to take a nuanced approach that takes into account the contributions the individual may be able to make to the country. This commenter stated there should be an opportunity for individuals and their sponsoring institutions to make the argument that an individual has exceptional talent and insight that should be used to advance research, and that an individual does not present a security risk, even if he or she meets the criteria for a restricted person.

The statutory requirements are clear, and it is not necessary for the research community to assist in the interpretation and application of the term 'restricted person.' In accordance with the Act, the Administrator may limit or deny access to PPQ and VS select agents and toxins to individuals whom the Attorney General has identified as a ''restricted person'' under 18 U.S.C. 175b. Furthermore, the Administrator must deny access to overlap select agents and toxins to individuals whom the Attorney General has identified as a ''restricted person.'' According to 18 U.S.C. 175b, ''the term ''restricted person'' means an individual who:

- Is under indictment for a crime punishable for a term exceeding 1 year;
- Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
- Is a fugitive from justice;
- Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
- Is an alien illegally or unlawfully in the United States;
- Has been adjudicated as a mental defective or has been committed to any mental institution;
- Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or
- Has been discharged from the Armed Services of the United States under ''dishonorable conditions.''

Based on the foregoing, we are making no change in response to this comment.

Interim 7 CFR 331.10(g) and 9 CFR 121.11(g) provided that APHIS will notify the responsible official if an individual is granted full or limited access, or denied access to listed agents or toxins. Both sections further provided that APHIS will notify the individual if he/she is denied access or is granted only limited access.

Several commenters recommended that any entities or individuals denied access to select agents and toxins be notified of the reasons for the denial; otherwise, they are unable to make a meaningful request for an administrative review.

APHIS will provide written notice of any denial, limitation, or revocation of access approval, including the reason(s) therefore. However, since this is an administrative action ''taken'' by APHIS, it is unnecessary to include this information in the regulations. Accordingly, we are deleting this paragraph in both sections in this final rule.

The regulations (interim 7 CFR 331.10(j) and 9 CFR 121.11(k); newly designated 7 CFR 331.10(h) and 9 CFR 121.10(i)) provide that access approval is valid for a maximum of 5 years.

One commenter recommended that APHIS reconsider the timeframes for renewal of registration packages (3 years) and access approval (5 years). The commenter stated that it would be easier for the regulated community if the renewals were concurrent and could be sent at one time.

In establishing the timeframe for registration, we took into consideration the risks of the select agents and toxins and the fact that APHIS' permits are valid for a similar timeframe, while, in establishing the timeframe for access approvals, we took into consideration the burden on the public and the fact that the Act allows for approvals to be valid for up to 5 years. We believe that these timeframes are reasonable and consistent with the requirements of the Act. We do not believe that it will be easier for the regulated community if the renewals are concurrent and can be sent at one time. Access approvals are granted by the Administrator or the HHS Secretary on a rolling basis due to frequent staff changes at entities and variations in the time it takes for the Attorney General to conduct an individual's security risk assessment. If APHIS adopted the same timeframe for registration and access approval, it is likely that some individuals in an entity would have to renew their access approvals in a much shorter timeframe than other individuals in the same entity. We believe this would cause undue burden on the public. Accordingly, we are making no changes based on this comment.

The regulations (interim 7 CFR 331.10(k) and 9 CFR 121.11(l); newly designated 7 CFR 331.10(i) and 9 CFR 121.10(j)) require immediate notification when an individual's access to agents or toxins is terminated by the entity and the reasons therefore.

A commenter requested clarification as to what constitutes ''immediately.'' The commenter stated that large entities would find it difficult to provide written notices within 24 hours. The commenter recommended that APHIS require an initial notification by phone or fax within 72 hours that is followed up by a written notice within 7 business days.

The regulations do not require written notice of a termination of access. Notice of a termination of access may be provided by telephone, fax, or e-mail. We are making no change in response to this comment.

Security

Interim 7 CFR 331.11 required that an individual or entity develop and implement a Biocontainment and Security Plan. Interim 9 CFR 121.12 contained similar requirements for a Biosafety and Security Plan. In both sections, paragraph (a)(2) stated that the security systems and procedures must be designed according to a site-specific risk assessment and provide graded protection in accordance with the threat posed by the agent or toxin. Both sections also set out the types of information that should be contained in the security plan.

A commenter asserted that biological lab security should be administered by only one Federal agency (*i.e,* the Department of Homeland Security) to ensure consistency.

Section 212(b) of the Act requires APHIS to establish and enforce safeguard and security measure to prevent access to select agents and toxins for use in domestic or international terrorism or for any other criminal purpose. In addition, the Act provides for interagency coordination between APHIS and CDC regarding overlap select agents and toxins. As discussed below, APHIS and CDC have amended the regulations so that the security requirements are identical and APHIS and CDC have established procedures to ensure consistent regulation of select agents and toxins. For these reasons, we are making no change in response to this comment.

A commenter recommended that APHIS and CDC adopt identical security provisions. Several commenters asked whose security, inspection, and compliance standards will be used for overlap agents—APHIS' or CDC's. These commenters also asked what will happen if APHIS and CDC do not concur.

Both the APHIS and CDC select agent regulations apply to overlap select agents and toxins. To eliminate confusion about whose security standards will be used for overlap select agents and toxins, we are amending the security sections in this final rule so that the APHIS and CDC security requirements are identical (newly designated 7 CFR 331.11 and 9 CFR 121.11). These changes are discussed in detail below. We believe these changes will help to ensure consistent regulation of select agents and toxins by APHIS and CDC, including compliance inspections. We note that compliance inspections for security will be based on the regulations and that inspectors will be looking for security that provides graded protection commensurate with the risk of the select agent or toxin, given its intended use.

Several commenters expressed concern that the regulations do not provide for preclearance of security plans before an entity invests in a security system.

In this final rule, we recommend that an individual or entity consider the following document when developing a security plan—''Laboratory Security and Emergency Response Guidance for Laboratories Working With Select Agents,'' in Morbidity and Mortality Weekly Report. An individual or entity should review this document before contacting APHIS for technical assistance. We will provide technical assistance and guidance upon request. However, in recognition of the commenters' concerns, we note that APHIS and CDC are working with interagency groups and security experts to draft a document that will provide additional guidance about the security required for select agents and toxins. This document will be available in spring 2005. We will provide this guidance document to the regulated community when it is available.

A commenter stated that the regulations should clearly distinguish between lab security and entity security, especially for large academic settings where a secure lab may coexist with educational and research labs.

We disagree. The security regulations are designed to prevent unauthorized access, theft, loss, or release of select agents and toxins. The regulations require that an entity's security plan be designed according to a site-specific risk assessment. Such a risk assessment would take into consideration the security needed for a select agent lab in a large academic setting. Therefore, we are making no change based on this comment.

One commenter asked what constituted an adequate description of safety and security in the required plans. Another commenter asked who will judge the adequacy of a security plan.

A security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. APHIS or CDC will determine if a security plan is adequate. We are making no changes in response to these comments.

The introductory text in interim 7 CFR 331.11(a)(2) and 9 CFR 121.12(a)(2) stated that the security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin. Both sections further provided that the site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities identified. Both sections also stated that the security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs and must mitigate the risks identified.

A commenter suggested replacing the phrase ''in accordance with the threat posed by the agent'' with the phrase ''in accordance with the consequences posed by the agent or toxin.'' Another commenter pointed out that the terms ''risk assessment,'' ''threat assessment,'' ''vulnerability assessment,'' and ''threats'' are confusing to those with little experience in this area and should be clarified. A commenter suggested that APHIS replace the phrase ''risks associated with those vulnerabilities are mitigated'' with the phrase ''consequences associated with those vulnerabilities are mitigated.''

In response to these comments, in this final rule we are deleting this text in both sections and adding in its place the requirement that an entity's security plan be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release (newly designated 7 CFR 331.11(a) and 9 CFR 121.11(a)). In addition, we are amending both sections to require that the security plan be designed according to a site-specific risk assessment and provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. We believe these changes will clarify the requirements and make the text in this section consistent with other sections in the regulations (*e.g.*, biocontainment/biosafety).

One commenter recommended that entities be required to comply with Appendix F of the BMBL as well as the specific USDA manuals cited in the rule. The commenter stated that this would mandate the use of state-of-the-art approaches for safety and security. A commenter stated that the security regulations are inadequate (*i.e.*, key locks and key control) and recommended that the pathogens be secured with a modern access control system. Another commenter stated that the regulations should specify minimum security standards. The commenter recommended the following: (1) A minimum of three levels of access control (*e.g.*, access to the building, access to the wing of the building, and access to the laboratory); (2) a minimum of two levels of access control with video surveillance; (3) a minimum of one level of access control with security personnel; and (4) a minimum of one level of access control with an alarm system with off-site monitoring.

On the other hand, several commenters recommended a performance standard for compliance with the regulations. One commenter stated that Appendix F of the BMBL does not provide appropriate guidance for developing a performance-based security program because it implies the need for a rigorous security program applicable uniformly to all biosafety levels. The commenter noted that overly prescriptive requirements will impede the development of effective and affordable plans and will result in constraining the availability of select agents and toxins for the legitimate

purposes specified in the Act. Another commenter stated that toxins should not be subject to the same biocontainment and security measures as viruses, bacteria, fungi, and plant pathogens (which are capable of replication). The commenter suggested a two-tiered approach, with a higher level of security and biocontainment for materials that can be propagated. Similarly, a commenter stated the security requirements should recognize that not all listed agents are equal from a weaponization perspective; therefore, a set of graded protection requirements should be established so that the most dangerous pathogens and the most likely to be weaponized are protected at higher levels than the majority of the select agents.

Because different select agents and toxins pose differing degrees of risk, we believe it would be counterproductive to attempt to prepare a detailed list of prescriptive requirements for entities (*i.e.*, a ''one size fits all'' design standard). Therefore, the regulations contain performance standards for biocontainment/biosafety, security, and incident response that take into account the risks presented by a particular agent or toxin, given its intended use.

With regard to security, newly designated 7 CFR 331.11 and 9 CFR 121.11 require each individual or entity required to register under each part to develop and implement a written security plan. This security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. In addition, newly designated 7 CFR 331.11 and 9 CFR 121.11 require the individual or entity to adhere to specified security requirements or implement measures to achieve an equivalent or greater level of security. We believe these security provisions provide enough flexibility and specificity to allow an individual or entity to develop and implement a security plan that will safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

However, in recognition of the commenters' concerns, we reiterate that APHIS and CDC are working with interagency groups and security experts to draft a document that will provide additional guidance about the security required for select agents and toxins. This document will be available in spring 2005. The 5th edition of the BMBL, which is under development, will provide additional guidance on laboratory security.

Interim 7 CFR 331.11(a)(2)(iii) and 9 CFR 121.12(a)(2)(iii) required that the security plan describe, among other things, cybersecurity.

One commenter recommended that the term cybersecurity be replaced with ''information and cybersecurity.'' The commenter also recommended spelling out the assets that should be protected and how they are to be protected.

In this final rule, we are amending these provisions by removing the word ''cybersecurity'' and adding in its place the words ''information systems control'' (newly designated 7 CFR 331.11(c)(1) and 9 CFR 121.11(c)(1)). This change is consistent with changes made throughout this final rule to ensure that information about select agents and toxins is protected.

Interim 7 CFR 331.11(a)(2)(iv) and 9 CFR 121.12(a)(2)(iv) provided that, with respect to areas containing listed agents or toxins, an entity or individual must adhere to the specified security requirements or implement measures to achieve an equivalent or greater level of security.

Two commenters requested clarification of the term ''area'' with regard to large multi-use laboratories. One commenter stated there is little benefit in terms of security to require access control, specialized training, and personnel background checks for individuals who are only sharing lab space with individuals working with select agents or toxins. Another commenter suggested that the regulations should be flexible enough to allow local solution of this issue (*i.e.*, allowing the entity to designate a portion of the lab as a select agent area for which use and entry restrictions would be governed by the regulations). A commenter recommended that, where labs are used intermittently for select agent research, free access be permitted when select agents and toxins are not in use and when the agents/toxins are secured in a safe or other secured storage.

As previously noted, the security requirements are designed to prevent unauthorized access, theft, loss, or release of select agents and toxins. We believe the regulations provide enough flexibility for an entity to determine the best way to accomplish this goal. However, since the term ''area'' appears to be confusing, in this final rule we are deleting the phrase ''with respect to areas containing listed agents or toxins'' (newly designated 7 CFR 331.11(d) and 9 CFR 121.11(d)).

Interim 7 CFR 331.11(a)(2)(iv)(A) and 9 CFR 121.12(a)(2)(iv)(A) stated that an entity must allow unescorted access only to those approved individuals who are performing a specifically authorized function during hours required to perform that job.

In its final rule, CDC is amending the comparable provision in its rule in response to comments. To be consistent with CDC's regulations, we are making a corresponding change in this final rule. Specifically, we are amending both sections to provide that an entity may allow access only to individuals with access approval from the Administrator or the HHS Secretary (newly designated 7 CFR 331.11(d)(1) and 9 CFR 121.11(d)(1)).

Interim 7 CFR 331.11(a)(2)(iv)(B) and 9 CFR 121.12(a)(2)(iv)(B) required that individuals who are not approved under §§ 331.10 or 121.11, respectively, be allowed to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored.

A commenter requested clarification of the terms ''escorting'' and ''continually monitored.''

These terms are commonly understood and do not require further clarification in the regulations. However, upon further review, we are amending these provisions to make it clear that an individual who is not approved for access by the Administrator or the HHS Secretary may conduct routine cleaning, maintenance, repairs, and other activities not related to select agents or toxins only when continuously escorted by an approved individual (newly designated 7 CFR 331.11(d)(2) and 9 CFR 121.11(d)(2)).

Interim 7 CFR 331.11(a)(2)(iv)(C) and 9 CFR 121.12(a)(2)(iv)(C) required entities and individuals to control access to containers where listed agents and toxins are stored by requiring that such containers be locked when not in the direct view of an approved individual and by using other monitoring measures, as needed.

One commenter stated that the phrase, ''when not in direct view of an approved individual,'' implies that these areas do not need to be secured when an authorized person is present, and that this is inappropriate. The commenter said that an area containing select agents should be secure at all times and that only authorized persons should have access to a freezer. The commenter stated that an individual should not bear the burden of being responsible for the security of the freezer. Another commenter argued that this requirement is unnecessarily stringent and is not feasible in many labs. This commenter recommended that the agent or toxin be under the direct control of an individual, meaning that an unauthorized person could

approach the agent or toxin without coming into the view of approved staff. A commenter stated there is no need to require locked containers. The commenter noted that a freezer that is located outside an access-controlled area should be locked, while a freezer that is located inside such an area need not be locked.

We agree that containers where select agents and toxins are stored must be secured against unauthorized access at all times. Accordingly, we are amending both sections to state that an entity must control access to containers by requiring that freezers, refrigerators, cabinets, and other containers be secured against unauthorized access (newly designated 7 CFR 331.11(d)(3) and 9 CFR 121.11(d)(3)).

Interim 7 CFR 331.11(a)(2)(iv)(D) and 9 CFR 121.12(a)(2)(iv)(D) required the inspection of all packages upon entry and exit.

Several commenters stated that it is not practical to require inspection of all packages upon entry and exit, that doing so provides almost no security value, and that doing so may be unsafe. One commenter asked if the requirement applied to packages of agents being shipped/received or if it applied to briefcases, backpacks, etc. Another commenter asked if sharps containers or Petri dishes must be inspected.

We agree that it is not practical to require inspection of all packages upon entry and exit. Therefore, in this final rule, we are amending both sections to require that an entity inspect all suspicious packages before they are brought into or removed from an area where select agents or toxins are used or stored (newly designated 7 CFR 331.11(d)(4) and 9 CFR 121.11(d)(4)).

Interim 7 CFR 331.11(a)(2)(iv)(E) and 9 CFR 121.12(a)(2)(iv)(E) required an entity to establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging and movement is conducted under the supervision of an approved individual.

A commenter stated that the requirement for a protocol for intra-entity transfers is vague and inadequate. The commenter suggested that intra-entity movement of select agents should follow a documented chain of custody process that minimizes any possibility of diversion.

We agree. Therefore, in this final rule, we are amending both sections to require entities to establish a protocol for intra-entity transfers, including chain of custody documentation and provisions for ensuring that packaging and movement is conducted under the supervision of an individual with access approval from the Administrator or the HHS Secretary, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release (newly designated 7 CFR 331.11(d)(5) and 9 CFR 121.11(d)(5)). This change is consistent with the recordkeeping requirements in newly designated 7 CFR 331.17 and 9 CFR 121.17.

To be consistent with CDC's regulations, we are adding a new paragraph (d)(8) in 7 CFR 331.11 and 9 CFR 121.11 that requires an individual or entity to separate areas where select agents and toxins are stored or used from the public areas of the building.

One commenter stated that the BMBL and NIH Guidelines require labs to post biohazard signs on access doors that list the agents present in the lab, which may compromise lab security.

In this final rule, 9 CFR 121.12 (Biosafety) provides that an individual or entity should consider the BMBL and NIH Guidelines when developing a biosafety plan. However, it is the entity's responsibility to determine if posting biohazard signs on access doors would compromise lab security. We are making no change based on this comment.

Biocontainment/Biosafety

Interim 7 CFR 331.11 required individuals and entities to develop and implement a Biocontainment and Security Plan that is commensurate with the risk of the agent or toxin, given its intended use. It also required that the containment procedures be sufficient to contain the agent or toxin (*e.g.*, physical structure and features of entity, and operational and procedural safeguards). Interim 9 CFR 121.12 contained similar requirements for a Biosafety and Security Plan.

In this final rule, newly designated 7 CFR 331.12 requires that an individual or entity develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use. Newly designated 9 CFR 121.12 contains similar requirements for a biosafety plan. The titles and provisions of the plans are different because the select agents and toxins listed in 7 CFR 331.3 do not pose a severe threat to human health and, therefore, it is unnecessary to require that the plant-related plan address personnel safety and health.

Several commenters stated that the biosafety section in the final rule should reference existing Department of Health and Human Services guidelines and current Occupational Safety and Health Administration (OSHA) regulations as authoritative codes of practice that entities should consider in developing and implementing a performance-based safety plan. On the other hand, several commenters urged APHIS and CDC to develop joint biosafety guidelines for select agents that would supplant the BMBL and NIH Guidelines.

In this final rule, we are retaining the existing performance standard but we are providing a list of references that an individual or entity should consider in developing its biocontainment/biosafety plan (newly designated 7 CFR 331.12(c) and 9 CFR 121.12(c)). This change should provide more guidance on acceptable biosafety practices.

Restricted Experiments

In interim 9 CFR 121.10(c), we provided that the responsible official must ensure that the following experiments are not conducted unless approved by the Administrator, after consultation with experts: (1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a pathogenic trait or drug resistance trait to biological agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture; and (2) experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD_{50}<100 ng/kg body weight.

We adopted this provision in the December 2002 interim rule in order to be consistent with CDC and to address concerns about laboratory manipulation of microbes that alter their characteristics (*e.g.*, increased virulence, pathogenicity, or host range; alter mode of transmission or route of transmission) and increase the risks to human, animal, or plant health. At the time, we did not believe it was necessary to require approval for experiments involving recombinant DNA of PPQ select agents because these experiments are regulated under 7 CFR part 340. However, we are adding this provision to 7 CFR part 331 in this final rule to ensure that these experiments are covered and to provide consistency in the select agent regulations.

To facilitate compliance with these requirements, in this final rule we are moving these provisions to a new section in each part titled, ''Restricted experiments'' (7 CFR 331.13 and 9 CFR 121.13, respectively), and we are adding a footnote to both sections that indicates that guidance on the requirements for experiments involving recombinant DNA may be obtained from the publication, ''NIH Guidelines for

Research Involving Recombinant DNA Molecules.'' Moreover, 7 CFR 331.13 provides that these experiments must be conducted under conditions prescribed by the Administrator, and that the Administrator may revoke approval to conduct these experiments, or suspend or revoke a certificate of registration, if the individual or entity fails to comply with the requirements of that part. A corresponding provision in 9 CFR 121.13 provides for consultation with the HHS Secretary. This has always been the way we have interpreted all of these requirements; however, we are adding these provisions to both sections for clarity.

One commenter stated that the inclusion of the words ''pathogenic trait'' establishes an additional class of experiments that require approval from the Administrator. The commenter recommended that the APHIS and CDC requirements be identical.

We agree. Accordingly, we are deleting the words ''pathogenic trait'' in both sections of this final rule (newly designated 7 CFR 331.13(a)(1) and 9 CFR 121.13(a)).

One commenter stated that the regulations should be amended to refer to the NIH Guidelines rather than list the types of experiments that are restricted in the regulations. The commenter noted that the NIH Guidelines are subject to change and the regulations would not be as current as the guidelines and more difficult to amend, if necessary.

One of the reasons APHIS included these provisions in the regulations was to ensure that these categories of experiments are conducted only if safe to do so. By including these provisions in the regulations, we are providing notice to the public and establishing enforceable regulatory requirements. APHIS would have difficulty enforcing the provisions of the NIH Guidelines. If it becomes necessary to revise the list of restricted experiments, we will initiate rulemaking and provide notice and opportunity for public comment. For these reasons, we are making no change based on this comment.

A commenter suggested that the NIH recombinant advisory committee be designated to review the restricted experiments.

We do not believe it is necessary to designate the NIH recombinant advisory committee to review applications to conduct restricted experiments. The Administrator of APHIS will approve such experiments after consultation with subject matter experts and, for overlap select agents and toxins, CDC. Accordingly, we are making no changes based on this comment.

One commenter stated that interim 9 CFR 121.10(c)(1) (newly designated § 121.13(a)) is open to interpretation and, therefore, needs to be more specific. This commenter also suggested that the restricted experiment provisions should contain an exception for small scale *in vitro* experiments.

We disagree that this provision needs to be more specific. However, we note that additional guidance on the requirements for experiments involving recombinant DNA may be obtained from APHIS or the NIH Guidelines. We also disagree that the restricted experiment provisions should contain an exemption for small scale *in vitro* experiments. APHIS included these provisions in the regulations to ensure that these experiments are conducted only if safe to do so. The commenter provided no information to indicate that small scale *in vitro* experiments are safe and, therefore, should be exempted from the restricted experiment provisions. Accordingly, we are making no changes in response to this comment.

A commenter stated that an entity utilizes the deliberate formation of antibiotic resistance as a common research tool and that the restricted experiments provisions will limit this standard research practice. The commenter noted that transposon insertion libraries are common experimental creations used to generate gene knockouts and study the effect on expression and phenotype; however, this often results in an array of genomes containing antibiotic resistance markers used for selection and screening. The commenter argued that this common practice should not need approval and that it is too burdensome on the entity to obtain approval for each of several thousand insertional mutants that would be created for a single genome.

As previously noted, APHIS included these provisions in the regulations to ensure that these experiments are conducted only if safe to do so. We believe the manipulation of a select agent in order to create antibiotic resistance increases the risks to human, animal, or plant health and, therefore, warrants APHIS' approval. We are making no change based on this comment.

Incident Response

In interim 7 CFR 331.11(a)(3) and 9 CFR 121.12(a)(3), we required that the Biocontainment and Security Plan/ Biosafety and Security Plan include incident response plans for containment breach, security breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. These plans were required to address personnel safety and health, containment, inventory control, and notification of managers and responders. In addition, the plans were required to address bomb threats, severe weather (floods, hurricanes, tornadoes), earthquakes, power outages, and other natural disasters or emergencies.

A commenter stated that the requirements for APHIS' incident response plan and CDC's emergency response plan should be the same.

We agree. Therefore, the revised incident response sections in this final rule (newly designated 7 CFR 331.14 and 9 CFR 121.14) are consistent with the incident response section in CDC's final rule. In this final rule, we are adding the CDC requirement that an incident response plan must be coordinated with any entity-wide plans. To ensure that such plans are available for review by an entity's employees, we are also requiring that the plans be kept in the workplace and made available to employees for review. In addition, as described below in response to a request for clarification of the term ''incidents,'' we are clarifying the types of incidents and information that must be included in the plan. Finally, we are adding the CDC requirement that the response procedures account for the hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

A commenter requested clarification of the term ''incidents.'' In this final rule, newly designated 7 CFR 331.14 and 9 CFR 121.14 require that the incident response plan fully describe the entity's response procedures for theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats and suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc.

One commenter stated that the reference to ''inventory control'' is ambiguous and needs to be defined.

We agree that the term ''inventory control'' is not clear. Therefore, we are deleting the reference to inventory control in this final rule. However, we are retaining the requirement that an incident response plan describe the entity's response procedures for inventory discrepancies.

Training

Interim 7 CFR 331.12 (newly designated § 331.15) required the responsible official to provide appropriate training in containment and security procedures to all individuals with access to listed agents and toxins,

while interim 9 CFR 121.13 (newly designated § 121.15) required the responsible official to provide appropriate training in biosafety, containment, and security procedures to all individuals with access to listed agents and toxins. Both sections required the responsible official to provide information and training to an individual at the time the individual is assigned to work with a listed agent and toxin, and to provide refresher training annually.

A commenter requested clarification about the training requirements. This commenter wondered what would be considered appropriate training, what qualifications an individual would need to train others, and who decides if the training is adequate. Another commenter recommended that APHIS revise the training provisions to require training for approved individuals working with select agents and toxins and unapproved individuals working in or visiting areas where select agents and toxins are handled or stored. The commenter suggested that such training may be modified according to the needs of the individual, the work they will do, and their potential exposure. A commenter noted that APHIS' training requirements cover fewer staff than CDC's training requirements (*i.e.*, only those individuals handling the agents or toxins). The commenter recommended that the APHIS and CDC requirements be consistent.

In response to these comments, in this final rule we are amending both sections to require that an individual or entity provide information and training on biocontainment/biosafety and security to each individual with access approval from the Administrator or the HHS Secretary before he/she has such access (newly designated 7 CFR 331.15(a) and 9 CFR 121.15(a)). We are also requiring that an individual or entity provide training to each individual not approved for access by the Administrator or the HHS Secretary before he/she works in or visits areas where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. Finally, refresher training must be provided annually (newly designated 7 CFR 331.15(b) and 9 CFR 121.15(b)). These changes will make the APHIS and CDC regulations consistent. We note the training should be provided by an individual who has the appropriate training and skills. APHIS will determine if an individual's training is adequate.

One commenter recommended that APHIS adopt the CDC provisions in interim 42 CFR 73.13(d) that allows an entity to certify that personnel have been trained.

In interim 42 CFR 73.13(d), CDC provided that, in lieu of initial training for those individuals already involved in handling select agents or toxins, the responsible official may certify that an individual has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities. CDC included this provision to minimize the disruption of research or educational projects that were under way as of the effective date of the December 2002 interim rule. CDC is deleting this provision in its final rule. For this reason, we are making no change based on this comment.

Transfer of Biological Agents and Toxins

Interim 7 CFR 331.13 and 9 CFR 121.14 (newly designated 7 CFR 331.16 and 9 CFR 121.16) set out the transfer requirements and procedures. In this final rule, we are amending newly designated 7 CFR 331.16 and 9 CFR 121.16 to clarify the transfer provisions. Specifically, we are amending both sections by providing that, in addition to any permit required under the regulations, a transfer of a select agent or toxin may be authorized if: (1) The sender has a certificate of registration that covers the agent or toxin to be transferred and meets the requirements of each part, meets the exemption requirements for the select agent or toxin to be transferred, or is transferring the select agent or toxin from outside of the United States and meets all import requirements, and (2) at the time of transfer, the recipient has a certificate of registration that includes the select agent or toxin to be transferred and meets all of the requirements of each part (newly designated 7 CFR 331.16(b) and 9 CFR 121.16(b)). This information was contained in the interim rule but the final rule more clearly sets out the requirements for the sender and recipient. We are also amending the transfer provisions in 9 CFR 121.16 to provide that a select agent or toxin contained in a specimen for proficiency testing may be transferred without prior authorization from APHIS or CDC provided that, at least 7 calendar days prior to the transfer, the sender reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient. This change, in conjunction with the reporting requirements for identifications of select agents or toxins in 9 CFR 121.5, 121.6, and 121.9, will allow us to more effectively monitor proficiency testing activities.

In addition, we are amending both sections to provide that the recipient must immediately notify APHIS or CDC if a package containing a select agent or toxin has been damaged to the extent that a release of the select agent or toxin may have occurred (newly designated 7 CFR 331.16(f) and 9 CFR 121.16(g)). These changes will make the APHIS and CDC regulations consistent.

Both sections (newly designated 7 CFR 331.16(g) and 9 CFR 121.16(h)) also provide that an authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (*e.g.*, change in the certificate of registration for the sender or recipient, change in the application for transfer). This change is intended to ensure timely transfers of select agents and toxins and provide notice to the public that APHIS may terminate a transfer authorization under certain circumstances.

One commenter stated that the regulations should provide for transfer of agents and toxins from an unregistered entity to a registered entity to prevent destruction of valuable historical, archival, and educational materials.

We agree. Accordingly, in this final rule, we are amending the transfer provisions in interim 7 CFR 331.13 and 9 CFR 121.14 to provide that, on a case-by-case basis, the Administrator may authorize a transfer of a select agent or toxin, not otherwise eligible for transfer under each part, under conditions prescribed by the Administrator (newly designated 7 CFR 331.16(c) and 9 CFR 121.16(c)).

One commenter maintained that APHIS should permit hand-carried transfers of select agents or toxins with the same reporting requirements already described in the regulations.

Given the risks posed by select agents and toxins, we do not believe that hand-carried transfers of such agents or toxins is consistent with the intent of the Act. By prohibiting hand-carried transfers, we ensure that select agents or toxins are packaged appropriately and that there is documentary evidence of the transfer (*e.g.*, tracking numbers, confirmation of delivery, etc). We are making no changes based on this comment.

One commenter stated that the requirement that APHIS or CDC approve transfers between entities is highly likely to produce unreasonable delays. The commenter suggested that the

regulations be revised to require that APHIS respond within an appropriate interval (*e.g.*, 1 to 2 days).

We do not expect the transfer requirements in the regulations to produce unreasonable delays. The requirement for approval prior to a transfer of a select agent or toxin is not a new requirement, nor is it unreasonable given the risks posed by select agents or toxins. The transfer requirements for select agents and toxins incorporate the permit requirements under the plant pest regulations in 7 CFR part 330 and the organisms and vectors regulations in 9 CFR part 122, which require APHIS' approval prior to transfer. We are making no changes based on this comment.

A commenter asserted that the transfer provisions are incompatible with biosecurity. The commenter stated that they require the principal investigator to prohibit access to the material up to the point of shipment, after which the package is handled by a host of individuals out of the control of the responsible official or the principal investigator. Several commenters expressed concern about the U.S. Department of Transportation's labeling requirements for packages containing select agents or toxins. These commenters pointed out that the labeling requirements clearly indicate which packages should be stolen. One commenter recommended eliminating the requirement for external labeling. This commenter also recommended adding tamper-indicating procedures in the packaging so that the recipient would know the package had been tampered with.

These issues are outside the scope of this rulemaking. Accordingly, we are making no changes based on these comments.

Records

Interim 7 CFR 331.14 and 9 CFR 121.15 required the responsible official to maintain complete, up-to-date records of information necessary to give an accounting of all of the activities related to listed agents and toxins. Such records must be maintained for 3 years and produced upon request to APHIS inspectors and appropriate Federal, State, and local law enforcement authorities.

A commenter stated that the requirements for inventory records of select agents are unclear. The commenter pointed out that research labs generate and destroy material on a daily, if not hourly, basis. The commenter wondered if the inventory requirement pertained to stock collections or to all infectious materials generated. Another commenter stated that keeping track of vials is a waste of Federal resources.

We agree that the requirements for inventory records are unclear. To provide clarification and to be consistent with CDC's approach, in this final rule the inventory recordkeeping requirements in both parts (newly designated 7 CFR 331.17 and 9 CFR 121.17) require the maintenance of an accurate, current inventory for each select agent held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials) and for each toxin held. The provisions for select agents and toxins are different to account for the differences between select agents and toxins; we do not believe it is feasible to record quantities of replicating organisms (*i.e.*, select agents). In addition, we are providing more information about the types of information that must be included in the inventory records for each select agent or toxin. For example, an inventory for a select agent must include the name and characteristics of the agent, the quantity acquired from another entity, where stored, when moved from storage and by whom, purpose of use, transfer records, etc., while an inventory for a toxin must include the name and characteristics of the toxin, the quantity acquired from another entity, the initial and current quantity, where stored, when moved from storage and by whom, transfer records, etc.

Interim 7 CFR 331.14(a)(4) and 9 CFR 121.15(a)(4) required an individual or entity to maintain accurate and current inventory records (including source and characterization data).

One commenter recommended that APHIS define the terms ''characterization data'' and ''accurate.'' To clarify the term ''characterization data,'' in this final rule we are providing examples of the characterization information that should be maintained by the entity for each select agent (*e.g.*, strain designation, GenBank Accession number, etc.). The term ''accurate'' is commonly defined as free from mistakes or errors. We do not believe it is necessary to define this term in the regulations.

A commenter suggested that all records should be marked and protected at the ''Official Use Only'' level.

To be consistent with CDC's regulations, in this final rule newly designated 7 CFR 331.17 and 9 CFR 121.17 require an entity to implement a system to ensure that all records and databases created under each part are accurate, have controlled access, and can be verified for authenticity. We do not believe it is necessary to require that an entity mark and protect all of its records at the ''Official Use Only'' level to satisfy this requirement. Therefore, we are not implementing this suggestion.

One commenter suggested that all transfer forms be securely stored for 5 years, instead of 3 years. Taking into consideration the burden on the public and APHIS' investigational needs, we believe that it is reasonable to require that all records, including transfer forms, be maintained for 3 years. Accordingly, we are making no change based on this comment.

Inspections

Interim 7 CFR 331.15(a) provided that any APHIS inspector must be allowed, without previous notification, to enter and inspect the entire premises, all materials and equipment, and all records required to be maintained by the regulations, while interim 9 CFR 121.16(a) contained a similar provision for APHIS or CDC inspectors.

To be consistent with CDC's regulations, newly designated 7 CFR 331.18(a) and 9 CFR 121.18(a) provide that APHIS, without prior notification, must be allowed to inspect any site at which activities regulated under each part are conducted and must be allowed to inspect and copy any records relating to the activities covered under each part.

Interim 7 CFR 331.15(b) provided that, prior to issuing a certificate of registration, APHIS may inspect and evaluate the premises and records to ensure compliance with the regulations and the biosafety, containment and security requirements. Interim 9 CFR 121.16(b) contained a similar provision for APHIS or CDC inspectors.

In this final rule, we are removing the phrase ''and the containment and security requirements'' (newly designated 7 CFR 331.18(b)) and removing the phrase ''and the biosafety, containment, and security requirements'' (newly designated 9 CFR 121.18(b)). These phrases are unnecessary since we already state in both sections that, prior to issuing a certificate of registration, APHIS may inspect and evaluate an entity's premises and records to ensure compliance with the regulations.

A commenter requested additional information about compliance inspections. In particular, the commenter asked what level of training and security clearances would be required for inspectors and whether there would be separate inspectors to

assess the biosafety and security requirements. The commenter also asked what standards will be used by the inspectors to assess compliance with the regulations.

APHIS inspectors will have the appropriate training and security clearances (at least a security risk assessment) to inspect and evaluate an entity's premises and records to ensure compliance with the regulations. APHIS inspectors will use the standards established in the regulations and published guidelines (*e.g.*, BMBL) to determine compliance. While we expect that, normally, only one inspector will be needed to conduct an inspection, occasionally more than one inspector may be needed to evaluate an entity's biosafety, containment, and security.

APHIS and CDC will coordinate inspections to minimize the burden on the entity. This coordination will ensure that inspections by APHIS and CDC are not duplicative. However, additional inspections may be required under certain circumstances. For instance, another inspection may be required for amendments to a certificate of registration (*e.g.*, addition of a laboratory) or to satisfy APHIS' permit requirements.

Notification in the Event of Theft, Loss, or Release

Interim 7 CFR 331.16(a) and 9 CFR 121.17(a) required the responsible official to orally notify APHIS and appropriate Federal, State, or local law enforcement agencies immediately upon discovery of a theft or loss of listed agents or toxins. We also required that the oral notification be followed by a written report within 7 days. In this final rule, newly designated 7 CFR 331.19(a) and 9 CFR 121.19(a) provide that thefts or losses must be reported to APHIS or CDC. In addition, these paragraphs clarify that thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. These changes will make the APHIS and CDC regulations consistent. Finally, we are specifying the information that must be reported to APHIS or CDC (newly designated 7 CFR 331.19(a) and 9 CFR 121.19(a)). We believe this change will clarify the requirements for notification of theft or loss of select agents and toxins.

Interim 7 CFR 331.16(b) and 9 CFR 121.17(b) provided that the responsible official must orally notify APHIS immediately upon discovery that a release of a listed agent or toxin has occurred outside the biocontainment area. We also required that the oral notification of a release be followed by a written report within 7 days. The regulations further provided that APHIS will notify relevant Federal, State, and local authorities, and the public, if necessary. In § 121.17(b), we additionally provided that, if the release involves an overlap agent or toxin, we will also notify the Secretary of Health and Human Services.

In this final rule, newly designated 7 CFR 331.19(b) requires that APHIS or CDC be notified immediately upon discovery of a release of a PPQ select agent or toxin outside the primary barriers of the biocontainment area while 9 CFR 121.19(b) requires that APHIS or CDC be notified immediately upon discovery of a release of a VS or overlap select agent or toxin causing occupational exposure or a release outside the primary barriers of the biocontainment area. The requirement for notification of a release outside of the primary barriers of the biocontainment area is a clarification. This is how we have always interpreted the provision regarding release outside the biocontainment area; however, we are making this change to make it clear to the public. In 9 CFR 121.19(b), we are adding the provision for occupational exposure to be consistent with CDC's regulations. We did not include this provision in 7 CFR 331.19 because PPQ select agents and toxins do not pose a severe threat to human health and, therefore, it is unnecessary to address personnel safety and health. In both sections, we are also specifying the information that must be reported to APHIS or CDC. We believe these changes will clarify the requirements for notification of a release.

Finally, we are deleting the provision that APHIS will notify relevant Federal, State, and local authorities, and the public in the event a release poses a threat to animal health or animal products. This is an administrative action taken by APHIS and it is unnecessary to include this information in the regulations.

A commenter requested clarification of the term ''unintentional release.'' The commenter stated that it can be interpreted to include any exposure or release at any biosafety level.

The term ''unintentional release'' is not used in either the interim regulations or this final rule. Therefore, we are making no change based on this comment.

Several commenters urged APHIS to exempt from notification those accidents (*i.e.*, releases) that take place entirely within biosafety labs where the select agent is being handled at the appropriate biosafety level. One commenter went on to state that an exposed worker may be so concerned about needing to report an accident to APHIS that he or she may decide not to inform anyone of a potential exposure, resulting in an immediate risk to the person and a possible risk to the population.

Given the risks associated with select agents and toxins, we believe it is necessary to be notified of all occupational exposures. It is the entity's responsibility to ensure that its employees comply with these reporting requirements. For these reasons, we are making no changes based on these comments.

Administrative Review

Interim 7 CFR 331.17 and 9 CFR 121.18 provided that an individual or entity may appeal a denial or revocation of registration. In addition, these sections provided that an individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins may appeal that decision. Both sections set out the process for an administrative review.

In this final rule, the administrative review sections also provide that an individual or entity may appeal the suspension of registration. This provision was included in the sections on denial, revocation, and suspension of registration (interim 7 CFR 331.7 and 9 CFR 121.8) but was inadvertently not included in interim 7 CFR 331.17 and 9 CFR 121.18 (newly designated 7 CFR 331.20 and 9 CFR 121.20). In addition, we are amending both sections to allow an individual to appeal revocation of access approval. This change corresponds to a change in newly designated 7 CFR 331.10 and 9 CFR 121.10 that allows revocation of an individual's access approval in the event that an individual becomes a restricted person under 18 U.S.C. 175b or is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power as defined in 50 U.S.C. 1801.

A commenter stated that the final rule should include provisions for entities and individuals to appeal security risk assessment decisions or seek exemptions for legitimate research.

The regulations already allow an individual who has been denied access to select agents or toxins or who has been granted only limited access to such

agents or toxins to appeal that decision (interim 7 CFR 331.17 and 9 CFR 121.18; newly designated 7 CFR 331.20 and 9 CFR 121.20). However, in accordance with the Act, an entity may not appeal the denial or limitation of an individual's access to select agents or toxins. The regulations do not provide exemptions for research. However, we note that an individual's access to PPQ select agents or toxins and VS select agents or toxins may be limited or denied if an individual is a restricted person under 18 U.S.C. 175b. In addition, an individual's access to PPQ select agents or toxins, VS select agents or toxins, or overlap select agents or toxins may be limited or denied if an individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power as defined in 50 U.S.C. 1801. For these reasons, we are making no changes based on this comment.

Miscellaneous

We are also making minor, nonsubstantive changes to the regulations to correct misspellings and internal references, reflect changes to the form numbers, ensure a consistent format in both parts, and eliminate redundancy.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule, with the changes discussed in this document.

This final rule also affirms the information contained in the interim rule concerning Executive Orders 12372 and 12988.

Effective Date

For the reasons discussed in the Supplementary Information section of this rule, we have determined that it is no longer necessary to include *Phakopsora pachyrhizi* (Asian soybean rust) and plum pox *potyvirus* on the list of PPQ select agents and toxins. Therefore, this final rule amends 7 CFR 331.3(b) by removing *P. pachyrhizi* and plum pox *potyvirus* from that list. Making these amendments to 7 CFR 331.3(b) effective immediately will relieve restrictions we no longer find warranted and aid ongoing research into effective means of managing Asian soybean rust in the United States. Pursuant to the provisions of 5 U.S.C. 553, we have determined that this aspect of the final rule relieves restrictions and thus may be made effective less than 30 days after publication in the **Federal Register**. Accordingly, the Administrator of the Animal and Plant Health Inspection Service has determined that the amendments made to 7 CFR 331.3(b) in this rule should be effective upon signature. The remaining provisions of this final rule will become effective 30 days after date of the rule's publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

For this rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis, as required by Executive Order 12866, as well as an analysis on the potential economic effects of this final rule on small entities, as required under 5 U.S.C. 603. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

Certain pathogens or toxins produced by biological organisms that are released intentionally or accidentally can result in disease, wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and large-scale loss of life.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), provides for the regulation of certain biological agents [1] and toxins [2] that have the potential to pose a severe threat to public health and safety, to animal health, to plant health, or to animal and plant products. The Act also requires that the Secretary of Agriculture establish and enforce standards and procedures governing the possession and use of the listed biological agents and toxins, including the establishment and enforcement of safety requirements for the transfer of listed agents and toxins; the establishment and enforcement of safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or other criminal purpose; and the establishment of procedures to protect animal and plant health, and animal and plant products, in the event of a transfer in violation of the established safety and security measures. APHIS has the primary responsibility for implementing the provisions of the Act within USDA. VS select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or animal products. PPQ select agents and toxins are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins are those that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS and CDC, which has the primary responsibility for implementing the provisions of the Act for the Department of Health and Human Services.

Benefits of the Rule

This rule will require registration, biocontainment/biosafety, incident response and security measures for the possession, use, and transfer of the select agents and toxins listed in 7 CFR part 331 and 9 CFR part 121. This rule is intended to prevent the misuse of those select agents and toxins, and will therefore reduce the potential for those pathogens to harm humans, animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally introduced into the United States, the consequences would be significant. Some of these select agents have the potential to cause ailment and death in humans. Direct losses in agriculture could occur as a result of the exposure, such as death or debility of affected production animals, or yield loss in plants. Industry could also be affected through the imposition of domestic and foreign quarantines, which result in a loss of markets. The Federal and State Governments would

[1] Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: (1) Death, disease or other biological malfunction in a human, an animal, a plant, or another living organism; (2) deterioration of food, water, equipment, supplies, or material of any kind; or (3) deleterious alteration of the environment.

[2] The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes: (1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or (2) any poisonous isomer or biological product, homolog, or derivative of such a substance.

also incur costs associated with eradication and quarantine enforcement to prevent further spread, and in the case of intentional introduction—law enforcement. In addition, there is the potential for a disruption in the domestic food supply, whether through contamination, consumer perception, or both. Past food safety incidents have shown that consumer perceptions (both domestic and international) about an implicated food product and about the producing country or sector's ability to produce safe food are slow to recover and can have a lasting influence on food demand and global trade.[3] As such, the benefits associated with the rule are the avoided losses to the animals or plants that could be attacked by these organisms, and their products and markets.

The costs associated with outbreaks can be very high as is demonstrated by natural outbreaks associated with select agents that have occurred. For example, it has been estimated that the losses to agriculture and the food chain from the recent foot-and-mouth disease (FMD) outbreak in the United Kingdom (UK), including the costs compensated by the government, amount to about £3.1 billion ($4.7 billion). In 1999, it was estimated that the potential impacts of an FMD outbreak in California alone would be between $8.5 and $13.5 billion.[4] Also, a bovine spongiform encephalopathy (BSE) crisis occurred in the UK (which has a cattle industry about one-tenth the size of that in the United States) in 1996. It has been estimated [5] that the total resource costs to the UK economy as a result of BSE in the first 12 months after the onset of the 1996 crisis were in the range of £740 million to £980 million ($1.2 billion to $1.5 billion), or just over 0.1 percent of the gross domestic product of the United Kingdom. In addition to these losses, the UK lost its entire export market for beef following the crisis.

The above cited consequences relate to natural or accidental introduction. Deliberate introduction greatly increases the probability of an agent or toxin becoming established and causing wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and possible loss of life. The perpetrators would have the advantage of controlling the time of introduction of the agent, introducing agents into remote or highly susceptible areas, multiple introductions of the same agent, or simultaneous release of different agents. Intentional introductions permit an increased probability of survival of a pathogen, the use of highly virulent strains and high concentrations of inoculum, and precise timing of release to coincide with maximal colonization potential.[6]

Costs of the Rule

The rule is intended to ensure that any entity that possesses, uses or transfers a select agent or toxin is registered and has safeguard, containment, and disposal requirements that are commensurate with the risk of that agent or toxin. Affected entities vary widely, and therefore, the biosafety/biocontainment, incident response and physical security situation will vary widely from one entity to another, as will the specific changes that will need to occur at a given entity to comply with this rule.

Affected Entities

Entities that possess, use, or transfer VS, PPQ or overlap select agents or toxins will be affected by this rule. Because of the nature of some of these entities and some of the select agents or toxins they possess, APHIS and CDC share common regulatory authority. However, APHIS and CDC have established procedures that will allow an entity to interact with only one agency—either APHIS or CDC—with respect to all matters involving select agents and toxins. This analysis considers only those entities for which APHIS is considered the primary regulatory agency.[7]

The affected entities are primarily research and diagnostic facilities. They include Federal, State, and university laboratories, and private commercial and non-profit enterprises. Currently, there are 76 [8] academic, commercial, State and Federal government facilities that have applied for a certificate of registration from APHIS for PPQ, VS, and/or overlap agents and toxins. Approximately 34 percent of these entities are academic, 37 percent are private commercial enterprises, 28 percent are government, and 1 percent are non-profit.

The level of security at the entities that possess, use or transfer select agents and toxins is currently very diverse, ranging from a locked freezer to a lock on the door to razor wire perimeter fencing, a guard post, locks or coded entry, and visitor escorts.

Exemptions and Exclusions From the Rule

A number of exclusions and exemptions from the rule exist that reduce the number of entities that otherwise might have been affected by this rule. For example, nonviable select agents and nonfunctional toxins are excluded from the requirements of this rule. Some attenuated strains of a select agent or toxin may be excluded based on a determination that the strain does not pose a severe threat to animal health or to animal products. In addition, overlap toxins are excluded if they are under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor and the aggregate amount does not, at any time, exceed certain amounts.

In addition, a number of exemptions also exist. In particular, exemptions cover diagnostic laboratories and others when select agents and toxins contained in a specimen are presented for diagnosis or verification and proficiency testing. Diagnostic reagents and vaccines that are, bear, or contain VS select agents or toxins that are produced at USDA diagnostic facilities are also exempt from the requirements. For the most part, products that are, bear, or contain VS or overlap select agents or toxins are exempt from the requirements if the products have been cleared, approved, licensed, or registered under a number of Federal statutes. Experimental products and investigational products can also be exempted.

In addition, the Administrator may grant exemptions from the applicability of the regulations as they apply to VS or PPQ select agents and toxins if the Administrator determines that such exemptions are consistent with protecting animal or plant health, or animal or plant products. While an entity will not be exempt if it keeps a positive control of a select agent or toxin, alternatives will exist. If an entity decides to keep a positive control of a select agent or toxin, it will have to register and may need to make changes to its operations in order to do so.

Those not specifically exempted have to submit an exemption application if

[3] Buzby, J.C. *Effects of food-safety perceptions on food demand and global trade.* Changing Structure of Global Food Consumption and Trade/WRS–01–1. Economic Research Service/USDA.

[4] Ekboir, J.M. *Potential impact of foot-and-mouth disease in California: the role and contribution of animal health surveillance and monitoring services.* Davis, CA: Agricultural Issues Center, Division of Agriculture and Natural Resources, University of California, Davis, 1999.

[5] DTZ Pieda Consulting. *Economic Impact of BSE on the UK economy.* A Report commissioned by the UK Agricultural Departments and HM Treasury.

[6] National Research Council.

[7] Those entities for which the CDC is considered the primary regulatory agency are considered in conjunction with the CDC rule.

[8] Thus far, APHIS has received 148 applications for registration or exemption. Of those, 72 were exempt, have been shifted to CDC, been withdrawn, or denied.

they wish to become exempt. Thus far, APHIS has received 34 exemption applications, and anticipates receiving an additional one per year. It is estimated that applying for an exemption requires 1.17 hours (0.17 managerial hours at $86.09 per hour [9], and 1 technical hour at $69.34 per hour), or $84 per exemption application. Based on the number of exemption applications received, the total initial cost is estimated to have been $2,900, while the yearly cost for new applicants would be about $100. Exemptions are valid for a maximum of 3 years; therefore the costs of applying for an exemption would recur every 3 years.

Remaining exempt under this rule will require the submission of the proper paperwork dealing with identifications and the transfer or destruction of select agents and toxins. Registered diagnostic laboratories will also be required to report identifications of select agents and toxins when presented for diagnosis. The number of these identifications can vary widely in a given year, climbing dramatically when outbreaks occur. However, during agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. APHIS expects to receive an average of 1,000 notifications of identifications from diagnostic laboratories in a given year. It is estimated that complying with the notification requirements will require 1 hour (0.17 managerial hours and 0.83 technical hours), or $72 per notification. Based on 1,000 notifications, the estimated total cost is $72,000 per year.

Registration

Under this rule, unless exempted an individual or entity shall not possess, use, or transfer any select agent or toxin without a certificate of registration issued by APHIS or CDC. The registration process is designed to obtain critical information concerning individuals or entities in possession of certain agents or toxins, as well as the specific characteristics of the agents and toxins. Information to determine that individuals and entities seeking to register have a lawful purpose to possess, use, or transfer agents or toxins will also be required as part of the registration process. This will involve security risk assessments by the Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation, and collecting and providing the required information. The checks will require that individuals provide identifying information. In addition, this information will need to include fingerprints. It is estimated that this cost will be $5 to $30 per set for those done on paper. It may cost up to $50 per set for electronic prints, but these could be processed far more quickly. A given entity could expect to spend between $50 and $5000 obtaining and submitting fingerprints, with between 10 and 100 employees needing fingerprints per entity. To the extent that there is staff turnover at an entity, these costs could be recurring. With a total of 2,300 security risk assessments to be performed initially, and an average fingerprinting cost of $27.50 per individual, the total cost of obtaining fingerprints would be $63,250. With 1,300 new assessments to be performed yearly, the annual cost of obtaining fingerprints could be expected to be $37,750. APHIS may request the Attorney General to expedite an individual's security risk assessment upon request by the responsible official and a showing of good cause. APHIS expects to receive 20 of these requests initially and 13 a year thereafter. These requests are expected to take 0.5 managerial hours, or $43 per occurrence. This gives a total cost of $1,000 in the first year, and $560 a year thereafter.

It is estimated that it will take a total of 3 managerial hours and 0.75 technical hours for a complete form with one principal investigator (PI) plus 0.75 technical hours per additional PI. Affected entities have between 1 and 9 PIs.[10] It is, therefore, estimated to take 3 managerial hours and between 0.75 and 6.75 technical hours to complete the registration package, at a cost of between $310 and $726 per entity. Based on the number of PIs at the 76 entities currently applying for registration, the total cost of registration is estimated to be $29,000. APHIS expects to receive 8 new applications for registration in a given year, with a total cost of $3,300 per year. It is estimated that 75 percent of entities will amend their registrations twice in a given year. These amendments are estimated to take 1 managerial hour, or $86 per amendment. Based on 76 registrations this gives a cost of $9,800. In addition, because registrations will be valid for up to 3 years, re-application will be required.[11] It is estimated that re-applying for registration will require 3 hours with one PI (2.67 managerial hours and between 0.33 and 2.97 technical hours) or $253 to $436 per entity to collect and provide the required information. The total cost of re-application is estimated at $21,000 every 3 years based on the 76 entities currently applying for registration, and the number of PIs at the entities.

As a condition of registration, an individual or entity must develop and implement a written security plan that provides graded protection in accordance with the risk of the select agent or toxin, given its intended use. The plan must describe inventory control procedures, physical security and information systems control. The individual or entity must also develop and implement a written biosafety/biocontainment plan that is commensurate with the risk of the agent or toxin, given its intended use. It is estimated that the development of the biosafety/biocontainment plan may take 20 managerial hours and 40 technical hours at a given entity for a cost of $4,500. However, many entities will already have this type of plan in place and in writing. For example, under the plant pest permit system, standard operating procedures at an entity are already required to be submitted. Also, university safety officers generally require that safety requirements be in writing. If we conservatively assume that one-half of the 76 affected entities need to develop these plans the total cost would be $171,000. The development of the physical security plan would most likely take place as a part of the site-specific entity security assessment required under the rule (*see Security*).

As a further condition of registration, an individual or entity must develop and implement a written incident response plan. The incident response plan must fully describe the entity's response procedures for releases, theft or loss of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats and suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent

[9] For purposes of this analysis we use estimates of an average hourly respondent labor rate (including fringe and overhead) of $86.09 for managerial staff, and $69.34 for technical staff. Based on the 2000 Occupational Employment Statistics Survey, Bureau of Labor Statistics.

[10] Based on information from the registration applications, 40 percent of the registered entities have 1 PI, 30 percent have 2 PIs, 11 percent have 3 PIs, 6 percent have 4 PIs, 3 percent have 5 PIs, 3 percent have 6 PIs, 3 percent have 7 PIs, and 1 percent have 9 PIs.

[11] To minimize the administrative burden associated with this new registration program, initially APHIS will assign expiration dates ranging from 24 to 36 months to stagger the dates for renewing registration. Upon renewal, it is expected that all certificates of registration will be valid for 3 years.

or toxin and appropriate actions to contain such agent or toxin. It is estimated that the development of the incident response plan may take 10 managerial hours and 25 technical hours at a given entity for a cost of $2,600. However, many entities will already have similar plans in place and in writing, i.e., as part of compliance with health and safety regulations. If we conservatively assume that one-half of the 76 affected entities need to develop these plans, the total cost would be $99,000.

Transfer

Under this rule, select agents and toxins may only be transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin. However, the sender may be an individual or entity exempt from the requirements of this rule, or an individual or entity located outside the United States. In addition, APHIS may authorize transfers for select agents or toxins that would not otherwise be eligible for transfer. Transfer must occur only with prior authorization, notification of receipt by the recipient, and notification of overdue or damaged shipments. APHIS expects there to be a total of 130 transfers in a given year. It is estimated that complying with the transfer requirements will require 1.75 hours (0.17 managerial hours and 1.58 technical hours), or $124 for each transfer. This gives a total cost of $16,000 per year.

Biosafety/Biocontainment

Biosafety and containment requirements ensure that the combination of work practices and physical containment are designed to reduce the risks of working with infectious material and the degree of protection is proportional to the risk associated with the agent. Higher biosafety levels (BSL) correspond to greater degrees of protection. For example, at a BSL–3 laboratory, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. Also, because there is special concern for reducing the risk of environmental exposure to pathogens of concern to agriculture, BSL–3-Ag adds filtration of supply and exhaust air, sewage decontamination, exit personnel showers, and entity integrity testing. While the BSL terminology is not formally used in relation to laboratories working with plant agents or toxins, a parallel philosophy of matching pest risk to biocontainment is used in the plant pest permit system. Under this rule, the biosafety and containment procedures at an entity must be sufficient to contain the agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

Acquiring adequate biosafety and containment measures can be costly. For example, as a result of work related to anthrax testing at APHIS' National Veterinary Services Laboratories, a portion of the laboratories' air handling system had to be replaced at a cost of $75,000. However, the biosafety and containment requirements contained in this rule should require little change at affected entities. USDA permits [12] cover the importation and interstate movement of agents and toxins. Prior to the implementation of the December 2002 interim rule, these permits already required the biosafety and containment level to be commensurate with the risk associated with the pathogen covered in the permit. Therefore, to the extent that affected entities are already permittees, the biosafety and containment requirements in this rule will have already been required at those entities. Before the enactment of the Act, there may have been entities operating legally outside the permit system, but who are not exempt from this rule. The rule may involve additional biosafety or containment burdens for those entities, but the extent of these burdens cannot be estimated.

Security

The rule will require that any entity where select agents and toxins are held adequately provide for the physical security of the premises. These requirements are intended to ensure the appropriate levels of protection against, theft or loss of select agents or toxins, and other acts that may cause unacceptable adverse impacts on national security or on the health of the public or the environment. The security systems and standard operating procedures must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, or loss. The security systems and standard operating procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use.

The costs of providing security at entities where the select toxins and agents are held can be considerable. USDA has recently upgraded, or is currently upgrading, security at a number of its own entities, including laboratories. While these costs are not a result of this rule, they are illustrative of the spending that can be necessary to upgrade security. By department policy, all USDA biosafety level 3 (BSL–3) laboratories are required to meet physical security requirements. The level of security mandated in this policy meets or exceeds the levels required in this rule. For example, upgrades at NVSL in Ames, IA were completed in 2002 at a cost of $550,077 ($6.63/ft2, 83,000ft^2 total area). Installations of electronic security components can include closed circuit television (CCTV) (cameras, VCR, and control equipment), intrusion detection system (IDS) (access-control card-readers, card-keys, operating computer and software), all cabling associated with the security system, and integrating the system with the off-site monitoring. Other security related expenses that could be needed at a given entity following an entity security assessment include entry control equipment (x-ray, metal detectors). Other features would entail yearly recurring costs (*i.e.,* off-site monitoring, an equipment maintenance agreement, and guard service).

The security systems and standard operating procedures must be designed according to a site-specific risk assessment. This site-specific risk assessment is completed to determine the existing security status and needs of a specific entity. The cost of a security assessment of a laboratory is based largely on the required expertise and would be somewhat dependant on the size of the entity. At APHIS laboratories these assessments have ranged from $17,000 to $25,000 per location.[13] Many affected entities will have had entity security assessments done in another context prior to the interim rule on select agents and toxins, or will need far less extensive and therefore expensive assessments.

Electronic security may need to be a major part an entity's physical security. Based on average actual security system installations for APHIS facilities, a cost per square foot for electronic security upgrades was developed.[14] The security needs and existing systems at these entities varied. The matrix cost per square foot includes: CCTV; IDS; integration; perimeter protection; design; construction; and construction

[12] Prior to the enactment of the Public Health Security and Bioterrorism Response Act of 2002, USDA issued permits for importation and interstate movement of agents and toxins, including those now listed in 7 CFR part 331 and 9 CFR part 121.

[13] Robert Rice, Security Manager, APHIS select agent program.

[14] Robert Rice, Security Manager, APHIS select agent program.

management, but not biometric technology. The cost per square foot assumes single story entities and has been adjusted for laboratory type entities. For buildings under 80,000 ft2 the average cost/ft^2 is $8.71. In addition, there is an adjustment factor for retrofitting existing buildings. It should be noted that for very small entities, the cost/ft^2 can be considerably higher.[15] It should also be noted that these costs per ft^2 are based on security installations of state-of-the-art technology. In addition to the entity security assessment and access control discussed above, a given entity could need none, some, or all of the following to maintain its physical security. Entry control equipment includes x-ray—small unit ($28,000 per unit), x-ray—large unit ($40,000 per unit), and metal detector(s) ($20,000 per unit). Other features would entail yearly recurring costs. Off-site monitoring ($10,000 to $45,000 per year); an equipment maintenance agreement ($12,000 to $30,000 per year); and guard service—unarmed ($30.00/hr per security post), armed ($35.00/hr per security post), and a supervisor ($40.00/hr).[16] Following September 11, 2001, more comprehensive security packages have been (or will be) added to APHIS facilities including many of these additional features. There are, however, alternatives to the specific services that can greatly reduce costs and could be acceptable depending on the security needs of a given entity, *e.g.,* remote monitoring and response to alarms instead of on-site guard service. Also, an entity may have some or all of the services already included in an overall facility operational and maintenance plan. An example would be a laboratory holding select agents or toxins that is part of an academic institution where support services are already incurred by the academic institution, *e.g.,* campus police for security response.

Because security needs are site-specific and the rule allows for site-specific security solutions, the approaches and applications will be varied. The above physical security components, and others, may have to be added in various quantities (including none) to meet the specific security needs of an entity. The entities covered in this rule can and do vary from a small laboratory contained within a larger facility to large dedicated buildings to large groups of buildings and land. Small laboratories in larger buildings are unlikely to need access controlled gates, a security fence, or even guard service (although a university or commercial entity may already have a security force which would be considered in assessing security needs). Larger entities will inevitably have more and different security needs than small ones. These entities naturally have more points of access and are more likely to need features such as fences or gates to control access. In addition, the costs themselves are very site specific; there can be literally hundreds of variables that will influence cost at a specific site. The variation begins with the needs of the individual entity (views of which can differ from administration, scientist, and physical security points of view) and is influenced by the characteristics of the site—for example, linked areas are in different buildings, on opposite sides of a fire wall, etc. Generally labor for installation (approximately $96/hour in Washington, DC for installation work on electronic access control)[17] is the most expensive and variable cost of these systems.

A review of 20 security plans of registered entities gives an indication of the nature of security present at affected entities. It also gives an indication of the nature of improvements to security that have occurred since the implementation of the interim rule, or are planned, or will need to occur at affected entities. All showed a good base of security. In fact, a number require no improvement under this rule. Improvements that have already occurred or have been recommended include installing intrusion detection systems, installing or expanding CCTV surveillance, card-key access control and standard locks. Often an entity's standard operating procedures for security sufficiently serve in place of a limited number or lack of electronic controls. Because many of the affected entities deal with select agents or toxins in an area that is fully contained in a larger structure, the lack of entry control equipment may not affect the level of graded protection. It should also be noted that only that portion of a given entity affected by select agent or toxin operations is required to be secured under this rule. On average, academic entities had 5,560 square feet, commercial entities 2,894 square feet, and government entities 4,848 square feet to be secured.[18]

This rule will require that all information resources related to select agents and toxins have an appropriate level of protection in the system that is used to acquire, store, manipulate, manage, move, control, display, switch, interchange, receive or transmit that information. Most affected entities have a variety of compelling reasons, including regulatory requirements,[19] for already protecting information.

Other Costs

All individuals with access to select agents or toxins are required to have the appropriate education, training and/or experience to handle or use such agents or toxins. In addition, additional training may be needed to familiarize staff with changes resulting from the rule. This requirement may necessitate that affected entities provide additional training. It is not known the extent to which training may be needed at affected entities, and therefore the cost of providing that training is not known. However, the National Center for Import and Export (NCIE) within APHIS Veterinary Services has a laboratory biosafety class to train inspectors. In FY 2002, APHIS spent $35,480 on participant and speaker travel, speaker honoraria, and equipment and supplies to train 18 inspectors, or about $2,000 each. If we assume that each of affected entities will have similar expenditures, and must train 25 individuals[20] the training cost would be $50,000 per entity or $3.8 million for all 76 entities. It should be noted that most of the APHIS training cost is in travel. To the extent that training at affected entities can occur on-site, the cost per individual could be reduced.

The rule requires that a registered entity maintain complete records concerning activities related to select agents or toxins. This includes an accurate, current inventory for each select agent held in long-term storage. It is estimated that it would take eight technical hours to complete an inventory of a freezer containing select agents or a toxin container. Assuming that there are on average 10 freezers,

[15] Equivalent security needs at two buildings can have significant differences in cost per ft^2. For example, the need for one $1000 video camera would add $1 to the ft^2 cost of a 1000 ft^2 facility, but only $0.1 to a 10,000 ft^2 one.

[16] Robert Rice, Security Manager, APHIS select agent program.

[17] Christian Lee, Physical Security Specialist, USDA–APHIS–FMD–ESB. Personal communication.

[18] Based on a review of 20 security plans for select agents or toxins submitted to APHIS. The review covered a broad spectrum of security plans, and type of entity. Plans were reviewed at random. Robert Rice, Security Manager, APHIS select agent program.

[19] Among others: Presidential Decision Directive 63, Critical Infrastructure Protection; the Computer Security Act of 1987 (Public Law (PL) 100–235); the Computer Fraud and Abuse Act (18 U.S.C. Sec. 1030 [1993]); Office of Management and Budget (OMB) Circular No. A–123, Management Accountability and Control; Appendix III of OMB Circular No. A–130, Management of Federal Information Resources; FED–STD–1037A, ''An Electronic Means for Communicating Information; and the Electronic Communications Privacy Act (18 U.S.C. 2701).

[20] The average number of individuals needing security risk assessments per entity.

and 3 toxin containers at a given registered entity, it would cost $7,200 per entity to create this baseline inventory. Based on 76 registered entities, the baseline inventory would cost a total of $548,000. The inventory will have to be verified periodically. Assuming that the registered entities would have to re-inventory one-half of their freezers each year to maintain an accurate and current inventory, yields a yearly inventory cost of $274,000.

Other record keeping includes copies of the biosafety/biocontainment, security and incident response plans, a list of individuals with access to select agents and toxins, training records, inventory records, permits and transfer documents, security records, and incident reports. It is estimated that complying with the record keeping requirements will require 10 hours per PI (3 managerial and 7 technical hours per PI), between 10 and 90 hours per entity per year or $745 to $6,700 per entity. The total cost of yearly record keeping is estimated to be $132,000 based on the current number of affected entities, and the number of PIs at those entities.

The rule also requires oral notification immediately upon discovery of the theft or loss of select agents or toxins, followed by a written report within 7 days. This is also the requirement for the discovery that a release of a select agent or toxin has occurred outside of the containment area of the entity. APHIS expects there to be two notifications of theft, loss or release in a given year. It is estimated that complying with these theft, loss and release notification requirements will require one hour (0.17 managerial hours and 0.83 technical hours), or $72 for each occurrence, for a total cost of $144 per year. It is assumed that an incident of theft or loss will also require a thorough inventory of the affected storage freezer or toxin container, at a cost of $560 per occurrence, for a yearly total of $1,120.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part. APHIS expects there to be one appeal in a given year. It is estimated that complying with the appeal requirements will require 2 managerial hours and 2 technical hours, or $311 for each occurrence.

Another potential cost of the rule is on the pace and quantity of research on select agents and toxins. If an entity chooses not to continue work with select agents or toxins to avoid the expenditures that will be required as a result of this rule, the impact on the progress of scientific knowledge is unknown and likely unknowable. However, the consequences of not securing select agents and toxins could be extreme.

Costs to APHIS

The rule will also involve costs to APHIS. The rule will require the government to process entity registrations, notifications of identification of agents and toxins, exemption applications, transfer applications, theft/loss notifications and appeals, perform inspection and compliance activities, provide technical assistance for compliance to affected entities, develop and maintain a database covering select agents and toxins, develop and maintain a secure space for the database, and obtain security clearances. The FY2004 budget for the APHIS select agent and toxin program is $4.3 million. User fees to offset government costs will not be collected by APHIS under this rule.

Potential Impact of This Rule

Approximately 70 percent of research & development (commercial and non-profit laboratories dealing with human, animal and/or plant agents), biological (except diagnostic) manufacturing, diagnostic manufacturing, pharmaceutical manufacturing, and other private establishments affected by this rule have fewer than 20 employees, and another 15 percent have between 20 and 49 employees.[21] Plant laboratories (Federal, commercial, State, and academic) tend to be very small, with fewer than 10 individuals having access to select agents or toxins. Veterinary diagnostic laboratories (commercial, State or university) and university research laboratories likely have fewer than 100 employees.[22] Federal entities covered by the rule will be affected by the registration requirements but should not have to make alterations due to the biosafety, containment and security requirements of the rule.

The portion of an affected entity where select agents or toxins are handled and that needs to be secure tends to be small. A review of 20 security plans of registered entities show an average of 4,449 ft^2 to be secured. Seventy percent of the entities have less than 5,000 ft^2 to be secured, 20 percent between 5,000 and 10,000 ft^2 to be secured, and 10 percent more than 10,000 ft^2 to be secured.[23]

For the purpose of assessing the impact of the security requirements of the rule, we make the following assumptions based on the available information:

- 70 percent of affected entities have an area to be secured of approximately 5,000 ft^2,
- 20 percent of affected entities have an area to be secured of approximately 7,500 ft^2,
- 10 percent of affected entities have an area to be secured of approximately 15,000 ft^2, and
- Because entities will have varying levels of existing security, security needs, and methods of meeting those needs, the average security upgrades in APHIS facilities is used as a proxy for upgrades at these entities. (The proxy is based on upgrading to state-of-the-art equipment, which may or may not be used at a given entity).

Using an average budget estimate for upgrading the electronic portion of a security system and the average area to secure by type of entity, we get estimates of the budget necessary to make these upgrades. Based on a budget estimate of $10.25/square foot,[24] an entity with 5,000 ft^2 to secure by installing electronic security countermeasures would need to budget $51,250, an entity with 7,500 ft^2 to secure would need to budget $76,875, and one with 15,000 ft^2 to secure would need to budget $153,750.

To obtain an aggregate cost estimate we apply these budget estimates based the size distribution of those entities. Applying a budget cost of $51,250 to the 70 percent of affected entities that have 5,000 ft^2 to secure gives a cost of $2.7 million. Applying a budget cost of $76,875 to the 20 percent of affected entities that have 7,500 ft^2 to secure gives a cost of $1.2 million. Applying a budget cost of $153,750 to the 10 percent of affected entities that have 15,000 ft^2 to secure gives a cost of $1.2 million.

[21] 1997 Economic Census. Department of Commerce, Census Bureau.

[22] AAVLD provided information on 10 veterinary diagnostic laboratories. These laboratories ranged in size form 11 to 100 employees including faculty, staff (part- and full-time), and students. In addition, the AAVLD president estimated that diagnostic laboratories in general would likely have between 6 and 80 employees. According to Dr. Denise Spenser, USDA–APHIS, university research on select agents likely involves fewer than 100 individuals (3 to 5 principal investigators out of about 25 faculty members in each of 3 or 4 departments—microbiology (veterinary microbiology), chemistry, and physiology, 3 to 5 (20 at most) investigators, technicians, and students in each laboratory).

[23] Based on a review of 20 security plans of affected entities.

[24] The baseline estimated cost/ft^2 of $8.71/$ft^2$ for facilities less than 30,000 ft2 in size, plus an adjustment of 17.7% for retrofitting existing structures.

It should be noted that as indicated above, utilizing APHIS'' costs as a proxy implies that all entities have baseline levels of electronic security similar to that of APHIS facilities and will upgrade to state-of-the-art technology. However, a review of security plans at affected entities shows that an upgrade state-of-the-art systems is not necessary or likely in most cases. Therefore, this proxy likely overstates the true cost of electronic security at these entities.

In addition to electronic security, an entity could need none, some, or all of the following:

• Entity security assessment, including developing a security plan as per the rule. Assuming that the 70 percent of entities with less than 5,000 ft^2 to secure spend $17,000, the 20 percent with between 5,000 and 10,000 ft^2 to secure spend $21,000, and the 10 percent with more than 10,000 ft^2 to secure spend $25,000 on these assessments gives a total cost of $1.4 million.

• Entry control equipment; includes x-ray—small unit ($28,000 per unit), x-ray—large unit ($40,000 per unit), and metal detector(s) ($20,000 per unit). Based on available information, we assume that 8 affected entities would need to add entry control equipment as a result of this rule. We further assume that each of those entities would spend an average of $30,000 on that equipment for a total cost of $240,000.

• Off-site monitoring can range from $10,000 to $45,000 per year. Assuming that the 70 percent of entities with less than 5,000 ft^2 to secure spend $10,000, the 20 percent with between 5,000 and 10,000 ft^2 to secure spend $27,500, and the 10 percent with more than 10,000 ft^2 to secure spend $45,000 on this off-site monitoring gives a total cost of $1.3 million.

• Equipment maintenance agreements can range in cost from $12,000 to $30,000 per year. Assuming that the 70 percent of entities with less than 5,000 ft^2 to secure spend $12,000, the 20 percent with between 5,000 and 10,000 ft^2 to secure spend $21,000, and the 10 percent with more than 10,000 ft^2 to secure spend $30,000 on these maintenance agreements gives a total cost of $1.2 million.

• Guard Service. Unarmed ($30.00/hr per security post), armed ($35.00/hr per security post), and a supervisor ($40.00/hr). When the site-specific security needs call for guards, it is the presence of a guard that is the most important factor. Therefore, unarmed guards would most likely be used. At most, a given entity would need a single unarmed guard on duty 24 hours a day. The majority of affected entities will rely on off-site monitoring, campus or local police, or existing guard presence. Therefore, we assume that the 70 percent of entities with less than 5,000 ft^2 to secure would add no additional guard service, the 20 percent with between 5,000 and 10,000 ft^2 to secure would add an additional guard 12 hours per day at a cost of $135,050 per year, and the 10 percent with more than 10,000 ft^2 to secure would add an additional guard 24 hours per day at a cost of $270,100 per year, giving a total annual cost of $814,000.[25]

This rule will involve other costs to the regulated community. It is estimated that complying with the exemption and notification requirements will have a total cost of $75,000 per year, $84 for each exemption application and $72 for each notification of identification. The rule will also involve the costs associated with the registration requirements. It is estimated that it will cost each entity $380 to collect and provide the required information, for a total cost of $29,000. Registration amendments are expected to cost $10,000 per year, $172 per occurrence. In addition, it is estimated that it will cost each entity $277 for a total of $21,000 to collect and provide the required information for re-application. Complying with the requirements concerning the transfer of select agents and toxins could cost $248 per occurrence or $16,000 per year. The rule could also entail costs for any needed upgrades to biosafety and containment, and information systems control. These costs are expected to be small. To the extent that affected entities are already permittees, the biosafety and containment requirements of the new act will have already been required at those entities. Affected entities have a variety of compelling reasons, including legislation, for already protecting information. The rule also requires that biosafety/biocontainment, security, and incident response plans be developed. It is estimated that the development of the biosafety/biocontainment plan could cost $4,500 per plan or a total of $171,000 if one-half of the affected entities need to develop new plans. The security plan would be developed as part of the entity security assessment discussed above. It is estimated that developing an incident response plan will cost $2,500 per plan for a total of $99,000 if one-half of the affected entities need to develop new plans. The cost to registrants associated with the individual security risk assessments is in obtaining fingerprints of individuals in the entity needing security screening. The average entity could expect to spend $825 obtaining fingerprints initially with a total for all entities of $63,250, and $470 annually for a total of $35,750. It is estimated that developing a baseline inventory of select agents and toxins at affected entities would cost $7,200 per entity for a total of $548,000, and the yearly inventory cost will be $3,600 per entity for a total of $274,000. Other recordkeeping is estimated at $1,742 per entity for a total of $132,000 per year. The estimated cost associated with training is $50,000 per entity for a total of $3.8 million. The estimated total cost associated with notifications of theft, loss and release of select agents or toxins is $72 per occurrence for a total of $144 per year. In addition, it is assumed that an incident of theft or loss will also require a thorough inventory of the affected storage freezer or toxin container, $560 per occurrence at a yearly total cost of $1,120. The estimated total cost associated with appeals under this rule is estimated to be $311 per year. The estimated cost associated with expedited reviews under this rule is estimated to be $43 per occurrence for a total of $1,000 initially and $560 per year thereafter.

The costs to APHIS include processing entity registrations, notifications of identification of agents and toxins, exemption applications, transfer applications, theft/loss notifications, appeals, performing entity inspections and providing technical assistance for compliance to affected entities, developing and maintaining a database covering select agents and toxins, developing and maintaining a secure space to house the database, and obtaining security clearances. The FY 2004 budget for the APHIS select agent and toxin program is $4.3 million.

Costs of the various components associated with the rule are summarized in the following table.

[25] Robert Rice, Security Manager, APHIS select agent program.

TABLE 1.—SUMMARY OF POTENTIAL COSTS [1]

Costs	One-time costs	Recurring costs
Exemptions from the Rule:		
Application	$2,900.	
Re-application		$2,900.
Notifications of identification		$72,000/yr.
Registration:		
Application	$29,000.	
Re-application		$21,000 every 3 yrs.
Amendments		$10,000/yr.
Biosafety/Biocontainment Plan	$171,000.	
Incident Response plan	$99,000.	
Fingerprinting associated with SRAs	$63,250	$35,750/yr.
Security plan/entity security assessment	$17,000 to $25,000 per entity. $1.4 million.	
Transfer		$16,000/yr.
Physical security procedures: [2]		
Electronic Security (cameras, card-readers, etc.)	$51,250 for 5,000 ft^2. $76,875 for 7,500 ft^2. $153,750 for 15,000 ft^2. $5.1 million.	
Entry control (x-ray, metal detector)	$30,000 each. $240,000.	
Off-site monitoring		$10,000 to $45,000 per entity. $1.3 million/yr.
Maintenance agreement		$12,000 to $30,000 per entity. $1.2 million/yr.
Guard service		$0 to $270,100 per entity. $814,000/yr.
Other costs:		
Training	$3.8 million.	
Baseline inventory	$548,000.	
Periodic inventory		$274,000/yr.
Recordkeeping		$132,000/yr.
Theft/loss/release		
Notification		$144/yr.
Additional inventory		1,120/yr.
Appeals		$311/yr.
Expedited reviews	$1,000	$560/yr.
Total	$11.5 million	$3.9 million.
Costs to APHIS:		
Budget for select agent program		$4.3 million.

[1] Unless otherwise noted, these are total costs for all affected entities.

[2] Because security needs are site-specific and the rule allows for site-specific security solutions, the approaches and applications will be varied. Actual additional physical security measures added will vary (including none) based on the current level of security and the specific security needs of a given entity. The electronic security costs assumes 70 percent of facilities are 5,000 ft^2, 20 percent of facilities are 7,500 ft^2, and 10 percent of facilities are 15,000 ft^2. The entry control equipment cost assumes 8 entities need such equipment. The off-site monitoring and maintenance agreement costs assume all affected entities need some monitoring. The guard service cost assumes entities would need, on average, from 0 to 24 additional hours daily of unarmed guard service.

For all affected entities, estimates of the various one-time costs associated with this rule total $11.5 million and the estimates of the annual recurring costs total $3.9 million. The above is given to provide perspective on the magnitude of the potential costs associated with this rule. The costs shown here are likely overstated, however, due to conservative assumptions used in the absence of better information. The entities covered in this rule can and do vary from a small laboratory contained within a larger facility to large dedicated buildings to large groups of buildings and land. Because security needs are site-specific and the rule allows for site-specific security solutions, the approaches and applications will be varied. Physical security measures may have to be added in various quantities (including none) to meet the specific security needs of an entity. In fact, the security plans submitted under the December 2002 interim rule shows that the need for additional security measures is limited in many cases. Also, some of the impacts of the rule are somewhat offset by previous requirements, such as permit requirements in place prior to the implementation of the December 2002 interim rule. The flexibility in the rule also allows for site-specific needs to be met in the most cost effective manner possible.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires that the Agency specifically consider the economic impact of rules on small entities. Those entities most likely to be impacted by the rule are those laboratories and other institutions conducting research and related activities that involve the use of select agents and toxins. Most affected entities (other than Federal or State governmental entities) would be considered part of NAICS code 541710, ''Research and Development in the Physical, Engineering, and Life Sciences.'' Some affected entities would be considered part of NAICS 541940, ''Veterinary Services,'' NAICS 611310, ''Colleges, Universities and Professional Schools,'' NAICS 325412 ''Pharmaceutical Preparation Manufacturing,'' NAICS 325413 ''In-Vitro Diagnostic Substance

Manufacturing,'' and NAICS 325414, ''Biological Product (except Diagnostic) Manufacturing.''

The Small Business Administration (SBA) has established guidelines for determining when establishments are to be considered small under the Regulatory Flexibility Act. An entity in NAICS 541710, 325413 or 325414 is considered small with 500 or fewer employees, in 325412 with 750 or fewer employees. An entity in NAICS 611310 is considered small with annual receipts/revenues of $6 million or less.

While the establishment size breakdown in the Economic Census does not precisely fit the SBA guidelines, it still shows that the vast majority (more than 90 percent) of life sciences research & development establishments can be considered small. More than 99 percent of biological (except diagnostic) manufacturing, more than 98 percent of diagnostic manufacturing, and at least 94 percent of pharmaceutical manufacturing are considered small. The economic census does not contain information on the establishment size of veterinary service entities. According to data from the U.S. Department of Education, about 31 percent of reporting postsecondary institutions had revenue of less than $6 million in fiscal year 1995–96.[26]

Based on the available information, this rule is not anticipated to have a substantial impact on a significant number of small entities.

Alternatives Considered

This rule has been prompted by the need to prevent the misuse of select agents and toxins and thereby reduce the potential for those pathogens to harm humans, animals, animal products, plants or plant products in the United States. In assessing the need for this rule, we considered several alternatives to the chosen course of action.

One alternative would be to maintain the status quo, where we rely on our authority to issue permits for the importation and interstate movement of agents and toxins as a basis for any actions we take to regulate select agents and toxins. We rejected this option. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), requires that the Secretary of Agriculture establish and enforce standards and procedures governing the possession and use of the listed biological agents and toxins, including the establishment and enforcement of safety requirements for the transfer of listed agents and toxins; the establishment and enforcement of safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or other criminal purpose; and the establishment of procedures to protect animal and plant health, and animal and plant products, in the event of a transfer in violation of the established safety and security measures.

Another alternative would involve variations to the chosen regulatory scheme. For example, we could have chosen prescriptive requirements for meeting the need for security around select agents and toxins. We rejected this option. Because different agents and toxins pose differing degrees risk, depending on factors such as their escape potential and availability of a suitable habitat (for plant-related agents) and transmission and effect of exposure to the agent or toxin (for overlap and animal agents or toxins), we believe that it would be counterproductive to attempt to prepare a detailed list of prescriptive requirements for entities (*i.e.*, a ''one size fits all'' design standard). Rather, we prepared a brief set of performance standards that we will consider to the degree to which they are appropriate to the risks presented by a particular agent or toxin, given its intended use and the location of the entity. In addition, these performance based standards allow for site-specific needs to be met in the most cost effective manner possible.

Conclusion

This rule is intended to prevent the misuse of select agents and toxins, and thereby reduce the potential for those pathogens to harm humans, animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally introduced into the United States, the consequences would be significant. Consequences could include disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. In any animal or plant disease outbreak, the government would incur the costs of eradication. Industry would be affected through the imposition of domestic and foreign quarantines, which would result in a loss of markets and destruction of animals/plants if commercial properties are found to be infected with the disease. Even though compensation can be paid for the destroyed property, repopulating (flocks, herds, fields, etc.) may be time consuming with additional losses from idle capital and lost markets. In addition, there is the potential for a disruption in the domestic food supply, whether through contamination, consumer perception, or both. Such a disruption can have a lasting influence on food demand and global trade.

While the costs associated with this rule could be considerable, some of those impacts are somewhat offset. For example, requirements such as USDA permit requirements for biosafety and containment and the mandate to update security at USDA facilities were in place prior to the implementation of the December 2002 interim rule. The flexibility in the rule also allows for site-specific needs to be met in the most cost effective manner possible. In addition, these costs are greatly outweighed by the benefits of preventing an unintentional or deliberate introduction of a select agent or toxin into the United States. The cost associated with outbreaks can be very high as is demonstrated by natural outbreaks that have occurred. Deliberate introduction greatly increases the probability of a select agent or toxin becoming established and causing wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and possible loss of life.

Paperwork Reduction Act

The December 2002 interim rule established regulations governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal health, to plant health, or to animal or plant products. This final rule includes certain regulatory provisions that differ from those included in the December 2002 interim rule. Some of those provisions involve changes from the information collection requirements set out in the December 2002 interim rule, which were approved by the Office of Management and Budget (OMB) under OMB control number 0579–0213 (expires May 31, 2005).

In a separate notice in today's issue of the **Federal Register**, APHIS is announcing that the information collection and recordkeeping requirements included in this final rule have been submitted for emergency approval to OMB.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA),

[26] IPEDS.

which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

■ Accordingly, 7 CFR part 331 and 9 CFR part 121 are revised to read as follows:

Title 7—Agriculture

■ 1. Revise part 331 to read as follows:

PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Sec.
331.1 Definitions.
331.2 Purpose and scope.
331.3 PPQ select agents and toxins.
331.4 [Reserved]
331.5 Exemptions.
331.6 [Reserved]
331.7 Registration and related security risk assessments.
331.8 Denial, revocation, or suspension of registration.
331.9 Responsible official.
331.10 Restricting access to select agents and toxins; security risk assessments.
331.11 Security.
331.12 Biocontainment.
331.13 Restricted experiments.
331.14 Incident response.
331.15 Training.
331.16 Transfers.
331.17 Records.
331.18 Inspections.
331.19 Notification of theft, loss, or release.
331.20 Administrative review.

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

§ 331.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Attorney General. The Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

Diagnosis. The analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

Entity. Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS Secretary. The Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin. A biological agent or toxin listed in 42 CFR 73.3.

Import. To move into, or the act of movement into, the territorial limits of the United States.

Interstate. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Permit. A written authorization by the Administrator to import or move interstate select agents or toxins, under conditions prescribed by the Administrator.

PPQ. The Plant Protection and Quarantine Programs of the Animal and Plant Health Inspection Service.

Responsible official. The individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Select agent and/or toxin. A biological agent or toxin listed in § 331.3.

Specimen. Samples of material from humans, animals, plants, or the environment, or isolates or cultures from such samples, for diagnosis, verification, or proficiency testing.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States. All of the States.

USDA. The U.S. Department of Agriculture.

Verification. The demonstration of obtaining established performance (*e.g.*, accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

§ 331.2 Purpose and scope.

This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to plant health or plant products.

§ 331.3 PPQ select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that the biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to plant health or to plant products.

(b) PPQ select agents and toxins:

Candidatus Liberobacter africanus;

Candidatus Liberobacter asiaticus;

Peronosclerospora philippinensis;

Ralstonia solanacearum, race 3, biovar 2;

Sclerophthora rayssiae var. *zeae*;

Synchytrium endobioticum;

Xanthomonas oryzae pv. *oryzicola*;

Xylella fastidiosa (citrus variegated chlorosis strain).

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional forms of any toxin listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*; or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro.*

(3) Select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable select agents or nonfunctional toxins.

(e) An attenuated strain of a select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to plant health or plant products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification of the applicant. Exclusions will be published periodically in the notice section of the **Federal Register** and will be listed on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html*.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin.

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to APHIS or CDC. The seizure must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the select agent or toxin. A copy of the completed form must be maintained for 3 years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin to APHIS or CDC by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for 3 years.

§ 331.4 [Reserved]

§ 331.5 Exemptions.

(a) Diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification, the agent or toxin is transferred in accordance with § 331.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin is immediately reported to APHIS or CDC by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification. Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas. A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) In addition to the exemption provided in paragraph (a) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting plant health or plant products. An individual or entity may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

§ 331.6 [Reserved]

§ 331.7 Registration and related security risk assessments.

(a) Unless exempted under § 331.5, an individual or entity shall not possess, use, or transfer any select agent or toxin without a certificate of registration issued by the Administrator.

(b) As a condition of registration, each entity must designate an individual to be its responsible official. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, the individual will be considered the responsible official.

(c)(1) As a condition of registration, the following must be approved by the Administrator or the HHS Secretary based on a security risk assessment by the Attorney General:

(i) The individual or entity;

(ii) The responsible official; and

(iii) Unless otherwise exempted under this section, any individual who owns or controls the entity.

(2) Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.

(3) An individual will be deemed to own or control an entity under the following conditions: [1]

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the

[1] These conditions may apply to more than one individual.

entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock; or

(B) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

(5) To obtain a security risk assessment, an individual or entity must submit the information necessary to conduct a security risk assessment to the Attorney General.

(d) To apply for a certificate of registration for only PPQ select agents or toxins, or for PPQ and VS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS. To apply for a certificate of registration for overlap select agents or toxins, overlap select agents or toxins and any combination of PPQ or VS select agents or toxins, or HHS select agents or toxins and any combination of PPQ or VS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS or CDC, but not both.

(e) Prior to the issuance of a certificate of registration, the responsible official must promptly provide notification of any changes to the application for registration by submitting the relevant page(s) of the registration application.

(f) The issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(g) A certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the responsible official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

(h) A certificate of registration may be amended to reflect changes in circumstances (*e.g.*, replacement of the responsible official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).

(1) Prior to any change, the responsible official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.[2]

(2) The responsible official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of an amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(3) No change may be made without such approval.

(i) An entity must immediately notify APHIS or CDC if it loses the services of its responsible official. In the event that an entity loses the services of its responsible official, an entity may continue to possess or use select agents or toxins only if it appoints as the responsible official another individual who has been approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of this part.

(j) A certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered.

(k) A certificate of registration will be valid for a maximum of 3 years.

§ 331.8 Denial, revocation, or suspension of registration.

(a) An application may be denied or a certificate of registration revoked or suspended if:

(1) The individual or entity, the responsible official, or an individual who owns or controls the entity is within any of the categories described in 18 U.S.C. 175b;

(2) The individual or entity, the responsible official, or an individual who owns or controls the entity is reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801;

(3) The individual or entity does not meet the requirements of this part;[3] or

(4) It is determined that such action is necessary to protect plant health or plant products.

(b) Upon revocation or suspension of a certificate of registration, the individual or entity must:

(1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order;

(2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release; and

(3) Comply with all disposition instructions issued by the Administrator for each select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation or suspension of registration may be appealed under § 331.20. However, any denial of an application for registration or revocation or suspension of a certificate of registration will remain in effect until a final agency decision has been rendered.

§ 331.9 Responsible official.

(a) An individual or entity required to register under this part must designate an individual to be the responsible official. The responsible official must:

(1) Be approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General;

(2) Be familiar with the requirements of this part;

(3) Have authority and responsibility to act on behalf of the entity;

(4) Ensure compliance with the requirements of this part; and

(5) Ensure that annual inspections are conducted of each laboratory where select agents or toxins are stored or used in order to ensure compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

(b) An entity may designate one or more individuals to be an alternate

[2] Depending on the change, a security risk assessment by the Attorney General may also be required (*e.g.*, replacement of the responsible official, changes in ownership or control of the entity, new researchers or graduate students, etc.).

[3] If registration is denied for this reason, we may provide technical assistance and guidance.

responsible official, who may act for the responsible official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official.

(c) The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen for diagnosis or verification.

(1) The identification of the select agent or toxin must be immediately reported by telephone, facsimile, or e-mail. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(2) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

§ 331.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (*e.g.*, carries, uses, or manipulates) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) An individual's security risk assessment may be expedited upon written request by the responsible official and a showing of good cause (*e.g.*, agricultural emergencies, national security, or a short-term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(f) An individual's access approval may be denied, limited, or revoked if:

(1) The individual is within any of the categories described in 18 U.S.C. 175b;

(2) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) It is determined that such action is necessary to protect plant health or plant products.

(g) An individual may appeal the Administrator's decision to deny, limit, or revoke access approval under § 331.20.

(h) Access approval is valid for a maximum of 5 years.

(i) The responsible official must immediately notify APHIS or CDC when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

§ 331.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control;

(2) Contain provisions for the control of access to select agents and toxins;

(3) Contain provisions for routine cleaning, maintenance, and repairs;

(4) Establish procedures for removing unauthorized or suspicious persons;

(5) Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes;

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records; and

(7) Contain provisions for ensuring that all individuals with access approval from the Administrator or the HHS Secretary understand and comply with the security procedures.

(d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:

(1) Allow access only to individuals with access approval from the Administrator or the HHS Secretary;

(2) Allow individuals not approved for access by the Administrator or the HHS Secretary to conduct routine cleaning, maintenance, repairs, and other activities not related to select agents or toxins only when continuously escorted by an approved individual;

(3) Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (*e.g.*, card access system, lock boxes);

(4) Inspect all suspicious packages before they are brought into or removed from an area where select agents or toxins are used or stored;

(5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the Administrator or the HHS Secretary, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release; and

(6) Require that individuals with access approval from the Administrator or the HHS Secretary refrain from sharing with any other person their unique means of accessing a select agent or toxin (*e.g.*, keycards or passwords);

(7) Require that individuals with access approval from the Administrator or the HHS Secretary immediately report any of the following to the responsible official:

(i) Any loss or compromise of keys, passwords, combinations, etc.;

(ii) Any suspicious persons or activities;

(iii) Any loss or theft of select agents or toxins;

(iv) Any release of a select agent or toxin; and

(v) Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised; and

(8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) In developing a security plan, an individual or entity should consider the document entitled, ''Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents,'' in Morbidity and Mortality Weekly Report (December 6, 2002); 51 (No. RR–19):1–6. This document is available on the Internet at *http://www.cdc.gov/mmwr.*

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the

effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 331.12 Biocontainment.

(a) An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use.[4] The biocontainment plan must contain sufficient information and documentation to describe the containment procedures.

(b) The biocontainment procedures must be sufficient to contain the select agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biocontainment plan, an individual or entity should consider the following:

(1) ''Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests'' (Robert P. Kahn and S.B. Mathur eds., 1999); and

(2) ''A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes'' (Patricia L. Traynor ed., 2001).

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 331.13 Restricted experiments.[5]

(a) An individual or entity may not conduct the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD_{50}<100 ng/kg body weight.

(b) The Administrator may revoke approval to conduct any of the experiments in paragraph (a) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(c) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information to the Administrator. A written decision granting or denying the request will be issued.

§ 331.14 Incident response.[6]

(a) An individual or entity required to register under this part must develop and implement a written incident response plan.[7] The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

(c) The incident response plan must also contain the following information:

(1) The name and contact information (*e.g.*, home and work) for the individual or entity (*e.g.*, responsible official, alternate responsible official(s), biosafety officer, etc.);

(2) The name and contact information for the building owner and/or manager, where applicable;

(3) The name and contact information for tenant offices, where applicable;

(4) The name and contact information for the physical security official for the building, where applicable;

(5) Personnel roles and lines of authority and communication;

(6) Planning and coordination with local emergency responders;

(7) Procedures to be followed by employees performing rescue or medical duties;

(8) Emergency medical treatment and first aid;

(9) A list of personal protective and emergency equipment, and their locations;

(10) Site security and control;

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge; and

(12) Decontamination procedures.

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 331.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment and security to each individual with access approval from the Administrator or the HHS Secretary before he/she has such access. In addition, an individual or entity must provide information and training on biocontainment and security to each individual not approved for access by the Administrator or the HHS Secretary before he/she works in or visits areas where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.

(b) Refresher training must be provided annually.

(c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of training, a description of the training provided, and the means used to verify that the employee understood the training.

§ 331.16 Transfers.

(a) Except as provided in paragraph (c) of this section, a select agent or toxin may only be transferred to an individual or entity registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by APHIS or CDC prior to the transfer.[8]

(b) In addition to any permit required under part 330 of this chapter, a transfer may be authorized if:

(1) The sender:

[4] Technical assistance and guidance may be obtained by contacting APHIS.

[5] For guidance, see the NIH publication, ''NIH Guidelines for Research Involving Recombinant DNA Molecules.'' This document is available on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.*

[6] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

[7] Technical assistance and guidance may be obtained by contacting APHIS.

[8] The requirements of this section do not apply to transfers within a registered entity (*i.e.*, the sender and the recipient are covered by the same certificate of registration).

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all the requirements of this part;

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred; or

(iii) Is transferring the select agent or toxin from outside of the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) On a case-by-case basis, the Administrator may authorize a transfer of a select agent or toxin not otherwise eligible for transfer under this part under conditions prescribed by the Administrator.

(d) To obtain authorization for a transfer, APHIS/CDC Form 2 must be submitted.

(e) The recipient must submit a completed APHIS/CDC Form 2 within 2 business days of receipt of a select agent or toxin.

(f) The recipient must immediately notify APHIS or CDC if the select agent or toxin has not been received within 48 hours after the expected delivery time or if the package containing the select agent or toxin has been damaged to the extent that a release of the select agent or toxin may have occurred.

(g) An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (*e.g.*, change in the certificate of registration for the sender or recipient, change in the application for transfer).

(h) The sender must comply with all applicable laws governing packaging and shipping.

§ 331.17 Records.

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.*, strain designation, GenBank Accession number, etc.);

(ii) The quantity acquired from another individual or entity (*e.g.*, containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) Where stored (*e.g.*, building, room, and freezer);

(iv) When moved from storage and by whom and when returned to storage and by whom;

(v) The select agent used and purpose of use;

(vi) Records created under § 331.16 (Transfers);

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient; and

(viii) Records created under § 331.19 (Notification of theft, loss, or release);

(2) An accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (*e.g.*, containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) The initial and current quantity amount (*e.g.*, milligrams, milliliters, grams, etc.);

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom;

(v) Where stored (*e.g.*, building, room, and freezer);

(vi) When moved from storage and by whom and when returned to storage and by whom, including quantity amount;

(vii) Records created under § 331.16 (Transfers);

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient;

(ix) Records created under § 331.19 (Notification of theft, loss, or release);

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom.

(3) A current list of all individuals that have been granted access approval by the Administrator or the HHS Secretary;

(4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and the date and time of entry;

(5) Accurate, current records created under § 331.9(c) (Responsible official), § 331.11 (Security), § 331.12 (Biocontainment), § 331.14 (Incident response), and § 331.15 (Training); and

(6) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and databases created under this part are accurate, have controlled access, and can be verified for authenticity.

(c) All records created under this part must be maintained for 3 years and promptly produced upon request.

§ 331.18 Inspections.

(a) Without prior notification, APHIS must be allowed to inspect any site at which activities regulated under this part are conducted and must be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, APHIS may inspect and evaluate their premises and records to ensure compliance with this part.

§ 331.19 Notification of theft, loss, or release.

(a) An individual or entity must immediately notify APHIS or CDC upon discovery of the theft or loss of a select agent or toxin. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(ii) An estimate of the quantity stolen or lost;

(iii) An estimate of the time during which the theft or loss occurred;

(iv) The location (building, room) from which the theft or loss occurred; and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report, the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

(b) An individual or entity must notify APHIS or CDC immediately upon discovery of a release of a select agent or toxin outside of the primary barriers of the biocontainment area.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(ii) An estimate of the quantity released;

(iii) The time and duration of the release;

(iv) The environment into which the release occurred (*e.g.*, in building or outside of building, waste system);

(v) The location (building, room) from which the release occurred; and

(vi) The number of individuals potentially exposed at the entity;

(vii) Actions taken to respond to the release; and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

§ 331.20 Administrative review.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part.[9] The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The Administrator's decision constitutes final agency action.

Title 9—Animals and Animal Products

■ 2. Revise part 121 to read as follows:

PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Sec.

121.1 Definitions.
121.2 Purpose and scope.
121.3 VS select agents and toxins.
121.4 Overlap select agents and toxins.
121.5 Exemptions for VS select agents and toxins.
121.6 Exemptions for overlap select agents and toxins.
121.7 Registration and related security risk assessments.
121.8 Denial, revocation, or suspension of registration.
121.9 Responsible official.
121.10 Restricting access to select agents and toxins; security risk assessments.
121.11 Security.
121.12 Biosafety.
121.13 Restricted experiments.
121.14 Incident response.
121.15 Training.
121.16 Transfers.
121.17 Records.
121.18 Inspections.
121.19 Notification of theft, loss, or release.
121.20 Administrative review.

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

[9] An entity may not appeal the denial or limitation of an individual's access to select agents or toxins.

§ 121.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Attorney General. The Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

Diagnosis. The analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

Entity. Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS Secretary. The Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin. A biological agent or toxin listed in 42 CFR 73.3.

Import. To move into, or the act of movement into, the territorial limits of the United States.

Interstate. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Overlap select agent and/or toxin. A biological agent or toxin that is listed in § 121.4 and 42 CFR 73.4.

Permit. A written authorization by the Administrator to import or move interstate select agents or toxins, under conditions prescribed by the Administrator.

Proficiency testing. The process of determining the competency of an individual or laboratory to perform a specified test or procedure.

Responsible official. The individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Select agent and/or toxin. Unless otherwise specified, all of the biological agents or toxins listed in §§ 121.3 and 121.4.

Specimen. Samples of material from humans, animals, plants, or the environment, or isolates or cultures from such samples, for diagnosis, verification, or proficiency testing.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States. All of the States.

USDA. The U.S. Department of Agriculture.

Verification. The demonstration of obtaining established performance (*e.g.,* accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

VS. The Veterinary Services Programs of the Animal and Plant Health Inspection Service.

VS select agent and/or toxin. A biological agent or toxin listed in § 121.3.

§ 121.2 Purpose and scope.

This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety,

to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS and CDC.

§ 121.3 VS select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to animal health or to animal products.

(b) VS select agents and toxins:

African horse sickness virus;

African swine fever virus;

Akabane virus;

Avian influenza virus (highly pathogenic);

Bluetongue virus (exotic);

Bovine spongiform encephalopathy agent;

Camel pox virus;

Classical swine fever virus;

Cowdria ruminantium (Heartwater);

Foot-and-mouth disease virus;

Goat pox virus;

Japanese encephalitis virus;

Lumpy skin disease virus;

Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1);

Menangle virus;

Mycoplasma capricolum/*M.* F38/*M. mycoides capri* (contagious caprine pleuropneumonia);

Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia);

Newcastle disease virus (velogenic);

Peste des petits ruminants virus;

Rinderpest virus;

Sheep pox virus;

Swine vesicular disease virus;

Vesicular stomatitis virus (exotic).

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.[1]

(2) Recombinant nucleic acids that encode for the functional forms of any toxin listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro;* or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro.*

(3) VS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) VS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any VS select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable VS select agents or nonfunctional VS toxins.[2]

(e) An attenuated strain of a VS select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to animal health or to animal products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification of the applicant. Exclusions will be published periodically in the notice section of the **Federal Register** and will be listed on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.*

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any VS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin.

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to APHIS or CDC.

(i) The seizure of any of the following VS select agents and toxins must be reported within 24 hours by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), bovine spongiform encephalopathy agent, classical swine fever virus, foot-and-mouth disease virus, Newcastle disease virus (velogenic), rinderpest virus, and swine vesicular disease virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the select agent or toxin.

(ii) For all other VS select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for 3 years.

§ 121.4 Overlap select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products.

(b) Overlap select agents and toxins:

Bacillus anthracis;

Botulinum neurotoxins;

Botulinum neurotoxin producing species of *Clostridium;*

Brucella abortus;

Brucella melitensis;

Brucella suis;

Burkholderia mallei;

Burkholderia pseudomallei;

Clostridium perfringens epsilon toxin;

Coccidioides immitis;

Coxiella burnetii;

Eastern equine encephalitis virus;

Francisella tularensis;

Hendra virus;

Nipah virus;

Rift Valley fever virus;

Shigatoxin;

Staphylococcal enterotoxins;

T–2 toxin;

Venezuelan equine encephalitis virus.

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Nucleic acids that can produce infectious forms of any of the overlap

[1] The importation and interstate movement of VS select agents or toxins listed in paragraphs (c)(1) through (c)(3) of this section may be subject to the permit requirements under part 122 of this subchapter.

[2] However, the importation and interstate movement of these nonviable select agents may be subject to the permit requirements under part 122 of this subchapter.

select agent viruses listed in paragraph (b) of this section.[3]

(2) Recombinant nucleic acids that encode for the functional forms of any overlap toxin listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro;* or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable overlap select agents or nonfunctional overlap toxins.[4]

(3) Overlap toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins, 100 mg of *Clostridium perfringens* epsilon toxin, 100 mg of Shigatoxin, 5 mg of Staphylococcal enterotoxins, and 1,000 mg of T–2 toxin.

(e) An attenuated strain of an overlap select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety, to animal health, or to animal products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification of the applicant. Exclusions will be published periodically in the notice section of the **Federal Register** and will be listed on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.*

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting overlap select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any overlap select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin.

(3) The Federal law enforcement agency reports the seizure of the overlap select agent or toxin to APHIS or CDC.

(i) The seizure of any of the following overlap select agents and toxins must be reported within 24 hours by telephone, facsimile, or e-mail: *Bacillus anthracis, Botulinum neurotoxins, Brucella melitensis, Francisella tularensis,* Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the overlap select agent or toxin.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(4) The Federal law enforcement agency reports the final disposition of the overlap select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for 3 years.

§ 121.5 Exemptions for VS select agents and toxins.

(a) Diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification, the agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin is reported to APHIS or CDC.

(i) The identification of any of the following select agents and toxins must be immediately reported by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), bovine spongiform encephalopathy agent, classical swine fever virus, foot-and-mouth disease virus, Newcastle disease virus (velogenic), rinderpest virus, and swine vesicular disease virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) For all other VS select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

(iii) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(iv) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) Diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 90 calendar days of receipt, the agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin, and its derivative, is reported to APHIS or CDC. To report the

[3] The importation and interstate movement of overlap select agents or toxins listed in paragraphs (c)(1) through (c)(3) of this section may be subject to the permit requirements under part 122 of this subchapter.

[4] However, the importation and interstate movement of these nonviable overlap select agents may be subject to the permit requirements under part 122 of this subchapter.

identification of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

(c) Diagnostic reagents and vaccines that are, bear, or contain VS select agents or toxins that are produced at USDA diagnostic facilities will be exempt from the requirements of this part.

(d) Unless the Administrator by order determines that additional regulation is necessary to protect animal health or animal products, products that are, bear, or contain VS select agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

(e) The Administrator may exempt from the requirements of this part an experimental product that is, bears, or contains a VS select agent or toxin if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal health or animal products. To apply for an exemption, an individual or entity must submit APHIS/CDC Form 5. A written decision granting or denying the exemption will be issued. The applicant must notify APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(f) In addition to the exemptions provided in paragraphs (a) through (e) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal health or animal products. An individual or entity may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

§ 121.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator or the HHS Secretary, within 7 calendar days after identification, the agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin is reported to APHIS or CDC.

(i) The identification of any of the following overlap select agents and toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis, Botulinum neurotoxins, Brucella melitensis, Francisella tularensis,* Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

(iii) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(iv) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator or the HHS Secretary, within 90 days of receipt, the agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin, and its derivative, is reported to APHIS or CDC. To report the identification of an overlap select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

(c) Unless the Administrator by order determines that additional regulation of a specific product is necessary to protect animal health or animal products, products that are, bear, or contain overlap select agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

(d) After consultation with the HHS Secretary, the Administrator may exempt from the requirements of this part an investigational product that is, bears, or contains an overlap select agent or toxin if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal health or animal products.

(1) To apply for an exemption, an individual or entity must submit APHIS/CDC Form 5.

(2) The Administrator will make a determination regarding an exemption within 14 calendar days after receipt of the application and notification that the investigation has been authorized under a Federal law. A written decision granting or denying the exemption will be issued.

(3) The applicant must notify APHIS or CDC when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The Administrator may exempt an individual or entity from the

requirements of this part for 30 calendar days if it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap select agent or toxin. The Administrator may extend the exemption once for an additional 30 days. An individual or entity may apply for this exemption by submitting APHIS/CDC Form 5. A written decision granting or denying the exemption will be issued.

(f) Upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements of this part for 30 calendar days if the Secretary of Health and Human Services has granted an exemption for a public health emergency involving an overlap select agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

§ 121.7 Registration and related security risk assessments.

(a) Unless exempted under § 121.5, an individual or entity shall not possess, use, or transfer any VS select agent or toxin without a certificate of registration issued by the Administrator. Unless exempted under § 121.6 or 42 CFR 73.6, an individual or entity shall not possess, use, or transfer any overlap select agent or toxin without a certificate of registration issued by the Administrator and the HHS Secretary.

(b) As a condition of registration, each entity must designate an individual to be its responsible official. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, the individual will be considered the responsible official.

(c)(1) As a condition of registration, the following must be approved by the Administrator or the HHS Secretary based on a security risk assessment by the Attorney General:

(i) The individual or entity;

(ii) The responsible official; and

(iii) Unless otherwise exempted under this section, any individual who owns or controls the entity.

(2) Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.

(3) An individual will be deemed to own or control an entity under the following conditions: [5]

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock; or

(B) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

(5) To obtain a security risk assessment, an individual or entity must submit the information necessary to conduct a security risk assessment to the Attorney General.

(d) To apply for a certificate of registration for only VS select agents or toxins, or for VS and PPQ select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS. To apply for a certificate of registration for overlap select agents or toxins, overlap select agents or toxins and any combination of PPQ or VS select agents or toxins, or HHS select agents or toxins and any combination of PPQ or VS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS or CDC, but not both.

(e) Prior to the issuance of a certificate of registration, the responsible official must promptly provide notification of any changes to the application for registration by submitting the relevant page(s) of the registration application.

(f) The issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(g) A certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the responsible official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

(h) A certificate of registration may be amended to reflect changes in circumstances (*e.g.*, replacement of the responsible official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).

(1) Prior to any change, the responsible official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.[6]

(2) The responsible official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of an amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(3) No change may be made without such approval.

(i) An entity must immediately notify APHIS or CDC if it loses the services of its responsible official. In the event that an entity loses the services of its responsible official, an entity may continue to possess or use select agents or toxins only if it appoints as the responsible official another individual who has been approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of this part.

(j) A certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered.

(k) A certificate of registration will be valid for a maximum of 3 years.

§ 121.8 Denial, revocation, or suspension of registration.

(a) An application may be denied or a certificate of registration revoked or suspended if:

(1) The individual or entity, the responsible official, or an individual who owns or controls the entity is within any of the categories described in 18 U.S.C. 175b;

(2) The individual or entity, the responsible official, or an individual

[5] These conditions may apply to more than one individual.

[6] Depending on the change, a security risk assessment by the Attorney General may also be required (*e.g.*, replacement of the responsible official, changes in ownership or control of the entity, new researchers or graduate students, etc.)

who owns or controls the entity is reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801;

(3) The individual or entity does not meet the requirements of this part;[7] or

(4) It is determined that such action is necessary to protect animal health or animal products.

(b) Upon revocation or suspension of a certificate of registration, the individual or entity must:

(1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order;

(2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release; and

(3) Comply with all disposition instructions issued by the Administrator for each select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 121.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

§ 121.9 Responsible official.

(a) An individual or entity required to register under this part must designate an individual to be the responsible official. The responsible official must:

(1) Be approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General;

(2) Be familiar with the requirements of this part;

(3) Have authority and responsibility to act on behalf of the entity;

(4) Ensure compliance with the requirements of this part; and

(5) Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

[7] If registration is denied for this reason, we may provide technical assistance and guidance.

(b) An entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official.

(c) The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification.

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), *Bacillus anthracis, Botulinum neurotoxins,* bovine spongiform encephalopathy agent, *Brucella melitensis,* classical swine fever virus, foot-and-mouth disease virus, *Francisella tularensis,* Hendra virus, Newcastle disease virus (velogenic), Nipah virus, Rift Valley fever virus, rinderpest virus, swine vesicular disease virus, and Venezuelan equine encephalitis virus. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(2) To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(3) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(d) The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

§ 121.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (*e.g.*, carries, uses, or manipulates) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) An individual's security risk assessment may be expedited upon written request by the responsible official and a showing of good cause (*e.g.*, public health or agricultural emergencies, national security, or a short-term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(f) An individual's access approval for VS select agents or toxins may be denied, limited, or revoked if:

(1) The individual is within any of the categories described in 18 U.S.C. 175b;

(2) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) It is determined that such action is necessary to protect animal health or animal products.

(g) For overlap select agents or toxins, an individual's access approval will be denied or revoked if the individual is within any of the categories described in 18 U.S.C. 175b. An individual's access approval may be denied, limited, or revoked for the reasons set forth in paragraphs (f)(2) through (f)(3) of this section.

(h) An individual may appeal the Administrator's decision to deny, limit, or revoke access approval under § 121.20.

(i) Access approval is valid for a maximum of 5 years.

(j) The responsible official must immediately notify APHIS or CDC when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

§ 121.11 Security.

(a) An individual or entity required to register under this part must develop

and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control;

(2) Contain provisions for the control of access to select agents and toxins;

(3) Contain provisions for routine cleaning, maintenance, and repairs;

(4) Establish procedures for removing unauthorized or suspicious persons;

(5) Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes;

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records; and

(7) Contain provisions for ensuring that all individuals with access approval from the Administrator or the HHS Secretary understand and comply with the security procedures.

(d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:

(1) Allow access only to individuals with access approval from the Administrator or the HHS Secretary;

(2) Allow individuals not approved for access by the Administrator or the HHS Secretary to conduct routine cleaning, maintenance, repairs, and other activities not related to select agents or toxins only when continuously escorted by an approved individual;

(3) Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (*e.g.*, card access system, lock boxes);

(4) Inspect all suspicious packages before they are brought into or removed from an area where select agents or toxins are used or stored;

(5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the Administrator or the HHS Secretary, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release; and

(6) Require that individuals with access approval from the Administrator or the HHS Secretary refrain from sharing with any other person their unique means of accessing a select agent or toxin (*e.g.*, keycards or passwords);

(7) Require that individuals with access approval from the Administrator or the HHS Secretary immediately report any of the following to the responsible official:

(i) Any loss or compromise of keys, passwords, combinations, etc.;

(ii) Any suspicious persons or activities;

(iii) Any loss or theft of select agents or toxins;

(iv) Any release of a select agent or toxin; and

(v) Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised; and

(8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) In developing a security plan, an individual or entity should consider the document entitled, ''Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents,'' in Morbidity and Mortality Weekly Report (December 6, 2002); 51 (No. RR–19):1–6. This document is available on the Internet at *http://www.cdc.gov/mmwr.*

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.[8] The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider the following:

(1) The CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories.'' This document may be obtained from the U.S. Government Printing Office. It is also available on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.*

(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR 1910.1200 and 1910.1450.

(3) The ''NIH Guidelines for Research Involving Recombinant DNA Molecules.'' This document is available on the Internet at *http://www.aphis.usda.gov./programs/ag_selectagent/index.html.*

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 121.13 Restricted experiments.[9]

(a) An individual or entity may not conduct a restricted experiment with a VS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the Administrator. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the Administrator and the HHS Secretary.

(b) Restricted experiments:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD_{50} <100 ng/kg body weight.

(c) The Administrator may revoke approval to conduct any of the experiments in paragraph (b) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(d) To apply for approval to conduct any of the experiments in paragraph (b) of this section, an individual or entity must submit a written request and

[8] Technical assistance and guidance may be obtained by contacting APHIS.

[9] For guidance, see the NIH publication, ''NIH Guidelines for Research Involving Recombinant DNA Molecules.'' This document is available on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.*

supporting scientific information. A written decision granting or denying the request will be issued.

§ 121.14 Incident response.[10]

(a) An individual or entity required to register under this part must develop and implement a written incident response plan.[11] The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

(c) The incident response plan must also contain the following information:

(1) The name and contact information (*e.g.*, home and work) for the individual or entity (*e.g.*, responsible official, alternate responsible official(s), biosafety officer, etc.);

(2) The name and contact information for the building owner and/or manager, where applicable;

(3) The name and contact information for tenant offices, where applicable;

(4) The name and contact information for the physical security official for the building, where applicable;

(5) Personnel roles and lines of authority and communication;

(6) Planning and coordination with local emergency responders;

(7) Procedures to be followed by employees performing rescue or medical duties;

(8) Emergency medical treatment and first aid;

(9) A list of personal protective and emergency equipment, and their locations;

(10) Site security and control;

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge; and

(12) Decontamination procedures.

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 121.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the Administrator or the HHS Secretary before he/she has such access. In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access by the Administrator or the HHS Secretary before he/she works in or visits areas where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.[12]

(b) Refresher training must be provided annually.

(c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of training, a description of the training provided, and the means used to verify that the employee understood the training.

§ 121.16 Transfers.

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by APHIS or CDC prior to the transfer.[13]

(b) In addition to any permit required under part 122 of this subchapter, a transfer may be authorized if:

(1) The sender:

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all the requirements of this part;

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred; or

(iii) Is transferring the select agent or toxin from outside of the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from APHIS or CDC provided that, at least 7 calendar days prior to the transfer, the sender reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the Administrator may authorize a transfer of a select agent or toxin not otherwise eligible for transfer under this part under conditions prescribed by the Administrator.

(e) To obtain authorization for a transfer, APHIS/CDC Form 2 must be submitted.

(f) The recipient must submit a completed APHIS/CDC Form 2 within 2 business days of receipt of a select agent or toxin.

(g) The recipient must immediately notify APHIS or CDC if the select agent or toxin has not been received within 48 hours after the expected delivery time or if the package containing the select agent or toxin has been damaged to the extent that a release of the select agent or toxin may have occurred.

(h) An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (*e.g.*, change in the certificate of registration for the sender or recipient, change in the application for transfer).

(i) The sender must comply with all applicable laws governing packaging and shipping.

§ 121.17 Records.

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.*, strain designation, GenBank Accession number, etc.);

[10] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

[11] Technical assistance and guidance may be obtained by contacting APHIS.

[12] For guidance, see the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories.'' This document is available on the Internet at *http://www.aphis.usda.gov/programs/ag_selectagent/index.html.*

[13] The requirements of this section do not apply to transfers within a registered entity (*i.e.*, the sender and the recipient are covered by the same certificate of registration).

(ii) The quantity acquired from another individual or entity (*e.g.*, containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) Where stored (*e.g.*, building, room, and freezer);

(iv) When moved from storage and by whom and when returned to storage and by whom;

(v) The select agent used and purpose of use;

(vi) Records created under § 121.16 or 42 CFR 73.16 (Transfers);

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient; and

(viii) Records created under § 121.19 or 42 CFR 73.19 (Notification of theft, loss, or release);

(2) An accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (*e.g.*, containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) The initial and current quantity amount (*e.g.*, milligrams, milliliters, grams, etc.);

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom;

(v) Where stored (*e.g.*, building, room, and freezer);

(vi) When moved from storage and by whom and when returned to storage and by whom, including quantity amount;

(vii) Records created under § 121.16 or 42 CFR 73.16 (Transfers);

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient;

(ix) Records created under § 121.19 or 42 CFR 73.19 (Notification of theft, loss, or release);

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom.

(3) A current list of all individuals that have been granted access approval by the Administrator or the HHS Secretary;

(4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and the date and time of entry;

(5) Accurate, current records created under § 121.9 or 42 CFR 73.9 (Responsible official), § 121.11 or 42 CFR 73.11 (Security), § 121.12 or 42 CFR 73.12 (Biosafety), § 121.14 or 42 CFR 73.14 (Incident response), and § 121.15 or 42 CFR 73.15 (Training); and

(6) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and databases created under this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for 3 years and promptly produced upon request.

§ 121.18 Inspections.

(a) Without prior notification, APHIS must be allowed to inspect any site at which activities regulated under this part are conducted and must be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, APHIS may inspect and evaluate the premises and records to ensure compliance with this part.

§ 121.19 Notification of theft, loss, or release.

(a) An individual or entity must immediately notify APHIS or CDC upon discovery of the theft or loss of a select agent or toxin. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(ii) An estimate of the quantity stolen or lost;

(iii) An estimate of the time during which the theft or loss occurred;

(iv) The location (building, room) from which the theft or loss occurred; and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report, the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

(b) An individual or entity must immediately notify APHIS or CDC upon discovery of a release of a select agent or toxin causing occupational exposure or a release of a select agent or toxin outside of the primary barriers of the biocontainment area.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(ii) An estimate of the quantity released;

(iii) The time and duration of the release;

(iv) The environment into which the release occurred (*e.g.*, in building or outside of building, waste system);

(v) The location (building, room) from which the release occurred; and

(vi) The number of individuals potentially exposed at the entity;

(vii) Actions taken to respond to the release; and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

§ 121.20 Administrative review.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part.[14] The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The Administrator's decision constitutes final agency action.

Done in Washington, DC, this 10th day of March, 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–5063 Filed 3–17–05; 8:45 am]

BILLING CODE 3410–34–P

[14] An entity may not appeal the denial or limitation of an individual's access to select agents or toxins.

Federal Register

Friday,
March 18, 2005

Part III

Department of Health and Human Services

42 CFR Parts 72 and 73

Office of Inspector General

42 CFR Part 1003

Possession, Use, and Transfer of Select Agents and Toxins; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 72 and 73

Office of Inspector General

42 CFR Part 1003

RIN 0920–AA09

Possession, Use, and Transfer of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention, Office of Inspector General, Department of Health Human Services (HHS).

ACTION: Final rule.

SUMMARY: This document establishes a final rule regarding possession, use, and transfer of select agents and toxins. The final rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and is designed to protect public health and safety.

In a companion document published in this issue of the **Federal Register**, the United States Department of Agriculture has established corresponding final rules designed to protect animal and plant health and animal and plant products.

DATES: The final rule is effective April 18, 2005.

FOR FURTHER INFORMATION CONTACT: Mark Hemphill, Chief of Policy, Select Agent Program, Centers For Disease Control and Prevention, 1600 Clifton Rd., MS E–79, Atlanta, GA 30333. Telephone: (404) 498–2255.

SUPPLEMENTARY INFORMATION: This document establishes a final rule regarding possession, use, and transfer of select agents and toxins. The final rule is based on the interim final rule, as amended (amended interim final rule). The initial interim final rule was published in the **Federal Register** on December 13, 2002 (67 FR 76886). It was amended by a second interim final rule published in the **Federal Register** on November 3, 2003 (68 FR 62245). The initial interim final rule established a comprehensive set of regulations that included requirements concerning registration and security risk assessments. The second interim final rule amended the first interim final rule by allowing for the issuance of provisional certificates of registration and provisional grants of access to select agents and toxins, subject to completion of security risk assessments, and compliance with all of the requirements of the initial interim final rule. The final rule, which is set forth at 42 FR part 73, implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) and is designed to protect public health and safety.

In general, this final rule contains provisions that apply to academic institutions and biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; and research facilities.

For the initial interim final rule, we provided for a 60-day comment period for written comments that ended February 11, 2003. We also held a public meeting on December 16, 2002. Relevant issues raised by the comments (oral comments made at the public meeting and 110 written comments) are discussed below. For the second interim final rule, we provided for a 60-day comment period for written comments that ended January 2, 2004. We received no comments in response to the second interim final rule. Based on the rationale set forth in the initial interim final rule, the second interim final rule, and this document, we are affirming the provisions of the amended interim final rule as a final rule with changes discussed below.

The final rule is designed to implement authorities under the Act to protect public health and safety. The United States Department of Agriculture (USDA) has established corresponding sets of regulations designed to protect animal and plant health and animal and plant products (9 CFR part 121 and 7 CFR part 331).

42 CFR Part 1003

The initial interim final rule amended 42 CFR part 1003 to establish delegations of authority and other provisions involving the Office of Inspector General (OIG) of HHS. In addition to adding a new paragraph (b)(16) to § 1003.102 to authorize the imposition of civil money penalties for violations of the regulatory provisions, the interim final rule also sought public comments on the possible inclusion of specific factors that might be used to assess specific penalty amounts. The amended interim final rule had no effect on the OIG amendments and we received no comments regarding these amendments. However, since amendatory language to the OIG regulations addressing determinations regarding the amount of a penalty was not originally included in the initial interim final rule, we are now revising § 1003.106(a)(1) to reference the newly codified § 1003.102(b)(16) and the factors to be taken into account when the OIG assesses civil money penalties. We are affirming all other amendments set forth in the interim final rule.

42 CFR 72.6 and Its Accompanying Appendix A

The provisions of the final rule supersede all of the provisions at 42 CFR 72.6 (captioned ''Additional requirements for facilities transferring or receiving select agents'') and its accompanying Appendix A. However, the provisions of 18 U.S.C. 175b include prohibitions that are based on the list of select agents in Appendix A of 42 CFR part 72 and exemptions to such list in § 72.6(h). Accordingly, we have deleted the superseded provisions and in their place have added language to indicate that for purposes of 18 U.S.C. 175b the list of select agents are set forth in §§ 73.3 and 73.4 and the exemptions are set forth in §§ 73.5 and 73.6.

Changes in Structure in Part 73

With respect to the sections in part 73, we changed the final rule to make the structure and format of the HHS regulations and the USDA regulations at 9 CFR part 121 more similar. The following chart shows the changes.

Amended interim final rule	Final rule
73.1 Definitions	73.1 Definitions.
73.2 Purpose and scope	73.2 Purpose and scope.
73.3 General prohibition	73.3 HHS select agents and toxins.
73.4 HHS select agents and toxins	73.4 Overlap select agents and toxins.
73.5 Overlap select agents and toxins	73.5 Exemptions for HHS select agents and toxins.
73.6 Exemptions from requirements under this part	73.6 Exemptions for overlap select agents and toxins.
73.71 Registration	73.7 Registration and related security risk assessments.
73.8 Security Risk Assessments	73.8 Denial, revocation, or suspension of registration.
73.9 Responsible Official	73.9 Responsible Official.

Amended interim final rule	Final rule
73.10 Safety	73.10 Restricting access to select agents and toxins; security risk assessments.
73.11 Security	73.11 Security.
73.12 Emergency response	73.12 Biosafety.
73.13 Training	73.13 Restricted experiments.
73.14 Transfers	73.14 Incident response.
73.15 Records	73.15 Training.
73.16 Inspections	73.16 Transfers.
73.17 Notification for theft, loss, or release	73.17 Records.
73.18 Administrative review	73.18 Inspections.
73.19 Civil money penalties	73.19 Notification of theft, loss, or release.
73.20 Criminal penalties	73.20 Administrative review.
73.21 Submissions and forms	73.21 Civil money penalties.

Section 73.0 Applicability and Related Requirements

Under the provisions of § 73.0 of the initial interim final rule, a number of the provisions became applicable on February 7, 2003, while other provisions became applicable at subsequent scheduled times on or before November 12, 2003. A number of commenters requested that different applicability dates be established, but no commenters requested that applicability dates be later than November 12, 2003. As noted above, the interim final rule was amended allowing, subject to completion of security risk assessments and compliance with all other requirements set forth in the initial interim final rule, for the issuance of provisional certificates of registration and provisional grants of access to select agents and toxins. These security risk assessments have been completed.

Accordingly, we are removing all of the provisions of § 73.0. They have served their purpose by implementing the statutorily mandated principles of protecting public health and safety while minimizing disruption or termination of research or educational projects.

''Access'' and ''Area''

Commenters argued that the terms ''area'' and ''access'' are unclear. In response, we have eliminated references to area and used it in the regulations only when we believe it is clear in context. Also, consistent with many suggestions by commenters, we have provided language in § 73.10(b) to clarify that ''An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (*e.g.*, ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.'' In addition, we clarified the language that an individual with ''access approval from the HHS Secretary or Administrator'' is an individual who has been granted access to select agents or toxins from the HHS Secretary or Administrator following a security risk assessment.

Section 73.1 Definitions

We added definitions of ''Administrator'', ''Animal and Plant Health Inspection Service (APHIS)'', ''Attorney General'', ''Responsible Official'' and ''State'', made corrections to the definitions of ''HHS Secretary'', ''Proficiency testing'', and ''United States'', and deleted the definition of ''USDA Secretary.'' Also, we changed the definitions of ''diagnosis'' and ''verification'' to more fully reflect their common meanings in the regulated community. Moreover, we added a definition of ''specimen'' to reflect its common meaning in the regulated community. All terms not defined in this section shall have the meaning that is commonly understood in the scientific community based on the context in which those terms appear in this part.

Entity

One commenter stated the definition of ''entity'' does not include ''person'' or ''individual.'' To prevent legal confusion and arguments, the commenter recommended that in ''§ 73.1—Definitions the term 'entity' be redefined to include a 'person' and/or an 'individual' and that the same defined term(s) be used in all section''. We made no changes in the definition section based on this comment. However, for clarification purposes, we have added ''individual or entity'' language throughout the document.

Another commenter claimed that the term ''entity'' is subject to interpretation. The commenter stated that it does not make sense for a large multi-campus university to base cumulative limits on toxins or the designation of the Responsible Official on the entity when the actual labs are separated by hundreds of miles. We made no changes in the definition section based on this comment. The issue is addressed below in the registration section.

Responsible Official

Commenters recommended that CDC add the APHIS definition for Responsible Official, which reads, ''The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this Part.'' We agreed with the commenters that CDC and APHIS adopt a common definition for the term ''Responsible Official.'' Accordingly, we are adding the definition for ''Responsible Official''.

Section 73.2 Purpose and Scope and § 73.3 General Prohibition

We received no comments concerning §§ 73.2 and 73.3. Since the language in § 73.3 is consistently addressed throughout the document, we deleted this section.

Section 73.3 HHS Select Agents and Toxins and § 73.4 Overlap Select Agents and Toxins

Some of the select agents and toxins regulated by HHS under part 73 are also regulated by USDA under 9 CFR part 121. The select agents and toxins subject to regulation by both agencies are identified as ''overlap select agents and toxins'' and those regulated solely by HHS are identified as ''HHS select agents and toxins.''

General

Commenters recommended that the final rule include an appendix that would provide a summary of the risk assessment data that supports the listing of each select agent and toxin. Commenters argued that ''These data will heighten the awareness of individuals who possess and use a listed agent to the most important risk characteristics of the listed agents' and ''This knowledge will promote safe practices and proficiency in the handling of a listed agent.''

Commenters also argued that this will help affected entities make assessments for the future. CDC did not include risk assessment data in the regulations but did provide such information in the rule's preamble. We do not believe it is necessary to provide a summary of the risk assessment data that supports the listing of each select agent or toxin in order to heighten awareness of the risk characteristics of such agents and toxins and promote safe practice and proficiency in handling of such agents and toxins. Information about the risk characteristics of a select agent or toxin and safe handling practices is available in scientific literature and other publications (*e.g.*, the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories''). As noted in the preamble of the August 2002 interim rule, the Act requires the HHS Secretary to consider the following criteria in determining whether to list an agent or toxin: (1) The effect on human health of exposure to the agent or toxin; (2) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans; (3) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and (4) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate. The Secretary directed the CDC to convene an inter-agency working group to determine which biological agents and toxins required regulation based on the criteria noted above. In June 2002, CDC convened an interagency working group to review the current list of select agents and toxins and develop recommendations for a select agent list. Members of the working group included representatives from the Department of Health and Human Services/Office of the Secretary (DHHS/OS), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of the Army (DoD/Army), the Department of the Navy (DoD/Navy), the Department of the Air Force (DoD/AF), the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), the Department of Labor/Occupational Safety and Health Administration (OSHA), the National Institute of Occupational Safety and Health (CDC/NIOSH), the Department of Transportation (DoT), the Department of Commerce (DoC), the Department of Energy (DoE), the Department of Justice (DoJ), the Federal Bureau of Investigation (FBI), the Central Intelligence Agency (CIA), the Defense Intelligence Agency (DoD/DIA), and the U.S. Postal Service (USPS). For these reasons, we are making no change based on this comment.

Prion Agents

One commenter asserted that the Creutzfeldt-Jacob Disease and Kuru agents should be added to the list of HHS select agents and toxins. The commenter noted that the ''Arguments for omission include the difficulty of obtaining these agents, the extreme difficulty of replicating them, low infectivity by the oral route, and the absence of person-to-person infectivity.'' The commenter then argued that they should be included based on the conclusions ''that a single real or claimed incident of contaminating a childhood vaccine with a prion would cause indescribable anguish'' and that ''The difficulty of confirming or refuting a claim that prions had been added to a vaccine would cripple most legitimate public health programs and result in epidemics of preventable diseases.'' The commenter concluded by stating that ''In my judgment, the remote but extreme risk fully justifies the cost of including prions that are infectious to humans.'' We made no changes based on this comment. Based upon the criteria that the HHS Secretary must consider, it was the consensus of the Secretary's Select Agent and Toxin Working Group that Creutzfeldt-Jacob Disease (CJD) and Kuru agents should not be added to the list because the degree of contagiousness of prions are too low to pose a significant mass casualty threat. While they are infectious under some circumstances, such as cannibalism in New Guinea causing Kuru or Creutzfeldt-Jacob Disease by the consumption of infected bovine central nervous system tissue, there is no evidence of contact or aerosol transmission of prions from one human to another.

Viruses

The amended interim final rule included Cercopithecine herpesvirus 1 (Herpes B virus) on the list of viruses designated as HHS select agents and toxins. Commenters acknowledged that the virus naturally infects many species of macaques and can produce a serious, often fatal, infection in humans when not treated. Commenters argued that Herpes B virus should not be included as a select agent based on the following assertions:

- ''The inclusion of the virus on the list will produce no significant improvements in safety for the American public.
- Human infections are extremely rare—this is evidenced by the finding that of the literally hundreds of thousands of people who have worked with macaques over the past seventy years, there have been at most 50 human cases establishing infections with 23 documented deaths (one commenter argued that the low number of human cases may reflect infrequent shedding in macaque hosts or difficulty in the transmission of the agent to humans).
- The virus is capable of being treated with several available antiviral compounds.
- The inclusion of the virus on the list will significantly complicate transport for biomedical and biodefense research of macaques that are healthy, but chronically infected with B virus.
- The virus does not present a sufficient risk of infection by the aerosol route.
- The virus is a highly unlikely candidate for a bioterrorism agent.''

Commenters further stated that if the intent of inclusion is to monitor laboratories that cultivate large volumes of the virus *in vitro* then the rule should only cover this aspect.

We made no changes based on these comments. We have concluded that Cercopithecine herpesvirus 1 (Herpes B virus) has high morbidity, can be replicated in large concentrations, and can cause infections via the aerosol route. The regulations exclude ''any select agent or toxin that is in its naturally occurring environment provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.'' This would include species of macaques that have been naturally infected with Cercopithecine herpesvirus 1 (Herpes B virus) as long as the virus has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

The amended interim final rule included Eastern Equine Encephalitis virus on the list of viruses designated as overlap select agents and toxins. One commenter asserted that the South/Central American subtypes of the virus should be deleted from the list. This was based on the finding that ''The Naval Medical Research Center Detachment (Lima, Peru) has studied over 6,600 cases of febrile illness in Iquitos [sic] and surrounding areas since 1994, but has never detected a single case of human EEE despite repeated isolations of the virus (two of the three

South American subtypes) from mosquitoes in the same locations (Douglas Watts, UTMB, unpublished).'' The commenters concluded that ''therefore, the South/Central American subtypes are probably completely avirulent for people and not a bioterrorism risk.'' We made no changes based on this comment. There are no published data supporting the commenters' assertion. Further, a literature search indicated that there are examples of South American EEE strains that are lethal in humans and studies of animal models have produced conflicting results.

Fungi

The list of select agents includes *Coccidioides posadasii* and *Coccidioides immitis.* One commenter questioned whether either of these should be included on the list of select agents and toxins. We made no changes based on this comment. These agents cause high morbidity in humans, are highly infectious via the aerosol route, and sporulate easily in culture. Also, there is no vaccine available.

Toxins

One commenter recommended that Mistletoe lectin I, Modeccin, and Volkensin be reviewed for inclusion in the list of select agents and toxins. The commenter argued that ''These toxins are toxicologically similar (LD50 and medical affect) to Ricin and Abrin [both are included as select toxins] and are readily available since they freely grow without cultivation.'' We made no changes based on this comment. Like ricin, these toxins have only moderate toxicity compared to other toxins on the list. However, unlike ricin, these toxins are not readily available in partially purified forms in sufficient quantities to pose a significant public health threat.

The amended interim final rule included Diacetoxyscirpenol and T–2 toxin on the list of select agents and toxins. One commenter asserted that it is pointless to include them on the list because they can easily be produced using readily available materials. The amended interim final rule also included conotoxins, saxitoxin, and tetrodotoxin on the list of select agents and toxins. One commenter asserted that the list of select agents should not include ''chemically fragile, small molecule/peptide neurotoxins (tetrodotoxin, saxitoxin, end u-conotoxin [sic]), that exhibit limited stability at room temperature.'' The commenter argued that ''conotoxins and agatoxins are, for example, very rapidly degraded in water because they are triple-disulfide bonded polypeptides that require reducing agents (beta mercaptoethanol or dithicthreitol [sic] on the bench, glutethione [sic] in the organism) to retain their proper folded, disulfide-bonded structure.'' The commenter further argued that ''The disulfide bonds are very readily oxidized and the oxidized toxin molecules have no toxic activity whatsoever'' and that ''Indeed, one of our headaches with these toxins is that shipments are sometimes useless because the toxin has become oxidized.'' We made no changes based on these comments. These toxins pose a significant public health threat because they have acute toxicity, could be produced in large quantities, and can be transferred by an aerosol method. We agreed with the commenter that once those toxins have been degraded, oxidized, or in any other form in which the toxic has become nonfunctional, they would be excluded from regulation under this part.

The amended interim final rule included Staphylococcal enterotoxins on the list of select agents and toxins. One commenter asserted that it should be removed from the list based on the conclusion that even though ''Staph. food intoxication can make you wish you were dead for 24 to 48 hours'' the ''general public death rate is only 0.03% and for the very young and very old it is 4.4%.'' We made no changes based on this comment. These toxins pose a significant public health threat because they have acute toxicity, could be produced in large quantities, and can be transferred by an aerosol method.

The amended interim final rule included Botulinum neurotoxins on the list of select agents and toxins. However, under the amended interim final rule, botulinum neurotoxins are not regulated if the aggregate amount under the control of a principal investigator does not, at any time, exceed 0.5 mg. One commenter asserted that there should be no exemption for botulinum neurotoxins. The commenter argued that ''based on primate studies, the human lethal amount of botulinum toxin by intravenous exposure is 0.10 microgram, by aerosol exposure (inhalation) is 0.75 microgram, and by oral exposure (ingestion) is 75.0 micrograms'' and concluded that ''the proposed 500 microgram amount of unregistered and unregulated botulinum toxin represents, respectively, 5000 intravenous lethal doses, 667 inhalational lethal doses, and 6.7 oral lethal doses.'' The commenter further asserted that Botulism Research Coordinating Committee and National Institute of Allergy and Infectious Disease's Blue Ribbon Technical Advisory Panel on Botulinum Toxin concluded without dissent that an exclusion should not be in effect. The commenter also argued ''increased funding for biodefense work may attract newcomers to the field, who lack previous experience in working with botulinum toxin and therefore are at greater risk of laboratory accident'' and that it might be possible for a ''front laboratory or institution to order just under 500 micrograms of botulinum toxin from each of the several commercial vendors simultaneously and accumulate a cache of toxin that a terrorist might access.'' We made no changes based on this comment. This final rule represents a legislative mandate to balance the regulatory oversight of agents and toxins that have the potential to pose a severe threat to public health and safety while maintaining availability of these agents and toxins for research and educational activities. The amount of each toxin that could be possessed without regulation by a principal investigator, a treating physician or veterinarian, or a commercial manufacture or distributor was determined on the basis of toxin potency and how much one could safely possess without constituting a potential threat to public safety or raising concerns about use as a weapon that would have a widespread effect. The level specified in the rule was determined after consultation with subject matter experts on this toxin. The determination that a toxin posed a severe public health threat was based on the ability for the mass distribution of the toxin for mass casualty purposes.

To address the commenter's concerns, the lethal amounts cited represent theoretical amounts extrapolated from primate studies based upon optimal conditions. The value of ''5,000 intravenous lethal doses'' requires a mode of delivery that is impractical for inflicting mass casualties. The value of ''667 aerosol lethal doses'' assumes 100% dissemination efficiency for a protein aerosol which is highly unlikely and does not take into consideration that botulinum neurotoxin is not very stable under ambient conditions. The public comment estimates that there are less than 7 oral human lethal doses in 0.5 mg of botulinum neurotoxin. However, the excluded amount of botulinum neurotoxin would have to be optimally disseminated to cause the estimated number of fatalities.

As noted above, with certain exceptions, the amended interim final rule included Botulinum neurotoxins on the list of select agents and toxins. One commenter questioned whether there are Botulinum toxins that are not

neurotoxins and asserted that if the answer is yes the name should be changed to ''Botulinum toxins'' and if the answer is no the name should be changed to ''Botulinum neurotoxins only.'' We made no changes based on this comment. We are regulating the neurotoxins and the organism that produces the neurotoxin.

The amended interim final rule states that the list of HHS select toxins subject to regulation ''does not include the following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of abrin; 100 mg of conotoxins; 1,000 mg of diacetoxyscirpenol; 100 mg of ricin; 100 mg of saxitoxin; 100 mg of shiga-like ribosome inactivating proteins; or 100 mg of tetrodotoxin.'' The amended interim final rule states that the list of overlap select toxins subject to regulation ''does not include the following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 0.5 mg of botulinum neurotoxins; 5 mg of Staphylococcal enterotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of shigatoxin; or 1,000 mg of T–2 toxin.''

One commenter asserted that the regulations should not provide exemptions for any toxins based on an aggregate amount. We made no changes based on this comment. The quantity amounts exempted have been determined by subject matter experts and would not pose a significant public health threat.

Also, as noted above, for toxins to be excluded they must be ''under the control of a principal investigator.'' The term ''principal investigator'' is defined as ''the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.'' We are retaining these provisions but are broadening the list of those eligible to exercise such control to include not only principal investigators, but also treating physicians and veterinarians, and commercial manufacturers or distributors.

Although the language of the exclusion provisions in the amended interim final rule focused on principal investigators, we did not intend to cause the possession or transport of otherwise excluded toxins to be covered by the amended interim final rule if the entity has a legitimate use for the toxin such as would be the case for treating physicians and veterinarians (including those providing off-label use) or commercial manufacturers or distributors. In any event, we believe that the specified toxins at levels below the threshold levels do not meet the Act's criteria for inclusion as select agents or toxins (having the potential to pose a severe threat to public health and safety) regardless of whether they are under the control of a principal investigator, a treating physician or veterinarian, or a commercial manufacturer or distributor. To attempt to regulate these *de minimus* quantities would impose an unreasonable regulatory burden on the public. Accordingly, we changed the regulations to provide that the exclusions would apply if under the control of a principal investigator, a treating physician or veterinarian, or a commercial manufacturer or distributor.

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

The provisions of the amended interim final rule concerning genetic elements, recombinant nucleic acids, and recombinant organisms include as select agents and toxins:

(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed *in vivo* or *in vitro;* or

(iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro.*

(3) Viruses, bacteria, fungi, and toxins listed in paragraphs (a) through (d) of this section that have been genetically modified.

Commenters recommended that for purposes of clarity paragraph (1) should state: ''Nucleic acids that can encode infectious and/or replication competent forms of any of the select agent viruses.'' One commenter recommended that the following should be added at the end of paragraph (1) in both §§ 73.3 (e) and 73.4 (e): ''or a nucleic acid (synthetic or naturally derived) comprising at least 15% of the genome of a select agent.'' We agreed that clarification was needed and changed the language in paragraph (1) accordingly. The regulation now states that only nucleic acids (regardless of size) or replication competent forms of any select agent viruses that are subject to these regulations are those nucleic acids that can produce infectious select agent viruses.

One commenter asserted that subparagraphs (i), (ii), and (iii) should be deleted from paragraph (2) based on the argument that nucleic acids in paragraph (2) covers all forms that encode for the functional forms. In response, we changed paragraph (2) to cover: ''Recombinant nucleic acids that encode for the functional form(s) of any HHS or overlap toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro;* or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro.*''

We believe this covers all of the functional forms.

Commenters asserted that ''the government should require that service providers test for Select Agent sequences'' before they are made and transferred. The commenters argued that ''Although the Select Agent program covers transfer and possession of Select Agents, if DNA synthesis companies do not check the sequences they could inadvertently synthesize and transfer a Select Agent.'' We made no changes based on these comments. It is incumbent upon the entities that manufacture substances to know what they are manufacturing and to ensure that they comply with the provisions of the regulations in part 73 and 9 CFR part 121.

One commenter asserted that a database listing regulated genetic sequences should be created for the regulated community. We made no changes based on this comment. We believe that a database listing all the genetic sequences that can produce infectious forms of any of the select agent viruses or that can encode for the functional forms of any of the toxins listed is not practicable. However, the National Center for Biotechnology Information maintains a publicly available database (*http://www.ncbi.nlm.nih.gov/*) of nucleic acid sequence information that the regulated community could use as a resource in determining if the genetic sequence to be created is subject to this regulation.

Exclusions

The amended interim final rule states that the list of select agents and toxins does not include any select agent or toxin that is ''in its naturally occurring

environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.'' One commenter requested clarification regarding what was meant by ''natural environment.'' The commenter asked ''For example, are milk samples that contain *Coxiella burnetii,* or macque [*sic*] tissue with Herpes B virus a natural environment?'' and ''Is an entity required to report the ''identification'' of a select agent from these samples, or is the entity exempted based on natural environment?'' Consistent with this comment, commenters asserted that naturally occurring wild-type shiga toxin-producing *E. coli* strains should not be included in the list of select agents and toxins. We made no changes based on these comments. Wild-type shiga toxin-producing *E. coli* strains are not subject to this part. However, Shigatoxin and Shiga-like ribosome inactivating proteins produced by this agent are subject to this part. Select agents in their naturally occurring environment could include animals that are naturally infected with a select agent or toxin (*e.g.,* macaques that are naturally infected with Cercopithecine herpesvirus 1 or milk samples that contain *Coxiella burnetti*). However, a select agent or toxin that has been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source, including tissues from animals or agents or toxins obtained from milk samples that have been naturally infected with a select agent or toxin, is subject to this part and in such a case the entity is required to report the select agent or toxin upon identification.

One commenter asserted that the regulations should exclude fixed tissues that are, bear, or contain select agents or toxins. We made no changes based on this comment. The amended interim final rule excluded non-viable select agents and nonfunctional toxins. This includes such fixed tissues provided the agents that may be present are rendered non-viable.

Under the amended interim final rule, non-viable select agents or nonfunctional toxins are excluded from regulation. One commenter requested that we add definitions of ''non-viable'' and ''nonfunctional'' based on the assertion that ''Some organisms can survive in nature, others only with laboratory conditions, while others will not grow under any conditions.'' We made no changes based on this comment. Regardless of the environment in which an organism can or cannot survive, the standard established by the regulations is whether the organism is viable, or whether the toxin is functional, based on the plain meaning of the words. Further, the regulations are clear in that they exclude ''any select agent or toxin that is in its naturally occurring environment provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.'' The regulations also exclude ''non-viable select agents or nonfunctional toxins.''

The amended interim final rule excluded from the regulation certain toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed specified amounts. One commenter asserted that the term ''aggregate amount'' is unclear and questioned whether it means ''weight of pure plus weight of impure'' or ''weight of pure plus weight of pure in impure''? The commenter recommended that it be defined to mean the latter. For clarification purposes, we have deleted the language ''in the purified form or in combinations of pure and impure forms'' so that it is clear that the regulations are dealing with the total amount of the toxins regardless of the form.

The amended interim final rule provided that the HHS Secretary may exclude attenuated strains of select agents or toxins upon a determination that they do not pose a severe threat to public health and safety. The amended interim final rule also provided that in response to an application submitted to the HHS Secretary, the HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. It further stated that an exclusion will be effective upon notification to the applicant and that exclusions would be published in the notice section of the **Federal Register** and listed on the CDC Web site at *http://www.cdc.gov/.* In addition, it stated that the list would be included in the rule.

After consultations with subject matter experts, review of relevant published studies, and review of information provided by the applicants, a number of attenuated strains have been excluded from the list of select agents and toxins based on the criteria that these agents do not pose a severe threat to public health and safety. One commenter asserted that ''Given the cost of compliance with these regulations, the appropriate list of select agents, including a list of exempted [*sic*] strains, should be in place at the time the regulations are implemented.'' In response, we note that a number of excluded attenuated strains are *identified* on the CDC Web site. We also listed them in the amended interim final rule. To minimize the potential delays related to rulemaking, in this final rule we are providing that excluded attenuated strains of select agents or toxins will be periodically published in the **Federal Register** notice and maintained on the Internet at *http://www.cdc.gov.* We believe these measures will provide sufficient notice to the public. Therefore, we are making no change based on this comment.

Commenters asserted that specific criteria for evaluating exclusions for attenuated strains of select agents and toxins should be added to the regulations and further asserted that the broad microbiological community, not just government agency representatives, must be involved in this process. We made no changes based on these comments. The Act sets the criteria for excluding attenuated strains, *i.e.,* they may be excluded if they do not pose a severe threat to public health and safety, (42 U.S.C. 262a(a)). We will consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups depending on the attenuated strain being considered.

A number of commenters asserted that the government should ensure that prompt determinations are made in response to applications for exclusions. One commenter suggested that a timeline for responses be established. We made no changes based on these comments. We will do our best to make prompt determinations, but the highest priority is to protect public health and safety.

For clarification, we added the language that if an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.

In addition, in this final rule, we are adding a new paragraph (f) to 42 CFR 73.3 and 73.4 to address concerns raised by Federal law enforcement agencies related to seizures (*i.e.*, possession) of known select agents or toxins. Paragraph (f) provides that any known select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of the regulations during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that (1) as soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys

the agent or toxin by a recognized sterilization or inactivation process; (2) the Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release and reports any theft, loss, or release of such agent or toxin; and (3) the Federal law enforcement agency reports the seizure of the select agent or toxin by submitting the APHIS/CDC Form 4.

This provision will allow Federal law enforcement agencies to conduct certain law enforcement activities (*e.g.,* collecting evidence from a laboratory crime scene) without being in violation of the regulations. We note, however, that this provision does not authorize the seizure of a select agent or toxin by a Federal law enforcement agency; rather, it establishes the conditions under which a Federal law enforcement agency may seize a known select agent or toxin without violating the regulations. Any seizure of a known select agent or toxin by a Federal law enforcement agency must be conducted in accordance with all applicable laws and regulations.

To address concerns raised by Federal law enforcement agencies related to seizures (*i.e.,* possession) of select agents or toxins, in this final rule we are adding a new paragraph (f) to §§ 73.6(a) and 73.7(a) to address situations in which the select agents or toxins have been identified prior to seizure. In the event that a Federal law enforcement agency seizes a suspected select agent or toxin or unknown material, this material will be regarded as a specimen presented for diagnosis or verification and, therefore, will not be subject to the regulations until it has been identified as a select agent or toxin.

Sections 73.5 and 73.6 Exemptions for HHS and Overlap Select Agents and Toxins and Diagnosis, Verification, or Proficiency Testing

The amended interim final rule provided that an individual or entity is exempt from the provisions of part 73, other than transfer provisions, if the entity only conducted activities with select agents or toxins that were contained in specimens presented for diagnosis, verification, or proficiency testing. We clarified the language to state ''Clinical or diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen''. This clarification was made in recognition that in certain cases regulated individuals and entities may also be conducting non-regulated activities.

The exemption provisions apply only if, among other things, the individual or entity within specified time periods (seven calendar days after identification of select agents and toxins used for diagnosis or verification; within 90 calendar days after receipt of select agents or toxins used for proficiency testing) submits a completed form regarding the disposition of the select agents or toxins. We have added language stating that less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak. This will help prevent large numbers of reports in those instances when such reports would not be useful for taking action to protect the public's health and safety. In addition, CDC and APHIS have combined their immediate notification list for overlap select agents and toxins (*Bacillus anthracis,* Botulinum neurotoxins, *Francisella tularensis, Brucella melitensis,* Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus). Therefore, entities will be able to immediately notify either agency.

One commenter asserted that the exemption provisions should not exist based on the argument that select agents and toxins may be obtained from the environment and those conducting diagnosis, verification, or proficiency testing are capable of isolating and growing them. The commenter further asserted that at the very least all clinical and diagnostic laboratory employees should be subject to the security risk assessments. We made no changes based on this comment. Such changes would be contrary to the exemption provisions mandated by the Act (42 U.S.C. 262a).

Commenters argued that the exemption provisions should contain safeguarding requirements that would apply to select agents and toxins from the time they are identified until they are transferred or destroyed. One commenter argued that the safeguarding requirements should be the same as those that would apply if they were not subject to the exemption provisions. In response, we agree that the entity must take measures to safeguard the select agents or toxins. Accordingly, we have included a provision in the regulations to require the entity to secure the specimens or isolates containing a select agent or toxin during the period from identification until transfer or destruction. In addition, we added the provisions that the individual or entity must also meet the requirements of § 73.19 (Notification of theft, loss, or release). We believe that any theft, loss, or release of a select agent or toxin must be reported to protect public health and safety.

Commenters opposed the exemption provisions concerning diagnosis or testing that require an entity to transfer or destroy select agents or toxins. The commenters opposed the destruction option by asserting that by encouraging diagnostic laboratories such as state health facilities to destroy all isolates, the ability to deal with future outbreaks and terrorist events would be undermined. More specifically, they argued:

- ''Destruction will result in the loss of valuable scientific material since much of our knowledge of the ecology and epidemiology of emerging and select agents, and our future ability to identify the source of a terrorist introduction, depend on having collections of reference agents available for genetic and phenotypic analyses.
- If an agent is introduced by a terrorist group in a failed attempt to cause an outbreak, and the samples are all destroyed, retrospective analyses of activities preceding a significant bioterrorist event will be hampered by the loss of information.''

One commenter also asserted that the final rule should require CDC to consult with the state public health laboratory director or other appropriate contact such as the state health officer before destroying a select agent or toxin based on the conclusion that ''There may be circumstances in which a state public health laboratory director would want such specimens or isolates preserved to support epidemiologic investigations in the state * * * such as isolated cases of *Yersinia pestis* infection in the Southwest, but for which state-based infection control activities must proceed.'' One commenter suggested that a team from the Department of Justice could ''arrive and monitor the situation, and safeguard the isolate.''

The regulations require that a diagnostic or testing entity transfer or destroy a select agent or toxin if, and only if, such an entity does not want to be registered pursuant to the Select Agent regulations. If any entity has a legitimate need to keep possession of a select agent or toxin it may do so once it has become registered. We have added a provision to allow a diagnostic or testing entity to retain possession of a select agent or toxin in situations where it has been determined that such action is necessary to protect public health and safety.

Commenters argued that the seven day requirement for transferring or destroying select agents or toxins used for diagnosis or testing is too short a

time limit. We made no changes based on these comments. Based on input from technical experts and risks posed by select agents and toxins, we believe seven calendar days provides a sufficient amount of time for the entity to destroy or transfer the select agents or toxins after identification. However, as noted above, we have included language for special allowance of these provisions when necessary to protect public health and safety.

One commenter asserted that the final rule should not require an entity to submit to CDC a record of destruction of select agents or toxins or as an alternative should require ''entities to maintain a record of destruction, which would be subject to inspection by CDC and/or APHIS.'' The commenter argued that ''This action would reduce the associated paperwork burden and maintain consistency with the intent of the regulations.'' The commenter further stated that ''Unlike transfers from other regulated entities, a transfer record does not precede isolation through diagnostic procedures.'' We made no changes based on this comment. The Act requires a report of the identification of select agents or toxins (42 U.S.C. 262a(g)(1)(a)). We need to be advised of the disposition to ensure compliance with the requirements of the regulations and to ensure the protection of public health and safety.

Exempted Products

The amended interim final rule provides for exemption from the regulations under certain circumstances for products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the specified laws, insofar as their use is only for the approved purpose and meets the requirements of such laws. Commenters asserted that the requirement that the use be limited to approved purposes be deleted because of the allowance of off-label use. In response, we agree and have deleted the ''approved purpose'' language. We see no reason to distinguish between products that are used for off-label, but in a manner that doesn't violate the law, and products that are used in accordance with the approved labeling.

One commenter recommended that the regulations list the exempted products. We made no changes based on this comment. The regulations provide the criteria for determining which products are exempt and it would be impracticable for the maintenance of such a list.

The amended interim final rule provided that the HHS Secretary on a case-by-case basis may exempt from the requirements of the part 73 regulations an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under any of four specified Federal acts and additional regulation is not necessary to protect public health and safety. The final rule allows such an exemption under any Federal act since the statutory authority allows exemptions for investigational products under any Federal act.

Section 73.7 Registration and Related Security Risk Assessments, § 73.8 Denial, Revocation, or Suspension of Registration, and § 73.10 Restricting Access to Select Agents and Toxins; Security Risk Assessments

[These Subjects Are in §§ 73.7 and 73.8 in the Amended Interim Final Rule]

General

We have revised the provisions regarding registration and security risk assessments and, as noted above, have placed these provisions in three sections: § 73.7 (Registration and related security risk assessments), § 73.8 (Denial, revocation, or suspension of registration), and § 73.10 (Restricting access to select agents and toxins; security risk assessments). To conduct certain activities regulated under part 73, the revised provisions, consistent with the provisions of the amended interim final rule, require that the individual or entity obtain a certificate of registration and that the following must have an approval from the HHS Secretary or Administrator following a security risk assessment by the Attorney General: the individual or entity, any individual who owns or controls the entity, the Responsible Official of the entity, and any individual who is to access select agents or toxins under the entity's certificate of registration.

One commenter, a private, non-profit organization that provides medical research personnel to work at government entities for the purpose of performing work covered by the regulations, requested that the regulations be changed to state that such a private non-profit organization would not be subject to any requirements imposed by the regulations. We made no changes based on this comment. The entity conducting regulated activities must obtain a certificate of registration and otherwise comply with the Part 73 regulation. Also, any individuals having access to select agents or toxins on behalf of an entity must meet the requirements for such activities, regardless of the type of entity.

One commenter asserted that the regulations should specifically ''prohibit HHS, USDA or other federal agencies from using the information collected through the registration process to evaluate the merit of proposals involving research on select agents or toxins.'' We made no changes based on this comment. The regulations contain provisions to implement the intent of the Act which is to provide protection against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The part 73 regulations contain no provisions for evaluating the merits of research proposals and are not intended to cover such activities.

One commenter asserted that the approval process for security risk assessments should include requirements for credit checks and random drug screening. We made no changes based on this comment. With respect to security risk assessments, the Act provides that the Attorney General shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of identifying restricted persons and for identifying those reasonably suspected of committing certain crimes, being involved with an organization that engages in domestic or international terrorism, or being an agent of a foreign power. The Act does not provide for credit checks or random drug screening.

Commenters asserted that the regulations should explicitly provide that the clearance process is confidential. We made no changes based on these comments. Information obtained as a result of the security risk assessment process will be protected in accordance with the provisions of the Privacy Act.

Individual Who Owns or Controls the Entity

Commenters asserted that provisions requiring a security risk assessment approval for an individual who ''owns or controls the entity'' should not apply to educational institutions. One commenter asserted that ''under most state laws governing the organization of nonprofit entities such as a university, there are no owners of the entity, *i.e.*, no stockholders or partners, because the entity is organized for the good of the public, not for the good of the 'stockholders' or 'investors.' '' They expressed concern regarding possible delays if these provisions were broadly interpreted to include members of the board of trustees or other similar officials. One commenter asserted that

''the interpretation of ''control'' should be limited to those individuals who will have actual access to the select agents.'' One commenter recommended that we define ''ownership or control'' to mean the right to exercise control of an entity ''regardless whether such right results from a substantial economic interest or contractual or other right to manage an entity.''

In response, we have added the following language:

(2) Federal, State, or local governmental agencies, including public institutions of higher education, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.

(3) An individual will be deemed to own or control an entity under the following conditions: [1]

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or

(B) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).''

We believe the language is consistent with the statutory language in section 351 A(e)(6)(B) from the Act which exempts Federal, State, or local governmental agencies including public institutions of higher education from the security risk assessments for the entity and the individual who owns or controls such entity. However, the Act does not exempt other individuals or entities even those nonprofit entities from the security risk assessment provisions. In addition, we believe those individuals that own or control the entity relevant to the entity's possession, use, or transfer of select agents or toxins should be required to undergo a security risk assessment. However, we determined that not all owners or controllers of an entity were relevant to an entity's possession, use, or transfer of a select agent and added language to identify those individuals who were in a ''managerial or executive capacity with regard to the entity's select agents or toxins'' such as laboratory directors.

One commenter asserted that the security risk assessment provisions should apply to entities that own or control entities possessing or transferring select agents. We made no changes based on this comment. The Act requires a security risk assessment for an entity (at any level) that conducts regulated activities and for individuals who own or control such entity.

Coordination of Activities

Commenters recommended that CDC and APHIS coordinate their activities regarding select agents and toxins through a single office. The commenters argued that such coordination through one office would decrease regulatory burdens, ensure consistency in agency decision making, and ultimately promote compliance. They also argued that without a single office, entities conducting activities regulated solely by USDA and solely by HHS would be required to submit dual registrations, obtain dual security risk assessments, and prepare other dual packages, such as safety plans and security plans. One commenter argued that such duplication is contrary to the statutory requirements.

In order to minimize the burden to the public required to register to possess, use or transfer select agents and toxins, a single point of contact has been developed. This single point of contact is responsible for coordinating all activities and communications with respect to the entity's registration, including coordination with both the non-lead agency and with Federal Bureau of Investigations, Criminal Justice Information Services Division. This single point of contact will retain responsibility for the application for the life of the registration certificate (2–3 years). In addition, a single shared web-based system is under development that will allow the regulated community to conduct transactions electronically via a single web portal. We envision that this system will enable the entity to dynamically communicate in a digitally secured environment using a single web portal. The web portal will provide a platform for electronic exchange of information. It will allow entities to access data related to their own registration data and allow them to create, amend, and submit registration applications; requests for approvals for transfers, exemptions, or exclusions; and any other required forms without the need to print, mail, or e-mail hard copies. Hard copy registration materials and other required forms will still be accepted. The single web portal will be available in winter 2005.

Changes

The amended interim final rule stated that the Responsible Official must promptly notify the HHS Secretary if a change occurs in any information submitted to the HHS Secretary in the application for the certificate of registration or amendments. This included modifications to the list of individuals with approvals for security risk assessments, changes in area of work, or changes in protocols or objectives of studies. Commenters recommended deleting the word ''protocol'' based on the argument that prior approval before implementing the protocol change would hinder research. They also argued that ''Protocols can change frequently in active research programs without altering the relevant biosafety and laboratory information or the objectives of the work.'' In response, we have deleted the word ''protocol'' and clarified the regulations to state that an entity may take regulated actions concerning select agents or toxins, activities, locations, or personnel only to the extent that such actions are specifically approved under a certificate of registration, including any amendments.

Timely Decision-Making

Commenters expressed concern regarding the absence of time limits for determinations of registration and security risk assessments and recommended that the regulations include a process by which an entity can begin or continue its research with select agents and toxins until such time as the relevant government agencies complete their respective reviews and respond to the entity's applications for security risk assessments and registrations. Some commenters requested that the regulations ''be amended to provide that if the person subject to the background check suffers a delay in excess of 10 work days, that person should be permitted to work with select agents under the direct supervision of an approved person (provided that all other requirements are met).'' Another commenter suggested

[1] These conditions may apply to more than one individual.

that the regulations should allow an individual access to select agents and toxins if ''escorted'' during the waiting period. We made no changes based on these comments. The amended interim final rule did provide for a phase-in of the security risk assessment requirement to allow ongoing research to continue pending the completion of a records check by the FBI. However, as explained above, the phase-in provisions have been removed because they have served their purpose. Entities and individuals have had time to come into compliance without compromising research or educational projects. The Act is clear that individuals should not be allowed access to select agents and toxins until after completion of the security risk assessment.

Under the registration provisions, a certificate of registration concerning overlap agents will only be issued if both the HHS Secretary and Administrator concur. One commenter suggested that language be added to discuss ''what the entity is to do to assist or mitigate the conflict between the two regulatory agencies or, for example, how to appeal for resolution.'' We made no changes based on this comment. As discussed above, a single point of contact has been implemented in order to minimize the burden to the public required to register in order to possess, use or transfer select agents and toxins. Therefore, the responsibility for resolving such conflicts rests with CDC and APHIS and the agencies are prepared to take action to resolve any conflicts as quickly as possible.

Coverage of Certificate of Registration

The amended interim final rule provided that ''A certificate of registration will cover activities at only one general physical location (a building or a complex of buildings at a single mailing address).''

Commenters recommended that an entity have the option to apply for a single certificate of registration to cover activities at all buildings on a campus or site under the control and authority of the Responsible Official. The commenters indicated that this would include both contiguous and dispersed sites within a local geographical area. The commenters argued that separate registrations for each general physical location (defined as ''a building or a complex of buildings at a single mailing address'') is overly burdensome in terms of staffing, training, and naming of Responsible Officials, and record keeping. They also argued that the amended interim final rule ''authorizes the Responsible Official to identify one or more alternate Responsible Officials to provide coverage for and assist the Responsible Official and that this nullifies the argument that separate registrations are necessary to ensure against over-extending the Responsible Official.'' In addition, they argued that ''administrative and control functions at research and academic institutions, including environmental health and safety and security programs, are efficiently managed by a centralized department responsible for more than one physical location.''

One commenter asserted that this provision should be changed to state that a certificate of registration will cover activities of a single administrative organization under a single Responsible Official provided that all buildings are contained within a circle of 25 miles diameter. The commenter noted that ''each building on a university campus may have a different mailing address even though the campus is under a single administration.'' The commenter asserted that this would allow ''a university to include a detached medical school or research park in its registration, simplifying paperwork for all concerned'' while still allowing ''full government inspection in a single visit'' and provide ''a realistic commuting distance for the Responsible Official.''

One commenter indicated that a certificate of registration should allow a Responsible Official to discharge his/her responsibilities at several adjacent addresses. The commenter asserted that ''Addresses are generally used to facilitate mail deliveries, not to establish areas of responsibility.''

In response, we note that our goal is to set forth a standard to ensure that the Responsible Official will not be overextended and will be able to perform the activities required for that position. Moreover, we believe that in some cases a Responsible Official may be able to meet these criteria even if the area were larger than set forth in the amended interim final rule. Therefore, we have changed the rule to allow a certificate of registration to cover activities at one physical location (room, building, or group of buildings) where the Responsible Official will be able to perform the responsibilities required for that position.

However, we made no changes concerning the responsibilities of Responsible Officials and alternate Responsible Officials. The regulations were designed to place responsibility for ensuring compliance with the part 73 regulations in one position. Also, the regulations provide that an alternate Responsible Official could act only if the Responsible Official were unavailable. We believe that placing responsibility in one position will help achieve a higher level of compliance than would be obtained from a system of shared responsibility.

Periods of Validity and Reapplication

The amended interim final rule provided, with exceptions, that a certificate of registration is valid for up to three years. The amended interim final rule also provided that an approval based on a security risk assessment is valid for five years. Commenters recommended that the certificate of registration be valid for up to five years. They argued that this would make the registration provisions consistent with the security risk assessment provisions and that this ''would simplify paperwork logistics for the entity and reduce the cost to the government for the registration process.'' One commenter asserted that an approval based on a security risk assessment should be valid for the same time period as the certificate of registration so that the approval period would coincide with the timing for resubmittals of the registration application package. We made no changes based on these comments. We believe it is reasonable to provide that a certificate of registration will be valid for a maximum of three years. A three year registration period takes into consideration the burden on the public and the risks posed by select agents and toxins. In addition, it is consistent with APHIS' permit systems and other established programs for laboratory certification or registration (*e.g.*, Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists (CAP)), which are generally valid for two to three years. The validity period of five years for an individual's security risk assessment was established based on a Department of Justice determination that five years was the appropriate period. Even though it appears that the two different timeframes would increase the burden on the public, as a practical matter the registration of an entity and the completion of most individual security risk assessments are not connected, with the exceptions being only the Responsible Official, Alternate Responsible Official, and any individual who owns or controls the entity. Although both seem to have happened at once as the Program became established and the regulations became effective, in fact the Select Agent Program has observed a significant ''turn over'' in the individuals from registered entities. Therefore at the time an entity begins its submissions for re-registration, it could have individuals

that have approved security risk assessments from anywhere from almost three years to one day. Therefore, changing the validity of an individual security risk assessment to be consistent with the registration period would cause undue burden on the public.

With respect to reapplications, one commenter asserted that resubmittal schedules should be ''well defined'' (*e.g.*, resubmit at least 90 calendar days prior to expiration). Although we cannot provide a specific timeframe, we recommend the individual or entity reapply at least eight weeks prior to the expiration date of the existing certificate of registration.

Moreover, we have added provisions to help prevent an unnecessary lapse in a certificate of registration when the Responsible Official of an entity leaves and the entity is left with no individual to serve as the Responsible Official. In this regard, we added provisions to allow an entity to continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part.

The amended interim final rule stated that an entity must provide written notice at least five business days before destroying a select agent or toxin, if the destruction would be for the purpose of discontinuing activities with a select agent or toxin covered by a certificate of registration. The amended interim final rule further stated that ''This will allow the HHS Secretary and/or the USDA Secretary to observe the destruction or take other action as appropriate.'' We are deleting this provision. Under the registration provisions, the Responsible Official must provide prompt notification in writing, if a change occurs in any information submitted in the application for the certificate of registration or amendments. If the entity has not yet received a certificate of registration then the Responsible Official must provide updated information in writing; if the entity has received a certificate of registration then the Responsible Official must promptly provide an amendment to their certificate of registration. This would include adding or removing a select agent or toxin. However, there is no need to impose a five-day notification requirement.

In addition, in this final rule, we are adding the language that a certificate of registration will be denied, revoked, or suspended if it is determined that such action is necessary to protect public health and safety. We are also clarifying the actions an entity must take in the event that the certificate of registration is suspended or revoked. Specifically, we are adding a paragraph to require that, upon notification of revocation or suspension, the individual or entity must: (1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order; (2) immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release; and (3) comply with all disposition instructions issued by the HHS Secretary for each select agent or toxin covered by the revocation or suspension.

Security Risk Assessments

Commenters recommended that the Final Rule define the information the entity must submit to the Attorney General for the security risk assessments. Currently, the individual completes the FBI form (FD–961) and then mails the FD–961 form and fingerprint cards as one package directly to the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS). Since this process could change, the specific information for submission was not included in the regulatory text. Specific guidance on the process has been made available on the Internet at *http://www.cdc.gov.*

Commenters asserted that the regulations should allow security risk assessment approvals for individuals to be portable from entity to entity, from location to location, and from project to project. One commenter recommended that an individual's clearance remain valid if the scientist moves to another institution as long as the scientist's new employer amends its registration document promptly to include the individual. The commenter also recommended ''that the Department clarify that an individual's clearance will continue to be valid if his or her laboratory is relocated among any of the facilities under the oversight of the entity's Responsible Official'' and added that ''The change in location should, of course, be reflected in a timely amendment of the entity's registration.'' We made no changes based on these comments. However, CDC, APHIS, and the Attorney General have agreed to and have already implemented a policy that an additional security risk assessment is not needed in cases where an individual has a current security risk assessment and will be merely visiting another entity. If a registered entity wants a visiting individual to have access to select agents or toxins, the RO of home entity will have to send to the RO of host entity a letter stating that the individual is currently identified on the home entity's Select Agent registration and that the individual has a current SRA approval. The host entity RO can then submit this letter and an amendment to their registration. Once the visit is complete, the host entity would then amend their registration to remove the visiting individual's name. In some circumstances the host entity may decide to leave the individual on the registration, if the same individual will be visiting the entity again. Specific guidance on the process has been made available to the public on the Select Agent Program web site.

In addition, in this final rule, we have added the requirement that an individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins. We believe this requirement is necessary to ensure that the individual has the appropriate education, training, and/or experience to handle such agents or toxins.

One commenter in a discussion concerning national Department of Energy (DOE) laboratories requested that language be added ''that would allow the L or Q clearance granted in DOE laboratories (or equivalent) to be considered synonymous with the security risk assessment process for the purposes of this regulation and that individuals with a current L or Q clearance be considered approved.'' We made no changes based on this comment. The Act requires the Attorney General to determine whether an individual is a restricted person; or reasonably suspected of committing an act of terror, being involved in a terrorist organization, or being an agent of a foreign power. The Attorney General may not be able to make such a determination based solely on the existence of an L or Q clearance.

One commenter asserted that we should take into consideration the conclusion that ''It is unlikely that an entity can provide information for a security risk assessment, other than the name of an individual, since many institutions have privacy policies that preclude their seeking certain personal information'' and ''Institutions are also subject to state laws on privacy, which vary widely.'' We made no changes based on this comment. Entity policy and State laws do not preempt the Act and the part 73 regulations. Accordingly, an entity must comply with the part 73 regulations to be eligible to conduct regulated activities concerning select agents and toxins.

The amended interim final rule provided that the HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as a ''restricted person'' under 18 U.S.C. 175b. Under this statutory provision, a ''restricted person'' is a person who:

- Is under indictment for a crime punishable by imprisonment for a term exceeding one year,
- Has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year,
- Is a fugitive from justice,
- Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)),
- Is an alien illegally or unlawfully in the United States,
- Has been adjudicated as a mental defective or has been committed to any mental institution,
- Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism, or
- Has been discharged from the Armed Services of the United States under dishonorable conditions.

Commenters expressed concern ''that these broad classifications will hinder legitimate research'' and are contrary to the requirement in the Act to ''ensure the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.'' They argued that the term ''restricted person'' would cover an individual who received a dishonorable discharge from the U.S. military for homosexuality and could not understand how precluding such individual from ever working on select agents would protect the security of the United States. Commenters also argued that ''it is predictable that some individuals who are currently productive, respected members of the scientific community and who have performed work with select agents or toxins meet one or more of the definitions of a 'restricted person.' '' We made no changes based on these comments. The provisions regarding ''restricted persons'' restate statutory requirements.

Commenters asserted that the regulations should contain a description of the process for limited approvals. We made no changes based on this comment. The Act and the part 73 regulations provide for the application of a security risk assessment approval. An individual or entity may obtain review of a decision denying or revoking a security risk assessment approval. Based on this review the HHS Secretary may, under certain circumstances, provide for a limited approval for a specified time based upon the finding that circumstances warrant such action in the interest of public health and safety or national security.

The amended interim final rule set forth a mechanism for obtaining an expedited review of an application for a security risk assessment. One commenter asserted that the ''DOE clearance process parallels (and in many cases exceeds) the efforts that will be reviewed by the Attorney General.'' The commenter argued that ''Hence, DOE and DOE subcontractor staff (or other federal agency staff) that have federal clearances should be among those to be considered for expedited review.'' We made no changes based on this comment. The Act allows for such an expedited review based on ''good cause'' and we do not believe that having a security clearance is relevant regarding whether the ''good cause'' standard would be met.

Section 73.9 Responsible Official

[This Subject Is in § 73.9 in the Amended Interim Final Rule]

The APHIS interim final rule included provisions stating that the Responsible Official is ''The individual designated by an entity to act on its behalf'' and that ''This individual must have the authority and control to ensure compliance with the regulations in this part.'' Commenters asserted that the part 73 regulations should include these provisions. They argued that the APHIS provisions provide the ''clarity needed in order to provide the expected accountability at sites registered by the CDC Select Agent program.'' We agreed with commenters and CDC and APHIS have included identical provisions for the Responsible Official.

Also, to ensure that all of the requirements of the regulations are met, we have clarified the language regarding the Responsible Official's annual inspection. The language previously located in § 73.10 Safety section of the amended interim final rule has been moved to the Responsible Official (§ 73.9) section stating that the Responsible Official must ensure that annual inspections are conducted for each laboratory where select agents and toxins are stored or used in order to determine compliance with requirements in this part. Further, we have included provisions requiring that deficiencies be corrected.

Commenters noted that the preamble to the initial interim final rule ''recommended that that the Responsible Official and alternate Responsible Officials are either biosafety officers or senior management officials of the entity, or both.'' Commenters suggested that we ''emphasize that it is the entity's responsibility to designate the appropriate individual to be the responsible official (*i.e.*, an individual who has the authority and control to ensure compliance with the regulations)'' and that ''To satisfy this requirement, a university may choose to designate the Dean of Agriculture to be the responsible official rather than the biosafety officer because the Dean of Agriculture may have better oversight and authority to ensure compliance with the regulations.'' Some suggested that duties may even be separated by having the biosafety officer or an individual who has a higher-level management position for ensuring overall compliance, responsible for day-to-day operations. One commenter suggested that the duties be shared between the Responsible Official and the Principal Investigator with the Principal Investigator responsible for those activities that required daily hands-on knowledge of the laboratory. We made no changes based on these comments. The Responsible Official should be an individual who can perform all of the duties required for that position. As we noted above, the regulations were designed to place responsibility for ensuring compliance with the part 73 regulations in one position because we believe that doing so will help achieve a higher level of compliance than would be obtained from a system of shared responsibility.

Commenters recommended revision of language throughout the regulations to change the emphasis regarding Responsible Officials from responsibility ''for'' complying with requirements to responsibility ''for ensuring'' compliance with requirements. They argued that the amended interim final rule implies that only the Responsible Official or alternate Responsible Official may perform actions intended to be performed by others detailed under their supervision. In addition, one commenter recommended that laboratory inspections be performed by a Biosafety Officer designated by and reporting to the Responsible Official rather than by the Responsible Official. In response, we have made changes as necessary to state when the Responsible

Official must conduct activities and when the Responsible Official is required to ''ensure'' compliance with requirements in the regulations. This change will allow the Responsible Official the flexibility to delegate certain responsibilities.

Since the reporting requirements of §§ 73.5 and 73.6 (Exemptions for HHS and overlap select agents and toxins) may pertain to regulated individuals and entities, we have clarified the language by adding the reporting requirements to the RO section. This reporting requirement will help us with monitoring activities related to select agents and toxins.

Section 73.11 Security

[This Subject Is in § 73.11 in the Amended Interim Final Rule]

Coordination With USDA

Commenters recommended that security plans established for compliance with the CDC rule should be sufficient to meet the requirements for a security plan under the APHIS regulations. They argued that otherwise an entity must prepare two security plans. We agreed with the commenters and CDC and APHIS made their language in the security section identical to ensure consistency between the regulations. In addition, we note that compliance inspections for security will be based on the regulations and that the inspectors will be looking for security that provides graded protection commensurate with the risk of the select agent or toxin, given its intended use.

A commenter asserted that biological laboratory security should be administered by only one Federal agency (*e.g.,* Department of Homeland Security) to ensure consistency. We made no changes based on this comment. Section 201(b) of the Act requires the HHS Secretary to establish and enforce safeguard and security measures to prevent the access to select agents and toxins for use in domestic or international terrorism or for any other criminal purpose. In addition, the Act provides for the interagency coordination between the HHS Secretary and Administrator regarding overlap select agents and toxins. CDC and APHIS have established procedures to ensure consistent regulation of select agents and toxins.

Performance Based

Some commenters asserted that the security requirements are too stringent based on the argument that they could hamper research. We made no changes based on this comment. Although the Act requires us to do what we can to allow research, the first duty under the Act is to protect public health and safety. The security requirements are designed to prevent unauthorized access, theft, loss, or release of select agents or toxins. The regulations require that an entity's security plan be designed according to a site-specific risk assessment. Such a risk assessment would take into consideration the security needed for a select agent laboratory in an academic setting.

Some commenters asserted that the security provisions should be prescriptive rather than performance based to prevent ''wide variation in the evaluation of threats and consequences, and a wide interpretation of what constitutes adequate security.'' Other commenters asserted that the security provisions are highly prescriptive and should be changed to provide only a general performance standard. These commenters pointed out difficulties in the amended interim final rule by arguing that requirements, such as a requirement that freezers containing select agents and toxins be locked may not always be appropriate (the whole room could be secure).

Because different select agents and toxins pose differing degrees of risk, we believe it would be counterproductive to attempt to prepare a detailed list of prescriptive requirements for entities (*i.e.*, a ''one size fits all'' design standard). Therefore, the regulations contain performance standards for biosafety, security, and incident response that take into account the risks presented by a particular select agent or toxin, given its intended use.

With regard to security, newly designated 42 CFR 73.11 requires each individual or entity required to register under this part to develop and implement a written security plan. This security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. In addition, newly designated 42 CFR 73.11 requires the individual or entity to adhere to specified security requirements or implement measures to achieve an equivalent or greater level of security. We believe these security provisions provide enough flexibility and specificity to allow an individual or entity to develop and implement a security plan that will safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

However, in recognition of the commenters' concerns, we reiterate that CDC and APHIS are working with interagency groups and security experts to draft a document that will provide additional guidance about the security required for select agents and toxins. This document will be available in spring 2005. The 5th edition of the BMBL, which is under development, will also provide additional guidance on laboratory security.

The interim final rule stated that freezers containing select agents and toxins must be locked or must be in the direct view of approved staff. Commenters asserted that these provisions may not be appropriate (the whole room could be secure). We agreed and have changed the language to require the entity to ''Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents and toxins are stored to be secured against unauthorized access (*e.g.*, card access system, lock boxes).''

One commenter stated the BMBL and NIH guidelines require labs to post biohazard signs on access doors that list the agents present in the laboratory, which may compromise laboratory security. We made no changes based on this comment. In this final rule, 42 CFR 73.12 (Biosafety) provides that an individual or entity should consider the BMBL and NIH Guidelines when developing a biosafety plan. However, it is the entity's responsibility to determine if posting biohazardous signs on access doors would compromise laboratory security.

A commenter pointed out that the terms ''risk assessment,'' ''threat assessment,'' and ''vulnerability assessment,'' are confusing to those with little experience in this area and should be clarified. A commenter suggested that the phrase ''risks associated with those vulnerabilities are mitigated'' be replaced with ''consequences associated with those vulnerabilities are mitigated.'' We agreed with the commenters and have deleted the text. In addition, we clarified the language to state that an entity's security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release; must be designed according to a site-specific risk assessment; and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use.

BMBL

One commenter asserted that the security provisions should mandate compliance with the BMBL, specifically Appendix F. We made no changes based on this comment. The security provisions contain guidelines similar to

that published in Appendix F of the 4th edition of the BMBL.

Security and Individuals

Commenters asserted that the amended interim final rule incorrectly indicated that special provisions would be required for all individuals providing routine cleaning, maintenance, and repairs and objected to such language based on the conclusion that some might obtain security risk assessment approvals. In response, we note that these provisions were intended to apply when the cleaning, maintenance, or repairs were performed by individuals without security risk assessment approvals. We have clarified the regulations accordingly.

Commenters asserted that the security provisions of the amended interim final rule indicate that they ''must develop a security plan that, among other requirements, establishes a procedure for reporting and removing unauthorized persons'' and requested clarification as to the meaning of the phrase ''unauthorized persons'' and the ''areas from which they must be removed.'' We made no changes based on these comments. In context, unauthorized persons are those unescorted individuals who do not have access approval from the HHS Secretary or Administrator and who are in areas where they could gain access to select agents or toxins.

Commenters argued that security provisions of the amended interim final rule would hinder collaboration among scientists. They asserted that ''A productive research program likely includes many scientists and technicians working collaboratively but with only a few actually handling infectious agents'' and that ''Isolating scientists who handle infectious agents will be detrimental to the program'' because ''The security requirements must enable unauthorized individuals to work together within the same physical space with [authorized] scientists.'' We made no changes based on these comments. We would defeat the purpose of the Act if we were to waive the security provisions. Those with access to select agents and toxins must meet the requirements of the regulations, including those requirements concerning security risk assessments. This would not prohibit escorted activities as long as the escorted scientists and technicians do not have access to select agents or toxins. We considered the potential cost of reduced collaboration among scientists, along with other non-quantifiable costs, as discussed in the section addressing ''Economic Impact.''

Commenters asserted that the security provisions should be changed to ''allow people who are not approved * * * to enter the area without escort provided that (1) All select agents and toxins have been secured in locked cabinets, rooms or other containers, (2) The containers cannot be forced open without tools and without visible signs of damage; (3) Rooms are secure against entry by unauthorized personnel; (4) Keys, combinations, etc. are controlled as presently required; (5) Access to the area is limited to employees of the entity.'' Commenters argued that this approach ''is consistent with requirements [such as those in 10 CFR 95.25] for handling classified documents under which people without clearance may enter rooms without escort provided the documents are secured in cabinets. In addition, commenters argued that this approach would ''also reduce the burden on the Attorney General's office, allowing it to perform more extensive checks on a smaller number of individuals.'' Similarly, commenters asserted that the final rule should provide that when ''laboratories are used intermittently for select agent research, free access [should] be permitted when select agents and toxins are not in use and when the select agents and toxins are secured in a safe or other secured storage. We made no changes based on these comments. The security requirements are designed to prevent unauthorized access, theft, loss, or release of select agents and toxins. We believe the regulations already are consistent with commenter's approach.

Commenters recommend the final rule distinguish between laboratory security and entity security. One commenter argued that ''In large academic settings it is possible for a fully secure laboratory facility to coexist with a functioning educational and research laboratory entity'' and ''Placing full security restrictions on a building primarily devoted to educational functions compromises an educational institution's ability to fulfill its primary functions.'' The commenter further argued that ''This, in turn, may force laboratories working with select agents to shut their biodefense studies or move elsewhere.'' We made no changes based on these comments. As discussed earlier, the security provisions are designed to prevent unauthorized access, theft, loss, or release of select agents and toxins. In most cases the security provisions would have little or no effect on the educational activities. The regulations require that an entity's security plan be designed according to a site-specific risk assessment. Such a risk assessment would take into consideration the security needed for a select agent laboratory in a large academic setting. However, we would defeat the purpose of the Act if we were to waive the security provisions to eliminate an impact on educational research conducted in the same laboratory that contains select agents and toxins.

Packages

The amended interim final rule required the inspection of all packages upon entry to and exit from an area containing select agents or toxins. Commenters asserted that such a requirement is not practical because of the number of packages of laboratory supplies, autoclaved waste, etc. that enter and exit a select agent laboratory every day. Some argued that the inspection provisions should apply only for packages received after shipment or transfer. Some commenters argued that only random inspections should be conducted. Some commenters argued that more detail should be provided. After further review, we have determined that the security purpose would be met if entities were required to inspect only suspicious packages. We have changed the rule to reflect this determination.

Commenters questioned who should be responsible for conducting the inspections of packages. Some commenters argued that the Responsible Official should be the one responsible for the inspections. We made no changes based on these comments. The final rule allows the entity to determine who should conduct the inspections of packages since the entity would be best able to determine the most appropriate and qualified individual for this activity.

Intra-Entity Transfers

The amended interim final rule provided that an entity must establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual with a security risk assessment approval. Based on questions by commenters, we have changed this language to clarify that the requirements apply only to intra-entity transfers of select agents and toxins. Commenters also argued that these provisions are not sufficiently restrictive since they could ''allow an individual to leave a package of select agents temporarily unattended in an open air

lock: that is not security.'' They further asserted that ''Intra-entity movement of select agents, when outside access-controlled laboratory areas, should follow a documented chain of custody process that minimizes any possibility of diversion.'' In response, based on the reasons provided by the commenters, we changed these provisions to require that the select agents and toxins must be secured against theft, loss, or release during intra-entity transfer and the entity must provide for chain of custody documentation. The provisions of renumbered § 73.17 (Records) already require recordkeeping that would establish the chain of custody.

Reporting

The amended interim final rule required that suspicious persons or activities be reported to the Responsible Official. Commenters asserted that the finding of suspicious persons or activities should be reported to the local law enforcement agency, followed by notification to the RO.'' They argued that ''Local law enforcement agencies are staffed 24/7/365 and they are equipped to deal with potential criminal aspects of suspicious activities.'' We made no changes based on this comment. We agree with the commenters that law enforcement agencies should be notified, but we believe the responsibility for reporting to the appropriate law enforcement agencies should be maintained by the Responsible Official.

Records

The amended interim final rule required the security plan to describe cyber security. Commenters asserted that ''The data related to the select agents, in many cases, are almost as valuable as the select agents themselves'' and requested clarification regarding the assets intended to be covered by the term ''cyber security.'' Commenters also asserted that the term ''cyber security'' should be replaced with ''information and cyber security.'' In response, we changed the language to require the security plan to contain procedures for ''information systems control'' and thereby more clearly indicate what was intended.

Review

The amended interim final rule states that ''The security plan must be reviewed by the RO at least annually and after any incident.'' Commenters recommended that this paragraph be revised to state ''The security plan must be reviewed, performance tested, and updated annually.'' We believe performance testing will help to ensure that the plan works and have changed the regulations to include these concepts.

Pre-Clearance

A commenter expressed concerns that the regulations do not provide for preclearance of security plans before an entity invests in a security system. We made no changes based on the comment. The provisions in the Final Rule clearly set forth what must be included regarding the security requirements. However, those entities needing additional technical assistance may reference the BMBL or contact the Select Agent Program.

Administrative

Commenters asserted that the final rule should designate who in the federal government is responsible for making determinations concerning the adequacy of the security plans. We made no changes based on this comment. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. The regulations allow for the delegation of authority of this function to the Select Agent staff or other appropriate office.

Commenters argued that security plans, and all information related to the security systems, be protected at the ''Official Use Only'' level. We made no changes based on this comment. The protection of all information held by the Select Agent Program is an operational responsibility and not a matter appropriate for inclusion in Part 73. However, as a matter of both policy and practice, the information is protected at the ''Sensitive But Unclassified'' level.

Section 73.12 Biosafety

[This Subject Is in § 73.10 in the Amended Interim Final Rule]

The amended interim final rule provided that an entity subject to the part 73 regulations must develop and implement a safety plan and in developing a safety plan, an entity should consider:

''(1) The biosafety standards and requirements for BSL 2, 3, or 4 operations, as they pertain to the respective select agents, that are contained in the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories,'' including all appendices except Appendix F.

(2) The specific requirements for handling toxins found in 29 CFR part 1910.1450, ''Occupational Exposure to Hazardous Chemicals in Laboratories'' and/or 29 CFR part 1910.1200, ''Hazard Communication,'' whichever applies and specific requirements for handling toxins found in Appendix I in the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories.''

(3) For provisions of the safety plan relating to genetic elements, recombinant nucleic acids and recombinant organisms, the ''NIH Guidelines for Research Involving Recombinant DNA Molecules,'' (NIH Guidelines). This includes, among other things, provisions regarding risk assessment, physical containment, biological containment, and local review and applies to all recombinant DNA research, regardless of funding.

Commenters argued that we should retain the provisions concerning the safety plan without change. One commenter suggested that compliance with the documents listed in the preceding paragraph should be made mandatory for all entities subject to the rule. Other commenters asserted that we should adopt performance-based standards. The safety provisions were intended to avoid the creation of a ''one size fits all'' set of safety standards due to the vast diversity of both entities and the reasons why they possess, use, and transfer select agents and toxins. However, we amended the language of the final rule to establish performance-based safety provisions. Accordingly, under the final rule, entities must not only develop and implement a safety plan, but must develop a plan that is commensurate with the risk of the agent or toxin, given its intended use. Further, the biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures. These provisions are designed to help ensure that the safety plan is effective.

Commenters recommended that safety plans established for compliance with the HHS rule should be sufficient to meet the requirements for a safety plan under the USDA regulations. They argued that otherwise an entity must issue two safety plans. Commenters further asserted that USDA and HHS should develop joint safety requirements for select agents and toxins to supplant the BMBL and NIH Guidelines. We agreed with the commenters and HHS and USDA made this section identical to ensure consistency between the regulations.

Section 73.13 Restricted Experiments

[This Subject Is in § 73.10 in the Amended Interim Final Rule]

The amended interim final rule stated that an entity may not conduct certain experiments unless approved by the

HHS Secretary after consultation with experts. Commenters suggested that the following be considered for providing such consultation: The National Research Council, the NIH Recombinant DNA Advisory Committee, and the Select Agent Advisory Committee. One commenter argued that ''It is critical that this review committee comprise appropriate experts in microbiology, highly pathogenic microorganisms and laboratory safety to ensure the best possible science advice.'' We made no changes based on these comments. We agree that we should obtain advice from experts as needed for decision making and will consult with subject matter experts as necessary.

One commenter expressed concern that the amended interim final rule did not contain a process for expert review and oversight of ''dangerous experiments.'' We made no changes based on this comment. Under the regulations, we will review applications to determine whether the experiments can be safely conducted, will require whatever conditions are necessary for safety, and will consult with subject matter experts as necessary. Also, under the regulations, we have authority to conduct inspections as necessary to ensure that the conditions are met.

One commenter raised issues regarding the deliberate formation of antibiotic resistance as a common research tool. The commenter asserted that if strictly imposed, the restricted experiment provisions would limit this standard research practice and provided an example concerning antibiotic resistance application. The commenter stated ''Transposon insertion libraries are common experimental creations used to generate gene knockouts and study the effect on expression and phenotype'' and ''this often results in an array of genomes containing antibiotic resistance markers used for selection and screening.'' The commenter then argued that ''The method is common enough not to need approval from a cabinet level position and too burdensome if approval is needed for each of several thousand insertional mutants that would be created for a single genome.'' We made no changes based on this comment. It is important that researchers consider the possible unintended effects from the deliberate formation of antibiotic resistance. The restricted experiment provisions apply only if the activities ''could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.'' We believe that the majority of research involving antibiotic resistant markers that are commonly used for selection and screening will not meet this criteria and therefore, will not require additional approval. Further, we believe that activities meeting this threshold should require such approval as has been the case for those entities subject to the ''NIH Guidelines for Research Involving Recombinant DNA Molecules''.

The preamble to the initial interim final rule stated that we reserved a paragraph for possible future specification of additional types of experiments that might warrant stringent scrutiny in the interest of safety. One commenter argued that the following experiments should be added to the reserved paragraph based on the conclusion that they warrant such stringent scrutiny (*i.e.*, should be allowed only if approved by the HHS Secretary after consultation with experts):

(1) Experiments involving construction of vaccine-resistant select agents or toxins.

(2) Experiments involving increasing the environmental stability of select agents or toxins.

(3) Experiments involving powder or aerosol production of select agents or toxins (other than preparation of lyophilized reference specimen <10 mg).

(4) Experiments involving powder or aerosol dispersal of select agents or toxins.

We made no changes based on this comment. We are studying whether these and other types of experiments should be added to § 73.13. Experiments will be proposed for addition to the listing of restricted experiments, as warranted, through the publication of a proposed amendment for public comment.

Commenters argued that the regulations should not list types of experiments that require approval because of the difficulty of amending regulations as needs change. Instead, commenters argued that the list should be included in the NIH Guidelines. We made no changes based on these comments. Publishing such information in the regulations will ensure that the public, including affected entities, are provided adequate notice concerning the list of experiments requiring approval requirements.

Commenters questioned whether the HHS Secretary should be involved in approving experiments. One commenter specifically questioned whether HHS has authority to proscribe experiments. We made no changes based on these comments. We believe we have such authority. In this regard, the Act at 42 U.S.C. 262a(c) states that the ''Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing possession and use of listed agents and toxins * * * in order to protect public health and safety.''

We added provisions for how applicants are to submit a written request for approval.

Section 73.14 Incident Response

[This Subject Is in § 73.12 in the Amended Interim Final Rule]

The amended interim final rule provided that an entity required to register must develop and implement an emergency response plan that meets the requirements of OSHA Hazardous waste operations and emergency response standard at 29 CFR part 1910.120. With respect to these OSHA standards, paragraph (a) addresses scope, application, and definitions and paragraph (q) addresses emergency responses to hazardous substance releases. The provisions of 40 CFR part 311 make 29 CFR part 1910.120 applicable to State and local government employees. The OSHA regulations also reference 29 CFR part 1910.38 which concerns the development and implementation of an emergency action plan.

In the final rule, we have eliminated references to the OSHA provisions and have set forth the provisions from the OSHA regulations that would apply for an incident response plan. The OSHA regulations at 29 CFR part 1910.120(q) include provisions for assisting in the handling of an emergency. Although entities handling select agents and toxins are subject to the OSHA regulations, our regulations are not intended to cover clean up operations but rather to ensure that entities are prepared to take whatever other action is necessary to respond to an incident. Also, we note that an entity may use all or a portion of a document prepared under other authorities as long as it meets the requirements of the incident response provisions of the part 73 regulations.

Commenters recommended that the incident response section of the final rule reference 29 CFR part 1910.1450 which concerns occupational exposure to hazardous chemicals in a laboratory. We made no changes based on this comment. Although entities may need to become familiar with the provisions of this section, it does not provide the basis for requirements under the part 73 regulations and we see no reason for referencing it in this section.

One commenter asserted that the incident response provisions are ''too stringent for select agents and toxins not

mandated for control within maximum containment facilities.'' The commenter asserted that ''These provisions are based in part on a GAO report that promotes threat and risk assessments in the planning of emergency responses to an actual domestic terrorist incident involving weapons of mass destruction and on OSHA regulations relating to hazardous waste sites'' and ''have little relevance to the inadvertent release or theft of select agents and toxins from biomedical research laboratories.'' We made no changes based on this comment. The commenter did not provide any specifics to support the general comment. We believe the incident response provisions are necessary to help ensure that entities plan ahead to be ready to take appropriate action to respond to any hazard that could arise.

Section 73.15 Training

[This Subject Is in § 73.13 in the Amended Interim Final Rule]

The training section in the amended interim final rule provided that a registered entity that falls outside of the OSHA Bloodborne Pathogen Standard (29 CFR part 1910.1030(a)) must provide safety and security information to any individual working in or visiting areas where select agents and toxins are handled or stored. Also, this section stated that: ''In lieu of initial training for those individuals already involved in handling select agents, the Responsible Official may certify in writing that the individual has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities.'' Commenters argued against certification based on the conclusion that each facility is different and facility specific training must be required regardless of knowledge, skills, or ability. Also, commenters argued that Bloodborne Pathogen training would not be a suitable substitute for training specific to the use of select agents. To address these issues, commenters recommended the following wording: ''An entity required to register under this part must provide information and training on safety and security for working with select agents and toxins to each individual approved for access and each individual not approved for access from the HHS Secretary or Administrator working in or visiting areas where select agents and toxins are handled or stored. The training may be modified according to the needs of the individual, the work they will do and their potential exposure. The training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030.'' We agree with the substance of these comments, including the reasons given for them. Accordingly, we made changes in § 73.15 to clearly reflect the intent of the regulations.

Section 73.16 Transfers

[This Subject Is in § 73.14 in the Amended Interim Final Rule]

One commenter argued that ''receipt of select agents and toxins by the Responsible Official is a valuable procedural control to ensure that all required compliance measures are in place prior to final delivery of the agent to the Investigator'' and further asserted that ''This procedure parallels the common and effective practice of requiring receipt of radionuclides by the Radiation Safety Officer prior to their distribution to the Principal Investigator.'' We made no changes based on this comment. The Responsible Official must approve the transfer and ultimately is responsible for compliance matters. However, we do not believe that it is necessary to require the Responsible Official to be the recipient. If a problem were to arise, the person having access and receiving the select agents or toxins would be the logical person to discover any issues or concerns related to the receipt of the select agents or toxins and advise the Responsible Official of such.

The part 73 regulations do not impose requirements on the transportation in commerce or exportation of select agents or toxins. However, requirements are imposed by the government on the transportation in commerce and exportation of select agents and toxins, including the following:

- Agriculture (9 CFR parts 92, 94, 95 96, 121, 122 and 130),
- Commerce (15 CFR parts 730 to 799),
- Health and Human Services (42 CFR parts 71 and 72),
- Occupational Health and Safety Administration (29 CFR part 1910.1030),
- Transportation (49 CFR parts 171 through 180), and
- Postal Service (39 CFR part 111).

Commenters asserted that § 73.11 should ''address the security of shipments while in transit between entities'' and that ''The current DOT requirement for external labeling on select agent packages should be eliminated.'' One commenter argued that ''transportation security needs to be addressed and required to be just as rigorous as security requirements for the labs.'' Another commenter argued that ''The fact that registered entities must comply with all applicable laws concerning packaging and labeling significantly increases the risk that select agents could be easily identified and diverted for illegal purposes during transportation by common carrier.'' Another commenter argued that ''The absence of requirements for registration, security risk assessments, and physical security for the common carriers that will be handling and transporting select agents between registered entities is cause for concern.'' Commenters also argued that ''Both the shipping and receiving entities should document a chain of custody for transfers of select agents'' and ''These chain of custody documents should be securely stored with the EA–101 form at both the shipping and receiving entities.'' Commenters also argued that ''tamper-indicating procedures should be included in the packaging so that the recipient would immediately know that the package he/she has received had been tampered with; this event should trigger an immediate report to HHS.'' We made no changes based on these comments. These issues are outside the scope of this rulemaking. However, we believe the provisions set forth in § 73.16, in addition to the other Federal laws regulating the transportation of hazardous materials in commerce and exportation of select agents and toxins, sufficiently protect public health and safety.

One commenter asserted that ''Intra-entity movement of select agents, when outside access-controlled laboratory areas, should follow a documented chain of custody process that minimizes any possibility of diversion.'' We made no changes based on this comment. The provisions of renumbered § 73.17 (Records) already require recordkeeping that would establish the chain of custody.

One commenter asserted that the transfer provisions should allow a non-registered entity to transfer a select agent or toxin to a registered entity based on the need to prevent destruction of valuable historical, archival or educational materials containing select agents or toxins. We agreed. Accordingly, we have added provisions to allow, on a case-by-case basis, the transfer of a select agent or toxin, not otherwise eligible for transfer.

One commenter asserted that a unique identifier should be assigned to each Transfer of Select Agent Form (APHIS/CDC Form 2) based on the argument that they are necessary to track and audit transfers. We made no changes based on this comment. We already add a unique authorization number to each approved transfer form.

One commenter recommended that the final rule require a response to a transfer request within an appropriate interval, *e.g.*, 1–2 business days. We made no changes based on these comments. It is impractical to specify a time interval for the approval of a transfer request since the authorization of the request is dependent upon the review of appropriate records that confirm the individuals and entities currently meet all the requirements to transfer the select agents or toxins.

The amended interim final rule provided that an entity must maintain transfer records for three years. Commenters asserted that the regulations should require that EA–101 forms be kept for five years. We made no changes based on these comments. Entities may wish to retain records for longer for three years. In keeping with the three year registration period, we did not extend the required time to keep records.

The amended interim final rule did not set a time limit for transfers. We are adding a provision stating that a transfer authorization is valid only for 30 calendar days. This is necessary to efficiently manage the transfer authorization system and ensure timely resolution of outstanding transfer activities.

The amended interim final rule stated that when the select agents or toxins are consumed or destroyed after a transfer, an entity must provide written notice within five business days of such action. We are deleting this provision. As noted above, under the registration provisions the Responsible Official must provide prompt notification in writing if a change occurs in any information submitted in the application for the certificate of registration or amendments. Since this would include adding or removing a select agent or toxin, there is no need for otherwise imposing a five-day notification requirement.

The amended interim final rule required the submission of an immediate report by the recipient if ''the package received containing select agents or toxins had been leaking or was otherwise damaged.'' We clarified these provisions to require the submission of an immediate report by the recipient if the package had ''been damaged to the extent that a release of the select agent or toxin may have occurred'' because leaking may not be apparent (*e.g.*, toxins). In addition, a damaged secondary container may not result in a compromised container to the extent that a release of the select agent or toxin may not have occurred. This more clearly expresses the intent and will help prevent a reader from concluding that an innocuous dent in a package must be reported.

In addition, we have added the provisions that ''A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, within 7 calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient'' for the tracking of select agents or toxins including those contained in a specimen presented for proficiency testing.

Section 73.17 Records

[This Subject Is Covered in § 73.15 in the Amended Interim Final Rule]

Commenters recommended that this section be revised to be performance based. We made no changes based on these comments. Performance-based requirements are appropriate when differing circumstances require flexibility in approach. The records section sets forth specific requirements which we believe apply fairly to all entities required to be registered.

Commenters asserted that ''It is not feasible to record quantities (*i.e.*, actual real-time numbers) of replicating organisms.'' Commenters recommended ''functional or performance based approaches to documenting replicating agents, such as using a logbook/data entry system to record information typically gathered during a research protocol as part of standard practice or GLP (*i.e.*, quantity of material inoculated, quantity of media added during the work, quantity material used/destroyed, final cell count, etc).'' In response to the comment, we clarified the language that ''accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials)'' must be maintained.

One commenter argued that ''It will be difficult to maintain real time/current records * * * for internal transfers of select agents until badge readers or bar code readers (with data accessible by the RO) are installed for each laboratory and for each storage area'' and stated further that ''Until we are able to install these access controls, we request flexibility regarding access control.'' We made no changes based on this comment. An accurate and current inventory must be maintained in order to ensure accuracy of records.

One commenter requested clarification regarding the phrase ''certain records and databases.'' For clarification purposes, we specified that the ''certain records and databases'' are those records and databases required to be created under this part.

The amended interim final rule stated ''for access to the area where select agents are used or stored that a record of the date and time the individual entered and left the area must be maintained.'' We are deleting the exiting record-keeping provision. We believe the requirements that entities maintain records of all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), the date and time of entry is sufficient in maintaining records of access into areas containing select agents and toxins.

Section 73.18 Inspections

[This Subject Is in § 73.16 in the Amended Interim Final Rule]

One commenter argued that for inspections ''a background in financial auditing alone is insufficient to review and critique the scientific practices and procedures involved'' and that ''Biosafety and biosecurity inspection teams should include professionals who have been educated and trained in, and have significant experience in, these multidisciplinary fields.'' We made no changes based on this comment. However, we agree with the commenter and our inspection teams include individuals who meet the criteria suggested by the commenter.

APHIS and CDC will coordinate inspections to minimize the burden on the entity. This coordination will ensure that inspections by APHIS and CDC are not duplicative. However, additional inspections may be required under certain circumstances. For instance, another inspection may be required for amendments to a certificate of registration (*e.g.*, addition of a laboratory) or to satisfy APHIS' permit requirements.

Section 73.19 Notification of Theft, Loss, or Release

[This Subject Is in § 73.17 in the Amended Interim Final Rule]

The amended interim final rule required reporting of theft, loss, or release of select agents or toxins. It required reporting of any ''release of a select agent or toxin causing occupational exposure or release outside of the primary containment barriers.'' Commenters asserted that reporting should not be required for a release unless there was an occupational

exposure outside of the biocontainment area of a registered entity. Similarly, one commenter recommended that the term ''release'' be defined ''as an escape of a select agent or toxin to the external environment (outside the building), outside of the select agent/toxin laboratory (or restricted area) or a spill or other exposure in the laboratory resulting in an OSHA recordable injury or illness.'' Commenters argued that entities would have appropriate procedures for safely responding to and managing spills within biocontainment areas of a facility. They also argued that without such a change there would be a waste of resources, disruption of research, and avoidance of reporting. We believe that all occupational exposures should be reported since exposures have the potential to adversely affect the public health and safety. In addition, we clarified the language to require notification ''upon discovery of a release of an agent or toxin causing occupational exposure or release of select agent or toxin outside of the primary barriers of the biocontainment area.''

One commenter opposed the reporting requirements for theft or loss of select agents and toxins based on the following assertions:

- Because of the improved recordkeeping requirements, illegal diversion of a select agent will most likely be done by subculturing an agent out of a vial without removing the vial or a detectable amount of material.
- It is likely that the unexplained disappearance of individual vials will not be noticed at the time of loss but days, weeks, months, years, or decades later making reconstruction of the circumstances virtually impossible.
- The unexplained absence of a vial of a select agent will most likely result from errors in the original inventory, or failure to adjust the inventory when vials are used legitimately.

We made no changes based on these assertions. To take no action when select agents or toxins are unaccounted for would reduce the ability of the HHS Secretary to respond in a timely matter to protect public health and safety.

One commenter noted that the amended interim final rule required safety and security ''incident'' reports but did not define events that constitute ''incidents.'' The commenter questioned ''Is any failure to comply with the regulations an ''incident''?'' and indicated that an ''incident'' should be limited to ''any occurrence or event which results, or threatens to result, in the unlawful transfer, possession, or use of a select agent or in the loss, theft, or other unauthorized transfer, use, or release of a select agent.'' In response to this comment, we clarified the regulations to require reporting of thefts, losses, or releases.

An entity must notify immediately CDC, APHIS, and appropriate Federal, State, or local law enforcement agencies upon discovery of the theft or loss of a select agent or toxin. In addition to other information required to be submitted, we have added the requirement that advises the entity to report the list of Federal, State, or local law enforcement agencies that the entity reported or intends to report the theft or loss. This will help coordinate the response effort.

Section 73.20 Administrative Review

[This Subject Is in § 73.18 in the Amended Interim Final Rule]

Commenters argued that the appeal provisions should have more detail. We made no changes based on these comments. Any additional appeal procedures will be provided, as necessary at the time of an appeal.

Commenters argued that the regulations should impose timeframes for making appeal decisions. We made no changes based on these comments. We will act to make decisions as quickly as possible. However, our first concern must be to make appropriate decisions that help to protect public health and safety.

Commenters asserted that the part 73 regulations should contain an administrative appeals procedure for researchers to request review of a designation as a ''restricted person'' or provide an exemption process for legitimate research. Commenters asserted that ''the absence of an appeals or exemption process is troubling given the possible inaccuracies in the information contained in the databases that are available to the Federal Government and others.'' We made no changes based on these comments. The Act prohibits a person designated as a restricted person from obtaining approval to have access to select agents or toxins and we have no authority to act contrary to the Act. However, individuals may challenge factual mistakes as described in the administrative appeal process for Section 73.20 (Administrative review).

Submissions and Forms

[This Subject Is in § 73.21 in the Amended Interim Final Rule]

We received no comments concerning submissions and forms section. Since addresses and telephone numbers are subject to change, we deleted this section. Specific guidance on the submissions and forms is available to the public on the Select Agent Program web site.

In addition, we recognize that the different form numbers for identical forms may be confusing to the regulated community. Accordingly, CDC and APHIS will be adopting a shared numbering system for the identical forms that uses the prefix ''APHIS/CDC Form''.

CDC form No.	APHIS form No.	Title of form	APHIS/CDC form No.
0.1319	2040	Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins.	1
EA–101	2041	Report of Transfer of Select Agents and Toxins	2
0.1316	2043	Report of Theft, Loss, or Release of Select Agents and Toxins	3
0.1318	2044	Report of Identification of a Select Agents or Toxin in a Clinical or Diagnostic Laboratory	4
0.1317	2042	Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational/Experimental Product.	5

Section 73.21 Civil Money Penalties

[This Subject Is in § 73.19 in the Amended Interim Final Rule]

One commenter recommended that entities be subjected to much higher maximum civil money penalties than individuals. We made no changes based on this comment. The maximum amounts for civil monetary penalties, set by statute, are in fact higher for entities than for individuals. As indicated earlier, however, we are making one technical revision to 42 CFR part 1003 by adding amendatory language in the introductory paragraph for § 1003.106(a)(1) to reference OIG's

newly codified penalty authority set forth in § 1003.102(b)(16).

Criminal Penalties

[This Subject Is in § 73.20 in the Amended Interim Final Rule]

We received no comments concerning criminal penalties. Since this section restates the provisions of the Act, we deleted this section.

Miscellaneous

We made nonsubstantive changes throughout the regulations for purposes of clarity. In addition, CDC and APHIS made the language similar to ensure consistency between the regulations.

Economic Impact

A dozen commenters addressed issues relevant to the rule's Regulatory Impact Analysis (RIA). Nearly all of these comments were submitted by universities or related organizations.

One commenter agreed with HHS's regulatory benefits analysis, *i.e.*, that adequate security for select agents is crucial to protect health and safety, and that the potential costs of accidental or intentional release of a select agent or toxin could far exceed the costs institutions will incur to implement the new regulations.

Approximately eight commenters stated that the cost of the rule would be significantly greater than estimated by CDC. Several university commenters reported estimated costs higher than CDC's estimates. These comments reported first year costs ranging from $1 million to $4 million, with annual maintenance costs thereafter from nearly $100,000 to up to $700,000 (compared to CDC's estimated annualized cost of $153,000). One university reported an estimate of $300,000 in security improvements, including electronic card access, alarm systems, and security cameras, all of which are suggested in the rule, but excluding recordkeeping and other personnel requirements.[2] For these same items, another university reported an estimate of $400,000 for a single university BSL–3 select agent lab, excluding other select agent labs at the same university. Another commenter reported that several large universities have estimated that their costs will greatly exceed CDC's estimates. Some commenters argued that the full cost of implementing the rule will not be known until CDC reviews and approves of individual safety and security plans.

One commenter stated that the rule would have been found to have a significant overall effect, far exceeding $100 million annually, if factors such as lost research productivity and indirect institutional costs had been considered. In addition, several commenters stated that the requirements would reduce the number of institutions and locations where select agent research will be performed. One stated that the requirements may be too costly and difficult for smaller entities and may cause them to forego work with select agents and toxins. One commenter cautioned against the loss of specimens, which comprise a ''library of infectious diseases.'' Several commenters felt that non-quantifiable impacts such as these, in turn, would impede the accumulation of knowledge, decrease the level of talent studying select agents, and shift knowledge outside of the U.S.

Several commenters questioned whether universities would be able to recover the costs of the rule given cost recovery practices, requirements, and caps. Other commenters asked or suggested that grant money be made available to cover the cost of the rule, either through current grant programs or new select agent infrastructure support grants. Others requested more generally that the final rule address mechanisms by which universities would recover the cost of compliance. One stated than an exemption of the minimum cost cap would be appropriate to ensure compliance. Some commenters (including State universities) cited already significant budget constraints. A few commenters stated that the costs of the rule represent an unfunded mandate unless a means of cost recovery is made available.

We carefully considered each of the comments that addressed the RIA, including the issues raised regarding non-quantifiable and indirect costs of the rule and the data presented. Based on this review, we determined that it was not necessary to revise the economic analysis to address the comments, although we did revise the RIA based on rule changes and newly-available data, as described later in this section. In passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress recognized that it was an important matter of national security to ensure that entities that possess, use, or transfer biological agents and toxins with the potential to pose a severe threat to humans met their responsibilities to keep these agents and toxins safe and secure. Development of both the amended interim final rule and the final rule took into consideration the potential economic impact of compliance with the biosecurity and physical security requirements. These costs and benefits were addressed in detail in the Regulatory Impact Analysis done for both the amended interim final rule and the final rule.

Although some commenters cited figures to support their assertion that the RIA understated the cost of the rule, the information provided within these comments generally did not contradict the conclusions presented in the RIA. For example, we believe the $4 million first-year cost and $700,000 annual maintenance cost that was reported by one of the commenters actually is consistent with the RIA, because the commenter represents a State-wide university system containing 10 schools; if the reported figures are divided across even five or six of the system's schools, then the reported costs are similar to those estimated in the RIA. Similarly, various comments estimated one-time costs at $400,000 for partial upgrades at one lab, and at $300,000 for partial upgrades at a different lab. Absent further details regarding the specific types of labs involved and the need for other upgrades, however, these figures appear to fall within the estimated RIA values.

The comments, in general, did not contain sufficient information to call the RIA's conclusions into questions. For example, one university estimated its one-time cost to be in excess of $1 million, which would appear to exceed the RIA's model facility estimate by 40 percent. In this case, however, the comment did not contain any additional information that would allow CDC to either validate the university's estimate or evaluate whether the particular lab might be an outlier with respect to costs.

We agree that the RIA has not attempted to quantify the value of lost research and other indirect institutional effects. We considered such effects, however, and for several reasons, we disagree with the contention that indirect effects would lead to overall impacts exceeding $100 million annually. First, based on our experience with the pre-notification and registration process, we believe there will be few instances where universities abandon lines of research in response to the rule. Out of the 200 or so entities that transferred or destroyed their select agents rather than registering under the rule, we believe that the majority did so for reasons that do not threaten future research, as suggested by the following three typical examples: (1) Researchers who already have completed efforts

[2] Other requirements described as contributing significantly to costs include recordkeeping, additional staff, and cyber/information security and training.

under past research grants; (2) universities that continue their select agent research but at fewer locations within the university system; and (3) hospitals that had used select agents for purposes other than research (*e.g.*, quality assurance testing) but which can readily substitute other agents. Second, even if an institution did discontinue its research, we expect that this research would not be ''lost.'' Instead, other universities likely would pick up these research lines, particularly research efforts funded through grants. Therefore, any research effects are likely to be small including, in particular, any shift of knowledge on select agents to outside of the U.S. Third, to the extent that any net reduction in research or other negative institutional effects were to occur, quantification of these effects would be highly speculative.

In conjunction with the development of the revised final rule, we revised the RIA in a number of respects and reduced the estimated cost of the rule to an annualized total of $16 million. The economic analysis were estimated based on the actual costs incurred by registering entities implementing the interim final rule that became fully applicable on November 12, 2003. This estimate reflects the cost of all incremental activities required by the final rule, which for the most part are the same activities as were initially required by the 2002 interim final rule. (Very few of the changes made by the final rule have any bearing on cost relative to the interim final rule.) [3] Nevertheless, the $16 million cost represents a substantial decrease relative to the $41 million figure estimated in 2002 for the interim final rule. The decline is due almost entirely to the availability of new data showing that (1) fewer entities registered with CDC than had been estimated, (2) fewer individuals required security risk assessments, and (3) a smaller number of transfers occur each year than was estimated.

We considered the possibility that the smaller numbers reflected in the actual data (relative to earlier estimates) might be the result of indirect impacts of the rule (*e.g.*, entities abandoning research rather than undertaking the registration process). Our experience during the pre-notification and registration process suggests, however, that this is not the case. Instead, we believe the original estimates were overstated as a result of the over-inclusive notification process we used to help ensure that all potentially affected entities would be made aware of the rule. Most of the overestimates reflect entities that have since notified us that they are not affected by the rule (*e.g.*, users of Botox) or that they are exempt entities. Others possess agents that would be considered excluded from the regulation. While we believe that 200 or so entities did transfer or destroy their select agents rather than register under the rule, we believe that the majority did so for reasons that do not threaten future research, as discussed previously.

With respect to the comments concerning any ''unfunded mandate'' imposed by the rule, we note that while the rule imposes certain costs on the regulated community, to reduce the burden of these new regulations the biosecurity and physical security requirements contained in this rule are based on guidance provided by the ''Biosafety in Microbioloical and Biomedical Laboratories,'' 4th Edition, published jointly by the CDC and the National Institutes of Health. Whether the federal government should provide funding for enhanced biosafety and physical security at facilities using select agents and toxins is beyond the scope of the regulations mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0920–0576. However, CDC is requesting an emergency clearance from OMB regarding this data collection with a 10 day public comment period. The emergency clearance is based on a revision of this data collection as a result of this final rule.

Please send written comments on the new information collection contained in this final rule to Seleda M. Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 10 days of this notice.

Copies of this information collection may be obtained from Seleda M. Perryman, CDC Assistant Reports Clearance Officer, at (404) 371–5973.

CDC is requesting continued OMB approval to collect this information through the use of five separate forms. These forms are: (1) Application for Registration, (2) Transfer of Select Agent or Toxin Form, (3) Facility Notification of Theft, Loss, or Release Form, (4) Clinical and Diagnostic Laboratory Reporting Form, and (5) Request for Exemption.

Reductions in Burden of Data Collection

The amended interim final rule stated that an entity must provide written notice at least five business days before destroying a select agent or toxin, if the destruction would be for the purpose of discontinuing activities with a select agent or toxin covered by a certificate of registration. The amended interim final rule further stated that ''This will allow the HHS Secretary and/or the USDA Secretary to observe the destruction or take other action as appropriate.'' We are deleting this provision. Under the registration provisions, the Responsible Official must provide prompt notification in writing, if a change occurs in any information submitted in the application for the certificate of registration or amendments. This would include adding or removing a select agent or toxin and it was determined that to impose an additional five-day notification requirement was not necessary. Therefore, there is a decrease in burden that was previously reported by the estimated time of 30 minutes to gather the information and submit this notification.

The amended interim final rule stated that when the select agents or toxins are consumed or destroyed after a transfer, an entity must provide written notice within five business days of such action. We are deleting this provision. As noted above, under the registration provisions the Responsible Official must provide prompt notification in writing if a change occurs in any information submitted in the application for the certificate of registration or amendments. Since this would include removing a select agent or toxin from a registration due to it being consumed or destroyed after a transfer, it was determined that there is no need to impose this additional five-day notification requirement. Therefore, there is a decrease in burden that was previously reported by the estimated time of 15 minutes to gather the information and submit this notification.

[3] First, the final rule eliminates an interim final rule provision (along with the associated costs) requiring laboratories to notify the HHS Secretary when destroying select agents or toxins for the purpose of discontinuing activities with the select agent or toxin. Second, the final rule adds a provision that laboratories test and evaluate the effectiveness of their biosafety, security, and incident response plans annually.

Potential Increases in Burden of Data Collection

The amended interim final rule stated entities required to register under this part must immediately notify a theft, loss, or release of select agent or toxin. We added the provisions that exempted clinical or diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis, verification, or proficiency testing must also meet the requirements of § 73.19 (Notification of theft, loss, or release). We believe that any theft, loss, or release of a select agent or toxin must be reported to protect public health and safety. Based upon the small number of reports received during the implementation of the Interim Final Rule, we believe that this would not result in a change in burden.

The amended interim final rule stated entities were required to report immediate notification to CDC for any of the following overlap select agents: *Bacillus anthracis,* Botulinum neurotoxins, and *Francisella tularensis* and immediately notify APHIS of all overlap select agents and toxins. In this final rule, CDC and APHIS have combined their immediate notification list for overlap select agents and toxins (*Bacillus anthracis,* Botulinum neurotoxins, *Brucella melitensis, Francisella tularensis,* Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus). Therefore, entities will be able to immediately notify either agency. Since entities were required to immediately notify both agencies in regards to overlap select agents and toxins and now only have to notify one agency, we believe that due to the small number of such reports received this would not result in a change in burden, but a change in process for the regulated community.

In addition, we have added the provisions in § 73.16 (Transfers) section that ''A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, within seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient'' for the tracking of select agents or toxins including those contained in a specimen presented for proficiency testing. Due to the small number of the ''Report of Identification of a Select Agents or Toxin in a Clinical or Diagnostic Laboratory'' forms received regarding proficiency testing specimens that were required to report under the current Interim Final Rule, we believe that this notification requirement would not result in a change in burden.

Executive Order 12866 and Regulatory Flexibility Act

This document has been reviewed by the Office of Management and Budget under Executive Order 12866. In the course of developing the rule, CDC considered the rule's costs and benefits. CDC's analysis is summarized below.

Affected Entities. To date, 451 entities have submitted an application for registration and 350 have been determined by CDC to require registration. The remaining 101 applications were not processed primarily because CDC determined that the entities sought to register for something other than a select agent. The 350 registered entities fall within six groups:

- Academic/University: 105 (approximately 30 percent);
- Government—State/Local: 104 (approximately 30 percent);
- Government—Federal: 61 (approximately 17 percent);
- Commercial: 39 (approximately 11 percent);
- Private non-profit/Research Institutions: 35 (approximately 10 percent); and
- Other: 6 (approximately 2 percent).

Approximately 8,394 staff has received a security risk assessment approval since the requirement to submit information to the Attorney General became effective on April 12, 2003. The number of employees with access to select agents or toxins ranges from approximately five individuals at smaller facilities to one hundred or more at some large universities and commercial facilities.

Costs. The estimation of the long term cost of implementing the select agent regulations was based on the actual costs incurred by registering entities implementing the interim final rule that became fully applicable on November 12, 2003. Additionally, before the interim final rule was issued in December 2002, CDC contacted a number of entities to assess existing practices. Because many of the laboratories that will register under this rule are already substantially in compliance with the practices required, the costs of the rule are relatively limited.

In combining the estimated impact of the interim final rule with any new impacts in the final rule, CDC estimates the total annualized cost of the final rule at $16 million,[4] with annualized costs per facility ranging from $15,300 to $170,000. CDC had originally estimated the total annualized cost of the interim final rule at $40 million. The revised estimate of $16 million incorporates improved estimates of the number of registered entities. We estimate that the costs of the rule will not exceed $100 million in any single year; therefore the rule is not economically significant under Executive Order 12866. We estimate the first-year costs of the rule for all affected entities to total $36 million (compared to the previous estimate for the interim final rule of $106 million), with subsequent annual costs totaling $14 million (compared to the previous estimate for the interim final rule of $30 million). On a per facility basis, the average costs of the rule range from $15,300 to $170,000 per facility, slightly higher on average than those estimated for the interim final rule ($9,000 to $198,000). This increase is due to the net effect of a few particular changes in the final rule,[5] but the costs may be overstated due to conservative assumptions used in the absence of better information. These cost estimates exclude the cost of any indirect impacts resulting from the rule, although, as previously discussed, we believe that any indirect impacts are likely to be minimal.

Benefits. The benefits to public health and safety from implementation of the rule are clear, although difficult to quantify. The benefits of the final rule will be the decreased risk of accidental or intentional release of a select agent or toxin derived from the establishment of Federal standards for biosafety, security, training, and personnel surety. The cost of such an event in human life could be very high. The release of a select agent or toxin could result in a public health emergency requiring an extensive and expensive response. This effort could include extensive public health measures, such as quarantine, preventative treatment and health testing for large numbers of potentially exposed persons, and extensive decontamination. Substantial costs could be incurred by hospitals and other medical facilities and institutions of government at all levels. A release, or widespread fear of one, also would

[4] Costs are annualized over 20 years at a 7 percent discount rate.

[5] First, the final rule eliminates an interim final rule provision (along with the associated costs) requiring laboratories to notify the HHS Secretary when destroying select agents or toxins for the purpose of discontinuing activities with the select agent or toxin. Second, the final rule adds a provision that laboratories test and evaluate the effectiveness of their biosafety, security, and incident response plans annually.

create significant secondary effects. It could disrupt business, transportation, and many other aspects of normal behavior, on both a short-term and potentially a long-term basis.

The impacts resulting from the October 2001 anthrax attacks provide an example of the costs that a release could incur. The anthrax attacks caused five fatalities and 17 illnesses, disrupted business and government activities, and caused widespread apprehension and changes in behavior. Costs included more than $23 million to decontaminate one Senate office building; approximately $2 billion in revenues lost to the postal service, and as much as $3 billion in additional costs to the postal service for cleanup of contamination and procurement of mailsanitizing equipment. Substantial costs due to lost productivity throughout the economy and from ongoing costs of the investigations into the incident are additional impacts.

Implementation of the final rule will continue to provide a means for the registration of those who possess select agents and toxins; ensure that their transfer, storage, and use can be tracked; provide for the screening of personnel with access to such agents or toxins; and require that entities in possession of such agents or toxins develop and implement effective means of biosafety and physical security. The benefit of these provisions is a reduced likelihood of either an accidental or intentional release of select agents and toxins and the consequent avoidance of costs associated with such a release.

Impacts resulting from the costs of the rule should not be significant. The annualized cost on small entities would not exceed one percent of sales or revenue stream and the initial cost would not exceed three percent of sales or revenue stream. A copy of the economic analysis, ''Regulatory Impact Analysis, 42 CFR part 73, Possession, Use, and Transfer of Select Biological Agents and Toxins Final Rule,'' is available from on the CDC Web site at *http://www.cdc.gov.* The HHS Secretary hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

One commenter stated the rule did not adequately address the cost of compliance and believed that the interim final rule had created an unfunded mandate. We made no changes based on this comment. In passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress recognized that it was an important matter of national security to ensure that entities that possess, use, or transfer biological agents and toxins with the potential to pose a severe threat to humans met their responsibilities to keep these agents and toxins safe and secure. Development of both the amended interim final rule and the final rule took into consideration the potential economic impact of compliance with the biosecurity and physical security requirements. These costs and benefits were addressed in detail in the Regulatory Impact Analysis done for both the amended interim final rule and the final rule. We do not believe that the select agent regulations created an unfunded mandate. Since each entity is unique depending on the select agents and toxins in its possession, use of those agents and toxins, and the laboratory facility and physical plants, we stated biosecurity and physical security requirements in performance standards that we believe were already industry standards. For example, the biosecurity standards rely on the guidance provided by the Biosafety in Microbiological and Biomedical Laboratories, 4th Edition jointly published by the CDC and the National Institutes of Health. Whether the federal government should provide funding for enhanced biosafety and physical security at facilities using select agents and toxins is beyond the scope of the regulations mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532 that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule does not result in such an expenditure.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

List of Subjects

42 CFR Part 72

Biologics, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

42 CFR Part 73

Biologics, Incorporation by reference, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties, Social security.

Dated: March 10, 2005.

Michael O. Leavitt,

Secretary.

42 CFR Chapter I—Public Health Service, Department of Health and Human Services

§ 72.4 Notice of delivery; failure to receive.

■ For the reasons stated in the preamble, 42 CFR Chapter I is amended as follows:

PART 72—[AMENDED]

■ 1. The authority citation for part 72 continues to read as follows:

Authority: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

■ 2. Add the following sentence at the end of § 72.4: * * * This section does not apply to select agents and toxins that are subject to requirements under the provisions of 42 CFR 73.16 concerning transfers of select agents and toxins.

■ 3. Revise § 72.6 to read as follows:

§ 72.6 Exemptions.

(a) through (g) [Reserved].

(h) For purposes of 18 U.S.C. 175b, the exemptions to the list referred to in Appendix A constitute the exemptions set forth at 42 CFR 73.5 and 73.6.

■ 4. Revise Appendix A to part 72 to read as follows:

Appendix A to Part 72—Select Agents

For purposes of 18 U.S.C. 175b, the list of select agents constitutes the list of select agents and toxins set forth at 42 CFR 73.3 and 73.4.

■ 5. For the reasons stated in the preamble, 42 CFR part 73 is revised to read as follows:

PART 73—SELECT AGENTS AND TOXINS

Sec.

73.1 Definitions.
73.2 Purpose and scope.
73.3 HHS select agents and toxins.
73.4 Overlap select agents and toxins.
73.5 Exemptions for HHS select agents and toxins.

73.6 Exemptions for overlap select agents and toxins.
73.7 Registration and related security risk assessments.
73.8 Denial, revocation, or suspension of registration.
73.9 Responsible Official.
73.10 Restricting access to select agents and toxins; security risk assessments.
73.11 Security.
73.12 Biosafety.
73.13 Restricted experiments.
73.14 Incident response.
73.15 Training.
73.16 Transfers.
73.17 Records.
73.18 Inspections.
73.19 Notification of theft, loss, or release.
73.20 Administrative review.
73.21 Civil money penalties.

Authority: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a).

§ 73.1 Definitions.

For purposes of this part:

Administrator means the Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS) means the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Attorney General means the Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

Entity means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS means the Department of Health and Human Services.

HHS Secretary means the Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin means a biological agent or toxin included in § 73.3.

Overlap select agent and/or toxin means a biological agent or toxin listed in § 73.4 and 9 CFR part 121.4.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Proficiency testing means the process of determining the competency of an individual or laboratory to perform a specified test or procedure.

Responsible Official means the individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Select agent and/or toxin means unless otherwise specified, all of the biological agents or toxins listed in §§ 73.3 and 73.4.

Specimen means samples of material from humans, animals, plants or the environment or isolates or cultures from such samples for the diagnosis, verification, or proficiency testing.

State means any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means all of the States.

USDA means the United States Department of Agriculture.

Verification means the demonstration of obtaining established performance (*e.g.,* accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

§ 73.2 Purpose and scope.

This part implements the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both CDC and APHIS.

§ 73.3 HHS select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety.

(b) HHS select agents and toxins:

Abrin
Cercopithecine herpesvirus 1 (Herpes B virus)
Coccidioides posadasii
Conotoxins
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Ebola viruses
Lassa fever virus
Marburg virus
Monkeypox virus
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever])
Variola major virus (Smallpox virus) and Variola minor virus (Alastrim)
Yersinia pestis

(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional form(s) of any of the toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro.*

(3) HHS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) HHS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any HHS select agent or toxin that is in its naturally occurring environment provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable HHS select agents or nonfunctional HHS toxins.

(3) HHS toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 100 mg of Abrin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of Tetrodotoxin.

(e) An attenuated strain of a HHS select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the **Federal Register** and will be listed on the CDC Web site at *http://www.cdc.gov/*.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any HHS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to CDC or APHIS.

(i) The seizure of Ebola viruses, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever virus (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

§ 73.4 Overlap select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products.

(b) Overlap select agents and toxins:

Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern Equine Encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T–2 toxin
Venezuelan Equine Encephalitis virus

(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional form(s) of any overlap toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro.*

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment provided that the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable overlap select agents or nonfunctional overlap toxins.

(3) Overlap toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; or 1,000 mg of T–2 toxin.

(e) An attenuated strain of an overlap select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety, to animal health, or to animal products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the **Federal Register** and will be listed on the CDC Web site at *http://www.cdc.gov/*.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting overlap select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any overlap select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the overlap select agent or toxin to CDC or APHIS.

(i) The seizure of *Bacillus anthracis,* Botulinum neurotoxins, *Brucella melitensis, Francisella tularensis,* Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the select agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the overlap select agent or toxin by the submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

§ 73.5 Exemptions for HHS select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law.

(i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Ebola viruses, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis.* This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary may exempt from the requirements of this part an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30

calendar days may be granted. To apply for an exemption or an extension of an exemption, an individual or entity must submit a completed APHIS/CDC Form 5 establishing the need to provide for the timely participation of the individual or entity in a response to a domestic or foreign public health emergency. A written decision granting or denying the request will be issued.

§ 73.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within seven calendar days after identification, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law.

(i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis,* Botulinum neurotoxins, *Brucella melitensis, Francisella tularensis,* Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of an overlap select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary, after consultation with Administrator, may exempt from the requirements of this part an investigational product that is, bears, or contains an overlap select agent or toxin, may be exempted when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30 calendar days may be granted. To apply for an exemption or an extension of an exemption, an individual or entity must submit a completed APHIS/CDC Form 5 establishing the need to provide for the timely participation of the individual or entity in a response to a domestic or foreign public health emergency. A written decision granting or denying the request will be issued.

(f) Upon request of the Administrator, the HHS Secretary may exempt an individual or entity from the requirements of this part, for 30 calendar days if the Administrator has granted the exemption for agricultural emergency. The HHS Secretary may extend the exemption once for an additional 30 calendar days.

§ 73.7 Registration and related security risk assessments.

(a) Unless exempted under § 73.5, an individual or entity shall not possess, use, or transfer any HHS select agent or toxin without a certificate of registration issued by the HHS Secretary. Unless exempted under § 73.6 or 9 CFR part 121.6, an individual or entity shall not possess, use, or transfer overlap select agents or toxins, without a certificate of registration issued by the HHS Secretary and Administrator.

(b) As a condition of registration, each entity must designate an individual to be its Responsible Official. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, the individual will be considered the Responsible Official.

(c)(1) As a condition of registration, the following must be approved by the HHS Secretary or Administrator based

on a security risk assessment by the Attorney General:

(i) The individual or entity,

(ii) The Responsible Official, and

(iii) Unless otherwise exempted under this section, any individual who owns or controls the entity.

(2) Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.

(3) An individual will be deemed to own or control an entity under the following conditions: [1]

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or

(B) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

(5) To obtain a security risk assessment, an individual or entity must submit the information necessary to conduct a security risk assessment to the Attorney General.

(d) To apply for a certificate of registration that covers only HHS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC. To apply for a certificate of registration that does not cover only HHS select agents or toxins (*i.e.,* covers at least one overlap select agent and/or toxin, or covers any combination of HHS select agents and/or toxins and USDA select agents and/or toxins), an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC or APHIS, but not both.

(e) Prior to the issuance of a certificate of registration, the Responsible Official must promptly provide notification of any changes to the application for registration by submitting the relevant page(s) of the registration application.

(f) The issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(g) A certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the Responsible Official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

(h) A certificate of registration may be amended to reflect changes in circumstances (*e.g.,* replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).

(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.

(2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(3) No change may be made without such approval.

(i) An entity must immediately notify CDC or APHIS if it loses the services of its Responsible Official. In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part.

(j) A certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered.

(k) A certificate of registration will be valid for a maximum of three years.

§ 73.8 Denial, revocation, or suspension of registration.

(a) An application may be denied or a certificate of registration revoked or suspended if:

(1) The individual or entity, the Responsible Official, or an individual who owns or controls the entity is within any of the categories described in 18 U.S.C. 175b,

(2) The individual or entity, the Responsible Official, or an individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5),

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(3) The individual or entity does not meet the requirements of this part, or

(4) It is determined that such action is necessary to protect public health and safety.

(b) Upon revocation or suspension of a certificate of registration, the individual or entity must:

(1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order,

(2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release, and

(3) Comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 73.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

§ 73.9 Responsible Official.

(a) An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must:

(1) Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General,

(2) Be familiar with the requirements of this part,

[1] These conditions may apply to more than one individual.

(3) Have authority and responsibility to act on behalf of the entity,

(4) Ensure compliance with the requirements of this part, and

(5) Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

(b) An entity may designate one or more individuals to be an alternate Responsible Official, who may act for the Responsible Official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.

(c) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification.

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis,* Botulinum neurotoxins, *Brucella melitensis, Francisella tularensis,* Ebola viruses, Hendra virus, Marburg virus, Lassa fever virus, Nipah virus, Rift Valley fever virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), Venezuelan equine encephalitis virus, or *Yersinia pestis.* The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(2) To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(3) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(d) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for three years.

§ 73.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (*e.g.,* ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) An individual's security risk assessment may be expedited upon written request by the Responsible Official and a showing of good cause (*e.g.,* public health or agricultural emergencies, national security, or a short term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(f) An individual's access approval will be denied or revoked if the individual is within any of the categories described in 18 U.S.C. 175b,

(g) An individual's access approval may be denied, limited, or revoked if:

(1) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime specified in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power (as defined in 50 U.S.C. 1801), or

(2) It is determined such action is necessary to protect public health and safety.

(h) An individual may appeal the HHS Secretary's decision to deny, limit, or revoke access approval under § 73.20.

(i) Access approval is valid for a maximum of five years.

(j) The Responsible Official must immediately notify CDC or APHIS when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

§ 73.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control,

(2) Contain provisions for the control of access to select agents and toxins,

(3) Contain provisions for routine cleaning, maintenance, and repairs,

(4) Establish procedures for removing unauthorized or suspicious persons,

(5) Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes,

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records, and

(7) Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.

(d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:

(1) Allow access only to individuals with access approval from the HHS Secretary or Administrator,

(2) Allow individuals not approved for access from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, or other activities not related to select agents or toxins only when continuously escorted by an approved individual,

(3) Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (*e.g.,* card access system, lock boxes),

(4) Inspect all suspicious packages before they are brought into or removed from the area where select agents or toxins are used or stored,

(5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents

and provisions for safeguarding against theft, loss, or release,

(6) Require that individuals with access approval from the HHS Secretary or Administrator refrain from sharing with any other person their unique means of accessing a select agent or toxin (*e.g.*, keycards or passwords),

(7) Require that individuals with access approval from the HHS Secretary or Administrator immediately report any of the following to the Responsible Official:

(i) Any loss or compromise of keys, passwords, combination, etc.,

(ii) Any suspicious persons or activities,

(iii) Any loss or theft of select agents or toxins,

(iv) Any release of a select agent or toxin, and

(v) Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised, and

(8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) In developing a security plan, an entity or individual should consider, the document entitled ''Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents. Morbidity and Mortality Weekly Report December 6, 2002; 51:RR–19:1–6.'' The document is available on the Internet at: *http://www.cdc.gov/mmwr.*

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 73.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider:

(1) The CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories'', including all appendices. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250–7954 or from the CDC Web site at *http://www.cdc.gov/.* Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia.

(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR parts 1910.1200 and 1910.1450.

(3) The ''NIH Guidelines for Research Involving Recombinant DNA Molecules,'' (NIH Guidelines). Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia, 30333 or from the CDC Web site at *http://www.cdc.gov/.* Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia.

(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 73.13 Restricted experiments.

(a) An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator.

(b) Restricted experiments:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an $LD_{50} < 100$ ng/kg body weight.

(c) The HHS Secretary may revoke approval to conduct any of the experiments in paragraph (b) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(d) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

§ 73.14 Incident response.

(a) An individual or entity required to register under this part must develop and implement a written incident response plan.[2] The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent and toxin and appropriate actions to contain such select agent or toxin.

(c) The incident response plan must also contain the following information:

(1) The name and contact information (*e.g.*, home and work) for the individual or entity (*e.g.*, responsible official, alternate responsible official(s), biosafety officer, etc.),

(2) The name and contact information for the building owner and/or manager, where applicable,

(3) The name and contact information for tenant offices, where applicable,

(4) The name and contact information for the physical security official for the building, where applicable,

(5) Personnel roles and lines of authority and communication,

(6) Planning and coordination with local emergency responders,

(7) Procedures to be followed by employees performing rescue or medical duties,

(8) Emergency medical treatment and first aid,

(9) A list of personal protective and emergency equipment, and their locations,

(10) Site security and control,

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge, and

(12) Decontamination procedures.

(d) The plan must be reviewed annually and revised as necessary.

[2] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 73.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access.[3] In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.

(b) Refresher training must be provided annually.

(c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

§ 73.16 Transfers.

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer.[4]

(b) A transfer may be authorized if:

(1) The sender:

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all requirements in this part,

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred, or

(iii) Is transferring the select agent or toxin from outside the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the HHS Secretary may authorize a transfer of a select agent or toxin, not otherwise eligible for transfer under this part under conditions prescribed by the HHS Secretary.

(e) To obtain authorization for transfer, APHIS/CDC Form 2 must be submitted.

(f) The recipient must submit a completed APHIS/CDC Form 2 within two business days of receipt of a select agent or toxin.

(g) The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred.

(h) An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (*e.g.*, change in the certificate of registration for the sender or recipient, change in the application for transfer).

(i) The sender must comply with all applicable laws concerning packaging and shipping.

§ 73.17 Records.

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:

(1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.*, strain designation, GenBank Accession number, etc.),

(ii) The quantity acquired from another individual or entity (*e.g.*, containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) Where stored (*e.g.,* building, room, and freezer),

(iv) When moved from storage and by whom and when returned to storage and by whom,

(v) The select agent used and purpose of use,

(vi) Records created under § 73.16 and 9 CFR 121.16 (Transfers),

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient, and

(viii) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release),

(2) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics,

(ii) The quantity acquired from another individual or entity (*e.g.*, containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) The initial and current quantity amount (*e.g.*, milligrams, milliliters, grams, etc.),

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom,

(v) Where stored (*e.g.*, building, room, and freezer),

(vi) When moved from storage and by whom and when returned to storage and by whom including quantity amount,

(vii) Records created under § 73.16 and 9 CFR part 121.16 (Transfers),

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient,

(ix) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release), and

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom,

(3) A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator,

(4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry,

(5) Accurate, current records created under § 73.9 and 9 CFR part 121.9 (Responsible Official), § 73.11 and 9 CFR part 121.11 (Security), § 73.12 and 9 CFR part 121.12 (Biosafety), § 73.14 and 9 CFR part 121. 14 (Incident response), and § 73.15 and 9 CFR part 121.15 (Training), and

(6) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and data bases created under

[3] The training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard set forth at 29 CFR 1910.1030.

[4] This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for three years and promptly produced upon request.

§ 73.18 Inspections.

(a) Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with this part.

§ 73.19 Notification of theft, loss, or release.

(a) Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported immediately by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information),

(ii) An estimate of the quantity lost or stolen,

(iii) An estimate of the time during which the theft or loss occurred,

(iv) The location (building, room) from which the theft or loss occurred, and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss.

(2) A completed APHIS/CDC Form 3 must submitted within seven calendar days.

(b) Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information),

(ii) An estimate of the quantity released,

(iii) The time and duration of the release,

(iv) The environment into which the release occurred (*e.g.*, in building or outside of building, waste system),

(v) The location (building, room) from which the release occurred,

(vi) The number of individuals potentially exposed at the entity,

(vii) Actions taken to respond to the release, and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

§ 73.20 Administrative review.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The HHS Secretary's decision constitutes final agency action.

§ 73.21 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board have been delegated authority to conduct hearings and to render decisions in accordance with 42 CFR part 1005 with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The Departmental Appeals Board of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

42 CFR Chapter V—Office of Inspector General—Health Care, Department of Health and Human Services

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7,1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

■ 2. Section 1003.106 is amended by revising introductory paragraph (a)(1) to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) *Amount of penalty.* (1) In determining the amount of any penalty or assessment in accordance with § 1003.102(a), (b)(1), (b)(4), and (b)(9) through (b)(16) of this part, the Department will take into account—

* * * * *

[FR Doc. 05–5216 Filed 3–17–05; 8:45 am]

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Federal Register

Friday,
March 18, 2005

Part IV

Securities and Exchange Commission

17 CFR Part 270
Mutual Fund Redemption Fees; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 270

[Release No. IC–26782; File No. S7–11–04]

RIN 3235–AJ17

Mutual Fund Redemption Fees

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; request for additional comment.

SUMMARY: The Securities and Exchange Commission (''Commission'' or ''SEC'') is adopting a new rule that allows registered open-end investment companies (''funds'') to impose a redemption fee, not to exceed two percent of the amount redeemed, to be retained by the fund. The redemption fee is intended to allow funds to recoup some of the direct and indirect costs incurred as a result of short-term trading strategies, such as market timing. The new rule also requires most funds to enter into written agreements with intermediaries (such as broker-dealers and retirement plan administrators) that hold shares on behalf of other investors, under which the intermediaries must agree to provide funds with certain shareholder identity and transaction information at the request of the fund and carry out certain instructions from the fund. The Commission is also requesting additional comment to obtain further views on whether it should establish uniform standards for redemption fees charged under the rule.

DATES: *Effective Date:* May 23, 2005.

Compliance Date: October 16, 2006. Section III of this release discusses the effective and compliance dates applicable to rule 22c–2.

Comment Date: Comments should be received on or before May 9, 2005.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number S7–11–04 on the subject line; or
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number S7–11–04. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: William C. Middlebrooks, Jr., Senior Counsel, or C. Hunter Jones, Assistant Director, Office of Regulatory Policy, (202) 551–6792, Division of Investment Management, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0506.

SUPPLEMENTARY INFORMATION: The Commission today is adopting rule 22c–2 [17 CFR 270.22c–2] under the Investment Company Act of 1940 [15 U.S.C. 80a] (the ''Investment Company Act'' or the ''Act'') and amendments to rule 11a–3 [17 CFR 270.11a–3] under the Act.[1] We invite additional comment on the issues discussed in Section II.C of this release.

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I. Background

Investors in mutual funds can redeem their shares on each business day and, by law, must receive their pro rata share of the fund's net assets.[2] This redemption right makes funds attractive to fund investors, most of whom are long-term investors, because it provides ready access to their money if they should need it. The redemption right also makes funds attractive to a small group of investors who use funds to implement short-term trading strategies,[3] such as market timing,[4] by making frequent purchases and redemptions in order to capture small gains.[5] Most fund shareholders, however, are not active traders of their shares.[6]

Excessive trading in mutual funds occurs at the expense of long-term investors, diluting the value of their shares.[7] It may disrupt the management

[1] Unless otherwise noted, all references to statutory sections are to the Investment Company Act of 1940, and all references to ''rule 22c–2'' or any paragraph of the rule will be to 17 CFR 270.22c–2; all references to rule 11a–3 or any paragraph of that rule will be to 17 CFR 270.11a–3 as amended. References to comment letters are to letters available in File No. S7–11–04.

[2] An open-end investment company (*i.e.*, a ''mutual fund'') issues ''redeemable securities,'' which entitle the holder of the securities to receive approximately his proportionate share of the fund's net asset value. *See* section 2(a)(32) of the Act [15 U.S.C. 80a–2(a)(32)] (defining ''redeemable security''); section 5(a)(1) of the Act [15 U.S.C. 80a–5(a)(1)] (defining ''open-end company'').

[3] These market strategies include time zone arbitrage, but may include others that are not dependent on the misvaluation of portfolio securities. *See, e.g., Borneman* v. *Principal Life Ins. Co.,* 291 F. Supp. 2d 935 (S.D. Iowa 2003), which involved a dispute resulting from an insurance company's market timing restrictions on annuityholders who were exploiting a correlation between changes in the value of shares of a separate account investing in international equities and one investing in domestic equities.

[4] Market timing includes (a) frequent buying and selling of shares of the same fund or (b) buying or selling fund shares in order to exploit inefficiencies in fund pricing. Market timing, while not illegal per se, can harm other fund shareholders because (a) it can dilute the value of their shares, if the market timer is exploiting pricing inefficiencies, (b) it can disrupt the management of the fund's investment portfolio, and (c) it can cause the targeted fund to incur costs borne by other shareholders to accommodate the market timer's frequent buying and selling of shares.

[5] *See* Edward S. O'Neal, *Purchase and Redemption Patterns of U.S. Equity Mutual Funds,* 33 Fin. Mgt. Assoc. 63, at text following n.1 (2004) (''[H]eightened redemption activity, even among a minority of fund investors, has liquidity-cost implications for all fund shareholders.'').

[6] *See Redemption Activity of Mutual Fund Owners,* Fundamentals (Investment Company Institute, Washington, D.C.), March 2001, at 1–3 (stating that the vast majority of fund shareholders do not frequently redeem their shares, and that a small percentage of shareholders account for the most active trading).

[7] *See* Gary L. Gastineau, *Protecting Fund Shareholders from Costly Share Trading,* 60 Fin. Analysts J. 22 (2004) (estimating that frequent buying and selling reduces an average stock fund's annual returns by at least 1%, which amounts to nearly $40 billion annually for all stock mutual funds). *See also* Jason Greene & Charles Hodges, *The Dilution Impact of Daily Fund Flows on Open-end Mutual Funds: Evidence and Policy Solutions,* 65 J. Fin. Econ. 131 (2002) (estimating annualized dilution from frequent trading, based on market timing, of 0.48% in international funds: ''the dilution impact has brought about a net wealth transfer from passive shareholders to active traders in international funds in excess of $420 million over a 26-month period.''). *See also* Roger M.

of a fund's portfolio and raise the fund's transaction costs because the fund manager must either hold extra cash or sell investments at inopportune times to meet redemptions.[8] Frequent trading also may result in unwanted taxable capital gains for the remaining fund shareholders. Funds have taken steps to deter excessive trading or have sought reimbursement from traders for the costs of their excessive transactions.[9]

These steps frequently include establishing market timing policies that prevent shareholders from making frequent exchanges among funds, and imposing a redemption fee—a small fee at the time a shareholder redeems shares, typically a short time after purchasing them.[10]

Many funds, however, have been unable to effectively enforce their market timing policies or impose redemption fees on the accounts of investors who purchase fund shares through broker-dealers, banks, insurance companies, and retirement plan administrators (''intermediaries''). These share holdings frequently are identified in the books of the fund (or its transfer agent) in the name of the intermediary, rather than in the name of the fund shareholder. Many intermediaries controlling these so-called ''omnibus accounts'' have provided the fund with insufficient information for the fund to apply redemption fees. Because of this lack of information, today many funds choose not to apply redemption fees, or are unable to enforce their policies against market timing with respect to shares held through these omnibus accounts. As a result, those shareholders have often been beyond the reach of fund directors' efforts to protect the fund and its shareholders from the harmful effects of short-term trading. A number of the market timing abuses identified through our investigations reveal that certain shareholders were concealing abusive market timing trades through omnibus accounts.[11]

Last year we proposed to address the widespread problem of short-term trading in fund shares by requiring funds to impose a redemption fee of two percent of the amount redeemed on shares held for five business days or less.[12] Under our proposal funds also would have had to require that intermediaries provide them weekly information about transactions of beneficial owners of shares held in omnibus accounts controlled by intermediaries. Our rule proposal was intended to reimburse the funds for the costs of short-term trading and to discourage short-term trading of fund shares by reducing the profitability of the trades.

II. Discussion

We received nearly 400 comments on the proposed rule. Although many commenters, including fund management companies, supported the proposal, most commenters objected to a rule that would *mandate* a redemption fee.[13] Many were concerned that the redemption fee would inadvertently apply to harmless transactions such as account rebalancings or redemptions after recent periodic contributions.[14] In contrast one commenter urged that, if we were to adopt a mandatory fee, we require that the fee be imposed on *all* short-term redemptions so that it would be easy to implement,[15] while others argued for a variety of exceptions under which a redemption fee would not apply.[16] Still others urged that we permit redemption fees greater than two percent.[17]

We continue to believe, and the weight of evidence submitted by commenters suggests, that redemption fees, together with effective valuation procedures,[18] can be an effective means

Edelen, *Investor Flows and the Assessed Performance of Open-end Mutual Funds,* 53 J. Fin. Econ. 439, 457 (1999) (quantifying the costs of liquidity in mutual funds as $0.017 to $0.022 per dollar of liquidity-motivated trading). A more recent study conducted by Edelen and others estimated that commissions and spreads alone cost the average equity fund as much as 75 basis points. *See* John M.R. Chalmers, *et al.*, *Fund Returns and Trading Expenses: Evidence on the Value of Active Fund Management,* (last modified Aug. 30, 2001), at 10 (available at *http://finance.wharton.upenn.edu/~edelen/PDFs/MF_tradexpenses.pdf.*

[8] *See* William Samuel Rocco, *Are You Safe from Market-Timers?,* Morningstar.com (June 22, 2004) available at *http://news.morningstar.com/doc/article/0,1,109373,00.html* (''Both the deliberate and the inadvertent short- to mid-term market-timers raise trading costs and undermine long-term performance by forcing managers to carry more cash than they otherwise would and make sales they otherwise wouldn't during sell-offs.'') (last visited Sept. 24, 2004); Paula Dwyer, *et al.*, *Mutual Funds Feel The Heat,* Bus. Wk., Oct. 20, 2003, at 50 (''[S]hareholders get short shrift when funds sell off good investments or hold extra cash to pay back the timers. Shareholder returns also decline because market timing raises mutual funds' own trading costs.''). *See also* Ken Hoover, *Why Mutual Funds Discourage Timers; Two Forms of Practice; They Increase Expenses, Can Disrupt Portfolios and Rob Other Investors,* Investor's Bus. Daily, Sept. 17, 2003, at AO9.

[9] Some of the approaches that funds have adopted include: (i) restricting exchange privileges, including delaying both the redemption and purchase sides of an exchange; (ii) limiting the number of trades within a specified period; (iii) delaying the payment of proceeds from redemptions for up to seven days (the maximum delay permitted under section 22(e) of the Act); (iv) satisfying redemption requests in-kind; and (v) identifying market timers and restricting their trading or barring them from the fund. *See* Disclosure Regarding Market Timing and Selective Disclosure of Portfolio Holdings, Investment Company Act Release No. 26287 (Dec. 11, 2003) [68 FR 70402 (Dec. 17, 2003)] at text preceding and following n.14 (discussing the various steps that funds have taken to discourage market timing).

[10] *See* Arden Dale, *Mutual-Fund ''Timers'' Get Clocked—Scandals Lead to Grief; How the Dreaded T-Word Became ''Active Investment,''* Wall St. J., Aug. 23, 2004, at C15 (''Tarred by the fund-trading scandal, the practice of rapid trading—also known as market timing—is under fire by fund companies. * * * To turn up the heat on timers, fund companies are adding new [redemption] fees.''). Lisa Singhania, *Mutual Fund Redemption Fees are Rising,* USA Today, July 12, 2001 (''Financial Research Corp. found the number of funds charging redemption fees rose 82 percent between Dec. 31, 1999 and Mar. 30, 2001.''). Funds' use of redemption fees is not new. We noted the use of redemption fees by funds in a 1966 report to Congress. Report of the Securities and Exchange Commission on the Public Policy Implications of Investment Company Growth, H.R. Rep. No. 89–2337, at 58, n.156 (1966) (''Redemption fees serve two purposes: (1) they tend to deter speculation in the fund's shares; and (2) they cover the fund's administrative costs in connection with the redemption.'').

[11] *See, e.g., SEC* v. *Security Trust Company, et al.*, Litigation Release No. 18653 (Apr. 1, 2004).

[12] *See* Mandatory Redemption Fees for Redeemable Fund Securities, Investment Company Act Release No. 26375A (Mar. 5, 2004) [69 FR 11762 (Mar. 11, 2004)] (''Proposing Release'') (the proposed rule provided exceptions from the redemption fee for *de minimis* redemptions, financial emergencies, money market funds, exchange-traded funds, and funds that permit short-term trading).

[13] A substantial number of commenters, including about 100 investors who submitted substantially the same comment letter, objected to the imposition of redemption fees generally.

[14] *See, e.g.*, Comment Letter of Charles Terrell (Mar. 20, 2004); Comment Letter of Stephanie Kelly (May 10, 2004); Comment Letter of Eugene Asken (Mar. 31, 2004).

[15] *See* Comment Letter of Fidelity Investments (June 4, 2004) (recommending that funds be required to implement redemption fees consistently, including to short-term trades in retirement plans or omnibus accounts).

[16] *See, e.g.*, Comment Letter of the Vanguard Group (May 10, 2004); Comment Letter of the Investment Company Institute (May 7, 2004).

[17] *See, e.g.*, Comment Letter of the Investment Company Institute (May 7, 2004) (stating that some funds may need to impose redemption fees greater than two percent to balance the interests of redeeming shareholders and shareholders that remain in the fund); Comment Letter of Consumer Federation of America and Fund Democracy, Inc. (May 11, 2004) (recommending a two percent redemption fee for sales within 30 days of purchase and permitting redemption fees of up to five percent for sales within five days of purchase). In the Proposing Release, we also requested that commenters address fair value pricing as it relates to market timing, including areas of uncertainty that require further guidance from the Commission. *See* Proposing Release, *supra* note , at Section II.F. Almost all the commenters that addressed fair value pricing supported it as an effective means to combat market timing, but many stated that fair value pricing alone is not sufficient to address short-term trading because it does not address the ability of market timers to trade for free while the costs of their trading are borne by long-term shareholders.

[18] The Investment Company Act requires funds to calculate their net asset values using the market value of the portfolio securities when market quotations for those securities are readily available,

Continued

to protect funds and fund shareholders by requiring that short-term traders compensate funds for the costs that may result from frequent trading.[19] Commenters persuaded us, however, that a mandatory fixed redemption fee imposed by Commission rule is not the best way to achieve our goals. Some funds may not have costs that warrant imposing any redemption fee; others may have lower costs and could protect their shareholders by imposing a redemption fee of less than two percent.[20] Boards of directors, as several commenters suggested, are better positioned to determine whether the fund needs a redemption fee and, if so, the amount of the fee.[21] We agree and have decided not to adopt a mandatory redemption fee.

Instead of requiring that each fund impose a redemption fee, the rule we are today adopting authorizes fund directors to impose a redemption fee of up to two percent of the amount redeemed when they determine that a fee is in their fund's best interest.[22] It permits each board to take steps it concludes are necessary to protect its investors, and provides the board flexibility to tailor the redemption fee to meet the needs of the fund. As a result of our adoption of this rule, which is described in more detail below, the staff no-action positions concerning redemption fees have terminated.[23]

We also are adopting a requirement that each fund enter into written agreements with its financial intermediaries, including those holding shares in omnibus accounts, providing the fund with access to information about transactions by fund shareholders. This information will permit funds to better enforce their market timing policies.[24] The agreement also must contain a provision requiring the intermediary to execute the fund's instructions to restrict or prohibit further purchases or exchanges by any shareholder identified by the fund as having engaged in trading that violates the fund's market timing policies.[25]

Finally, we are requesting comment on whether we should adopt a uniform redemption fee for those funds deciding to impose such a fee and, if so, the terms of such a fee. A uniform fee may be less costly for the thousands of fund intermediaries to collect, and may result in greater willingness on the part of these intermediaries to collect the fees. We discuss the new rule and our request for further comment in more detail below.

A. Redemption Fees

Rule 22c–2 requires that each fund's board of directors (including a majority of independent directors) either (i) approve a redemption fee that in its judgment is necessary or appropriate to recoup costs the fund may incur as a result of redemptions, or to otherwise eliminate or reduce dilution of the fund's outstanding securities, or (ii) determine that imposition of a redemption fee is not necessary or appropriate.[26] The rule thus requires each board before the compliance date to at least consider implementing a redemption fee program to counter short-term trading.[27]

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and, when a market quotation for a portfolio security is not readily available, by using the fair value of that security, as determined in good faith by the fund's board. 15 U.S.C. 80a–2(a)(41); 17 CFR 270.2a41–1. These valuation requirements are critical to ensuring that fund shares are purchased and redeemed at fair prices, shareholder interests are not diluted, and opportunities for arbitrage through short-term trading are diminished. We are working to address issues that arise under the valuation requirements and anticipate issuing a release in the near future.

[19] *See* Comment Letter of the Vanguard Group (May 10, 2004) (''In our experience, redemption fees, together with fair value pricing and active transaction monitoring, are very effective in curtailing short-term trading that may harm funds and their shareholders.''); Comment Letter of Consumer Federation of America and Fund Democracy, Inc. (May 11, 2004) (recommending that mandatory redemption fees supplement fair value pricing); Comment Letter of Fidelity Investments (June 4, 2004) (''Even for international funds it should be recognized that fair-value pricing cannot eliminate potential short-term trading. In our experience fair-value pricing of foreign markets can curtail potential arbitrage profits on days when markets move significantly, but is less reliable in preventing short-term trading profits on less active days: a price move of 25 or 50 basis points, for example. Redemption fees assure that traders are not tempted to try to capture these small potential profits at the expense of other investors.''). *See also, e.g.*, Gregory B. Kadlec, *On Solutions to the Mutual Fund Timing Problem* (Aug. 30, 2004) *http://www.ici.org/issues/timing/wht_04_mkt_time_solutions.pdf*, appended to Comment Letter of the Investment Company Institute (Sept. 2, 2004) (study commissioned and submitted by the Investment Company Institute, (''In principle, the timing problem could be fully resolved by either removing predictability from NAVs (*i.e.*, fair value pricing) or imposing barriers to its exploitation (*i.e.*, redemption fees). Because of the practical limitations of removing predictability and the cost of imposing barriers, the most effective and efficient solution involves a balanced and modest attack on each front.'').

[20] *See* Comment Letter of Fidelity Investments (June 4, 2004) (''We do not believe that lower-volatility funds that invest in more liquid markets—government bond funds, for example or balanced funds—should be required to adopt redemption fees in order to protect shareholders in international funds and a few other fund types from short-term trading.''); Comment Letter of Merrill Lynch, Pierce, Fenner & Smith Inc. (May 10, 2004) (''The short-term trading issue is actually a number of different, although related, issues, which affect different types of investment companies and products in different ways.''); Comment Letter of the Vanguard Group (May 10, 2004) (recommending that short-term bond funds be excepted from mandatory redemption fee rule).

[21] *See* Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004) (arguing that fund boards should decide whether redemption fees are appropriate in order to avoid a ''one-size fits all'' approach); Comment Letter of Fidelity Investments (June 4, 2004) (recommending that the rule require a fund board to consider whether redemption fees are appropriate, because a mandatory fee would, in many cases, penalize shareholders who are not engaging in excessive trading); Comment Letter of Merrill Lynch, Pierce, Fenner & Smith Inc. (May 10, 2004) (recommending that fund boards address the different issues resulting from short-term or frequent trading, as applicable, to different types of funds because a mandatory redemption fee would be unfair to many shareholders who are not frequent traders); Comment Letter of Rydex Investments (Apr. 20, 2004) (opposing ''one-size fits all'' mandatory redemption fee because fund boards should decide whether redemption fees are appropriate).

[22] Rule 22c–2 prohibits a fund from redeeming shares within seven days after the share purchase unless the fund meets three conditions. *See* rule 22c–2(a). First, the board of directors must either (i) approve a redemption fee, or (ii) determine that imposition of a redemption fee is either not necessary or not appropriate. Second, the fund (or its principal underwriter) must enter into a written agreement with each financial intermediary under which the intermediary agrees to (i) provide, at the fund's request, identity and transaction information about shareholders who hold their shares through an account with the intermediary, and (ii) execute instructions from the fund to restrict or prohibit future purchases or exchanges. Third, the fund must maintain a copy of each written agreement with a financial intermediary for six years.

[23] *See, e.g.*, John P. Reilly & Associates, SEC Staff No-Action Letter (July 12, 1979) (''Reilly No-Action Letter''); Neuberger & Berman Genesis Fund, Inc., SEC Staff No-Action Letter (Sept. 27, 1988) (''Genesis Fund No-Action Letter'').

[24] *See* Comment Letter of the American Council of Life Insurers (May 10, 2004) (suggesting as an alternative to imposing a mandatory redemption fee in the retirement plan context, that the Commission together with the Departments of Labor and Treasury authorize pension record keepers to take individual action against participants engaging in market timing or other abusive transactions in reliance on instructions from a plan's underlying funds.).

[25] *See infra* Section II.B.

[26] Rule 22c–2(a)(1). The requirement does not apply to money market funds, exchange-traded funds, and funds that affirmatively permit market timing of fund shares. *See* rule 22c–2(b). Any such fund that elects to impose a redemption fee, however, would need to comply with the other requirements of the rule. *See id.* Unlike the proposal, the exception in the final rule for funds that actively permit market timing does not require that the fund's treatment of short-term trading be a fundamental policy (*i.e.*, one that may be changed only with shareholder approval). *See* rule 22c–2(b)(3). We revised this condition so that a fund's board can quickly implement policies it determines are necessary to protect shareholders from the dilution and expense of short-term trading. *See* Comment Letter of Rydex Investments (April 20, 2004).

[27] For a discussion of the effective and compliance dates, *see infra* Section III. A fund that currently has a redemption fee would meet the rule's requirement, although the fund's directors may choose to review the redemption fee to determine whether the amount of the fee and the holding period continue to meet the fund's needs. Because the rule defines the term ''fund'' to include a separate series of any open-end investment company, the board of directors of any newly established separate series would have to make the determination required under rule 22c–2(a)(1) with respect to that series.

The proceeds of the redemption fee, in all cases, must be paid to the fund itself. The redemption fee is designed to reconcile conflicts between shareholders who would use the fund as a short-term trading vehicle, and those making long-term investments who would otherwise bear the costs imposed on the fund by short-term traders. Directors may impose the fee to offset the costs of short-term trading in fund shares, and/or to discourage market timing and other types of short-term trading strategies.[28]

The redemption fee may not exceed two percent of the amount redeemed. Some commenters called for us to permit higher redemption fees because such fees may be more effective at preventing abusive market timing transactions.[29] We believe that a higher redemption fee could harm ordinary shareholders who make an unexpected redemption as a result of a financial emergency. Moreover, it would in our judgment impose an undue restriction on the redeemability of shares required by the Act. The two percent limit is designed to strike a balance between two competing goals of the Commission—preserving the redeemability of mutual fund shares while reducing or eliminating the ability of shareholders who rapidly trade their shares to profit at the expense of their fellow shareholders.[30] Funds have, and should utilize, additional tools to prevent abusive market timing transactions.[31]

Directors may set a redemption fee of less than two percent under rule 22c–2.[32] Unlike the approach taken by certain funds in the past,[33] the amount of the redemption fee approved by directors need not be tied to the administrative and processing costs associated with redeeming fund shares.[34] By adopting rule 22c–2, we now are permitting redemption fees to be based on the judgment of the fund and its board rather than on a strict assessment of administrative and processing costs, which can be difficult to estimate and may vary from period to period.[35] Under rule 22c–2, a fund board setting the amount of the redemption fee could, for example, take into consideration indirect costs to the fund that arise from short-term trading of fund shares, such as liquidity costs, *i.e.*, the cost of investing a greater portion of the fund's portfolio in cash or cash items than would otherwise be necessary.[36]

Rule 22c–2 authorizes the board to approve a redemption fee on shares redeemed within seven or more calendar days after the shares were purchased.[37] Thus, the rule permits a fund board that adopts a redemption fee to determine, in its judgment, whether a period longer than seven calendar days is necessary or appropriate for the fund to protect its shareholders. This determination could, for example, include considerations as to whether different combinations of holding periods and redemption fee levels are appropriate for different funds that do not have the same vulnerability to market timing.[38]

B. Shareholder Transaction Information

Rule 22c–2 also requires funds to enter into written agreements with their intermediaries under which the intermediaries must, upon request, provide funds with certain shareholder identity and trading information.[39] This requirement will enable funds to obtain the information that they need to monitor the frequency of short-term trading in omnibus accounts and enforce their market timing policies.[40]

Many commenters opposed our proposal, which would have required financial intermediaries to deliver identification and transaction information each week. Commenters argued that weekly delivery and receipt of the information would be costly and burdensome for funds and financial intermediaries.[41] Most of these commenters preferred that financial intermediaries be required to provide the information at the fund's request.[42] Because some funds may need the information only on occasion, while others may need the information regularly, the final rule allows each fund to determine when it should receive the information.

Commenters also disagreed among themselves whether funds or intermediaries should be responsible for

[28] Under rule 38a–1, a fund must have policies and procedures reasonably designed to ensure compliance with the fund's disclosed policies regarding market timing. We noted when we adopted rule 38a–1 that these procedures should provide for monitoring of shareholder trades or flows of money in and out of the fund in order to detect market timing activity, and for consistent enforcement of the fund's policies regarding market timing. *See* Compliance Programs of Investment Companies and Investment Advisers, Investment Company Act Release No. 26299 (Dec. 17, 2003) [68 FR 74714 (Dec. 24, 2003)] (''Compliance Programs'').

[29] *See, e.g.*, Comment Letter of the Investment Company Institute (May 7, 2004); Comment Letter of Morningstar, Inc. (May 10, 2004).

[30] We also are using our exemptive authority under section 6(c) of the Act in adopting rule 22c–2. By adopting the rule, we are providing an exemption from the Act's requirement that investors redeeming shares of a mutual fund must receive their pro rata net asset value of their shares (section 2(a)(32) of the Act [15 U.S.C. 80a–2(a)(32)) and from the Act's prohibition against the issuance of a senior security. Shares not subject to the redemption fee could be considered to be a senior security, in violation of section 18(f)(1) of the Act [15 U.S.C. 80a–18(f)(1)] (prohibiting a fund from issuing a security that has priority over other securities with regard to distribution of assets).

[31] *See supra* note 9. Our decision today to provide fund managers with access to omnibus account transaction information should substantially enhance these tools by permitting funds to better identify frequent traders and detect violations of their market timing policies. We discuss this provision below. *See infra* Section II.C.

[32] The details of the redemption fee, the circumstances under which it would (and would not) be imposed, and the specific exceptions to imposition of the fee are currently disclosed to fund investors when they decide to invest in a fund and may include exceptions for particular transactions. *See* Forms N–1A, N–3, N–4, and N–6.

[33] *See* Reilly No-Action Letter, *supra* note 23. (''a mutual fund may make a charge to cover administrative expenses associated with redemption, but if that charge should exceed 2 percent, its shares may not be considered redeemable [as defined in section 2(a)(32) of the Act]. * * *''); Genesis Fund No-Action Letter, *supra* note 23 (stating that staff would not recommend enforcement action under section 18(f)(1) of the Act regarding the issuance of a senior security as a result of a fund's redemption fee policy).

[34] *See* Reilly No-Action Letter, *supra* note 23.

[35] We also are adopting conforming amendments to rule 11a–3 that reflect the approach taken in the rule. *See* rule 11a–3(a)(7) (revising the definition of ''redemption fee'' to mean a fee imposed pursuant to rule 22c–2); rule 11a–3(b)(2)(ii) (deleting the paragraph providing that any scheduled variation of a redemption fee must be reasonably related to the costs to the fund of processing the type of redemptions for which the fee is charged).

[36] We note that funds relying on staff no-action letters have not used redemption fees to recoup or offset those types of costs. The Commission took the approach embodied in the rule in the context of redemption fees imposed on exchanges. The Commission stated that the ''inclusion [in a redemption fee] of costs, other than those directly related to processing exchanges,'' would be considered by the Commission or staff on a case-by-case basis. *See* Offers of Exchange Involving Registered Investment Companies, Investment Company Act Release No. 17097 (Aug. 3, 1989) at n.37 (adopting rule 11a–3). The amendments to rule 11a–3 conform the redemption fee provisions in rules 11a–3 and 22c–2. *See supra* note 35.

[37] The proposed rule provided for imposition of the fee for redemptions within five *business* days. We have revised the holding period slightly in response to commenters who noted that fund complexes, broker-dealers, and other businesses observe different business holidays, and who supported a simpler approach of using seven *calendar* days. *See, e.g.*, Comment Letter of Fidelity Investments (June 4, 2004).

[38] *See id.*

[39] Rule 22c–2(a)(2)(i).

[40] The rule requires that the fund's agreement with the intermediary be in writing so that the fund can maintain a record of the agreement that Commission examination staff can review. *See infra* section II.C.3.

[41] *See, e.g.*, Comment Letter of Integrated Fund Services, Inc. (May 7, 2004) (the exchange of investor data would be costly and difficult to manage).

[42] *See, e.g.*, Comment Letter of American Century Investments (May 10, 2004); Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004); Comment Letter of the SPARK Institute, Inc. (May 10, 2004).

enforcing fund market timing policies. Intermediaries argued that funds should bear the responsibility for enforcing fund policies,[43] while the funds argued that the intermediaries were in a better position, at least with respect to shares held in omnibus accounts, because fund managers had inadequate information about the transactions.[44] In the past, such disagreements have in some cases resulted in no one enforcing fund market timing policies with respect to shares held in omnibus accounts. The rule we are adopting makes funds responsible for determining when they need a financial intermediary's assistance in monitoring and enforcing fund market timing policies.

These modifications to the final rule should reduce the costs of compliance to funds and financial intermediaries. Nevertheless, aggregate one-time costs for financial intermediaries to create systems to collect and transfer information to the funds may be significant.[45] At the same time, the rule should result in cost savings to funds and their long-term shareholders because funds will be able to better enforce their market timing policies against traders who engage in short-term trading through omnibus accounts. The rule also should result in the more consistent application of market timing policies between shareholders who purchase funds shares directly and those who purchase through omnibus accounts.

(1) *Fund Responsibilities.* Rule 22c–2 requires that each fund (or its principal underwriter), regardless of whether it imposes a redemption fee, enter into a written agreement with each of its financial intermediaries under which each intermediary must provide the fund, upon request, information about the identity of shareholders and about their transactions in fund shares.[46] Funds can use this information to monitor trading and identify shareholders in omnibus accounts engaged in frequent trading that is inconsistent with fund market timing policies.[47] Funds have flexibility to request information periodically, or when circumstances suggest that a financial intermediary is not assessing redemption fees or that abusive market timing activity is occurring.[48] Access to this trading information provides funds (and their chief compliance officers) an important new tool to monitor trading activity in order to detect market timing and to assure consistent enforcement of their market timing policies.[49] We expect funds that are susceptible to market timing will use it regularly.[50]

(2) *Financial Intermediaries.* Rule 22c–2 also requires the agreement with financial intermediaries to contain a provision under which the intermediary agrees to execute the fund's instructions to restrict or prohibit further purchases or exchanges by a specific shareholder (as identified by the fund) who has engaged in trading that violates the fund's market timing policies.[51] We have included this provision in response to comments regarding the difficulty of applying fund market timing restrictions to shares redeemed through omnibus accounts. Intermediaries currently may not enforce funds' market timing restrictions on their customers because, as one commenter explained, it is not in the intermediary's interest to do so.[52] Accordingly, even if funds receive shareholder trading information, as another commenter pointed out, it will have little practical value if the fund is unable to prevail upon the intermediary to enforce its market timing policies.[53] The requirement in the final rule that the written agreement provide for the intermediary to execute the fund's instructions should address these concerns.

We also have revised the definition of ''financial intermediary'' in the final rule, at the suggestion of several commenters. Under the rule, a ''financial intermediary'' includes: (i) A broker, dealer, bank, or any other entity that holds securities in nominee name; (ii) an insurance company that sponsors a registered separate account organized as a unit investment trust, master-feeder funds, and certain fund of fund arrangements not specifically excepted from the rule; and (iii) in the case of an employee benefit plan, the plan administrator or plan recordkeeper.[54] The definition clarifies that a ''financial intermediary'' can be either the plan administrator, who is responsible for the overall administration of the plan, or an entity that maintains the plan's

[43] *See, e.g.*, Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004) (arguing that ''[i]ntermediaries may not be able to enforce market-timing policies on behalf of hundreds of different fund families and thousands of different funds because the complexity of doing so would make the task prohibitively expensive.'').

[44] *See, e.g.*, Comment Letter of the Investment Company Institute (May 7, 2004) (recommending that the rule require an intermediary to take reasonable steps to implement restrictions imposed by a fund on short-term trading, in addition to facilitating the proper assessment of redemption fees). *See also SEC v. Scott B. Gann et al.*, Litigation Release No 19027 (Jan. 10, 2005) (available at: *http://www.sec.gov/litigation/litreleases/lr9027.htm*) (managers at a broker-dealer used multiple accounts and other techniques to evade trading bans that funds tried to establish with respect to their customers who were market timing); *In the Matter of Lawrence S. Powell et al.*, Investment Company Act Release No. 26722 (Jan. 11, 2005) (available at: *http://www.sec.gov/litigation/admin/34–51017.htm*) (registered representatives at a broker-dealer used multiple account and representative numbers to evade trading bans that funds had established for the representatives' market timing customers).

[45] We discuss the costs in greater detail in sections IV and VI below. Although financial intermediaries may have to create systems to assemble this information in a particular format, certain intermediaries currently are required to make and maintain records of the identity and transaction information required under the rule. *See, e.g.*, 17 CFR 240.17a–3(a)(1), 17 CFR 240.17a–3(a)(6), 17 CFR 240.17a–3(a)(17)(A)(i), 17 CFR 240.17a–4(b)(1) (requiring broker-dealers to make records of customer accounts and purchases and sales of securities and to preserve those records); 31 CFR 103.122(b)(2)(i)(A) and 31 CFR 103.122(b)(3) (requiring broker-dealers to adopt as part of their anti-money laundering program policies to obtain and maintain records of certain customer identification information and to retain customer identification records for five years).

[46] Rule 22c–2(a)(2)(i). Under the rule, financial intermediaries include broker-dealers, banks, or other entities that hold fund shares in nominee name. Rule 22c–2(c)(1)(i). Thus, the agreement would not be required with an intermediary with respect to shares that are held on a fully disclosed basis (*i.e.,* accounts in which the shareholder's name and other information are fully disclosed to the fund, which maintains account records on behalf of the shareholder). One commenter pointed out that in some cases, the fund may not know that a particular recordholder is, in fact, an intermediary. The Commission expects that funds and their transfer agents will use their best efforts to ascertain which recordholders are holding shares as intermediaries.

[47] Our privacy rule prevents a fund that receives this information from using the information for its own marketing purposes, unless permitted under the intermediary's privacy policies. *See* 17 CFR 248.11(a) and 248.15(a)(7)(i).

[48] Under the rule, a fund that does not impose a redemption fee may nonetheless request the transactional information from its intermediaries. In some cases, such funds may wish to access this information to determine whether a redemption fee is necessary. In addition, intermediaries may have agreed to enforce a fund's market timing policies, or have established procedures designed to preclude violations of the fund's trading policies. In these circumstances, a fund may not need to exercise its rights under the contract. Funds could contract with financial intermediaries for the period of time that intermediaries would have to retain the shareholder information for transmission to the fund.

[49] *See* Compliance Programs, *supra* note (stating that fund compliance procedures ''should provide for monitoring of shareholder trades or flows of money in and out of the funds in order to detect market timing activity, and for consistent enforcement of the fund's policies regarding market timing.'').

[50] *See, e.g.,* Comment Letter of the Coalition of Mutual Fund Investors (May 10, 2004) (urging Commission to require financial intermediaries to disclose shareholder identity and transactional information to funds on a daily or transactional basis to enable funds ''to ensure the uniform application of [fund redemption fee] policies and procedures.'').

[51] Rule 22c–2(a)(2)(ii).

[52] *See* Comment Letter of the Coalition of Mutual Fund Investors (May 10, 2004).

[53] *See* Comment Letter of the Investment Company Institute (May 7, 2004). *See also supra note.*

[54] *See* rule 22c–2(c)(1).

participant records, *i.e.,* the plan recordkeeper who typically is engaged by the plan administrator.[55]

C. Request for Additional Comment

In addition to adopting rule 22c–2, we request additional comments on whether we should establish a set of uniform standards that may facilitate intermediary assessment of redemption fees on shares held through omnibus accounts. We are requesting further comment on what any such standards should be, including the method for determining the duration of share ownership and exceptions from the application of the redemption fee.[56] Although we received comment on these issues during the initial comment period, those comments were offered in the context of a mandatory redemption fee. We also request comment on any other aspects of the rule in light of the additional solicitations for comment. For example, as funds begin to implement rule 22c–2, including entering into written agreements with financial intermediaries, we request comment on implementation of the rule's requirements.

We proposed a uniform *mandatory* redemption fee because the current voluntary arrangements may, as a practical matter, deny many funds the ability to impose redemption fees on shares held in omnibus accounts. As discussed below, intermediaries face certain costs in assessing redemption fees on a fund's behalf. Intermediaries therefore may prefer to offer only those funds that do not charge a redemption fee, or that do not apply the fee to redemptions made through omnibus accounts. Many funds today do not impose redemption fees for this reason. If intermediaries refuse to collect redemption fees, fund boards will be unable to use these fees to their full potential as a tool to protect fund investors.

One solution might be for the Commission to adopt a uniform redemption fee that would be applicable only to those funds that chose to impose a redemption fee. This approach may address the primary reason many fund intermediaries have refused to participate in redemption fee programs. Commenters representing both fund complexes and intermediaries asserted that the wide variations in the rate, duration, exceptions, and other features of redemption fees imposed by funds have made it costly for intermediaries to assess the redemption fees. These costs associated with a lack of uniformity may have contributed to the unwillingness of many intermediaries to assess fees on behalf of funds.[57] Commenters representing intermediaries have suggested to us that their willingness to undertake these efforts will likely depend on the costs they would bear, which could be substantially reduced if we were to establish the terms for a uniform redemption fee.[58] One commenter suggested that a uniform fee would be easier for investors to understand and would enable them to make comparisons among funds.[59]

We request comment on whether we should require a uniform standard for any redemption fees charged by a fund. Would a uniform standard encourage intermediaries to cooperate with fund managers by decreasing the costs and burdens on them? Would a uniform standard decrease certain costs that investors (or plan participants) would otherwise ultimately bear? On the other hand, given the extensive use of electronic systems to determine the applicability and amount of fees charged against brokerage, pension plan, and other accounts, would uniform parameters established by the Commission *not* appreciably decrease costs, but rather serve principally to reduce flexibility for funds?

1. Elements of a Uniform Redemption Fee

The mandatory redemption fee rule that we proposed last year established specific guidelines for redemption fees that funds would be required to impose, and that intermediaries would therefore be required to implement. Some of those features were fixed, such as the level of the fee (two percent) and the method used to calculate the time period between purchase and sale of shares in an account (first in, first out, or ''FIFO''). Other features were variable, such as the duration of the time period for the redemption fee (at least five business days) and the provision of waivers for *de minimis* redemption fees (waiver of redemption fees on redemptions of 2,500 dollars or less). We provided these guidelines in order to establish a certain degree of uniformity among redemption fees charged by funds, while permitting funds some flexibility in designing the redemption fee that best suited their circumstances.

During the comment period no consensus emerged regarding the features of a redemption fee that are most effective in deterring excessive trading and compensating a fund for the costs of such trading. The wide array of comments relating to the elements of the redemption fee may reflect, in part, the different views regarding the purpose of redemption fees. Some commenters viewed the redemption fee solely as a mechanism to recover costs associated with short-term trading, and therefore argued that the proposed exceptions were largely unnecessary.[60] Other commenters viewed redemption fees as a tool to penalize or deter market timers, and therefore gave importance to the intentions of the trader as well as the

[55] We have also included a definition of ''shareholder'' in the final rule. The term includes a beneficial owner of securities held in nominee name, a participant in a participant directed employee benefit plan, and a holder of interests in a master-feeder fund or an insurance company separate account organized as a unit investment trust. The term does not include a fund that relies on section 12(d)(1)(G) of the Act to invest in other funds in the same fund group. These funds often are used as conduits, allowing a shareholder to invest in multiple funds in the complex through a single fund. Although shareholders in the conduit fund may engage in abusive trading strategies, a conduit fund itself would appear to have little incentive to engage in such strategies because they may adversely affect another fund in the same complex. The definition of ''shareholder'' also excludes a section 529 account or the holder of an interest in such an account. The loss of tax benefits that a holder would incur as a result of changing investments more than once a year makes it unlikely that the holder would use a section 529 account for short-term trading.

[56] *See* Proposing Release, *supra* note 12.

[57] *See* Comment Letter of the Vanguard Group (May 10, 2004) (''The Commission has recognized that many intermediaries are currently unable to deduct redemption fees or have found it impractical to develop the systems and procedures necessary to monitor and enforce multiple trading restrictions * * * While [Vanguard's] efforts to implement effective controls over frequent trading have been somewhat successful on an ad hoc basis, we believe that the industry will never achieve complete success without the SEC's regulatory support * * * If the Commission mandates a consistent approach [to redemption fee policies], intermediaries will be encouraged to develop the systems and procedures required to apply redemption fees to remain competitive.''); Comment Letter of the American Society of Pension Actuaries (Apr. 21, 2004) (''[T]he existence of non-uniform redemption fee structures will create a competitive disadvantage for retirement plan administrators and intermediaries who offer 'open architecture' multiple fund family platforms relative to mutual fund companies providing retirement plan services that offer only a single family of funds.'').

[58] *See, e.g.,* Comment Letter of the American Society of Pension Actuaries (Oct. 8, 2004); Comment Letter of Hewitt Associates LLC (May 10, 2004); Comment Letter of the SPARK Institute, Inc. (May 10, 2004).

[59] Comment Letter of the American Society of Pension Actuaries (Oct. 8, 2004). For example, it might be much easier for an investor to compare a fund with a one percent redemption fee to one that had a two percent redemption fee, if the prospective investor did not have to take into account the method of measuring holding periods, *e.g.,* between LIFO and FIFO. *See infra* notes 64–66 and accompanying text.

[60] *See, e.g.,* Comment Letter of Fidelity Investments (June 4, 2004) (''When funds have redemption fees, they should be required to be applied consistently, since the purpose of redemption fees is to recover for a fund the costs imposed upon it through short-term trading, regardless of who is engaged in such trading.'').

susceptibility of certain transactions to abusive short-term trading.[61]

The myriad of commenters' views expressed about the proposed mandatory rule has led us to request additional comment on the redemption fee parameters, if any, that should be specified for all funds that voluntarily choose to charge redemption fees.[62] We are considering whether to revise the rule to require some or all of the following uniform fee parameters, on which we request comment:[63]

a. Share Accounting. We are considering adopting, as proposed, a provision that would require funds to determine the amount of any redemption fee by using the FIFO method, *i.e.,* by treating the shares held the longest time as being redeemed first, and shares held the shortest time as being redeemed last.[64] This is the method commonly employed by funds that currently charge redemption fees, and was supported by most commenters.[65] We proposed use of the FIFO method because it was less likely than other methods, such as LIFO (treating the shares most recently purchased as being redeemed first), to result in a redemption fee being imposed on ordinary shareholder redemptions.[66] We request comment on whether rule 22c–2 should require that, if a fund imposes a redemption fee, the fee be determined by the use of FIFO, or alternatively by the use of some other method.

b. De Minimis Waivers. We are considering requiring that the redemption fee not be charged if the amount of the fee would be fifty dollars or less. Under such a provision, a shareholder in a fund with a two percent redemption fee could redeem as much as 2,500 dollars of shares within seven days of purchasing them without paying a redemption fee. Use of FIFO accounting for share transactions, as discussed above, will likely result in few redemptions normally made by most investors incurring a redemption fee, except when the shareholder redeems all of his or her fund shares. The primary effect of a *de minimis* provision, therefore, would be to prevent recent purchases of fund shares from being charged a redemption fee when a shareholder makes a complete redemption of his or her shares in a particular fund.

Most commenters who addressed this exception supported a uniform *de minimis* waiver provision.[67] Many intermediaries strongly urged that we make a *de minimis* exemption mandatory to avoid the costs they asserted they would incur to accommodate various different *de minimis* arrangements.[68] Some commenters opposed allowing any *de minimis* exceptions, arguing that such exceptions permit market timers to break up transactions into smaller amounts in order to avoid the fee.[69] We request comment whether the rule should permit, or require, funds to waive redemption fees under a certain dollar amount.

c. *Amount of Redemption Fee; Length of Holding Period.* As discussed above, we do not contemplate establishing a uniform amount for the redemption fee, *i.e.,* the percentage charged upon early redemption.[70] Nor do we anticipate establishing a uniform minimum holding period (beyond the seven day minimum specified in the rule). As a result, fund boards will retain flexibility to address the needs of their funds. It is our understanding that systems employed by fund intermediaries can more easily handle variations in the amount of the fee and holding periods than, for example, some of the other exceptions discussed in this section.[71] We seek comment on whether intermediaries would be able to administer fees more easily if the fee and holding period vary among funds but the parameters discussed below are uniform, than if all of these elements were variable. We would expect that the rule would not permit funds to vary the redemption fee based on the amount of time that fund shares are held.[72] We request comment on such a provision.

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[61] *See, e.g.,* Comment Letter of the Vanguard Group (May 10, 2004) (''In our experience, redemption fees, together with fair value pricing and active transaction monitoring, are very effective in curtailing short-term trading that may harm funds and their shareholders.'').

[62] Some commenters raised concerns about redemption fees charged to investors who invest in funds through insurance company separate accounts. *See, e.g.,* Comment Letter of Pacific Life Insurance Company (May 10, 2004); Comment Letter of Transamerica Occidental Life Insurance Company (May 10, 2004); Comment Letter of NAVA (May 7, 2004). Although variable insurance contracts are designed to provide individuals with retirement or death benefits, they have been purchased as investment vehicles by hedge funds and other aggressive traders in order to engage in market timing. Indeed, because there are no immediate tax consequences, we understand that market timing may be a greater problem for separate accounts and the mutual funds in which they invest. Although we appreciate the administrative burdens insurance companies will bear in order to initially implement redemption fees, we do not believe such one-time burdens are a basis for excluding funds underlying separate accounts, as some commenters suggested. Nor do we believe, as several commenters suggested, that the application of rule 22c-2 will present an insuperable conflict with state insurance laws when a redemption fee is imposed on transactions by holders of existing variable annuity or variable life insurance contracts. The redemption fee would be imposed by the *fund* rather than pursuant to a contract issued by the insurance company. *See Miller* v. *Nationwide Life Ins. Co.,* 391 F.3d 698 (5th Cir. 2004).

[63] These elements were addressed in our Proposing Release, *supra* note 12.

[64] *See* proposed rule 22c–2(d). *See also* Proposing Release, *supra* note 12, at nn.30–33 and accompanying text (requesting comment on whether and how rule 22c–2 should specify the method of calculating how long fund shares are held).

[65] Many commenters acknowledged that a ''last in, first out'' (''LIFO'') method might capture more abusive short-term trading, but nonetheless supported FIFO because it would minimize the negative, unintended consequences when small, long-term investors are charged redemption fees on transactions unrelated to market-timing, and because redemption fee systems that are currently in place at many funds, broker-dealers and transfer agents assess fees on a FIFO basis. *See, e.g.,* Comment Letter of the Securities Industry Association (May 10, 2004). Commenters also pointed out other advantages to the use of FIFO. *See, e.g.,* Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004) (arguing that FIFO is already used by broker-dealers and transfer agents to calculate the tax effects of redemptions). *But see* Comment Letter of the Vanguard Group (May 10, 2004) (stating that LIFO offers a ''simpler and more comprehensive'' solution than FIFO does); Comment Letter of Capital Research and Management (May 10, 2004) (arguing that using LIFO is essential for a redemption fee program to be effective against excessive trading).

[66] *See* Proposing Release, *supra* note 12, at n.32.

[67] *See, e.g.,* Comment Letter of Morningstar, Inc. (May 10, 2004).

[68] The proposed rule would have permitted, but not required, funds to forego assessment of a redemption fee on redemptions of $2,500 or less, *i.e.*, redemption fees of $50 or less (''*de minimis* exception''). Most commenters who addressed this exception supported it. However, many of the financial intermediaries strongly recommended that the *de minimis* exception be mandatory to avoid the system and compliance costs necessary to accommodate funds that have different *de minimis* rules. *See, e.g.,* Comment Letter of Merrill Lynch, Pierce, Fenner & Smith Inc. (May 10, 2004). Other commenters recommended that the rule state a *de minimis* provision in terms of the amount of the redemption fee rather than the amount of the redemption in order to address a redemption in which only a portion of the shares redeemed were purchased within the previous seven days and thus subject to a redemption fee. *See* Comment Letter of the Investment Company Institute (May 7, 2004).

[69] *See, e.g.*, Comment Letter of the Investment Company Institute (May 7, 2004).

[70] *See* Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004) (''From a systems and implementation standpoint, it is absolutely essential that the Proposed Rule not inadvertently create multiple tiered redemption fees on a single fund * * * Imposing on a single fund different levels of redemption fees that vary based on the holding period would create significant confusion on the part of investors. The costs and complexity of implementing such a system would be substantial.'').

[71] *See* Comment Letter of the American Benefits Council (Oct. 15, 2004) (''However, our most significant point regarding uniformity concerns differences in the types of transactions to which fees will be applied by the various funds.'').

[72] In the Proposing Release, we suggested that funds might charge a fee on redemptions that occur during the first five days, which would be different from the fee that would be charged afterwards. Proposing Release, *supra* note 12 at n.26. Commenters objected to a provision that would require or permit different levels of fees based on

d. Investor Initiated Transactions. We are considering whether the rule should require that any redemption fee charged by a fund be limited to transactions initiated by investors. Under such an approach, redemption fees would not be assessed with respect to (i) shares purchased with reinvested dividends or other distributions,[73] and (ii) shares purchased or redeemed pursuant to a prearranged contract, instruction or plan, such as purchases, redemptions, transfers, or exchanges [74] that are not discretionary transactions for employee benefit plans.[75] As discussed above, many commenters (particularly administrators of retirement plans) were concerned that the redemption fee would inadvertently apply to harmless transactions such as account rebalancings or redemptions after recent periodic contributions, and strongly favored this approach, urging us to include such an exception in any rule we adopt.[76]

We request comment on the need for such an exception. Is it necessary if we provide for FIFO accounting for share holding periods and a *de minimis* exception that addresses complete redemptions? Can funds identify which transactions (other than those made in connection with retirement plans) would qualify for this exception? If not, should the rule make such an exception mandatory only with respect to shareholders who hold through retirement plans? Alternatively, should we make such an exception voluntary? Such an approach would not *require* all funds to provide the exception, but would leave it to funds and their intermediaries to work out the terms of such an approach.

Those commenters who favor a mandatory exception should address how the rule would identify such transactions in the context of different types of intermediaries. Would the formulation that we set out above be workable?

e. Financial Emergencies. We envision that the rule would permit funds to grant a redemption fee waiver in the case of an unanticipated financial emergency, upon the written request of the shareholder. Most commenters who addressed the issue opposed the mandatory financial emergency exception that we proposed last year.[77] Some argued that the exception would rarely be invoked for legitimate purposes, and thus could be used to circumvent redemption fees.[78] Others, including many intermediaries, stated that an open-ended ''financial emergency'' exception could be difficult to administer and may cover too many circumstances, such as market declines.[79] We request additional comment whether the rule should require funds to waive redemption fees in the case of unanticipated financial emergencies. We request comment whether such a provision would discourage funds from adopting redemption fees—an issue that we did not address in our proposed rule because it provided for mandatory redemption fees. We also seek comment on what circumstances should constitute a financial emergency.

f. Other Exceptions and Waivers. We also request comment on whether the rule should include additional exceptions that would limit the circumstances under which funds may charge redemption fees. For example, should funds generally be required to apply any redemption fee to all underlying shareholders, and not exclude fees on the redemption of shares held through omnibus accounts? If so, would the fund need to be able to obtain additional shareholder information regarding shares that are transferred from one omnibus account to another? For example, would the fund need information from an intermediary (such as a retirement plan administrator) that submits a net fund order (on behalf of the plan) to a financial intermediary that holds the plan's shares in an omnibus account? Requiring that a redemption fee apply to all fund shareholders would be designed to eliminate the special treatment of omnibus accounts that has permitted abusive market timers to avoid redemption fees, and in some cases to avoid detection.[80] Conversely, should the rule permit a fund to waive the fee (*i.e.*, decide not to impose the fee on a case-by-case basis) only in accordance with policies and procedures approved by the board of directors, including a majority of the independent directors? Should a fund be required to maintain records of such waivers?

We also request comment on whether there are certain types of funds that should receive special treatment under the redemption fee rule. For example, should there be special provisions regarding funds that invest small amounts in other funds in reliance on section 12(d)(1)(F) of the Act? Should there be an exception for unit investment trusts? Because a unit investment trust invests in specified securities, is it unlikely to engage in market timing? Should redemptions by section 529 plans that invest in funds be excepted from redemption fees? Investors that hold interests in section 529 plans seem unlikely to engage in short-term trading because they lose tax benefits if they change investments in the account more than once a year.[81]

g. Variable Insurance Contracts. We also envision that the rule would not permit the assessment of redemption fees on the redemption, pursuant to partial or full contract withdrawals, of shares issued by an insurance company separate account organized as a unit investment trust that is registered under the Investment Company Act. These types of redemptions are unlikely to occur as part of a market timing or rapid trading strategy, and will permit contract holders to exercise a ''free look'' provision of their contracts

the time that shares are held. *See, e.g.,* Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004).

[73] An investor who chooses to reinvest the dividends and distributions on his shares typically makes the election in advance, and cannot vary the timing or amount of the purchases. Commenters emphasized that these systematic transactions generally are not susceptible to short-term trading abuses. *See, e.g.,* Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004); Comment Letter of the American Society of Pension Actuaries (Apr. 21, 2004) (''[Pension plan] participants do not have the capability to 'time' mutual fund share purchases in connection with payroll contributions or periodic loan repayments because the timing of these purchases depends upon when the employer deposits the funds into the plan, and the contributions are invested according to standing participant instructions.'').

[74] Intermediaries, as well as many individual investors, supported an exemption for redemption transactions executed pursuant to prearranged instructions, such as periodic contributions, periodic rebalancings, or other ''involuntary'' transactions. These types of transactions appear to pose little or no short-term trading risk.

[75] *See* rule 16b–3(b)(1)(i), (ii), and (iii) under the Securities Exchange Act of 1934 [17 CFR 240.16b–3(b)(1)(i), (ii), and (iii)] (definition for purposes of the beneficial ownership reporting requirements of ''discretionary transaction'' under an employee benefit plan).

[76] *See supra* note 14 and accompanying text.

[77] The mandatory redemption fee rule that we proposed last year provided, in the case of an unanticipated financial emergency, that a fund must waive the redemption fee upon written request if the amount of shares redeemed is $10,000 or less, and that a fund could waive the redemption fee if the amount were greater. *See* proposed rule 22c–2(e)(1)(ii).

[78] *See, e.g.,* Comment Letter of the Investment Company Institute (May 7, 2004); Comment Letter of the Vanguard Group (May 10, 2004).

[79] *See, e.g.,* Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004); Comment Letter of the American Bankers Association (May 20, 2004) (recommending that the definition of unforeseeable emergency should conform to the standards for a hardship withdrawal under section 401(k) of the Internal Revenue Code).

[80] One commenter pointed out that the redemption fee rule or the release should clarify that intermediaries who hold fund shares through omnibus accounts should not themselves be subject to redemption fees. Comment Letter of the Investment Company Institute (May 7, 2004).

[81] *See* Comment Letter of the Investment Company Institute (May 7, 2004).

without paying a redemption fee.[82] We received a significant number of comment letters from insurance companies that were concerned about the potential conflict that mandatory redemption fees could generate with some state insurance laws. We request additional comment whether other provisions are needed to address the special circumstances of insurance company separate accounts.

2. Financial Intermediaries

The mandatory redemption fee rule that we proposed last year would have provided funds and the financial intermediaries through which investors purchase and redeem shares three methods of assuring that the appropriate redemption fees are imposed.[83] First, fund intermediaries could transmit to the fund (or its transfer agent) at the time of each transaction the account number used by the intermediary to identify the transaction.[84] Second, intermediaries could enter into an agreement with the fund requiring the intermediary to identify redemptions of account holders that would trigger the application of the redemption fee, and transmit holdings and transaction information to the fund (or its transfer agent) sufficient to allow the fund to assess the amount of the redemption fee.[85] Third, the fund could enter into an agreement with a financial intermediary requiring the intermediary to impose the redemption fees and remit the proceeds to the fund.[86]

These methods were designed to work for different types of intermediaries. Commenters were divided on whether the rule should provide flexibility to funds and intermediaries to choose alternative means to assess redemption fees in omnibus accounts. Some funds and intermediaries supported the rule's flexibility.[87] Other funds and intermediaries, including many insurance companies, opposed the proposed framework, arguing that it would require both funds and their intermediaries to accommodate all three alternatives, which would be very costly.[88] Instead, these commenters suggested that most funds and intermediaries are likely to use the third option because it may be the most cost-effective.[89] We request further comment on whether the rule should limit the ways that redemption fees may be assessed to promote greater uniformity in the enforcement of redemption fees across funds and their intermediaries. Should we retain all three options to accommodate, for example, the small intermediary that does not have the capability to collect and transmit redemption fees? If we retained these options, which entity should determine the option used to assess redemption fees?

3. Recordkeeping

Under rule 22c–2, if the fund's board approves a redemption fee, then the fund must retain a copy of the written agreement between the fund and financial intermediary under which the intermediary agrees to provide the required shareholder information in omnibus accounts.[90] This recordkeeping requirement is designed to assist our examination staff in assessing compliance with the new rule. We request comment whether we should adopt an additional requirement that a fund retain copies of the materials provided to the board in connection with the board's approval of a redemption fee.

III. Effective and Compliance Dates

The new rule will be effective on May 23, 2005. The compliance date of the rule is October 16, 2006.[91] The transition period for rule 22c–2 is intended to give funds and their financial intermediaries ample time to make needed contractual amendments and system enhancements.

IV. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. As discussed in Section II above, rule 22c–2 permits each fund, with the approval of its board (including a majority of independent directors), to impose and retain a redemption fee that does not exceed two percent of the amount redeemed. The Commission is also requiring funds (or their principal underwriters) to enter into written agreements with intermediaries who hold shares on behalf of other investors, under which the intermediaries must provide funds with certain shareholder identity and transaction information at the request of the fund and must execute certain of the funds' instructions.

A. Benefits

We anticipate that funds and shareholders will benefit from the rule. Rule 22c–2 is designed to allow a fund to deter, and provide for reimbursement for the costs of, short-term trading in fund shares. Short-term trading can increase transaction costs for the fund, disrupt the fund's stated portfolio management strategy, require maintenance of an elevated cash position, and result in lost investment opportunities and forced liquidations. Short-term trading also can result in unwanted taxable capital gains for fund shareholders and reduce the fund's long-term performance. This trading also can dilute the value of fund shares held by long-term shareholders if a short-term trader, or market timer, buys and sells shares rapidly to take advantage of market inefficiencies when the price of a mutual fund does not reflect the current market value of the stocks held by that mutual fund.[92] Although short-term traders can profit from engaging in frequent trading of fund shares, the costs associated with

[82] A ''free look'' provision permits a contract owner, within a short period of time after purchasing the contract, to surrender the contract without cost. Other exceptions that we have discussed above (and on which we request comment) also may work well to accommodate insurance company investments. *See supra* notes 73–75 and accompanying text. Those revisions would include a requirement that redemption fees apply only to investor initiated transactions, which would mean that redemption fees would not be imposed on automatic transactions as a result of, for example, periodic redemptions to pay the cost of insurance charges, or systematic withdrawal plans.

[83] *See* Proposing Release, *supra* note 12, at section II.D (discussing proposed rule 22c–2(b)).

[84] This information would permit the fund to match the current transaction with previous transactions by the same account and assess the redemption fee when it is applicable. This approach is designed to accommodate broker-dealers that both hold fund shares in omnibus account form as well as maintain accounts that are fully disclosed to the funds directly. Some broker-dealers using the National Securities Clearing Corporation already transmit taxpayer identification numbers to fund transfer agents for certain types of ''networking'' arrangements. *See* NASD, Report of the Omnibus Account Task Force Members, Jan. 30, 2004, at n.6 (''Omnibus Report'') (available in File No. S7–11–04).

[85] Under this approach, the intermediary would be required to submit substantially less data along with each transaction than under the first method.

[86] The NASD Omnibus Account Task Force found this method to be the most viable approach. *See* Omnibus Report, *supra* note 84.

[87] *See, e.g.*, Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004); Comment Letter of the Investment Company Institute (May 7, 2004); Comment Letter of the Vanguard Group (May 10, 2004); Comment Letter of Merrill Lynch, Pierce, Fenner & Smith Inc. (May 10, 2004).

[88] *See, e.g.*, Comment Letter of Fidelity Investments (June 4, 2004); Comment Letter of Transamerica Occidental Life Insurance (May 10, 2004); Comment Letter of Nationwide Financial Services, Inc. (May 10, 2004).

[89] *See, e.g.*, Comment Letter of American Century Investments (May 10, 2004).

[90] Rule 22c–2(a)(3).

[91] If the Commission changes the rule in response to its request for comment, the compliance period may be extended.

[92] Dilution could occur if fund shares are overpriced and short-term traders receive proceeds based on the overvalued shares.

such trading are borne by all fund shareholders.

Rule 22c–2 also is designed to enable funds to monitor the frequency of short-term trading in omnibus accounts and to take steps, where appropriate, to respond to this trading. We believe that this requirement will facilitate greater cooperation between funds and their intermediaries. The right to access this trading information provides funds with an important new tool to monitor trading activity in order to detect market timing and to assure consistent enforcement of their market timing policies.

To the extent that rule 22c–2 discourages short-term trading, long-term investors may have more confidence in the financial markets as a whole, and funds in particular. Increased investor confidence may result because the rule enables funds to obtain from financial intermediaries information that will allow funds to identify investors who are market timing through omnibus accounts. Funds would benefit by an increase in investor confidence because long-term investors would be less likely to seek alternative financial products in which to invest. Because the fund that imposes the redemption fee retains the fee, long-term shareholders of those funds essentially will be reimbursed for some, if not all, of the redemption costs caused by the short-term traders.

The recordkeeping requirements outlined above in Section II.C.3. are designed to assure the documentation of the fund's agreement with its intermediaries concerning the availability of shareholder identity and transaction information in omnibus accounts. These records will assist our examination staff in determining compliance with the rule.

B. Costs

The new rule will result in additional costs for funds and their financial intermediaries, which we expect will be passed on to investors or borne by fund advisers. The bulk of these costs, however, are one-time costs, whereas the benefits of the board determination and the adoption of a redemption fee for some funds and their shareholders will be enduring.[93] The rule we adopt today is intended to be responsive to the cost concerns that have been articulated by a number of commenters, including both funds and financial intermediaries.

We received a number of comments regarding the costs associated with the proposed mandatory redemption fee rule. The comments primarily addressed the costs of providing shareholder identity and transaction information in omnibus accounts. Many funds and intermediaries expressed concern that the proposed rule, in particular the proposed weekly reporting requirement, would have resulted in significant costs for both funds and financial intermediaries that may not be justified by its benefits.

The intermediaries generally have stressed the importance of uniformity as a means of reducing some of these costs; otherwise, they argued, systems and compliance costs would be significant. In addition, since intermediaries must comply with specific instructions by a fund to restrict or prohibit further purchases or exchanges in transactions of fund shares by a shareholder, intermediaries may incur costs associated with making these terms explicit to their clients.

We modified the proposal in several ways in response to commenters' concerns. These revisions to the proposed rule should result in significant savings to retirement plans and other intermediaries, as well as funds. First, unlike our proposal, the rule does not *require* funds to impose a redemption fee. Thus, a fund and its board may decide that a redemption fee is not necessary or appropriate to address short-term trading. We also concluded that the proposed weekly reporting requirement was unnecessarily burdensome and costly, and instead we are requiring that funds enter into agreements with intermediaries under which, as commenters recommended, shareholder identity and transaction information will be available to funds upon request.[94] Although this modification should reduce costs under the final rule for financial intermediaries and funds, financial intermediaries in the aggregate may still face significant one-time costs to develop systems to assemble the information for transfer to funds on request.[95] For purposes of the Paperwork Reduction Act analysis, we estimate that each fund will incur capital costs of $100,000, for an aggregate cost of $162,000,000 for all funds.[96] We also estimate that each intermediary will incur capital costs of $150,000 for an aggregate cost of $949,500,000 for all intermediaries.[97]

The one-time costs may vary significantly among individual financial intermediaries depending on circumstances, such as the number of funds with which the intermediary must communicate, the frequency of communication, and whether the intermediary develops systems itself or purchases systems from a third party provider. At the same time, the rule should result in cost savings to funds and their long-term shareholders because funds will be able to better enforce their market timing policies against traders who engage in short-term trading through omnibus accounts. The final rule also should result in the more consistent application of market timing policies between shareholders who purchase funds shares directly and those who purchase shares through omnibus accounts.

Today, we also are requesting additional comment on whether we should adopt uniform standards for all redemption fee programs. We seek comment on whether uniform parameters, if adopted, would reduce the systems and compliance costs on both funds and intermediaries. For example, we are requesting further comment on whether we should mandate that all funds use the FIFO method, which is the method used by the vast majority of funds that impose redemption fees. We believe, and the commenters have generally argued, that the standardization of certain redemption fee parameters could reduce the costs of implementing redemption fee programs, as compared to allowing greater variety among redemption fee programs. We seek comment on the effect, if any, standardization could have on the cost of implementing a redemption fee program.

V. Consideration of Promotion of Efficiency, Competition and Capital Formation

Section 2(c) of the Investment Company Act requires the Commission, when engaging in rulemaking that

[93] *See supra* Section IV.A.

[94] *See, e.g.*, Comment Letter of American Century Investments (May 10, 2004); Comment Letter of Charles Schwab & Co., Inc. (May 10, 2004); Comment Letter of the SPARK Institute (May 10, 2004).

We are requiring funds to retain copies of their written agreements with their intermediaries, which should result in limited additional costs because most funds (or principal underwriters) already have agreements with their distributors. The agreement between the fund or its principal underwriter and the intermediary is usually referred to as the ''selling agreement.''

[95] *See* discussion in Section VI below. Commenters that expressed concerns with costs did not provide detailed data or supporting information regarding estimated one-time costs for intermediaries to develop systems to collect the information, ongoing costs of maintaining those systems, or the cost to funds of collecting and receiving that information.

[96] *See* discussion *infra* Section VI.

[97] We further estimate that intermediaries will face ongoing annual costs of $60,000 per intermediary for an aggregate yearly cost of $379,800,000 for all intermediaries. *See infra* Section VI.

requires it to consider or determine whether an action is necessary or appropriate in the public interest, to consider whether the action will promote efficiency, competition, and capital formation.

As discussed above, rule 22c–2 will enable funds to impose, where appropriate, redemption fees designed to reimburse the fund for the direct and indirect costs associated with short-term trading strategies, including market timing. The rule also is designed to supplement other means of combating market timing practices by imposing a cost on those transactions. This new rule will promote efficiency by deterring short-term trading, and by giving funds the information they need to monitor short-term trading in omnibus accounts. Funds, armed with the ability to obtain the identity and transactional information of each fund shareholder, will be able to monitor shareholder trades or flows of money in and out of funds held by intermediaries, and enforce their market timing policies and procedures.

We do not anticipate that this rule will harm competition. The rule will help ensure that a fund's market timing policies, which may or may not include redemption fees, are applied consistently between direct purchase investors and investors that invest through intermediaries. By placing these shareholders on a more level basis than currently exists, short-term traders in omnibus accounts will no longer be able to trade for free at the expense of their fellow shareholders who purchase shares directly.

We recognize the potential for anti-competitive behavior under a rule that does not mandate redemption fees. The competitive pressure of marketing funds, especially smaller funds, coupled with the costs of imposing redemption fees in omnibus accounts, may deter some funds from imposing redemption fees. Intermediaries may use their market power to prevent funds from applying the fees, or to provide incentives for fund groups to waive fees. Accordingly, we are requesting comment on whether the uniform parameters discussed above will encourage intermediaries to cooperate with funds.

Several commenters cautioned that the proposed mandatory redemption fee rule could have anti-competitive effects on intermediaries because it would disproportionately burden small intermediaries, who may incur the largest relative costs as a result of the new rule. We believe the modification to the proposed weekly reporting requirement, as discussed above, will greatly benefit small intermediaries. We also are asking comment on whether we should implement uniform redemption fee requirements, which could reduce the costs incurred by small intermediaries.

We anticipate that the new rule will indirectly foster capital formation by bolstering investor confidence. The rule is likely to reduce the risk of securities law violations, such as market timing violations. In addition, the rule will encourage the use of redemption fees as a tool to address short-term trading because funds will be able to access shareholder information in omnibus accounts, thus preventing short-term traders from diluting the interests of long-term investors, who represent the vast majority of fund shareholders. The fund's retention of redemption fees should result in lower expense ratios and costs for these shareholders. If short-term trading declines, then shareholders should receive better investment performance. To the extent that the rule enhances investor confidence in funds, investors are more likely to make assets available through intermediaries for investment in the capital markets.

VI. Paperwork Reduction Act

As we discussed in the Proposing Release, the rule would result in new ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995.[98] We published notice soliciting comments on the collection of information requirements in the Proposing Release and submitted these requirements to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The Commission has resubmitted these proposed collections of information to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The title for the collection of information requirements associated with the rule is ''Rule 22c–2 under the Investment Company Act of 1940, ''Redemption fees for redeemable securities.'''' 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 control number.

The collections of information created by rule 22c–2 are necessary for funds to be able to assess redemption fees and monitor short-term trading, including market timing, in omnibus accounts. One of the collections of information is mandatory. As stated earlier, under rule 22c–2, funds and intermediaries must enter into written agreements under which the intermediary agrees to provide certain shareholder identity and transaction information upon request by the fund.[99] We are imposing a new requirement that funds retain a copy of the agreement that is or was in effect within the past six years in an easily accessible place.[100] We do not expect that this requirement will impose additional costs on funds because most funds in the ordinary course of their business retain these agreements with their intermediaries. This collection of information is necessary for our staff to use in its examination and oversight program. Responses provided in the context of the Commission's examination and oversight program are generally kept confidential.

We requested comment on whether the estimates contained in the Proposing Release were reasonable. We received extensive comments on the projected costs of the proposal. In many cases, funds and intermediaries, including a number of small broker-dealer firms, generally argued that the system functionality or start-up costs necessary to assess and collect redemption fees on shares held through omnibus accounts, coupled with the operational and maintenance costs, would be significant and in some cases greater than what we estimated.[101] In particular, commenters found the weekly reporting requirement to be burdensome;[102] the estimated costs to comply with this requirement were by far the largest component of the aggregate cost burden that was estimated in the Proposing Release.[103]

In response to commenters' concerns, we have decided not to require that

[98] 44 U.S.C. 3501–3520.

[99] In the proposal, we estimated this contract modification would create a one-time burden of 4.5 hours per fund (4 hours by in-house counsel, .5 hours by support staff) for a total burden of 12,150 hours (2,700 funds × 4.5 hours = 12,150 hours).

[100] Rule 22c–2(a)(3). In the Proposing Release, we requested comment on whether funds should retain their agreements with intermediaries as part of their recordkeeping obligations. We did not receive any comments.

[101] In the Proposing Release we estimated that, over a three year period, the weighted average annual cost to all funds and intermediaries would approximate $673,171,200. One commenter estimated the costs to funds and intermediaries to be $2,278,363,734 per year. *See* Comment Letter of First Trust Corporation (May 10, 2004).

[102] Some small intermediaries recommended that the shareholder identity and transaction data be transmitted on a monthly or quarterly basis. *See e.g.*, Comment Letter of James Desmond (Apr. 13, 2004); Comment Letter of Lloyd Drucker (Mar. 22, 2004).

[103] In the Proposing Release, in order for intermediaries to comply with the weekly reporting requirement, we estimated the aggregate start-up costs for all intermediaries to be $1,020,000,000, and the ongoing costs to be $680,000,000 per year on an aggregate basis.

funds impose redemption fees. Instead, we are allowing funds and their boards to determine whether, and under what circumstances, a redemption fee is necessary to protect the fund from excessive trading.[104] We are also reducing the burden on funds and intermediaries by requiring that funds' agreements with financial intermediaries provide for intermediaries to transmit shareholder identity and transaction data at the fund's request, rather than on a weekly basis as originally proposed. This modification should significantly reduce the costs incurred by funds and their intermediaries.

The Commission staff estimates that there are currently 2,700 active registered open-end investment companies. For purposes of this section, we estimate that 60 percent of funds (1,620) will request the shareholder information. In addition, for purposes of this estimate, we assume that funds will request the shareholder identity and transaction data quarterly, or four times a year. We anticipate that 6,330 financial intermediaries, a slightly lower number of intermediaries than estimated in the Proposing Release, will be subject to the collection of information requirements.[105] We anticipate that all funds would have to modify their agreements or contracts with their intermediaries. This modification would create a one-time burden of 4.5 hours per fund (4 hours of in-house counsel time, .5 hours of support staff time)[106] for a total burden of 12,150 hours,[107] at a cost of $3,353,279.[108] In light of our decision to allow funds to determine whether, and under what circumstances, to obtain the shareholder transactional data in omnibus accounts, we are revising some of the estimates that we provided in the Proposing Release. Similar to the proposed rule, we estimate that, under rule 22c–2, there would be a burden on funds to collect and evaluate the data, and intermediaries to transmit it. However, that burden is substantially reduced under rule 22c–2 because, as stated above, the intermediary will provide the data to the fund upon the fund's request, rather than weekly.

We estimate the annual burden on a fund to collect information it requests from financial intermediaries will be 160 hours[109] for a total burden of 259,200 hours for all funds.[110] We estimate the capital costs for a fund will be $100,000 per fund for an aggregate cost of $162,000,000 for all funds.[111] We estimate the ongoing yearly cost will be $6,640 per fund for an aggregate yearly cost for all funds of $10,756,800.[112] We estimate the annual burden for financial intermediaries to establish systems for the collection and transfer of data to funds will be 240 hours per intermediary for a total burden of 1,519,200 hours for all financial intermediaries.[113] We estimate the capital costs will be $150,000 per financial intermediary for an aggregate cost of $949,500,000.[114] We estimate ongoing costs of $60,000 per financial intermediary for an aggregate yearly cost of $379,800,000 for all intermediaries.[115]

The estimated collection burden for all 9,030 respondents (*i.e.*, 2,700 funds + 6,330 intermediaries) under rule 22c–2, is determined by calculating an average of the first year burden and the subsequent annual burdens. Over the three-year period, we estimate the weighted average aggregate annual information collection burden will be 1,895,250 hours.[116] The Commission estimates that there will be a total of 25,320 responses annually, which includes responses by funds and intermediaries.[117]

The total annual cost of the new information collection requirements for all 7,950 respondents (*i.e.*, 1,620 funds + 6,330 intermediaries), is determined by calculating an average of the first year cost and the subsequent annual costs. Over the three-year period, we estimate the weighted average aggregate annual cost will be $630,871,200.[118]

VII. Final Regulatory Flexibility Analysis

This Final Regulatory Flexibility Analysis (''FRFA'') has been prepared in accordance with 5 U.S.C. 604. It relates to rule 22c–2 and the amendments to rule 11a–3 under the Investment Company Act. The Initial Regulatory Flexibility Analysis (''IRFA''), which was prepared in accordance with 5 U.S.C. 603, was published in the Proposing Release.[119]

[104] For instance, funds may decline to impose redemption fees on shares purchased as a result of transactions that pose little risk of short-term trading, such as payroll contributions and periodic rebalancings.

[105] In the Proposing Release we estimated that 6,800 intermediaries would be subject to the information collection requirements of rule 22c–2. Since we proposed the rule, we have learned that approximately 470 of the 6,800 intermediaries are broker-dealers that transmit the shareholder data to funds on a fully-disclosed basis. Funds would not need to request the shareholder data from these broker-dealers, and therefore would not need to establish the systems to comply with this portion of the rule.

[106] These estimates are based on discussions with fund representatives.

[107] This estimate is based on the following calculation: 2,700 funds × 4.5 hours = 12,150 hours.

[108] This estimate is based on the following calculations: (4 attorney hours × $66.31 = $265.24) + (.5 support staff hour × $21.50 = $10.75) = $275.99; (12,150 hours × $275.99 = $3,353,278.50). The hourly rates in this release are derived from the average annual salaries reported for employees outside of New York City in Securities Industry Association, Management and Professional Earnings in the Securities Industry (2003) and Securities Industry Association, Office Salaries in the Securities Industry (2003).

[109] This estimate is based on the following calculation: 40 hours per quarter × 4 quarters = 160 hours per year.

[110] This estimate is based on the following calculation: 160 hours per fund × 1,620 funds = 259,200 hours per year.

[111] This estimate is based on the following calculation: $100,000 per fund × 1,620 funds = $162,000,000.

[112] This estimate is based on the following calculation: $6,640 per fund × 1,620 funds = $10,756,800.

[113] This estimate is based on the following calculation: 240 hours per intermediary × 6,330 intermediaries = 1,519,200 hours.

[114] This estimate is based on the following calculation: $150,000 per intermediary × 6,330 intermediaries = $949,500,000.

[115] This estimate is based on the following calculation: ($60,000 per intermediary × 6,330 intermediaries = $379,800,000). We have reduced the ongoing costs incurred by each intermediary to $60,000 (we estimated that the ongoing costs would be $100,000 in the Proposing Release) to reflect the elimination of the weekly reporting requirement.

[116] In the first year after adoption we estimate the aggregate collection of information burdens resulting from the written agreement requirement will be: (i) 271,350 hours (12,150 hours for contract modifications + 259,200 hours for the information collection requirements) for funds; and (ii) 1,519,200 hours for intermediaries. Thus, in the first year after adoption, we estimate the aggregate burden for all respondents will be 1,790,550 hours (271,350 hours for funds + 1,519,200 hours for intermediaries). In the second and third years after adoption, we estimate the annual burden for respondents will fall by 12,150 hours, because the burden attributable to one-time contract modifications will no longer be incurred by funds. Thus, we estimate the average annual burden over the three-year period for which we are seeking approval will be 1,782,450 hours (1,790,550 first year's burden + 1,778,400 second year's burden + 1,778,400 third year's burden/3).

[117] Specifically, the staff estimates that annually there will be 25,320 responses under rule 22c–2 (6,330 intermediaries × 4 responses per year).

[118] In the first year after adoption of rule 22c–2 we estimate the aggregate cost burden of the information collection requirement for funds will be $162,000,000; and for intermediaries will be $949,500,000. Thus, in the first year after adoption, we estimate the aggregate cost burden for all respondents will be $1,111,500,000. In the second and third years after adoption, we expect the annual cost burden for respondents to fall to $390,556,800 because funds and intermediaries will incur only the ongoing operation and maintenance costs of systems that have been put in place during the first year. Specifically, in each of the second and third years after adoption (i) we estimate the aggregate cost burden for the information collection requirements for funds will be $10,756,800; and (ii) for intermediaries will be $379,800,000. Thus, we estimate that the average annual cost burden over the three-year period for which we are seeking approval will be $630,871,200 ($1,111,500,000 first year's burden + $390,556,800 second year's burden + $390,556,800 third year's burden/3).

[119] *See* Proposing Release, *supra* note 12, at Section VI.

A. Need for, and Objectives of, the Rule

As described more fully in Section I of this Release, rule 22c–2 is necessary to enable funds to recover some, if not all, of the direct and indirect (*e.g.*, market impact and opportunity) costs incurred by the fund when shareholders engage in short-term trading of the fund's shares, and to deter short-term trading, including market timing activity. As stated in Section I, many funds have not imposed redemption fees on shares held in omnibus accounts because they often do not know the identities and transactions of the beneficial owners of those shares, and may be unable to obtain the cooperation of the intermediaries to impose the fee. Rule 22c–2 requires that funds enter into written agreements with financial intermediaries that will allow funds to obtain this information on request, and to direct intermediaries to prohibit or restrict further purchases or exchanges by shareholders who have engaged in trading that violates the funds' market timing policies.

B. Significant Issues Raised by Public Comment

We requested comment on the IRFA. We also specifically requested comment on the number of small entities that would be affected by the proposed rule, the likely impact of the proposal on small entities, the nature of any impact, and empirical data supporting the extent of the impact. We received a number of comments on the impact on small entities. These commenters, primarily small financial intermediaries, generally expressed concern that the costs associated with the proposed mandatory redemption fee would be significant and disproportionately affect small entities because of the costs to record, store, track and transmit data.[120]

We are concerned about the impact of the rule on small entities, and therefore have amended the rule to address many commenter concerns. Rule 22c–2 no longer requires funds to impose a redemption fee if they determine that a fee is not necessary or appropriate to prevent dilution. Under rule 22c–2, rather than requiring funds to obtain shareholder information from financial intermediaries on a weekly basis, intermediaries must agree to provide the information upon a fund's request, *e.g.*, periodically or when circumstances suggest that redemption fees are not being assessed or that abusive market timing activity is occurring. In addition, the rule does not prevent funds from excluding certain types of transactions that do not involve shareholder discretion from the fee, *e.g.*, redemptions that follow purchases made pursuant to periodic portfolio rebalancings.[121] We believe that this flexibility will be very helpful to small recordkeeping firms by enabling them to negotiate greater uniformity in the administration of retirement plans. In addition, we request comment on whether we should require a uniform standard for any redemption fees charged by a fund and whether such uniformity could result in cost reductions for funds and financial intermediaries.

C. Small Entities Subject to the Rule

A small business or small organization (collectively, ''small entity'') for purposes of the Regulatory Flexibility Act is a fund that, together with other funds 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.[122] Of approximately 3,925 funds (2,700 registered open-end investment companies and 825 registered unit investment trusts), approximately 163 are small entities.[123] A broker-dealer is considered a small entity if its total capital is less than $500,000, and it is not affiliated with a broker-dealer that has $500,000 or more in total capital.[124] Of approximately 6,800 registered broker-dealers, approximately 880 are small entities, of these, approximately 470 are broker-dealers that already transmit the shareholder data to funds on a fully-disclosed basis. Funds would not need to request the shareholder identity and transaction data from these broker-dealers. These particular intermediaries therefore would not need to establish or maintain systems to comply with this portion of the rule, so we have not included them in our start-up or ongoing maintenance calculations.

As discussed above, rule 22c–2 provides funds and their boards with the ability to impose a redemption fee designed to reimburse the fund for the direct and indirect costs incurred as a result of short-term trading strategies, such as market timing. To facilitate the uniform application of redemption fees to all shareholders of the fund, including shareholders who own their shares through financial intermediaries, rule 22c–2 requires that funds and financial intermediaries enter into written agreements that allow funds to obtain shareholder identity and transaction information and to direct the financial intermediary to execute the funds' instructions in certain circumstances. While we expect that the rule will require that some funds and intermediaries develop or upgrade software or other technological systems to enforce certain market timing policies, or make trading information available in omnibus accounts,[125] we anticipate that the modifications, as discussed above, will reduce the costs incurred by small entities.

D. Reporting, Recordkeeping, and Other Compliance Requirements

The rule does not introduce any new mandatory reporting requirement. The rule does contain a new mandatory recordkeeping requirement. The fund must retain a copy of the written agreement between the fund and financial intermediary under which the intermediary agrees to provide the required shareholder information in omnibus accounts.[126]

E. Commission Action To Minimize Effect on Small Entities

The Regulatory Flexibility Act directs the Commission to consider significant alternatives that would accomplish the stated objective, while minimizing any significant adverse impact on small entities. Alternatives in this category would include: (i) Establishing different compliance or reporting standards that take into account the resources available to small entities; (ii) clarifying, consolidating, or simplifying the compliance requirements under the rule for small entities; (iii) using performance rather than design standards; and (iv) exempting small entities from coverage of the rule, or any part of the rule.

[120] Although the estimates varied, most intermediaries estimated that their first year start-up costs to comply with the proposed rule would be between $200,000 and $300,000. In the Proposing Release, we estimated the first year start-up costs for intermediaries that used the option set forth in proposed rule 22c–2(b)(1), in conjunction with the weekly reporting requirement, would be $250,000.

[121] Intermediaries generally recommended that redemption fees should apply only to transfers and exchanges in participant-directed employee benefit plans, and stated that excluding ''involuntary'' transactions from redemption fee requirements would significantly reduce the costs associated with the rule.

[122] 17 CFR 270.0–10.

[123] Some or all of these entities may contain multiple series or portfolios. If a registered investment company is a small entity, the portfolios or series it contains are also small entities.

[124] 17 CFR 240.0–10.

[125] In some cases, the fund (or its transfer agent) will have to upgrade its recordkeeping systems; however, some may already have software that can be used, or modestly modified, to accommodate the matching of purchases and redemptions. In addition, the costs may be substantially less for broker-dealers and other financial intermediaries that already have transfer agent systems in place that can be modified to identify short-term trading.

[126] Rule 22c–2(a)(3).

The Commission does not believe that the establishment of special compliance requirements or timetables for small entities is feasible or necessary. The rule arises from enforcement actions and settlements that underscore the need to reimburse funds so that long-term shareholders will not be disadvantaged by shareholders that engage in frequent trading and by fund managers that selectively permit such short-term trading. Excepting small entities from the rule could disadvantage fund shareholders of small entities and compromise the effectiveness of the rule.

With respect to further clarifying, consolidating or simplifying the compliance requirements of the rule, using performance rather than design standards, and exempting small entities from coverage of the rule or any part of the rule, we believe such changes are impracticable. Small entities are as vulnerable to the problems uncovered in recent enforcement actions and settlements as large entities. Therefore, shareholders of small entities are equally in need of protection from short-term traders. We believe that the rule will enable funds to more effectively discourage short-term trading of all fund shares, including those held in omnibus accounts. A recent staff review of fair valuation practices of mutual funds found that one of the biggest obstacles to preventing short-term trading is the existence of omnibus account platforms. Exempting small entities from coverage of the rule or any part of the rule could compromise the effectiveness of the rule.

VIII. Statutory Authority

The Commission is adopting rule 22c–2, and amendments to rule 11a–3 pursuant to the authority set forth in sections 6(c), 11(a), 22(c) and 38(a) of the Investment Company Act [15 U.S.C. 80a–6(c), 80a–11(a), 80a–22(c) and 80a–37(a)].

List of Subjects in 17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Rule

■ For reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 1. The authority citation for part 270 continues to read in part as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, and 80a–39, unless otherwise noted.

* * * * *

■ 2. Section 270.11a–3 is amended by:

■ a. Revising paragraph (a)(7); and

■ b. Removing the undesignated paragraph following paragraph (b)(2)(ii). The revision reads as follows.

§ 270.11a–3 Offers of exchange by open-end investment companies other than separate accounts.

(a) * * *

(7) *Redemption fee* means a fee that is imposed by the fund pursuant to section 270.22c–2; and

* * * * *

■ 3. Section 270.22c–2 is added to read as follows:

§ 270.22c–2 Redemption fees for redeemable securities.

(a) *Redemption fee.* It is unlawful for any fund issuing redeemable securities, its principal underwriter, or any dealer in such securities, to redeem a redeemable security issued by the fund within seven calendar days after the security was purchased, unless it complies with the following requirements:

(1) *Board determination.* The fund's board of directors, including a majority of directors who are not interested persons of the fund, must either:

(i) Approve a redemption fee, in an amount (but no more than two percent of the value of shares redeemed) and on shares redeemed within a time period (but no less than seven calendar days), that in its judgment is necessary or appropriate to recoup for the fund the costs it may incur as a result of those redemptions or to otherwise eliminate or reduce so far as practicable any dilution of the value of the outstanding securities issued by the fund, the proceeds of which fee will be retained by the fund; or

(ii) Determine that imposition of a redemption fee is either not necessary or not appropriate.

(2) *Shareholder information.* The fund or its principal underwriter must enter into a written agreement with each financial intermediary of the fund, under which the intermediary agrees to:

(i) Provide, promptly upon request by the fund, the Taxpayer Identification Number of all shareholders that purchased, redeemed, transferred, or exchanged shares held through an account with the financial intermediary, and the amount and dates of such shareholder purchases, redemptions, transfers, and exchanges; and

(ii) Execute any instructions from the fund to restrict or prohibit further purchases or exchanges of fund shares by a shareholder who has been identified by the fund as having engaged in transactions of fund shares (directly or indirectly through the intermediary's account) that violate policies established by the fund for the purpose of eliminating or reducing any dilution of the value of the outstanding securities issued by the fund.

(3) *Recordkeeping.* The fund must maintain a copy of the written agreement under paragraph (a)(2) that is in effect, or at any time within the past six years was in effect, in an easily accessible place.

(b) *Excepted funds.* The requirements of paragraphs (a) of this section do not apply to the following funds, unless they elect to impose a redemption fee pursuant to paragraph (a)(1) of this section:

(1) Money market funds;

(2) Any fund that issues securities that are listed on a national securities exchange; and

(3) Any fund that affirmatively permits short-term trading of its securities, if its prospectus clearly and prominently discloses that the fund permits short-term trading of its securities and that such trading may result in additional costs for the fund.

(c) *Definitions.* For the purposes of this section:

(1) *Financial intermediary* means:

(i) Any broker, dealer, bank, or other entity that holds securities of record issued by the fund, in nominee name;

(ii) A unit investment trust or fund that invests in the fund in reliance on section 12(d)(1)(E) of the Act (15 U.S.C. 80a–12(d)(1)(E)); and

(iii) In the case of a participant-directed employee benefit plan that owns the securities issued by the fund, a retirement plan's administrator under section 3(16)(A) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(16)(A)) or any entity that maintains the plan's participant records.

(2) *Fund* means an open-end management investment company that is registered or required to register under section 8 of the Act (15 U.S.C. 80a–8), and includes a separate series of such an investment company.

(3) *Money market fund* means an open-end management investment company that is registered under the Act and is regulated as a money market fund under § 270.2a–7.

(4) *Shareholder* includes a beneficial owner of securities held in nominee name, a participant in a participant-directed employee benefit plan, and a holder of interests in a fund or unit investment trust that has invested in the

fund in reliance on section 12(d)(1)(E) of the Act.

A shareholder does not include a fund investing pursuant to section 12(d)(1)(G) of the Act (15 U.S.C. 80a–12(d)(1)(G)), a trust established pursuant to section 529 of the Internal Revenue Code (26 U.S.C. 529), or a holder of an interest in such a trust.

By the Commission.

Dated: March 11, 2005.

J. Lynn Taylor,

Assistant Secretary.

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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.

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- Poly(2-vinylpyridine-co-styrene) and salts of volatile fatty acids; technical amendment; published 3-18-05
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- California; comments due by 3-24-05; published 2-22-05 [FR 05-03234]

Potatoes (Irish) grown in—
- Idaho and Oregon; comments due by 3-25-05; published 1-24-05 [FR 05-01178]

AGRICULTURE DEPARTMENT

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AGRICULTURE DEPARTMENT

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  - Atlantic commercial shark; comments due by 3-25-05; published 3-10-05 [FR 05-04743]
- Caribbean, Gulf, and South Atlantic fisheries—
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COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

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- Pilot Mentor-Protege Program; Open for comments until further notice; published 12-15-04 [FR 04-27351]

EDUCATION DEPARTMENT

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  - Smaller Learning Communities Program; Open for comments until further notice; published 2-25-05 [FR E5-00767]

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- Environmental Management Site-Specific Advisory Board—
  - Oak Ridge Reservation, TN; Open for comments until further notice; published 11-19-04 [FR 04-25693]

ENERGY DEPARTMENT

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  - Commercial packaged boilers; Open for comments until further notice; published 10-21-04 [FR 04-17730]

ENERGY DEPARTMENT

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  - 8-hour ozone national ambient air quality standard; implementation; reconsideration and public hearing; comments due by 3-21-05; published 2-3-05 [FR 05-01997]

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- Mississippi; comments due by 3-25-05; published 2-23-05 [FR 05-03363]

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  - Concentrated animal feeding operations in New Mexico and Oklahoma; general permit for discharges; Open for comments until further notice; published 12-7-04 [FR 04-26817]
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LIST OF PUBLIC LAWS

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The text of laws is not published in the **Federal Register** but may be ordered

in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

S. 5/P.L. 109–2

Class Action Fairness Act of 2005 (Feb. 18, 2005; 119 Stat. 4)

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